SECURITIES & EXCHANGE COMMISSION EDGAR FILING

Modular Medical, Inc.

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

FORM 10-K

(Mark One)

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

For the fiscal year ended March 31, 2020

or

o TRANSITION REPORT PURSUANT TO SECTION 13 OR 15 (d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission File Number: 000-49671

MODULAR MEDICAL, INC.

(Exact name of registrant as specified in its charter)

Nevada	**87-0620495**
(State or Other Jurisdiction of Incorporation or Organization)	(IRS Employer Identification No.)

16772 West Bernardo Drive, San Diego, CA 92127
(Address of Principal Executive Offices) (Zip Code)

(858) 800-3500
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered

Securities registered pursuant to Section 12(g) of the Act:

Common Stock, par value $0.001
(Title of class)

(Title of class)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes o No x

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Exchange Act.

Yes o No x

Indicate by check mark if the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes x No o

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes o No x

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

Large accelerated filer	o	Accelerated filer	o
Non-accelerated filer	x	Smaller reporting company	x
Emerging growth company	x		

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes o No x

The aggregate market value of the voting common stock held by non-affiliates of the registrant, based on the average of the bid and asked price of the common stock on the OTC Pink Open Market of $0.24 per share, was $950,914 as of September 30, 2019.

The number of shares of the registrant's common stock outstanding, par value $0.001 per share, as of June 26, 2020, was 18,454,459.

ANNUAL REPORT ON FORM 10-K
FOR THE YEAR ENDED MARCH 31, 2020

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PART I

FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K (this Report) contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements discuss matters that are not historical facts. Because they discuss future events or conditions, forward-looking statements may include, without limitation, words such as "anticipate," "believe," "estimate," "intend," "could," "should," "would," "may," "seek," "plan," "might," "will," "expect," "predict," "project," "forecast," "potential," "continue," negatives thereof, or similar expressions. These forward-looking statements are found at various places throughout this Report and include, without limitation, information concerning possible or assumed future results of our operations; business strategies; dates; future cash flows; financing plans; plans and objectives of management; any other statements regarding future operations, future cash needs, business plans and future financial results, and any other statements that are not historical facts. Any or all of the forward-looking statements included in this Report and in any other reports or public statements made by us are not guarantees of future performance and may turn out to be inaccurate. These forward-looking statements represent our intentions, plans, expectations, assumptions and beliefs about future events and are subject to risks, uncertainties and other factors including, without limitation, the direct and indirect effects of coronavirus disease 2019, or COVID-19, and related issues that may arise therefrom. Many of those factors are outside of our control and could cause actual results to differ materially from those expressed or implied by those forward-looking statements. In light of these risks, uncertainties and assumptions, the events described in the forward-looking statements might not occur or might occur to a different extent or at a different time than we have described. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this Report. All subsequent written and oral forward-looking statements concerning other matters addressed in this Report and attributable to us or any person acting on our behalf are expressly qualified in their entirety by the cautionary statements contained or referred to in this Report. We undertake no obligation to update or revise any forward-looking statements, whether as a result of new information, future events, a change in events, conditions, circumstances or assumptions underlying such statements, or otherwise.

Our fiscal year ends on March 31 of each calendar year. Each reference to a fiscal year in this Report, refers to the fiscal year ended March 31 of the calendar year indicated (for example, fiscal 2020 refers to the fiscal year ended March 31, 2020). Unless the context requires otherwise, references to "we," "us," "our," and the "Company" refer to Modular Medical, Inc. and its consolidated subsidiary.

ITEM 1. BUSINESS

Overview

We are a development stage medical device company focused on the design, development and eventual commercialization of an innovative insulin pump to address shortcomings and problems represented by the relatively limited adoption of currently available pumps for insulin-requiring people with diabetes.

Diabetes is typically classified as either type 1 or type 2:

- Type 1 diabetes is characterized by the body's nearly complete inability to produce insulin. It is frequently diagnosed during childhood or adolescence. Individuals with type 1 diabetes require daily insulin therapy to survive.

- Type 2 diabetes represents over 90% of all individuals diagnosed with diabetes and is characterized by the body's inability to either properly utilize insulin or produce enough insulin. Initially, many people with type 2 diabetes attempt to manage their diabetes with improvements in diet and exercise and/or the use of oral medications and/or injection of glucagon-like peptide-1, or GLP-1, drugs. However, as their diabetes advances, patients progress to requiring insulin therapies, such as once-daily long-acting insulin, and, ultimately, mealtime rapid-acting insulin therapy.

Glucose, the primary source of energy for cells, must be maintained at certain levels in the blood in order to permit optimal cell function and health. In people with diabetes, blood glucose levels fluctuate between very high, a condition known as hyperglycemia, and very low, a condition called hypoglycemia. Hyperglycemia can lead to serious long-term complications, including blindness, kidney disease, nervous system disease, occlusive vascular diseases, lower-limb amputation, stroke and cardiovascular disease, or death. Hypoglycemia can lead to confusion or loss of consciousness, often requiring a visit to the emergency room or in certain cases result in death.

The International Diabetes Federation, or IDF, estimates that, in 2019, approximately 460 million people had diabetes worldwide, and, that by 2045, this number will increase to 700 million people. According to the U.S. Centers for Disease Control and Prevention, or CDC, 2020 National Diabetes Statistics Report, approximately 27 million people in the United States have diagnosed diabetes, of which type 1 diabetes accounts for approximately 5%, or approximately 1.4 million people. All people with type 1 diabetes, which is our primary market, require daily insulin. According to the CDC, approximately 14% of people with type 2 diabetes in the United States, or 3.2 million people, require insulin to manage their diabetes. In this Report, we refer to people with type 1 diabetes and people with type 2 diabetes who require mealtime insulin as "insulin-requiring people with diabetes."

Currently, there are two primary therapies available for insulin-requiring people with diabetes: multiple daily insulin injections directly into the body through syringes or insulin pens, referred to as Multiple Daily Injection, or MDI, therapy, or the use of an insulin pump to deliver a continuous subcutaneous insulin infusion, or CSII, into the body. Generally, CSII therapy is considered to provide a number of advantages over MDI therapy, primarily an improvement in glycemic control, as measured by certain diabetes management tests. Use of CSII has proven to improve clinical outcomes while, importantly, reducing emergency room visits associated with low glucose.

Notwithstanding these advantages, the difficulty in use resulting from the complexity and cumbersome design of available insulin pumps, as well as high and often prohibitive costs for both the patient and insurance provider, has resulted not only in dissatisfaction among many existing pump users, but also has severely limited the adoption rate of insulin pumps by a segment of the diabetes population, who we refer to in this Report as “almost pumpers.”

We generally define almost pumpers as persons with insulin-requiring diabetes who are aware of pumps and the potential benefits, but because of the shortcomings, cost and complexity of use problems prevalent in available insulin pumps, continue to receive their daily insulin through MDI.

Our initial target market for our insulin pump is the almost pumper population located in the United States.

Based upon our knowledge of the diabetes industry and information available and/or obtained by us, we believe that an estimated 32% of Americans with type 1 diabetes use insulin pump therapy and an estimated 30% of Americans with type 1 diabetes are whom we classify as almost pumpers. The remainder of the population treat their diabetes via MDI.

Our design and development team is led by Paul DiPerna, our chairman, chief executive officer and a 40% shareholder. Mr. DiPerna has over 30 years of high-level experience in developing, designing and obtaining U.S. Food and Drug Administration, or FDA, approval for and managing the commercialization of medical devices, including consumer and hospital-based insulin pumps, while working for such industry leading medical device companies as Baxter Healthcare, Inc., a supplier of drug therapies and associated pumping technologies, and Tandem Diabetes Care, Inc., or Tandem, a leading supplier of pumping technology to the existing insulin pumping marketplace, Mr. DiPerna was the founder of Tandem and designer of its initial product.

Our Insulin Pump Prototype

Over the past five years, we have designed and developed working prototypes of our low-cost insulin pump that are now undergoing the testing required to submit for FDA approval. During this period, we have and continue to devote substantial time and resources to better understand the needs and preferences of almost pumpers to enable us to modify and refine our insulin pump to the needs and preferences of this target market. To help us better understand their needs and preferences, we obtained information about our target market and their care givers through one on one interviews, human factors testing, on-line and in person surveys, and focus groups at industry related tradeshows and conferences.

Pre-Commercialization Steps

While we have substantially completed the general engineering and mechanical aspects of our current insulin pump prototype, prior to commercializing, we still must successfully complete a number of material steps including:

- Continue to modify, refine and finalize our prototype so that it meets:
    - the general needs and preferences of our almost-pumper target market based upon our knowledge of the diabetes industry and information available and/or obtained by us from almost pumpers and their caregivers; and
    - the general guidelines of third-party payors, private and public insurance companies, preferred provider organizations and other managed care providers with particular focus on the guidelines established by the Center for Medicare and Medicaid Services, or CMS which administrates the United States Medicare program, or Medicare. To assist us in making such modifications and refinements, we have retained independent consultants to focus on ensuring that our product satisfies the existing coverage and reimbursement criteria of such third-party payors.
- Continue to work closely with our regulatory consultants to complete, finalize and file our submission to the FDA for 510(k) clearance and all other documentation necessary to obtain approval of our insulin pump. This will include:
    - engaging the FDA in a pre-submission conference to ensure that we understand and meet the FDA’s requirements, expectations and standards with regard to approval of our product. At this meeting, our team, including our FDA regulatory consultant, will receive FDA comments and guidance regarding our proposed submission during the pre-market notification period for 510(k) clearance (including any suggested modifications to the device description, indications for use or summary of supporting data contained in the notification);

- preparing and ensuring that our pre-market notification, which will be part of our FDA submission, demonstrates that our insulin pump, which is substantially equivalent to an insulin pump previously cleared by the FDA and legally marketed to the public; and

- preparing our submission to the FDA, to include all of the appropriate results of tests (relating to, among other things, user effectiveness, sterility, pump efficiency and shipping compatibility) demonstrating safety and efficacy of our insulin pump in satisfaction of the mandates of the Federal Food, Drug and Cosmetics Act, or the FDCA, including requirements with regard to registration and listing, labeling, medical device reporting and good manufacturing practices. We currently expect to make this submission in the fourth calendar quarter of 2020.

  Our manufacturing process will progress during the submission process to select a manufacturer of our insulin pump through a competitive bidding process and prepare for our introduction.

- Refining our manufacturing process during the submission process to identify and select a manufacturer of our insulin pump through a competitive bidding process, as we prepare for our product introduction;

- Take such actions, if any, as may be required by the FDA as a condition to granting approval and providing 510(k) clearance for our insulin pump; and

- Retain appropriate sales and marketing personnel to develop, implement and launch a promotional campaign for our insulin pump substantially focused on our target market.

As with any medical device attempting to enter and successfully compete with existing products in an established and competitive marketplace, we will face significant hurdles to accomplish the above steps to commercialization including:

- Obtaining FDA 510(k) clearance to market and sell our insulin pump to the public;

- Obtaining any other FDA-required approvals with regard to our product, as required by the FDCA;

- Educating endocrinologists, physician's assistants, nurse practitioners and nurse educators, who typically prescribe pump usage, and certified diabetes educators and dieticians, who provide education and guidance to diabetes patients, as to what we believe to be the superior qualities of our product;

- Demonstrating to general practitioners, who have historically been skeptical of the heightened support inherent in insulin pumps, our product's ease of use and convenience;

- Ensuring that our final product does, in fact, meet the needs of almost-pumpers;

- Overcoming the historic obstacles and reluctance of almost-pumpers to using insulin pumps to treat their diabetes; and

- Ensuring that third party payors agree to cover all or a substantial portion of the purchase price and recurring costs of the use of our insulin pump.

We believe that there are a number of shortcomings and issues with currently available insulin pumps that prevent a substantial number of people requiring insulin on a daily basis from adjusting an insulin pump to treat their diabetes. We believe, that by tailoring our insulin pump to address such factors, we can expand the scope and adoption rate of insulin pump usage. We believe that, to achieve broader market acceptance, an insulin pump must be easier to learn how to use, be less time consuming to operate, more intuitive to both patients and physicians and meet the standards for coverage by insurance providers, including so that co-payments required from patients are affordable and the hurdles to insurance coverage are significantly reduced.

Among the more prominent issues are:

- *Complexity*: Many existing pumps are highly complex and require significant technical expertise to use effectively. We believe such pumps were designed for "super users," whom have high levels of motivation and technical competence. The complexity of pumps proves daunting to less technically inclined users.

- *Cumbersome*: We believe that a majority of existing pumps are bulky and difficult to manage, in many cases requiring additional equipment to introduce a catheter to the patient's body and up to 48 inches of tubing, which must be replaced frequently to connect this catheter to a pump. This requires users to carry spare parts and other equipment adding to the encumbrance of using the pump.

- *Cost*: Costs associated with insulin pump therapy are high and can be prohibitive, especially for those on fixed or limited incomes. These costs vary by pump, but multi-thousand-dollar upfront payments often with substantial co-payments in addition to possible daily co-payments on consumables can easily place current pumps out of reach for patients. This makes insurance providers hesitant to pay for them, leading to limited or absent reimbursement/coverage.

Our team has substantial knowledge of the diabetes space and experience in developing, winning approval for, and bringing insulin pumps to market. Based on this experience, we believe that our innovative insulin pump, using a new and proprietary method of pumping insulin, can address most or all of these shortcomings. It provides a state-of-the-art insulin pump capable of both basal (steady flow) and bolus (mealtime dosing) insulin disbursement and with a natural migration path to multi-chamber/multi liquid pumps with exciting array of new therapies being available to patients. Our goal is to become the leader in expanding access to insulin pump technology to a wider portion of diabetes sufferers and provide not just care for the super users, but "diabetes care for the rest of us."

Mr. DiPerna, our founder, chairman and chief executive officer, chief financial officer, secretary and treasurer began his career in approximately 1980 as a mechanical design engineer in the automated test equipment industry before moving in approximately 1989 to a start-up company in the blood separation sciences industry. This company was acquired in approximately 1991 by Baxter Healthcare, or Baxter. Following such acquisition, Mr. DiPerna became employed by Baxter and held various positions during his approximate 12 years at Baxter. While at Baxter, Mr. DiPerna led significant projects and initiatives including leading a team of approximately 50 engineers in developing equipment in the blood separation sciences industry. In approximately 1996, Mr. DiPerna was promoted to General Manager of Baxter's business development group to identify expansion opportunities in the medical device industry for Baxter. While holding such position, Mr. DiPerna led a team of approximately 20 personnel responsible for researching custom orthopedics, digital dentistry and rapid prototyping. In such role, one of Mr. DiPerna's assignments was identifying opportunities in the diabetes industry. As a result, Mr. DiPerna developed an expertise and knowledge and became well known in the diabetes industry and led attempts by Baxter to acquire three then-leading insulin pump manufacturers. In 2003, Mr. DiPerna, using his knowledge and experience acquired at Baxter in the diabetes industry and in the "pump" product business in particular, left Baxter and founded what subsequently became Tandem Diabetes Care, Inc., or Tandem. While at Tandem, Mr. DiPerna held various positions, including member of the board of directors, chief executive officer and chief technology officer. Tandem is a medical device company that designs, develops and commercializes products for people with insulin-dependent diabetes. Tandem's common stock is listed on the NASDAQ Stock Market under the symbol "TNDM." Tandem was founded by Mr. DiPerna to design, develop and commercialize a "state of the art" user-friendly insulin pump. Under the leadership of Mr. DiPerna, Tandem raised approximately $52,000,000 from well-known venture-capital firms. Mr. DiPerna was the person primarily responsible for the design concept and development of Tandem's insulin pump, which, after commercial introduction, it is estimated by Mr. DiPerna such insulin pump had a quick ramp up to 5,000 purchasers. In 2011, Mr. DiPerna resigned from his executive officer position and board seat at Tandem and continued to advise the company through 2013. He co-invented a medical device used for blood-borne infection control called the "Curos Cap." Curos Cap was owned by a private company which was acquired by 3M Corporation in 2015 for $150,000,000. Thereafter, Mr. DiPerna founded a company Fuel Source Partners, LLC to incubate early stage medical device products and accumulate technical talent. One of such proposed products was spun-out to Quasuras in March 2015, which we acquired in July 2017. Mr. DiPerna holds a number of issued and pending patents and is a member of the American Diabetes Association. Mr. DiPerna received a Master's in Engineering Management from Northeastern University and a BS in Mechanical Engineering from the University of Lowell. From January 2017 until July 2019, Mr. DiPerna joined National Cardiac Incorporated as its Chief Executive Officer and as a board member to leverage their technology in the cardiac monitoring space.

The Market

Generally, there are two primary therapies used by people with insulin-requiring diabetes: insulin injections and insulin pumps. Each is designed to supplement or replace the insulin-producing function of the pancreas. Insulin injections are often referred to as multiple daily injection, or MDI, and involve the use of syringes or insulin pens to inject insulin into the body, as required. Insulin pumps are used to provide a steady flow of insulin (often referred to as continuous subcutaneous insulin infusion or basal rate insulin) and bursts of mealtime insulin (boluses). Insulin pump therapy has been shown to provide people with insulin-requiring diabetes with numerous advantages compared to MDI. The steady flow of insulin and the easier application of mealtime boluses has been shown by numerous clinical studies to result in lower HbA1c (a measure of the amount of glucose in the bloodstream) when compared to MDI therapy. This results in lower rates of hospitalization and a reduction in overall adverse events for people with diabetes.

We believe that the greater efficacy of pumps compared to MDI makes insulin pumps a more optimal choice for persons in managing diabetes, but that the shortcomings and challenges around existing pumps have held back adoption rates.

According to the CDC, in the United States, in 2020, 88 million people, or 1 out of 3 adults, had pre-diabetes, approximately 27 million people had been diagnosed with diabetes and an additional 7 million people had diabetes that was undiagnosed. The CDC also indicated that diabetes was the seventh leading cause of death in the United States in 2017, which according to the CDC, may be underreported. Diabetes was the leading cause of kidney failure, lower-limb amputations, and adult-onset blindness and represented more than $327 billion in medical costs in 2017.

We believe that due to a number of factors including the large consumption of processed foods and the growing obesity problem in the United States, the number of persons requiring daily administration of insulin is and will continue to grow at rapid rates.

The category of persons with diabetes requiring daily insulin administration is our target market and we believe our proposed product has the potential to substantially improve the day to day quality of life of such persons.

The Opportunity

We believe the insulin pump market is large and growing, but, generally, has been poorly served by existing products that have limited the adoption of insulin pumps. We believe an insulin pump having the correct mix of efficiency, reliability, features that are easy to understand and use, and offered at an affordable price point will drive a substantial percentage of “almost-pumpers” to use insulin pumps and persons currently using available, but less than optimal pumps, to switch to such a more desirable product. We believe that such an insulin pump can improve glucose control, and, therefore, the user’s quality of life while substantially mitigating adverse diabetes related health risks and many if not all of the challenges and shortcomings discussed herein.

We believe there is a substantial opportunity to penetrate the type 2 MDI marketplace, whether through this new insulin pump or further simplification of pumps for the type 2 marketplace.

As set forth in general terms herein, we believe existing pumps have numerous shortcomings and challenges including:

Outdated style**.** Consumer electronics devices have evolved in both form and function. Diabetes pumps have not experienced similar progress. We believe that consumers will be more receptive of products designed with the user experience in mind and that many have low tolerance for complex, difficult procedures for use and maintenance of products.

Bulky size. We believe that consumers view traditional pumps, especially those with tubing, to be large, bulky, and inconvenient to carry or wear, especially when compared to modern consumer electronic devices. The size of the pump further contributes to users being embarrassed by the pump. We believe a simple patch style of pump will drive adoption.

Pump mechanism limitations. Traditional pumps generally utilize a syringe and plunger mechanism to deliver insulin. We believe this design limits the ability to reduce the size of the pump, and also potentially exposes the user to the unintended delivery of the full volume of insulin within the pump, which can cause hypoglycemia or death. We believe that the fear of adverse health events due to technical malfunctions related to traditional pump mechanism limitations deters the adoption of insulin pump therapy.

Costs. Existing pumps are expensive, with the more popular models having purchase prices exceeding $4,000 for individuals without health insurance and often require significant patient copays. Others have daily use costs that exceed the reimbursement rates of many health insurance plans, forcing some users to spend thousands of dollars a year in copays. We believe this makes insurers hesitant to pay for pumps for any but their best and most compliant patients and places them out of reach for many patients who cannot afford such out of pocket expenses.

Our Solution

Our proposed pump is being designed and developed to address the above shortcomings and to appeal to (i) the substantial group of “almost-pumpers” who are currently interested in using an insulin pump, but have not done so because of the complexity, cost or cumbersome nature of existing products, and (ii) people who are using one of the currently available insulin pumps but are dissatisfied with such products. We believe that, owing to our new proprietary technology, our proposed insulin pump will be the simplest and least expensive product on the market and the easiest for providers to prescribe.

Our current pump prototype of our proposed pump has been built to test what we believe to be our novel approach to insulin pumps. By providing a pump that we believe will establish industry standards in terms of technology, simplicity to understand, ease of use and price, we believe our proposed pump will offer the vast majority of benefits afforded by more expensive and complex pumps but while accessible to a substantially greater percentage of diabetes sufferers requiring daily insulin therapy.

We believe people generally will not use technology that intimidates them and physicians are hesitant to prescribe such technology. We believe mass market products, such as is intended for our proposed pump must be “user friendly” and affordable. We believe this approach is fundamentally different from that applied to the existing pump market today where most pumps are continuously adding complex features and are “user friendly” to only the most technically astute and are becoming more complex and difficult to use.

Our current goal is to successfully design, develop and obtain all required regulatory approvals for our proposed insulin pump, and, thereafter, commercialize, market and sell the finished product. Our long-term goal is to become a leading provider of insulin pump therapy by focusing on both consumer and clinical needs.

To achieve our above stated immediate and current goals, we intend to pursue the following business strategies:

Use of innovative proprietary technology.

Based upon Mr. DiPerna's substantial experience in engineering design and innovative technology in the medical device industry and, in particular, with insulin pumps, we have generated proprietary technology that will be incorporated into our proposed insulin pump. Generally, this technology is involved in the delivery of insulin to the user at the appropriate and necessary times. We believe this technology will greatly assist us in creating a simpler user-friendly pump. We believe the proposed design, engineering and technology being incorporated into our proposed pump, will make our proposed pump substantially simpler and more affordable than those currently available. These features, together with the safety and reliability of our proposed pump, are designed to create the next generation of insulin pumps that will be superior to those currently available and make it available to consumers across mostly all socioeconomic groups in the United States and around the world.

Keep costs low during our design and development process.

To attempt to ensure that we have sufficient funds to design, develop and obtain all required regulatory approvals for our proposed insulin pump without having to sacrifice quality and efficiency, we intend to maintain a tight budget and limit expenditures where possible. We believe this will be possible because of the extensive knowledge and experience of Mr. DiPerna not only in the diabetes industry and more specifically in the insulin pump device market, but also his experience in designing and developing insulin pumps and other medical devices and his ability to manage a small, focused development team. We currently expect various other expenses such as product scale up, sales and marketing costs will not be incurred until such time as development work is completed and regulatory approvals obtained.

Employ experienced engineers picked, supervised and led by Mr. DiPerna, a highly experienced and respected engineer and executive in the insulin pump industry.

To attempt to ensure our proposed insulin pump is "state of the art," functional, and efficient, as well as to conserve funds, significantly all of our employees will initially be hand-picked engineers under the leadership of Mr. DiPerna. We believe that there is a strong pool of engineers with significant applicable experience and knowledge who we will be able to initially employ on a contract and/or outsource basis to help us design and develop our proposed insulin pump. We believe by hiring such persons on an out-source basis, we will save substantial resources and by having Mr. DiPerna lead and focus the team on technological and mechanical aspects of our proposed insulin pump, we believe our team will be well guided, focused, cost efficient, and able to efficiently design and develop our product that we believe can eventually be an industry standard.

Government Regulation

The medical device industry is regulated extensively by governmental authorities, principally the FDA and corresponding state regulatory agencies. The regulations are very complex and are subject to rapid change and varying interpretations. Regulatory restrictions or changes could limit our ability to bring our proposed product to the commercialization stage as a result of higher than anticipated costs to obtain regulatory approval. The FDA and other U.S. governmental agencies regulate numerous elements of our proposed product at various stages, including:

- product design and development;
- pre-clinical and clinical testing and trials;
- product safety;
- establishment registration and product listing;
- labeling and storage;
- marketing, manufacturing, sales and distribution;
- pre-market clearance or approval;
- servicing and post-market surveillance;
- advertising and promotion; and
- recalls and field safety corrective actions.

Even if we obtain all regulatory approvals, before we can market or sell our proposed product, we must obtain either clearance under Section 510(k) of the FDCA or approval of a pre-market approval application, a PMA, from the FDA, unless an exemption from pre-market review applies. In the 510(k) clearance process, the FDA must determine that a proposed device is "substantially equivalent" to a device legally on the market, known as a "predicate" device, with respect to intended use, technology and safety and effectiveness, in order to clear the proposed device for marketing. Clinical data is sometimes required to support a determination of substantial equivalence. The PMA pathway requires an applicant to demonstrate the safety and effectiveness of the device based on extensive data. The PMA process is typically required for devices that are deemed to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices, such as our proposed insulin pump. Products that are approved through a PMA application generally need FDA approval before they can be modified. Similarly, some modifications made to products cleared through a 510(k) may require a new 510(k). The process of obtaining regulatory clearances or approvals to market a medical device, such as our proposed insulin pump, can be costly and time-consuming, and we may not be able to obtain such clearances or approvals on a timely basis or at all for our proposed product.

If the FDA requires us to go through a more rigorous examination for our proposed product than we currently expect, we will require substantial additional funding sooner than anticipated and/or our product could be severely delayed, or our efforts ceased. We anticipate that our proposed product will require the more costly, lengthy and uncertain PMA approval process.

The FDA can delay, limit or deny clearance or approval of our proposed pump device for many reasons, including:

- our inability to demonstrate that our product is safe and effective for its intended users;
- the data from our clinical trials may be insufficient to support clearance or approval; and
- failure of the manufacturing process or facilities we use to meet applicable requirements.

In addition, the FDA may change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions which may prevent or delay approval or clearance of our proposed product.

Any delay in, or failure to receive or maintain, clearance or approval for our products under development could prevent us from generating revenue therefrom or achieving profitability. Additionally, the FDA and other regulatory authorities have broad enforcement powers. Regulatory enforcement or inquiries, or other increased scrutiny on us, could dissuade some customers from using our proposed product and adversely affect our reputation and the perceived safety and efficacy of our proposed product.

Failure to comply with applicable regulations could jeopardize our ability to commercialize and sell our proposed pump and result in enforcement actions such as fines, civil penalties, injunctions, warning letters, recalls of products, delays in the introduction of products into the market, refusal of the FDA or other regulators to grant future clearances or approvals, and the suspension or withdrawal of existing approvals by the FDA or other regulators. Any of these sanctions could result in higher than anticipated costs and have a material adverse effect on our reputation, business and financial condition.

Employees

As of March 31, 2020, we had 13 employees all of whom are located in the United States, consisting of 10 in research and development and manufacturing operations and 3 in marketing and general and administrative functions

Competition

Medtronic, Inc., Tandem Diabetes Care, Inc. and Insulet Corporation are all much larger companies with substantially greater resources than us that make similar products for the more sophisticated, technically capable person with diabetes. We do not intend to directly compete for those patients, instead we intend to offer a simple to use more cost-effective solution to attract the more mainstream patients.

Intellectual Property

Our success depends in part on our ability to obtain patents and trademarks, maintain trade secret and know-how protection, enforce our proprietary rights against infringers, and operate without infringing on the proprietary rights of third parties. Because of the length of time and expense associated with developing new products and bringing them through the regulatory approval process, the health care industry places considerable emphasis on obtaining patent protection and maintaining trade secret protection for new technologies, products, processes, know-how, and methods.

As of March 31, 2020, we had four pending U.S. utility patent applications and three foreign pending patent applications related to our proprietary fluid movement technology and the configuration of our product offering. There can be no assurance that the pending patent applications will result in the issuance of patents, that patents issued to or licensed by us will not be challenged or circumvented by competitors, or that these patents will be found to be valid or sufficiently broad to protect our technology or provide us with a competitive advantage.

Corporate History and Background

We were formed as a corporation under the laws of the State of Nevada in October 1998 under the name Bear Lake Recreation Inc. We had no material business operations from 2002 until July 2017, when we acquired Quasuras, Inc., a Delaware corporation (Quasuras), in the Acquisition (as defined below). Prior to the Acquisition, and, since at least 2002, we were a shell company, as defined in Rule 12b-2 promulgated under the Securities Exchange Act of 1934 (the Exchange Act).

The Control Block Acquisition. On April 26, 2017, pursuant to a Common Stock Purchase Agreement, dated as of April 5, 2017, by and among Manchester Explorer, LP, a Delaware limited partnership (Manchester Explorer), the Company and certain persons named therein, Manchester Explorer purchased from us 2,900,000 shares of our common stock representing in excess of a majority of our then issued and outstanding common stock, for a purchase price of $375,000 (the Control Block Acquisition), resulting in a change in control of the Company. In connection with the Control Block Acquisition, James E. Besser was appointed president and a director and Morgan C. Frank was appointed the chief executive officer, chief financial officer, secretary, treasurer and a director of ours and immediately following such appointments, our then officers and directors resigned. Mr. Besser is the managing member of and Mr. Frank is the portfolio manager and a consultant to Manchester Management Company, LLC, a Delaware limited liability company MMC). MMC is the general partner of Manchester Explorer and Jeb Partners, L.P. (Jeb Partners, and together with Manchester Explorer, collectively, the Purchasing Funds).

The Acquisition. On July 24, 2017, pursuant to a Reorganization and Share Exchange Agreement, by and among the Company, Paul M. DiPerna, the sole officer, director and a controlling stockholder of Quasuras, Messrs. Besser and Frank (Messrs. Besser, Frank and DiPerna, collectively, the 3 Quasuras Shareholders), and Quasuras, we acquired all of the issued and outstanding shares of Quasuras owned by the 3 Quasuras, resulting in Quasuras becoming our wholly-owned subsidiary (the Acquisition). Simultaneously with the closing of the Acquisition, Manchester Explorer cancelled the 2,900,000 shares of our common stock purchased in the Control Block Acquisition, Mr. Besser resigned as our president and a director and Mr. Frank resigned as our chief executive officer, chief financial officer, secretary, and treasurer, but remained a director, and Mr. DiPerna was appointed our chairman of the board of directors, chief executive officer, chief financial officer, secretary and treasurer.

In anticipation of the closing of the Acquisition, on June 27, 2017, we changed our name from “Bear Lake Recreation, Inc.” to “Modular Medical, Inc.” and changed our trading symbol from “BLKE” to “MODD.”

Following the closing of the Acquisition, on July 28, 2017, we filed a Current Report on Form 8-K, as amended (the Super 8-K), with the Securities and Exchange Commission (the SEC) to disclose the Acquisition and related transactions, and upon the filing of the Super 8-K we ceased being a shell company.

Smaller Reporting Company

We are subject to the reporting requirements of Section 13 of the Exchange Act, and we are subject to the disclosure requirements of Regulation S-K of the SEC, as a “smaller reporting company.” That designation relieves us of some of the disclosure requirements of Regulation S-K.

Available Information

You may read and copy any materials that we file with the SEC at the SEC’s Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549. You may also find all of the reports or registration statements that we have previously filed electronically with the SEC at its Internet site at www.sec.gov. Please call the SEC at 202-551-8090 for further information on this or other Public Reference Rooms. Our SEC reports and registration statements are also available from commercial document retrieval services, such as CCH Washington Service Bureau, whose telephone number is 1-800-955-0219.

ITEM 1A. RISK FACTORS

We are a developmental stage medical device company and have a history of significant operating losses; we expect to continue to incur operating losses, and we may never achieve or maintain profitability.

As a development-stage enterprise, we do not currently have revenues to generate cash flows to cover operating expenses. Since our inception, we have incurred operating losses in each year due to costs incurred in connection with research and development activities and general and administrative expenses associated with our operations. For the years ended March 31, 2020 and 2019, we incurred net losses of approximately $5.3 million and $2.5 million, respectively. At March 31, 2020, we had an accumulated deficit of approximately $8.6 million. As a result, we will need to raise additional capital in the future, which may or may not be available to us at all or only on unfavorable terms.

We expect to incur losses for the foreseeable future, as we continue the development of, and seek regulatory clearance and approvals for, our insulin pump. As our prototype insulin pump is currently our only product, if it fails to gain regulatory approval and market acceptance, we will not be able to generate any revenue, or explore other opportunities to enhance shareholder value, such as through a sale. If we fail to generate revenue and eventually become profitable, or if we are unable to fund our continuing losses, our shareholders could lose all or a substantial part of their investment.

We might not be able to continue as a going concern which would likely cause our stockholders to lose most or all of their investment.

Our audited financial statements for the year ended March 31, 2020 were prepared under the assumption that we would continue as a going concern. However, our independent registered public accounting firm included a "going concern" explanatory paragraph in its report on our financial statements for the year ended March 31, 2020, indicating that, without additional sources of funding, our cash at March 31, 2020 is not sufficient for us to operate as a going concern for a period of at least one year from the date that the financial statements included in this Report are issued. Management's plans concerning these matters, including our need to raise additional capital, are described in Management's Discussion and Analysis of Financial Conditions and Results of Operations included in Item 7 of this Report and in Note 1 to our consolidated financial statements included in Item 8 of this Report. However, we cannot assure you that our plans will be successful. In light of the foregoing, there is substantial doubt about our ability to continue as a going concern. If we cannot continue as a viable entity, our stockholders would likely lose most or all of their investment in us.

The full effects of COVID-19 and other potential future public health crises, epidemics, pandemics or similar events are uncertain and could have a material and adverse effect on our business, financial condition, operating results and cash flows.

The global outbreak of the coronavirus disease 2019, or COVID-19, was declared a pandemic by the World Health Organization and a national emergency by the U.S. government in March 2020. This has negatively affected the world economy, disrupted global supply chains, significantly restricted travel and transportation, resulted in mandated closures and orders to "shelter-in-place" and created significant disruption of the financial markets. The extent of the impact on our operational and financial performance will depend on future developments, including the duration and spread of the pandemic and related actions taken by U.S. and foreign government agencies to prevent disease spread, all of which are uncertain, out of our control and cannot be predicted.

In accordance with applicable U.S. governmental ordinances generally exempting essential businesses and/or critical infrastructure workforces from mandated closures and orders to "shelter-in-place," we are operating in support of essential products and services, subject to limitations and requirements in applicable state and county orders. We have been complying with county and state orders and have implemented a teleworking policy for our employees and contractors and significantly minimized the number of employees who visit our office. However, a facility closure, work slowdowns or temporary stoppage at one of our manufacturing suppliers could occur, which could have a longer-term impact and could delay our prototype production and ability to conduct business.

If our workforce is unable to work effectively, including because of illness, quarantines, absenteeism, government actions, facility closures, travel restrictions or other restrictions in connection with the COVID-19 pandemic, our operations will be negatively impacted. We may be unable to develop our product, and our costs may increase as a result of the COVID-19 outbreak. The impacts could worsen if there is an extended duration of any COVID-19 outbreak or a resurgence of COVID-19 infection in affected regions after they have begun to experience improvement.

We rely on other companies to provide components and to perform services for us. An extended period of supply chain disruption caused by the response to COVID-19 could impact our ability to produce our initial product quantities, and, if we are not able to implement alternatives or other mitigations, product deliveries would be adversely impacted and negatively impact our business, financial condition, operating results and cash flows. Limitations on government operations can also impact regulatory approvals that are necessary for us to operate our business.

The continued spread of COVID-19 has also led to disruption and volatility in the global capital markets. We were recently able to raise additional capital in a private placement that commenced in March 2020, however, we will need to raise additional capital to support our operations in the future. We may be unable to access the capital markets, and additional capital may only be available to us on terms that could be significantly detrimental to our existing stockholders and to our business.

We will need substantial additional funding to complete subsequent phases of our insulin pump product and to operate our business and such funding may not be available or, if it is available, such financing is likely to substantially dilute our existing shareholders.

The discovery, development, and commercialization of new medical devices, such as our insulin pump, entails significant costs. While we believe that we have generally completed the engineering and mechanical aspects of our insulin pump prototype, we still must modify, refine and finalize our insulin pump to, among other things, meet the general needs and preferences of the almost pumper marketplace and the guidelines of third-party payors. To enable us to accomplish these and other related items and continue to operate our business, we will need to raise substantial additional capital and/or enter into strategic partnerships or joint ventures to enable us to:

- fund clinical studies and seek regulatory approvals;
- build or access manufacturing and commercialization capabilities;

- develop, test, and, if approved, market our product;
- acquire or license additional internal systems and other infrastructure; and
- hire and support additional management, engineering and scientific personnel.

Until we can generate a sufficient amount of product revenue to finance our cash requirements, which we may never achieve, we expect to finance our cash needs primarily through public or private equity offerings, debt financings or through the establishment of possible strategic alliances. We cannot be certain that additional funding will be available on acceptable terms, or at all. If we are not able to secure additional equity funding when needed, we may have to delay, reduce the scope of, or eliminate one or more of our clinical studies, development programs or future commercialization initiatives. In addition, any additional equity funding that we do obtain will dilute the ownership held by our existing equity holders. The amount of this dilution may be substantially increased if the trading price of our common stock is lower at the time of any financing. Regardless, the economic dilution to shareholders will be significant if our stock price does not increase significantly, or if the effective price of any sale is below the price paid by a particular shareholder. Any debt financing that we obtain in the future could involve substantial restrictions on activities and creditors could seek a pledge of some or all of our assets. We have not identified potential sources for such financing that we will require, and we do not have commitments from any third parties to provide any future debt financing. If we fail to obtain funding as needed, we may be forced to cease or scale back operations, and our results, financial condition and stock price would be adversely affected.

We have a limited operating history and historical financial information upon which you may evaluate our performance.

You should consider, among other factors, our prospects for success in light of the risks and uncertainties encountered by companies that, like us, are in their early stages of development. We may not successfully address these risks and uncertainties or successfully complete our studies and/or implement our existing and new products. If we fail to do so, it could materially harm our business and impair the value of our common stock. Unanticipated problems, expenses and delays are frequently encountered in establishing a new business, conducting research, and developing new products. These include, but are not limited to, inadequate funding, failure to obtain regulatory approval, unforeseen research issues, lack of consumer acceptance, competition, sluggish product development, and inadequate sales and marketing. The failure by us to meet any of these conditions would have a materially adverse effect upon us and may force us to reduce or curtail operations. No assurance can be given that we can or will ever operate profitably.

We may not be able to meet our future capital needs.

To date, we have no revenue and we have limited cash liquidity and capital resources. We will need additional capital in the near future. Any equity financings will result in dilution and may contain other terms that are not favorable to our then-existing stockholders. Although we currently do not have any debt financing, any sources of debt financing that we may obtain in the future may result in a high interest expense. Any financing, if available, may be on unfavorable terms. If adequate funds are not obtained, we will be required to reduce or curtail operations.

The amount of financing we require will depend on a number of factors, many of which are beyond our control. Our results of operations, financial condition and stock price are likely to be adversely affected if our funding requirements increase or are otherwise greater than we expect.

Our future funding requirements will depend on many factors, including, but not limited to:

- the costs of our tests for our insulin pump product and other development activities conducted by us directly, and our ability to successfully conclude the studies and activities and achieve favorable results;
- our ability to attract future strategic partners to pay for or share costs related to our product development efforts;
- the costs and timing of seeking and obtaining regulatory clearance and approvals for our product;
- the costs of filing, prosecuting, maintaining and enforcing any patents and other intellectual property rights that we may have and defending against potential claims of infringement;
- decisions to hire additional scientific, engineering or administrative personnel or consultants;

- our ability to manage administrative and other costs of our operations; and
- the presence or absence of adverse developments in our research program.

If any of these factors cause our funding needs to be greater than expected, our operations, financial condition, ability to continue operations and stock price may be adversely affected.

Our future cash requirements may differ significantly from our current estimates.

Our cash requirements may differ significantly from our estimates from time to time, depending on a number of factors, including:

- the costs and results of our clinical studies regarding our insulin pump product;
- the time and costs involved in obtaining regulatory clearance and approvals;
- whether we are able to obtain funding under future licensing agreements, strategic partnerships, or other collaborative relationships, if any;
- the costs of compliance with laws, regulations, or judicial decisions applicable to us; and
- the costs of general and administrative infrastructure required to manage our business and protect corporate assets and shareholder interests

If we fail to raise additional funds on a timely basis, we will need to scale back our business plans, which would adversely affect our business, financial condition, and stock price, and we may even be forced to discontinue our operations and liquidate our assets. See “Our Business – Keep costs low during our design and development process,” below.

Technological breakthroughs in diabetes monitoring, treatment or prevention could render our insulin pump obsolete.

The diabetes treatment market is subject to rapid technological change and product innovation. Our insulin pump is based on our proprietary technology, but a number of companies, medical researchers and existing pharmaceutical companies are pursuing new delivery devices, delivery technologies, sensing technologies, procedures, drugs and other therapeutics for the monitoring, treatment and/or prevention of insulin-dependent diabetes. Any technological breakthroughs in diabetes monitoring, treatment or prevention could render our insulin pump obsolete, which, since our insulin pump is our only product, would have a material adverse effect on our business, financial condition and results of operations and could result in shareholders losing their entire investment.

Any failure to attract and retain skilled directors, executives, employees and consultants could impair our product development and commercialization activities.

Our business depends on the skills, performance, and dedication of our directors, executive officers and key engineering, scientific and technical advisors. Many of our current engineering or scientific advisors are independent contractors and are either self-employed or employed by other organizations. As a result, they may have conflicts of interest or other commitments, such as consulting or advisory contracts with other organizations, which may affect their ability to provide services to us in a timely manner. We will need to recruit additional directors, executive management employees, and advisers, particularly engineering, scientific and technical personnel, which will require additional financial resources. In addition, there is currently intense competition for skilled directors, executives and employees with relevant engineering, scientific and technical expertise, and this competition is likely to continue. If we are unable to attract and retain persons with sufficient engineering, scientific, technical and managerial experience, we may be forced to limit or delay our product development activities or may experience difficulties in successfully conducting our business, which would adversely affect our operations and financial condition. See “Our Business – Employ experienced engineers, recruited, supervised and led by Mr. DiPerna, a highly experienced respected engineer and executive in the insulin pump industry.”

We have limited internal research and development personnel, making us dependent on consulting relationships.

We consider research and development to be an important part of the process of designing, developing, obtaining regulatory required approvals and the eventual commercialization of our insulin pump. We continue to incur increased research and development expenditures, which are attributable to effort and expenses incurred in designing and developing our innovative insulin pump. We expect to continue to incur substantial costs related to research and development.

We currently have a limited number of research and development personnel, and rely and expect for the foreseeable future to continue to rely, on consultants, whom are not our employees, to perform significant functions for us. As a result, we are and expect to continue for the foreseeable future to be dependent on such third parties. Such third parties may be able to terminate their contractual relationships with us quickly and with little, if any, notice. Although we believe there is a relatively large and readily accessible network of third parties that we can draw from to replace any of our third-party consultants, no assurances can be given that we would be able to quickly and seamlessly find and hire suitable replacements. Any material interruption or delay in our research and development activities performed by our consultants could impair our ability to meet any deadlines and materially impair our then product design and development, regulatory approval and/or commercialization activities which could have a material adverse effect on our business, financial condition and stock price. In addition, if we do not appropriately manage our relationships with our consultants, we may not be able to efficiently manage the development, testing, regulatory approval and eventual commercialization of our insulin pump, which also could have a material and adverse effect on our business, financial condition and stock price.

We will need to outsource and rely on third parties for various aspects relating to the development, manufacture, sales and marketing of our insulin pump as well as in connection with assisting us in the preparation and filing of our FDA submission, and our future success will be dependent on the timeliness and effectiveness of the efforts of these third parties.

We are dependent on consultants for important aspects of our product development strategy. We do not have the required financial resources and personnel to carry out independently the development of our product, and do not have the capability or resources to manufacture, market or sell our current product. As a result, we contract with and rely on third parties for important functions, including in connection with the development and finalization of our insulin pump, the preparation and filing of our FDA submission and eventual manufacturing and commercialization of our product. We have recently entered into several agreements with third parties for such services. If problems develop in our relationships with third parties, or if such parties fail to perform as expected, it could lead to delays or lack of progress in obtaining FDA clearance, significant cost increases, changes in our strategies, and even failure of our product initiatives.

We may not be able to identify, negotiate and maintain the strategic alliances necessary to develop and commercialize our products and technologies, and we will be dependent on our corporate partners if we do.

We may seek to enter into a strategic alliance with a diabetes related service providing company for the further development and approval of our insulin pump product. At this time, we have not entered into any such strategic alliance. Strategic alliances, if entered into, could potentially provide us with additional funds, expertise, access, and other resources in exchange for exclusive or non-exclusive licenses or other rights to the product that we are currently developing or a product we may explore in the future. We cannot give any assurance that we will be able to enter into strategic relationships with a diabetes related service providing company or others in the near future or at all. In addition, we cannot assure you that any agreements that we do reach will achieve our goals or be on terms that prove to be economically beneficial to us. When we do enter into strategic or contractual relationships, we become dependent on the successful performance of our partners or counter-parties. If they fail to perform as expected, such failure could adversely affect our financial condition, lead to increases in our capital needs, or hinder or delay our development efforts. See “Our Business – Number of Total Employees” below.

We may not receive the necessary regulatory clearance or approvals for our insulin pump, and failure to timely obtain necessary clearances and/or approvals could harm our then operations, including to commercialize our product.

Before we can market a new medical device, such as our insulin pump, we must first receive clearance under Section 510(k) of the Federal Food, Drug, and Cosmetic Act, or the FDCA. In the 510(k) clearance process, before a device may be marketed, the FDA must determine that such proposed device is “substantially equivalent” to a legally-marketed “predicate” device, which includes a device that has been previously cleared through the 510(k) process, a device that was legally marketed prior to May 28, 1976 (pre-amendments device), a device that was originally on the U.S. market pursuant to an approved pre-market approval (PMA) and later down-classified, or a 510(k)-exempt device. To be “substantially equivalent,” the proposed device must have the same intended use as the predicate device, and either have the same technological characteristics as the predicate device or have different technological characteristics and not raise different questions of safety or effectiveness than the predicate device.

Certain future modifications made to our product, which we currently expect to be cleared through 510(k), may require a new 510(k) clearance. The 510(k) clearance process can be expensive, lengthy and uncertain. The FDA’s 510(k) clearance process usually takes from three to 12 months, but can last longer. Despite the time, effort and cost, a device may not be approved or cleared by the FDA. Any delay or failure to obtain necessary regulatory approvals could harm our business, including our ability to commercialize our product and our shareholders could lose their entire investment. Furthermore, even if we are granted the required regulatory clearances, such clearances may be subject to significant limitations on the indicated uses for the device, which may limit the market for our product.

If the FDA requires us to go through a lengthier, more rigorous examination for our product than we had expected, product introductions or modifications could be delayed or canceled, which could adversely affect our ability to grow our business.

The FDA can delay, limit or deny clearance or approval for our insulin pump medical device for many reasons, including:

- our inability to demonstrate to the satisfaction of the FDA that our product is safe or effective for its intended use;
- the disagreement of the FDA with the design or implementation of our clinical studies or the interpretation of data from our clinical studies;
- serious and unexpected adverse device effects experienced by participants in our clinical studies;
- the data from clinical studies may be insufficient to support clearance or approval, where required;
- our inability to demonstrate that the benefits of our pump outweigh the risks;
- the manufacturing process or facilities we intend to use may not meet applicable requirements; and
- the potential for approval policies or regulations of the FDA to change significantly in a manner rendering our data or regulatory filings insufficient for clearance or approval.

In addition, the FDA may change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions, which may prevent or delay approval or clearance of our product or impact our ability to modify our product after clearance on a timely basis. Such policy or regulatory changes could impose additional requirements upon us that could delay our ability to obtain clearance for our pump, increase the costs of compliance or restrict our ability to maintain our current approval. For example, as part of the Food and Drug Administration Safety and Innovation Act, or FDASIA, enacted in 2012, the U.S. Congress reauthorized the Medical Device User Fee Amendments with various FDA performance goal commitments and enacted several “Medical Device Regulatory Improvements” and miscellaneous reforms, which are further intended to clarify and improve medical device regulation both pre- and post-clearance and approval. Some of these proposals and reforms could impose additional regulatory requirements upon us that could delay our ability to obtain new clearance, increase the costs of compliance or restrict our ability to maintain any clearance or approval we are able to obtain.

As a general rule, demonstration of conformity of medical devices and their manufacturers with the essential requirements must be based, among other things, on the evaluation of data supporting the safety and performance of the products during normal conditions of use. Specifically, a manufacturer must demonstrate that the device achieves its intended performance during normal conditions of use, that the known and foreseeable risks, and any adverse events, are minimized and acceptable when weighed against the benefits of its intended performance, and that any claims made about the performance and safety of the device are supported by suitable evidence.

Our competitors may develop products that are more effective, safer and less expensive than ours.

Existing insulin pumps are expensive, with the more popular models having purchase prices exceeding $4,000 for individuals without health insurance and often require significant patient copays. Others have daily use costs that exceed the reimbursement rates of many health insurance plans, forcing some users to spend thousands of dollars a year in copays. We believe this makes insurers hesitant to pay for any pumps, except their most technologically proficient and compliant patients and places pumps out of reach for many patients whom cannot afford such out of pocket expenses.

We are engaged in the diabetes treatment sector of the healthcare marketplace, which is intensely competitive. There are current products that are quite effective at addressing the effects of diabetes, and we expect that new developments by other companies and academic institutions in the areas of diabetes treatment will continue. If approved for marketing by the FDA, depending on the approved clinical indication, our product will be competing with existing and future products related to treatments for diabetes.

Our competitors may:

- develop product candidates and market products that increase the levels of safety or efficacy that our product candidates will need to show in order to obtain regulatory approval;
- develop product candidates and market products that are less expensive or more effective than ours;
- commercialize competing products before we can launch any products we are working to develop;
- hold or obtain proprietary rights that could prevent us from commercializing our products; or
- introduce therapies or market medical products that render our potential product candidates obsolete.

We expect to compete against large medical device companies, such as Medtronic, Inc., Tandem Diabetes Care, Inc. and Insulet Corporation and smaller companies that are collaborating with larger medical device companies, new companies, academic institutions, government agencies and other public and private research organizations. These competitors, in nearly all cases, produce similar products relative to the treatment of diabetes that have substantially greater financial resources than we do. Our competitors also have significantly greater experience in:

- developing medical device and other product candidates;
- undertaking testing and clinical studies;
- building relationships with key customers and opinion-leading physicians;
- obtaining and maintaining FDA and other regulatory approvals;
- formulating and manufacturing medical devices;
- launching, marketing and selling medical devices; and
- providing management oversight for all of the above-listed operational functions.

If we fail to achieve superiority over other existing or newly developed products, we may be unable to obtain regulatory approval. If our competitors' market medical devices that are less expensive, safer or more effective than our insulin pump, or that gain or maintain greater market acceptance, we may not be able to compete effectively. See "Our Business – Competition" below.

We expect to rely on third party manufacturers and will be dependent on their quality and effectiveness.

Our insulin pump requires precise, high-quality manufacturing. The failure to achieve and maintain high manufacturing standards, including failure to detect or control anticipated or unanticipated manufacturing errors or the frequent occurrence of such errors, could result in patient injury or death, discontinuance or delay of ongoing or planned clinical studies, delays or failures in product testing or delivery, cost overruns, product recalls or withdrawals and other problems that could seriously hurt our business. Contract medical device manufacturers often encounter difficulties involving production yields, quality control and quality assurance and shortages of qualified personnel. These manufacturers are subject to stringent regulatory requirements, including the FDA's current good-manufacturing-practices regulations. If our contract manufacturers fail to maintain ongoing compliance at any time, the production of our product could be interrupted, resulting in delays or discontinuance of our clinical studies, additional costs and loss of potential revenues. See "Our Business – Keep costs low during design and development process" below.

We may not be able to successfully scale-up manufacturing of our product in sufficient quality and quantity, which would delay or prevent us from developing our product and commercializing our product.

In order to conduct larger-scale or late-stage clinical studies and for commercialization of our insulin pump, if 510(k) clearance is granted, we will need to manufacture it in larger quantities. We may not be able to successfully increase the manufacturing capacity for our product in a timely or cost-effective manner, or at all. In addition, quality issues may arise during scale-up activities. If we are unable to successfully scale up the manufacture of our product in sufficient quality and quantity, the development and testing of our product and regulatory approval or commercial launch may be delayed, which could significantly harm our business.

We may be subject to potential product liability and other claims that could materially impact our business and financial condition.

The development and sale of our insulin pump exposes us to the risk of significant damages from product liability and other claims, and the use of our product in clinical studies may result in adverse effects. We cannot predict all the possible harms or adverse effects that may result. We maintain a modest amount of product liability insurance to provide some protection from claims. Nonetheless, we may not have sufficient resources to pay for any liabilities resulting from a personal injury or other claim, even if it is partially covered by insurance. In addition to the possibility of direct claims, we may be required to indemnify third parties against damages and other liabilities arising out of our development, commercialization and other business activities, which would increase our liability exposure. If third parties that have agreed to indemnify us fail to do so, we may be held responsible for those damages and other liabilities as well.

Legislative, regulatory, or medical cost reimbursement changes may adversely impact our business.

New laws, regulations and judicial decisions, or new interpretations of existing laws, regulations and decisions, that relate to the health care system in the U.S. and in other jurisdictions may change the nature of and regulatory requirements relating to innovations in medical devices, testing and regulatory approvals, limit or eliminate payments for medical procedures and treatments, or subject the pricing of medical devices to government control. In addition, third-party payors in the U.S. are increasingly attempting to contain health care costs by limiting both coverage and the level of reimbursement of new products. Consequently, significant uncertainty exists as to the reimbursement status of newly approved health care products. Significant changes in the health care system in the U.S. or elsewhere, including changes resulting from adverse trends in third-party reimbursement programs, could have a material adverse effect on our projected future operating results and our ability to raise capital, commercialize products, and remain in business. See "Our Business – Government Regulations" below.

We are subject to extensive regulation by the U.S. Food and Drug Administration, which could restrict the sales and marketing of our insulin pump and could cause us to incur significant costs.

Our insulin pump is subject to extensive regulation by the FDA. These regulations relate to manufacturing, labeling, sale, promotion, distribution and shipping. Before a new medical device, or a new use of or claim for an existing product, can be marketed in the United States, it must first receive either 510(k) clearance or PMA from the FDA, unless an exemption applies. We may be required to obtain a new 510(k) clearance for significant post-market modifications to our insulin pump. Each of these processes can be expensive and lengthy, and entail significant user fees, unless exempt.

Medical devices may be marketed only for the indications for which they are approved or cleared. Further, 510(k) clearances can be revoked if safety or effectiveness problems develop.

The current regulatory requirements to which we are subject may change in the future in a way that adversely affects us. If we fail to comply with present or future regulatory requirements that are applicable to us, we may be subject to enforcement action by the FDA, which may include any of the following sanctions:

- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- customer notification, or orders for repair, replacement or refunds
- voluntary or mandatory recall or seizure of our current or future products;
- administrative detention by the FDA of medical devices believed to be adulterated or misbranded;
- imposing operating restrictions, suspension or shutdown of production;
- refusing our requests for 510(k) clearance or pre-market approval of any new products, new intended uses or modifications to our insulin pump;
- rescinding 510(k) clearance that has already been granted; and
- criminal prosecution.

The occurrence of any of these events would have a material adverse effect on our business, financial condition and results of operations and could result in shareholders losing their entire investment.

Our success depends substantially upon our ability to obtain and maintain intellectual property protection relating to our product and research technologies.

We have applied to the U.S. Patent and Trademark Office for patents on our proprietary fluid movement technology and the configuration of our insulin pump. There is no assurance that these patents will be issued, and no assurance that they will prevent other companies from competing with us. We will continue to attempt to patent our innovations as appropriate to help ensure a sustainable competitive advantage.

Due to evolving legal standards relating to the patentability, validity and enforceability of patents covering health care product inventions, our ability to enforce our existing patents and to obtain and enforce patents that may issue from any pending or future patent applications is uncertain and involves complex legal, scientific and factual questions. To date, no consistent policy has emerged regarding the breadth of claims allowed in medical device patents. Thus, we cannot be sure that any patents will issue from any pending or future patent applications owned by or licensed to us. Even if patents do issue, we cannot be sure that the claims of these patents will be held valid or enforceable by a court of law, will provide us with any significant protection against competing products, or will afford us a commercial advantage over competitive products. If, at some point in the future, one or more products resulting from our product candidates is approved for sale by the FDA and we do not have adequate intellectual property protection for those products, competitors could duplicate them for approval and sale in the United States without repeating the extensive testing required of us to obtain FDA approval. See "Our Business – Patents," below.

If we are sued for infringing on third-party intellectual property rights, it will be costly and time-consuming, and an unfavorable outcome would have a significant adverse effect on our business.

Our ability to commercialize our product depends on our ability to use, manufacture and sell our product without infringing the patents or other proprietary rights of third parties. Numerous U.S. and foreign issued patents and pending patent applications owned by third parties exist in the diabetes medical device area. There may be existing patents, unknown to us, on which our activities with our insulin pump candidate could infringe.

If a third party claims that our actions infringe on its patents or other proprietary rights, we could face a number of issues that could seriously harm our competitive position, including, but not limited to:

- infringement and other intellectual property claims that, even if meritless, can be costly and time-consuming, delay the regulatory approval process and divert management's attention from our core business operations;
- substantial damages for infringement, including consequential damages for lost of profits or market share, if a court determines that our products or technologies infringe on a third party's patent or other proprietary rights;
- a court prohibiting us from selling or licensing our products or technologies unless the holder licenses the patent or other proprietary rights to us, which it is not required to do; and
- even if a license is available from a holder, we may have to pay substantial royalties or grant cross-licenses to our patents or other proprietary rights.

If any of these events occur, it could significantly harm our operations and financial condition and negatively affect our stock price.

Healthcare reform laws could adversely affect our product and financial condition.

During the past several years, the U.S. healthcare industry has been subject to an increase in governmental regulation at both the federal and state levels. Efforts to control healthcare costs, including limiting access to care, alternative delivery models and changes in the methods used to determine reimbursement scenarios and rates, are ongoing at the federal and state government levels. There are provisions of law that provide for the creation of a new public-private Patient-Centered Outcomes Research Institute tasked with identifying comparative effectiveness research priorities. For example, establishing a research project agenda and contracting with entities to conduct the research in accordance with the agenda. Research findings published by this institute are publicly disseminated. It is difficult at this time to determine whether a comparative effectiveness analysis impacting our business will be done, and assuming one is, what impact that analysis will have on our insulin pump or our future financial results.

In addition, the Affordable Care Act, or the ACA, and related healthcare reform laws, regulations and initiatives have significantly increased regulation of managed care plans and decreased reimbursement to Medicare managed care. Some of these initiatives purport to, among other things, require that health plan members have greater access to drugs not included on a plan's formulary. Moreover, to alleviate budget shortfalls, states have reduced or frozen payments to Medicaid managed care plans. We cannot accurately predict the complete impact of these healthcare reform initiatives, but they could lead to a decreased demand for medical devices such as our insulin pump and other outcomes that could adversely.

Some of the provisions of the ACA have yet to be fully implemented, and certain provisions have been subject to judicial and Congressional challenges. In addition, there have been efforts by the Trump administration to repeal or replace certain aspects of the ACA and to alter the implementation of the ACA and related laws. For example, the Tax Cuts and Jobs Act enacted on December 22, 2017, eliminated the shared responsibility payment for individuals who fail to maintain minimum essential coverage under section 5000A of the Internal Revenue Code of 1986, commonly referred to as the "individual mandate," effective January 1, 2019. Further, the Bipartisan Budget Act of 2018 among other things, amended the Medicare statute, effective January 1, 2019, to reduce the coverage gap in most Medicare drug plans, commonly known as the "donut hole," by raising the manufacturer discount under the Medicare Part D coverage gap discount program to 70%. It is unclear how the ACA and its implementation, as well as efforts to repeal or replace, or invalidate, the ACA, or portions thereof, will affect our insulin pump or our business. Additional legislative changes, regulatory changes, and judicial challenges related to the ACA remain possible. It is possible that the ACA, as currently enacted or as it may be amended in the future, and other healthcare reform measures that may be adopted in the future, could have an adverse effect on our industry generally and on our ability to commercialize our insulin pump and achieve profitability.

If we are able to obtain all regulatory approvals and have completed all other steps needed to be taken to commercialize our insulin pump, if we or any contract manufacturers we select fails to comply with the FDA's quality system regulations, the manufacturing and distribution of our product could be interrupted, and our product sales and operating results could suffer.

A material step in the process of the commercialization of our product will involve selecting a manufacturer or manufacturers for our pump. We and any future contract manufacturers of our insulin pump will be required to comply with the FDA's quality system regulations, which impose a complex regulatory framework that covers the procedures and documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, storage and shipping of medical devices. The FDA enforces its quality system regulations through periodic unannounced inspections. We cannot assure you that, in the future, any manufacturing facilities owned by us or any contract manufacturer will pass any quality system inspection. In the event that our or any contract manufacturer's facilities fails a quality system inspection, the manufacturing or distribution of our product could be interrupted and our operations disrupted. Failure to take adequate and timely corrective action in response to an adverse quality system inspection could force a suspension or shutdown of any packaging and labeling operations or then manufacturing operations of any contract manufacturers, or a recall of our insulin pump. If any of these events were to occur, we at such time would not be able to provide our customers with the quantity of insulin pumps that they require on a timely basis, our reputation could be harmed and we could lose any customers we then have, any or all of which could have a material adverse effect on our business, financial condition and results of operations.

We may undertake infringement or other legal proceedings against third parties, causing us to spend substantial resources on litigation and exposing our own intellectual property portfolio to challenge.

We may come to believe that third parties are infringing on our patents or other proprietary rights. To prevent infringement or unauthorized use, we may need to file infringement and/or misappropriation suits, which are very expensive and time-consuming, could result in meritorious counterclaims against us and would distract management's attention. Also, in an infringement or misappropriation proceeding, a court may decide that one or more of our patents is invalid, unenforceable, or both, in which case third parties may be able to use our technology without paying license fees or royalties. Even if the validity of our patents is upheld, a court may refuse to stop the other party from using the technology at issue on the grounds that the other party's activities are not covered by our patents. See "Our Business – Patents," below.

We may become involved in disputes with our present or future contract partners over intellectual property ownership or other matters, which would have a significant effect on our business.

Inventions discovered in the course of performance of contracts with third parties or contractors may become jointly owned by such third party contractors and us, in some cases, and the exclusive property of one of us, in other cases. Under some circumstances, it may be difficult to determine who owns a particular invention or whether it is jointly owned, and disputes could arise regarding ownership or use of those inventions or jointly developed improvements thereto. Other disputes may also arise relating to the performance or alleged breach of our agreements with third parties. Any disputes could be costly and time-consuming, and an unfavorable outcome could have a significant adverse effect on our business. See "Our Business –Use of Proprietary Technology," below.

Assuming our insulin pump receives FDA clearance or approval, our insulin pump will still be subject to recalls, which would harm our reputation, business operations and financial results.

Even assuming we obtain FDA approval or clearance with regard to our insulin pump, the FDA has the authority to require the recall of our pump if we commence manufacturing of our insulin pump and we or any contract manufacturers we retain fail to comply with relevant regulations pertaining to manufacturing practices, labeling, advertising or promotional activities, or if new information is obtained concerning the safety or efficacy of the product. A government-mandated recall could occur if the FDA finds that there is a reasonable probability that our product would cause serious, adverse health consequences or death. A voluntary recall by us could occur as a result of manufacturing defects, labeling deficiencies, packaging defects or other failures to comply with applicable regulations. Any recall would divert management's attention and financial resources and harm our reputation with customers. A recall involving our insulin pump would be particularly harmful to our business, financial condition and results of operations because it is currently our only product.

Any disruption and/or instability in economic conditions and capital markets could adversely affect our ability to access the capital markets, and thus adversely affect our business and liquidity.

Negative economic conditions and issues with regard to the financial markets, could have a negative impact on our ability to access the capital markets, and thus have a negative impact on our then operations and liquidity. A general shortage of liquidity and credit combined with the substantial losses in worldwide equity markets could lead to an extended worldwide recession in the future. If such occurred, we would face significant challenges if conditions in the capital markets did not improve. Our ability to access the capital markets under such circumstances could be severely restricted at a time when we need to access such markets, which could have a negative impact on our business plans. Even if we are able to raise capital under such circumstances, it may not be at a price or on terms that are favorable to us. We cannot predict the occurrence of future disruptions or how long such negative conditions might continue.

Because our current insulin pump prototype is still in the development stage, it does not have reimbursement and is not approved for insurance coverage. If in the future we are approved for and are otherwise able to commercialize our insulin pump, but are unable to obtain adequate reimbursement or insurance coverage for such product from third-party payors, we will be unable to generate significant revenue.

Because our current insulin pump prototype is still in the development stage, it does not have reimbursement and is not approved for insurance coverage. The future availability of insurance coverage and reimbursement for newly approved medical devices is highly uncertain. In the United States, patients using insulin pumps are generally reimbursed for all or part of the product cost by Medicare or other third-party payors. Any future commercial success of our insulin pump will be substantially dependent on whether third-party coverage and reimbursement is available for future customers. Medicare, Medicaid, health maintenance organizations and other third-party payors are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement of new medical devices, and, as a result, they may not cover or provide adequate reimbursement for our insulin pump, assuming we are able to fully develop and obtain all regulatory approval to market it in the United States. Accordingly, unless government and other third- party payors provide coverage and reimbursement for our insulin pump, patients may not use it, which would cause investors to lose their entire investment.

We are subject to the oversight of the SEC and other regulatory agencies. Investigations by those agencies could divert management's focus and could have a material adverse effect on our reputation and financial condition.

We are subject to the regulation and oversight of the SEC and state regulatory agencies, in addition to the FDA. As a result, we may face legal or administrative proceedings by these agencies. We are unable to predict the effect of any investigations on our business, financial condition or reputation. In addition, publicity surrounding any investigation, even if ultimately resolved in our favor, could have a material adverse effect on our business. See "Our Business – Government Regulation" below.

We are a "smaller reporting company" and, as a result of the reduced disclosure and governance requirements applicable to smaller reporting companies, our common stock may be less attractive to investors.

We are a "smaller reporting company," and are subject to lesser disclosure obligations in our SEC filings compared to other issuers. Specifically, "smaller reporting companies" are able to provide simplified executive compensation disclosures in their filings, are exempt from the provisions of Section 404(b) of the Sarbanes-Oxley Act requiring that independent registered public accounting firms provide an attestation report on the effectiveness of internal control over financial reporting and have certain other decreased disclosure obligations in their SEC filings, including, among other things, only being required to provide two years of audited financial statements in annual reports. Decreased disclosures in our SEC filings due to our status as a "smaller reporting company" may make it harder for investors to analyze our operating results and financial prospects.

Our shares of common stock are quoted on the OTC Pink Open Market, and there is no active trading market for our common stock.

Our shares of common stock are traded on the OTC Pink Open Market. There is currently no trading market, and for over three years there has not been any active trading market for our common stock. There can be no assurance that an active trading market for our common stock will develop, or, even if one develops, it will be sustained.

We do not expect any cash dividends to be paid on our shares of common stock for the foreseeable future.

We have never declared or paid a cash dividend and we do not anticipate declaring or paying dividends on our common stock for the foreseeable future. We expect to use future financing proceeds and earnings, if any, to fund operating expenses. Consequently, shareholders' only opportunity to achieve a return on their investment is if the price of our stock appreciates and they sell their shares at a profit. We cannot assure stockholders of a positive return on their investment when they sell their shares or that stockholders will not lose the entire amount of their investment. In addition, no dividend is permitted to be declared and/or paid on our shares of common stock unless and until we have made all required dividend payments on the then-outstanding Series A Preferred Stock.

If the beneficial ownership of our common stock continues to be highly concentrated, it may prevent our shareholders from influencing significant corporate decisions; agreement to elect directors.

As of March 31, 2020, our executive officers, directors and certain persons who may be deemed their affiliates beneficially owned substantially in excess of 50.1% of our issued and outstanding common stock. As a result, such persons may exercise substantial influence over the outcome of corporate actions requiring stockholder approval including, without limitation, the election of directors, certain mergers, consolidations and sales of all or substantially all of our assets or any other significant corporate transactions. Such persons may also vote against a change of control, even if such a change of control would benefit our other shareholders. In addition, pursuant to the July 2017 Acquisition Agreement, until July 24, 2022, our board of directors will consist of no less than two and no more than five directors, of which Mr. DiPerna, in addition to being our chairman, has the right to appoint two additional directors, which Manchester has the right to appoint two directors, of which Mr. DiPerna approved William Febbo and Liam Burns and Manchester approved Mr. Frank and Carmen Volkart. As a result of such agreement, until July 24, 2022, other shareholders will not have the ability to elect any directors either at the annual meeting or by written consent, even if such other shareholders believe that our board of directors is taking actions to which the shareholders object.

Sale of our common stock by shareholders could encourage short sales by third parties, which could contribute to the further decline of our stock price.

The significant downward pressure on the price of our common stock that would be caused by the sale of material amounts of our common stock could encourage short sales by third parties. Such an event could place further downward pressure on the price of our common stock.

We are an emerging growth company, and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies will make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012 (the JOBS Act). For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in this prospectus and our periodic reports and proxy statements and exemptions from the requirements of holding nonbinding advisory votes on executive compensation and stockholder approval of any golden parachute payments not previously approved. We could be an emerging growth company for up to five years following the year in which we complete this offering, although circumstances could cause us to lose that status earlier. We will remain an emerging growth company until the earlier of (i) the last day of the fiscal year (a) following the fifth anniversary of the completion of the first sale of shares covered by this prospectus, (b) in which we have total annual gross revenue of at least $1.07 billion or (c) in which we are deemed to be a large accelerated filer, which requires the market value of our common stock that is held by non-affiliates to exceed $700.0 million as of the prior June 30th, and (ii) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

Our common stock may be classified as "penny stock" and trading of our shares may be restricted by the SEC's penny stock regulations.

Our common stock is traded on the OTC Pink Open Market. Rules 15g-1 through 15g-9 promulgated under the Securities Exchange Act impose sales practice and disclosure requirements on certain brokers-dealers who engage in transactions involving a "penny stock." The SEC has adopted regulations which generally define "penny stock" to be any equity security that has a market price of less than $5.00 per share or an exercise price of less than $5.00 per share, subject to certain exceptions. Our common shares may be covered by the penny stock rules, which impose additional sales practice requirements on broker-dealers who sell to persons other than established customers and "accredited investors." The penny stock rules require a broker-dealer, prior to a transaction in a penny stock not otherwise exempt from the rules, to deliver a standardized risk disclosure document in a form prepared by the SEC, which provides information about penny stocks and the nature and level of risks in the penny stock market. The broker-dealer also must provide the customer with current bid and offer quotations for the penny stock, the compensation of the broker-dealer and its salesperson in the transaction, and monthly account statements showing the market value of each penny stock held in the customer's account. In addition, the penny stock rules require that, prior to a transaction in a penny stock that is not otherwise exempt, the broker-dealer must make a special written determination that the penny stock is a suitable investment for the purchaser and receive the purchaser's written agreement to the transaction. These disclosure requirements may have the effect of reducing the level of trading activity in the secondary market for stock that is subject to these penny stock rules. Consequently, these penny stock rules may affect the ability of broker-dealers to trade our common stock. We believe that the penny stock rules may discourage investor interest in and limit the marketability and reduce the level of trading activity of our common shares. The market price of our common stock may suffer as a result.

Future sales of our securities could adversely affect the market price of our common stock and our future capital-raising activities could involve the issuance of equity securities, which would dilute your investment and could result in a decline in the trading price of our common stock.

We may sell securities in the public or private equity markets at prices per share below the current market price of our common stock, even if we do not have an immediate need for additional capital at that time. Sales of substantial amounts of shares of our common stock, or the perception that such sales could occur, could adversely affect the prevailing market price of our shares and our ability to raise capital. We may issue additional shares of common stock in future financing transactions or as incentive compensation for our executive management and other key personnel, consultants and advisors. Issuing any equity securities would be dilutive to the equity interests represented by our then-outstanding shares of common stock. Moreover, sales of substantial amounts of shares in the public market, or the perception that such sales could occur, may adversely affect the prevailing market price of our common stock and make it more difficult for us to raise additional capital.

Our certificate of incorporation allows for our board of directors to create new series of preferred stock without further approval by our shareholders, which could adversely affect the rights of the holders of our common stock.

Our board of directors has the authority to fix and determine the relative rights and preferences of preferred stock. Currently our board of directors has the authority to designate and issue up to 5,000,000 shares of our preferred stock without further shareholder approval, of which 2,000,000 of such shares have been authorized by our board of directors to be designated as Series A Preferred Stock and are being offered for sale in our ongoing preferred stock public offering. In the future, our board of directors could authorize the issuance of one or more additional series of preferred stock that would grant to holders the preferred right to our assets upon liquidation, the right to receive dividend payments before dividends are distributed to the holders of common stock and the right to the redemption of the shares, together with a premium, prior to the redemption of our common stock. In addition, our board of directors could authorize the issuance of a series of preferred stock that has greater voting power than our common stock or that is convertible into our common stock, which could decrease the relative voting power of our common stock or result in dilution to our existing shareholders.

If we are unable to effectively implement or maintain a system of internal control over financial reporting, we may not be able to accurately or timely report our financial results and our stock price could be adversely affected.

Section 404 of the Sarbanes-Oxley Act of 2002 and related regulations require our management to evaluate the effectiveness of our internal control over financial reporting as of the end of each fiscal year. Based on its evaluations, our management concluded that there were material weaknesses in our internal control over financial reporting and management concluded that our internal controls over financial reporting were not effective as of March 31, 2019. Such material weaknesses related to inadequate internal controls over financial reporting, and the lack of segregation of duties in our financial reporting process. Specifically, management noted that we do not have a separately designated audit committee or an independent director. Thereafter, during fiscal 2020, we implemented remediation activities to address such weaknesses, including appointing new independent directors to our board of directors and forming an audit committee. While we believe we have remediated these material weaknesses, such that management determined that our internal controls over financial reporting were effective as of March 31, 2020, we cannot assure that, in the future, a material weakness or significant deficiency will not exist or otherwise be discovered. If that were to happen, it could harm our operating results and cause shareholders to lose confidence in our reported financial information. Any such loss of confidence would have a negative effect on the trading price of our securities.

Our board of directors is able to adopt recapitalizations through forward or reverse splits of our outstanding shares of common stock without shareholder approval.

Pursuant to our amended and restated articles of incorporation, our board of directors has the power, without obtaining shareholder approval, to effectuate recapitalizations of the Company through forward or reverse splits of our outstanding common stock. As a result of such provision, our board of directors can implement recapitalizations of the Company by effectuating a forward or reverse stock split of our outstanding common stock, which would increase or decrease each of our shareholder's number of shares owned, and our shareholders will have no right to approve or disapprove any such action even if such actions have a material adverse effect on them.

Our Series A Preferred Stock has required annual dividend payments and senior liquidation rights to our common stock.

Although we will escrow at each closing of our preferred stock public offering, three years of 13% dividend payments for each share of Series A Preferred Stock sold therein, which escrow funds will be used to pay three years of dividend payments on outstanding shares of our Series A Preferred Stock, following such three-year period, we will be required to make such dividend payments from funds then available to us. Additionally, we may elect in our discretion to redeem a portion or all of any then outstanding Series A Preferred Stock following the date three years from the closing of such offering to the extent we have funds available to use for such purposes. Our failure to make required dividend payments would result in a breach of our obligations to the holders thereof. Moreover, upon any liquidation and/or similar events of us, we are required to make liquidation payments of $25.00 plus any accrued, but unpaid, dividends to holders of the then-outstanding Series A Preferred Stock prior to making any such payments to the holders of then outstanding shares of our common stock.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None

ITEM 2: PROPERTIES

Our principal administrative and research and development functions are located in a leased facility in San Diego, California. We currently occupy approximately 7,300 square feet of space in the San Diego facility, and the lease extends through June 2023. We believe that our existing facility is adequate to meet our current needs.

ITEM 3: LEGAL PROCEEDINGS

We are not a party to any pending legal proceeding. To the knowledge of our management, no federal, state or local governmental agency is presently contemplating any proceeding against us. No director, executive officer or affiliate of ours or owner of record or beneficially of more than five percent of our common stock is a party adverse to us or has a material interest adverse to us in any proceeding.

ITEM 4: MINE SAFETY DISCLOSURES

Not applicable.

PART II

ITEM 5: MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Our common stock is currently quoted on the OTC Pink Open Market under the trading symbol "MODD." Trading in shares of our common stock is limited and sporadic. There is no established trading market for shares of our common stock and no assurances can be given that any such trading market will develop or be maintained.

Holders of Record

As of March 31, 2020, we had 99 holders of record of our common stock. This does not include beneficial owners holding common stock in street name. As such, the number of beneficial holders of our shares could be substantially larger than the number of shareholders of record.

Dividend Policy

We have never declared or paid any dividends on our capital stock. We currently expect to retain future earnings, if any, for use in the operation and expansion of our business and do not anticipate paying any cash dividends in the foreseeable future.

Securities Authorized for Issuance under Equity Compensation Plan

In October 2017, our board of directors approved the Amended 2017 Equity Incentive Plan (the 2017 Plan) and reserved 3,000,000 shares of our common stock to be issued thereunder. In January 2020, our board of directors approved an amendment to the 2017 Plan to increase the number of shares reserved for issuance by 1,000,000 shares. The following table shows shares of our common stock authorized for issuance under our 2017 Plan as of March 31, 2020:

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights	Weighted Average Exercise Price of Outstanding Options, Warrants and Rights	Number of Securities Remaining Available for Future Issuance under Equity Compensation Plans (excluding Securities reflected in Column (a))
	(a)	(b)	I
Equity compensation plans approved by security holders(1)	3,177,945	$ 1.58	822,055

(1) The 2017 Plan allows for grants in the form of incentive stock options, nonqualified stock options, stock units, stock awards, stock appreciation rights, and other stock-based awards. All of our officers, directors, employees, consultants and advisors are eligible to receive grants under the Plan. The maximum number of shares reserved for issuance under the Plan is 4,000,000. Options to purchase shares of common stock are granted at exercise prices not less than 100% of fair value on the dates of grant.

Recent Sales of Unregistered Securities

We initiated a private placement for shares of our common stock in March 2020 (the 2020 Placement). From March 2020 through June 15, 2020, we sold 584,198 shares of our common stock at a purchase price of $2.87 per share resulting in gross proceeds to us of $1,676,648 from the 2020 Placement.

In June 2019, we issued 30,000 shares of common stock to a consultant. The offer, sale and issuance of these securities were deemed to be exempt from registration either under the Securities Act, in reliance on Rule 701 promulgated under the Securities Act, as a transaction under compensatory benefit plans, or Section 4(a)(2) and Rule 506 of Regulation D of the Securities Act, as a transaction not involving a public offering. Appropriate legends were affixed to the securities issued in this transaction.

From November 2018 through March 29, 2019, in a private placement, we sold 1,856,988 shares of our common stock at a purchase price of $2.25 per share resulting in gross proceeds to us of $4,142,666 (the 2018 Placement). In the 2018 Private Placement, Mr. Besser purchased 88,889 shares for $200,000, JEB Partners purchased 160,000 shares for $360,000, and Manchester Explorer purchased 471,111 shares for $1,060,000.

The 2020 Placement and the 2018 Placement were made pursuant to exemptions from registration pursuant to Section 4(2) and/or Rule 506 of Regulation D of the Securities Act of 1933 (the Securities Act). We made such determinations based upon representations by the purchasers of such shares including, without limitation, that such purchasers were "accredited investors," as defined in the Securities Act. Appropriate legends were affixed to the securities issued in this transaction.

Repurchases of Equity Securities

None.

ITEM 6: SELECTED FINANCIAL DATA

Not required

ITEM 7: MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion of our financial condition and results of operations should be read in conjunction with the financial statements and related notes included in this Annual Report on Form 10-K. This discussion may contain forward-looking statements based upon current expectations that involve risks and uncertainties, including those discussed under Part I, Item 1A, "Risk Factors." These risks and uncertainties may cause actual results to differ materially from those discussed in the forward-looking statements.

Overview

We are a development-stage medical device company focused on the design, development and eventual commercialization of an innovative insulin pump to address shortcomings and problems represented by the relatively limited adoption of currently available pumps for insulin dependent people with diabetes. We have developed a hardware technology allowing people with insulin-dependent diabetes to receive their daily insulin in two ways, through a continuous "basal" delivery allowing a small amount of insulin to be in the blood at all times and a "bolus" delivery to address meal time glucose input and to address when the blood glucose level becomes excessively high. By addressing the time and effort required to effectively treat their condition, we believe we can address the less technically savvy, less motivated part of the market.

We have completed development of, but have not yet obtained U.S. Food and Drug Administration, or FDA, clearance for, our insulin pump, and we have therefore not generated any revenues from product sales. Our net losses were $5.3 million and $2.5 million for the years ended March 31, 2020 and 2019, respectively. As of March 31, 2020, we had working capital of $2.5 million and an accumulated deficit of $8.6 million.

Historically, we have financed our operations principally through private placements of our common stock. Based on our current operating plan, substantial doubt about our ability to continue as a going concern for a period of at least one year from the date that the financial statements included in Item 8 of this Report are issued exists. Our ability to continue as a going concern depends on our ability to raise additional capital, through the sale of equity or debt securities, to support our future operations. If we are unable to secure additional capital, we will be required to curtail our research and development initiatives and take additional measures to reduce costs.

Impacts of COVID-19

The global outbreak of the coronavirus disease 2019 (COVID-19) was declared a pandemic by the World Health Organization and a national emergency by the U.S. government in March 2020. This has negatively affected the U.S. and global economy, disrupted global supply chains, significantly restricted travel and transportation, resulted in mandated closures and orders to "shelter-in-place" and created significant disruption of the financial markets. The full extent of the COVID-19 impact on our operational and financial performance will depend on future developments, including, without limitation, the duration and spread of the pandemic and related actions taken by U.S. and foreign government agencies to prevent disease spread, all of which are uncertain, out of our control, and cannot be predicted.

In March 2020, Santa Diego County in California, where we are based, and the state of California issued "shelter-in-place" orders (the Orders). We have been complying with the Orders and have minimized business activities at our San Diego facility effective March 20, 2020. We have implemented a teleworking policy for our employees and contractors to reduce on-site activity at our facility. We have experienced longer lead times for certain components used to manufacture initial quantities of our products for our submission to the FDA, which is expected to occur in the quarter ending December 31, 2020. In addition, our teleworking policy, which was required to comply with the Orders, has required us to minimize the number of our employees and contractors that are working on site at our facility at any one time. We remain diligent in continuing to identify and manage risks to our business given the changing uncertainties related to COVID-19. While we believe that our operations personnel are currently in a position to build an adequate supply of products for our FDA submission, we recognize that unpredictable events could create difficulties in the months ahead. We may not be able to address these difficulties in a timely manner, which could delay our submission to the FDA and negatively impact our business, results of operations, financial condition and cash flows.

The continued spread of COVID-19 has also led to disruption and volatility in the global capital markets. We were recently able to raise additional capital in a private placement (see discussion below under *Liquidity*), however, we need to raise additional capital to support our operations in the future. We may be unable to access the capital markets or additional capital may only be available to us on terms that could be significantly detrimental to our existing stockholders and to our business.

For additional information on risks that could impact our future results, please refer to “Risk Factors” in Part I, Item 1A of this Report.

Results of Operations

The following discussion should be read in conjunction with our consolidated financial statements and related notes included elsewhere in this Report.

Research and Development

	Years ended March 31,		Year-over-Year Change	
	2020	2019	2019 to 2020	
Research and development	$ 3,034,152	$ 1,882,345	$ 1,151,807	61.2%

Our research and development expenses include personnel, overhead and other costs associated with the development of our insulin pump product. We expense research and development costs as they are incurred.

Research and development, or R&D, expenses increased in fiscal 2020 compared with fiscal 2019 primarily due to increased engineering and operations personnel and consulting costs. Our R&D employee headcount increased to 10 at March 31, 2020 from 4 at March 31, 2019. R&D expenses included stock-based compensation expenses of $422,625 and $487,578 for fiscal 2020 and fiscal 2019, respectively. We expect research and development expenses to continue to increase in fiscal 2021, as we continue to advance the development of our pump product and develop a low-volume manufacturing process.

General and Administrative

	Years ended March 31,		Year-over-Year Change	
	2020	2019	2019 to 2020	
General and administrative	$ 2,313,870	$ 694,954	$ 1,618,916	233%

General and administrative expenses consist primarily of personnel and related overhead costs for marketing, finance, human resources and general management.

General and administrative expenses, or G&A, increased in fiscal 2020 compared with fiscal 2019 primarily as a result of increased personnel and consulting costs, stock-based compensation expenses and professional services fees related to our financing activities. Our full-time G&A headcount increased to two at March 31, 2020 from none at March 31, 2019. G&A expenses included stock-based compensation expenses of $378,619 and $44,530 for fiscal 2020 and fiscal 2019, respectively.

Interest Income

	Years ended March 31,		Year-over-Year Change	
	2020	2019	2019 to 2020	
Interest income	$ 28,749	$ 39,390	$ (10,641)	(27)%

Interest income consists of interest earned on our cash deposits. The decrease in interest income for fiscal 2020 compared with fiscal 2019 was primarily attributable to lower average cash balances during fiscal 2020.

Liquidity and Going Concern

As a development-stage enterprise, we do not currently have revenues to generate cash flows to cover operating expenses. Since our inception, we have incurred operating losses and negative cash flows in each year due to costs incurred in connection with R&D activities and G&A expenses associated with our operations. For the years ended March 31, 2020 and 2019, we incurred net losses of approximately $5.3 million and $2.5 million, respectively. At March 31, 2020, we had a cash balance of $3.1 million and an accumulated deficit of approximately $8.6 million. When considered with our current operating plan, these conditions raise substantial doubt about our ability to continue as a going concern for a period of at least one year from the date that the financial statements included in Item 8 of this Report are issued. Our financial statements do not include adjustments to the amounts and classification of assets and liabilities that may be necessary should we be unable to continue as a going concern. Our ability to continue as a going concern depends on our ability to raise additional capital, through the sale of equity or debt securities to support our future operations, and we are currently seeking such additional financing. As discussed in the Notes to our consolidated financial statements in Item 8 of this Report, we are currently pursuing additional equity financing through a private placement of our common stock and a public offering of our preferred units. In addition, we obtained a $368,000 loan from Silicon Valley Bank in April 2020 under the U.S. Small Business Administration Paycheck Protection Program, and we currently expect the loan to be forgiven. Our operating needs include the planned costs to operate our business, including amounts required to fund research and development activities, including clinical studies, working capital and capital expenditures. Our future capital requirements and the adequacy of our available funds will depend on many factors, including our ability to successfully commercialize our product, competing technological and market developments, and the need to enter into collaborations with other companies or acquire other companies or technologies to enhance or complement our product offerings. If we are unable to secure additional capital, we will be required to curtail our research and development initiatives and take additional measures to reduce costs in order to conserve our cash.

In fiscal 2020, we used $4,094,839 in operating activities, which primarily resulted from our net loss of $ 5,320,873, partially offset by changes to operating assets and liabilities of $389,359, and adjusted for non-cash charges and gains, which included stock-based compensation expenses of $801,244, depreciation and amortization expenses of $35,431. The changes in assets and liabilities primarily related to the timing of payments to vendors, offset by an increase in security deposits. We used $1,807,934 of cash to fund operating activities during fiscal 2019, compared with $791,131 in fiscal 2018. Increased cash usage during fiscal 2020 and 2019 was due to increased operating activities related to the development and subsequent commercialization of our product.

In fiscal 2020, cash used in investing activities of $260,789 was due to the purchase of property and equipment. We used $77,124 of cash to purchase property and equipment and intangible assets during fiscal 2019.

Cash provided by financing activities for fiscal 2020 totaled $923,994 and was attributable to the sale of shares of our common stock in a private placement that was initiated in March 2020. A private placement of shares of our common stock accounted for $4,142,150 of cash from financing activities during fiscal 2019.

In May 2020, we commenced our best-efforts public offering of up to 2,000,000 of our preferred units at a public offering price of $25.00 per preferred unit. Each preferred unit consists of (i) one share of our 13% Series A Cumulative Redeemable Perpetual Preferred Stock, which has a $25.00 liquidation preference amount (the Series A Preferred Stock), and (ii) three common stock purchase warrants with each warrant entitling the holder to purchase for a period of 5 years from the date of issuance one share of our common stock at an exercise price of $11.00 per share, subject to adjustment. The preferred units, the Series A Preferred Stock, the common stock purchase warrants and the shares of common stock issuable upon exercise of the warrants are registered on our registration statement on Form S-1 (SEC No.: 333-237615) declared effective by the SEC on May 11, 2020. As of June 22, 2020, we had not sold any preferred units. At each closing of the preferred unit public offering, an amount equal to the first three years of dividend payments, or $9.75 per share of Series A Preferred Stock sold, will be retained by a dividend payment agent from the proceeds from such offering and will be used to pay dividends to the holders thereof for a three year period. The shares of Series A Preferred Stock are perpetual, have no maturity date, will not be subject to any sinking fund or other mandatory redemption, and will not be convertible into or exchangeable for any of our other securities. Commencing three years from the date of issuance of Series A Preferred Stock, we may redeem, at our option, the Series A Preferred Stock, in whole or in part, at a cash redemption price equal to $25.00 per share, plus all accrued and unpaid dividends. No holder of Series A Preferred Stock shall have any right to require as to redeem or repurchase the Series A Preferred Stock. The terms and conditions of the Series A Preferred Stock are set forth in the Certificate of Designation of Preferences, Rights and Limitations, which is Exhibit 3.1.1 to this Report. The terms and conditions of the warrants are set forth in the Form of Common Stock Purchase Warrant, which is Exhibit 4.2 to this Report.

Critical Accounting Policies and Estimates

Our consolidated financial statements are prepared in conformity with accounting principles generally accepted in the United States of America. Note 1 to the consolidated financial statements in Item 8 of this Report describes the significant accounting policies and methods used in the preparation of our consolidated financial statements. We have identified the accounting policies below as some of the more critical to our business and the understanding of our results of operations. These policies may involve estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses. Although we believe our judgments and estimates are appropriate, actual future results may differ from our estimates, and if different assumptions or conditions were to prevail, the results could be materially different from our reported results.

Use of estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America (GAAP) requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting periods. Estimates may include those pertaining to accruals, stock-based compensation and income taxes. Actual results could materially differ from those estimates.

Stock-based compensation

We recognize stock-based compensation for stock options granted to employees and non-employees on a straight-line basis over the requisite service period, usually the vesting period, based on the grant-date fair value. We estimate the value of stock options on the date of grant using the Black-Scholes pricing model. The determination of fair value of share-based payment awards on the date of grant using an option-pricing model is affected by the option price, as well as assumptions regarding a number of highly complex and subjective variables. These variables include, but are not limited to, the expected stock price volatility over the term of the awards, and projected stock option exercise behaviors.

Income taxes

We determine deferred tax assets and liabilities based upon the differences between the financial statement and tax bases of our assets and liabilities using tax rates in effect for the year in which we expect the differences to affect taxable income. A valuation allowance is established for any deferred tax assets for which it is more likely than not that all or a portion of the deferred tax assets will not be realized. Based on the available information and other factors, management believes it is more likely than not that our federal and state net deferred tax assets will not be fully realized, and we have recorded a full valuation allowance.

We account for uncertain tax positions in accordance with FASB Accounting Standards Codification (ASC) Topic 740, *Income Taxes*. When tax returns are filed, it is likely that some positions taken would be sustained upon examination by the taxing authorities, while others are subject to uncertainty about the merits of the position taken or the amount of the position that would be ultimately sustained. The benefit of a tax position is recognized in the consolidated financial statements in the period during which, based on all available evidence, management believes it is more likely than not that the position will be sustained upon examination, including the resolution of appeals or litigation processes, if any. Tax positions taken are not offset or aggregated with other positions. Tax positions that meet the more-likely-than-not recognition threshold are measured as the largest amount of tax benefit that is more than 50 percent likely of being realized upon settlement with the applicable taxing authority. The portion of the benefits associated with tax positions taken that exceeds the amount measured as described above is reflected as a liability for unrecognized tax benefits in the accompanying consolidated balance sheets along with any associated interest and penalties that would be payable to the taxing authorities upon examination. Interest associated with unrecognized tax benefits is classified as interest expense and penalties are classified in selling, general and administrative expenses in the consolidated statements of income.

Leases

We adopted Accounting Standards Update (ASU) No. 2016-02, *Leases* (ASC 842), and related ASUs, which provide supplementary guidance and clarifications on April 1, 2019. We elected the practical expedient approach and did not reassess whether any contracts that existed prior to adoption have or contain leases or the classification of our existing leases. Under ASC 842, all significant lease arrangements are generally recognized at lease commencement. Operating lease right-of-use (ROU) assets and lease liabilities are recognized at the commencement date. A ROU asset and corresponding lease liability is not recorded for leases with an initial term of 12 months or less (short-term leases), and we recognize lease expense for these leases as incurred over the lease term.

ROU assets represent our right to use an underlying asset during the reasonably certain lease terms, and lease liabilities represent our obligation to make lease payments arising from the lease. Our lease terms may include options to extend or terminate the lease when it is reasonably certain that we will exercise that option. Operating lease ROU assets and liabilities are recognized at the lease commencement date based on the present value of lease payments over the lease term. We use our incremental borrowing rate, based on the information available at commencement date in determining the present value of lease payments. The operating lease ROU asset also includes any lease payments related to initial direct cost and prepayments and excludes lease incentives. Lease expense is recognized on a straight-line basis over the lease term.

Off-Balance Sheet Arrangements

We do not maintain any off-balance sheet arrangements or obligations that are reasonably likely to have a material current or future effect on our financial condition, results of operations, liquidity or capital resources.

Recently Adopted Accounting Pronouncements

Recently Adopted Accounting Pronouncements are detailed in Note 1 in the Notes to the Consolidated Financial Statements included in Part II, Item 8 of this Report.

ITEM 7A: QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not required.

ITEM 8: FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

To the Audit Committee and
Stockholders of Modular Medical, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Modular Medical, Inc. (the "Company") as of March 31, 2020 and 2019, and the related consolidated statements of operations, stockholders' equity, and cash flows for the years then ended, and the related notes (collectively referred to as the financial statements). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of March 31, 2020 and 2019, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Emphasis of Matter

Going Concern

The accompanying consolidated financial statements have been prepared to assume the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company expects to continue to incur operating losses for the foreseeable future and incur cash outflows from operations as it continues to invest in the development and subsequent commercialization of its product. The Company expects that its research and development and general and administrative expenses will continue to increase, and, as a result, it will eventually need to generate significant product revenues to achieve profitability. These circumstances raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Effects of COVID-19

The spread of a novel strain of coronavirus (COVID-19) in the first quarter of 2020 has caused significant volatility in the United States marketplace. There is significant uncertainty around the breadth and duration of business disruptions related to COVID-19, as well as its impact on the U.S. economy. The extent of the impact of COVID-19 on the Company's operational and financial performance will depend on certain developments, including the duration and spread of the outbreak, and the impact on customers, employees and vendors, all of which are uncertain and cannot be determined at this time. The consolidated financial statements have not been adjusted as a result of this uncertainty.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Farber Hass Hurley LLP

We have served as the Company's auditor since 2018.

Chatsworth, California
June 29, 2020

Modular Medical, Inc. And its Subsidiary
(f/k/a - Bear Lake Recreation, Inc.)

Consolidated Balance Sheets

	March 31,	
ASSETS	**2020**	**2019**
CURRENT ASSETS		
Cash and cash equivalents	$ 3,122,134	$ 6,553,768
Prepaid expenses and other	64,159	15,590
TOTAL CURRENT ASSETS	3,186,293	6,569,358
Intangible assets, net	—	180
Property and equipment, net	301,308	75,948
Security deposit	100,000	7,500
Right of use asset, net	270,950	—
TOTAL NON-CURRENT ASSETS	672,258	83,628
TOTAL ASSETS	$ 3,858,551	$ 6,652,986
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable	$ 367,019	$ 138,314
Accrued expenses	202,160	40,615
Short-term lease liability	92,214	—
TOTAL CURRENT LIABILITIES	661,393	178,929
Long-term lease liability	178,736	—
Other liability	140,000	—
TOTAL LIABILITIES	980,129	178,729
Commitments and Contingencies (Note 10)		
STOCKHOLDERS' EQUITY		
Preferred Stock, $0.001 par value, 5,000,000 shares authorized, none issued and outstanding	—	—
Common Stock, $0.001 par value, 50,000,000 shares authorized, 17,870,261 shares and 17,840,261 shares issued and outstanding as of March 31, 2020 and 2019, respectively	17,870	17,840
Additional paid-in capital	10,505,592	9,684,578
Common stock issuable	923,994	19,800
Accumulated deficit	(8,569,034)	(3,248,161)
TOTAL STOCKHOLDERS' EQUITY	2,878,422	6,474,057
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 3,858,551	$ 6,652,986

The accompanying notes are an integral part of these audited consolidated financial statements

Modular Medical, Inc. And its Subsidiary
(f/k/a- Bear Lake Recreation, Inc.)

Consolidated Statements of Operations

	Years ended March 31,	
	2020	**2019**
Operating expenses		
Research and development	$ 3,034,152	$ 1,882,345
General and administrative expenses	2,313,870	694,954
Total operating expenses	5,348,022	2,577,299
Loss from operations	(5,348,022)	(2,577,299)
Other income		
Interest income	28,749	39,390
Loss before income taxes	(5,319,273)	(2,537,909)
Provision for income taxes	1,600	1,589
Net loss	$ (5,320,873)	$ (2,539,498)
Net loss per share		
Basic and diluted	$ (0.30)	$ (0.15)
Shares used in computing net loss per share		
Basic and diluted	17,864,769	16,589,633

The accompanying notes are an integral part of these audited consolidated financial statements

Modular Medical, Inc. And its Subsidiary
(f/k/a - Bear Lake Recreation, Inc.)

Consolidated Statements of Stockholders' Equity

	Common Stock		Additional Paid-In	Common Stock	Accumulated	Stockholders'
	Shares	Amount	Capital	Issuable	Deficit	Equity
Balance as of March 31, 2018	15,983,273	$ 15,983	$ 5,011,661	$ —	$ (708,663)	$ 4,318,981
Issuance of common stock	1,856,988	1,857	4,140,809	—	—	4,142,666
Shares issued for services	—	—		19,800	—	19,800
Stock-based compensation	—	—	532,108	—	—	532,108
Net loss	—	—	—	—	(2,539,498)	(2,539,498)
Balance as of March 31, 2019	17,840,261	$ 17,840	$ 9,684,578	$ 19,800	$ (3,248,161)	$ 6,474,057
Placement of common stock	—	—	—	923,994	—	923,994
Shares issued for services	30,000	30	19,770	(19,800)	—	—
Stock-based compensation	—	—	801,244	—	—	801,244
Net loss	—	—	—	—	(5,320,873)	(5,320,873)
Balance as of March 31, 2020	17,870,261	$ 17,870	$ 10,505,592	$ 923,994	$ (8,569,034)	$ 2,878,422

The accompanying notes are an integral part of these audited consolidated financial statements

Modular Medical, Inc. And its Subsidiary
(f/k/a - Bear Lake Recreation, Inc.)

Consolidated Statements of Cash Flows

	Year ended March 31,	
	2020	**2019**
Cash Flows from operating activities		
Net loss	$ (5,320,873)	$ (2,539,498)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	801,244	532,108
Depreciation and amortization	35,431	14,468
Shares for services	—	19,800
Changes in assets and liabilities		
Prepaid expenses and other assets	(48,391)	1,214
Security deposits	(92,500)	—
Accounts payable and accrued expenses	530,250	163,974
Net cash used in operating activities	(4,094,839)	(1,807,934)
Cash flows from investing activities		
Purchase of property and equipment	(260,789)	(77,124)
Net cash used in investing activities	(260,789)	(77,124)
Cash flows from financing activities		
Proceeds from private placement	923,994	4,142,666
Repayment to related party	—	(516)
Net cash provided by financing activities	923,994	4,142,150
Net increase (decrease) in cash and cash equivalents	(3,431,634)	2,257,092
Cash and cash equivalents, at beginning of year	6,553,768	4,296,676
Cash and cash equivalents, at end of year	$ 3,122,134	$ 6,553,768
Supplemental disclosure:		
Cash paid for:		
Income taxes	$ 1,600	$ 1,589

The accompanying notes are an integral part of these audited consolidated financial statements

Note 1 – THE COMPANY AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Modular Medical, Inc. (the Company) was incorporated in Nevada in October 1998 under the name Bear Lake Recreation, Inc. The Company had no material business operations from 2002 until approximately 2017 when it acquired all of the issued and outstanding shares of Quasuras, Inc., a Delaware corporation (Quasuras). As the major shareholder of Quasuras retained control of both the Company and Quasuras, the share exchange was accounted for as a reverse merger. As such, the Company recognized the assets and liabilities of Quasuras, acquired in the merger, at their historical carrying amounts. Prior to the acquisition of Quasuras and, since at least 2002, the Company was a shell company, as defined in Rule 12b-2 promulgated under the Securities Exchange Act of 1934 (the Exchange Act). In June 2017, the Company changed its name from Bear Lake Recreation, Inc. to Modular Medical, Inc.

The Company is a development-stage medical device company focused on the design, development and eventual commercialization of an innovative insulin pump to address shortcomings and problems represented by the relatively limited adoption of currently available pumps for insulin-dependent people with diabetes. The Company has developed a hardware technology allowing people with insulin-dependent diabetes to receive their daily insulin in two ways, through a continuous “basal” delivery allowing a small amount of insulin to be in the blood at all times and a “bolus” delivery to address meal time glucose input and to address when the blood glucose level becomes excessively high. By addressing the time and effort required to effectively treat their condition, the Company believes it can address the less technically savvy, less motivated part of the market.

The consolidated financial statements of the Company have been prepared in accordance with accounting principles generally accepted in the United States of America. The following summarizes the more significant of such policies:

Liquidity

Financial Accounting Standards Board (FASB) Accounting Standard Update (ASU) No. 2014-15 (ASU 2014-15), *Going* Concern, requires management to evaluate whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the entity’s ability to continue as a going concern within one year after the date that the financial statements are issued. If management identifies conditions or events that raise substantial doubt about an entity’s ability to continue as a going concern, management must consider if there are plans that are probable to be implemented, and whether it is probable that the plans will mitigate the conditions or events raising the substantial doubt about the entity’s ability to continue as a going concern. If the substantial doubt is not alleviated after consideration of management’s plans, the entity must include a statement in the notes to the financial statements indicating that there is substantial doubt about the entity’s ability to continue as a going concern within one year after the date that the financial statements are issued including: 1) the principal conditions or events that raise substantial doubt about the entity’s ability to continue as a going concern, 2) management’s evaluation of the significance of those conditions or events in relation to the entity’s ability to meet its obligations, and 3) management’s plans to attempt to mitigate the conditions or events causing the substantial doubt about the entity’s ability to continue as a going concern.

The Company expects to continue to incur operating losses for the foreseeable future and incur cash outflows from operations as it continues to invest in the development and subsequent commercialization of its product. The Company expects that its research and development and general and administrative expenses will continue to increase, and, as a result, it will eventually need to generate significant product revenues to achieve profitability. These circumstances raise substantial doubt about the Company’s ability to continue as a going concern within one year after the date that these financial statements are issued. Implementation of the Company’s plans and its ability to continue as a going concern will depend upon the Company’s ability to raise additional capital, through the sale of additional equity or debt securities, to support its future operations. There can be no assurance that such additional capital, whether in the form of debt or equity financing, will be sufficient or available and, if available, that such capital will be offered on terms and conditions acceptable to the Company. As discussed in Notes 6 and 11, the Company is currently pursuing additional equity financing through a private placement of its common stock and a public offering of its preferred units. In addition, the Company obtained a loan from Silicon Valley Bank in April 2020.

The Company’s operating needs include the planned costs to operate its business, including amounts required to fund working capital and capital expenditures. The Company’s future capital requirements and the adequacy of its available funds will depend on many factors, including the Company’s ability to successfully commercialize its product, competing technological and market developments, and the need to enter into collaborations with other companies or acquire other companies or technologies to enhance or complement its product offering. If the Company is unable to secure additional capital, it may be required to curtail its research and development initiatives and take additional measures to reduce costs in order to conserve its cash. These consolidated financial statements do not include any adjustments that might result from this uncertainty.

Basis of Presentation

The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary, Quasuras, Inc. All significant intercompany transactions and balances have been eliminated in consolidation. The Company's fiscal year ends on March 31 of each calendar year. Certain prior year amounts have been reclassified for consistency with the current period presentation. These reclassifications had no effect on the reported results of operations or cash flows.

Use of Estimates

The preparation of the accompanying consolidated financial statements in conformity with U.S. generally accepted accounting principles (GAAP) requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amount of revenues and expenses during the reporting period. Estimates may include those pertaining to accruals, stock-based compensation and income taxes. Actual results could differ from those estimates.

Reportable Segment

The Company operates in one business segment and uses one measurement of profitability for its business.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentration of credit risk consist primarily of cash and cash equivalents. Cash and cash equivalents are deposited with high credit-quality institutions within the United States, which are insured by the Federal Deposit Insurance Corporation (FDIC) up to limits of approximately $250,000.

Risks and Uncertainties

The Company is subject to risks from, among other things, competition associated with the industry in general, other risks associated with financing, liquidity requirements, rapidly changing customer requirements, limited operating history and the volatility of public markets.

COVID-19

The global outbreak of the coronavirus disease 2019 (COVID-19) was declared a pandemic by the World Health Organization and a national emergency by the U.S. government in March 2020. This has negatively affected the U.S. and global economy, disrupted global supply chains, significantly restricted travel and transportation, resulted in mandated closures and orders to "shelter-in-place" and created significant disruption of the financial markets. The full extent of the COVID-19 impact on the Company's operational and financial performance will depend on future developments, including the duration and spread of the pandemic and related actions taken by U.S. and foreign government agencies to prevent disease spread, all of which are uncertain, out of the Company's control, and cannot be predicted.

Cash and Cash Equivalents

Cash and cash equivalents include cash in hand and cash in demand deposits, certificates of deposit and all highly liquid debt instruments with original maturities of three months or less.

Property & Equipment

Property and equipment are originally recorded at cost. Depreciation is computed using the straight-line method over the estimated useful lives of the assets, generally three to five years. Depreciation is recorded in operating expenses in the consolidated statements of operations. Leasehold improvements and assets acquired through capital leases are amortized over the shorter of their estimated useful life or the lease term, and amortization is recorded in operating expenses in the consolidated statements of operations.

Fair Value of Financial Instruments

The Company measures the fair value of financial instruments using a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value into three broad levels:

- Level 1 inputs to the valuation methodology are quoted prices for identical assets or liabilities in active markets.
- Level 2 inputs to the valuation methodology include quoted prices for similar assets and liabilities in active markets, and inputs that are observable for the asset or liability, either directly or indirectly, for substantially the full term of the financial instrument.
- Level 3 inputs to the valuation methodology are unobservable and significant to the fair value measurement.

Due to their short-term nature, the carrying values of cash equivalents, accounts payable and accrued expenses, approximate fair value.

Research and Development

The Company expenses research and development expenditures as incurred.

General and Administrative

General and administrative expense consists primarily of payroll and benefit related costs, rent, office expenses, equipment supplies and meetings and travel.

Stock-Based Compensation

The Company recognizes stock-based compensation for stock options granted to employees and non-employees on a straight-line basis over the requisite service period, usually the vesting period, based on the grant-date fair value. The Company estimates the value of stock options on the date of grant using the Black-Scholes pricing model. The determination of fair value of share-based payment awards on the date of grant using an option-pricing model is affected by the option price, as well as assumptions regarding a number of highly complex and subjective variables. These variables include, but are not limited to, the expected stock price volatility over the term of the awards, and projected stock option exercise behaviors.

Per-Share Amounts

Basic net loss per share is computed by dividing net loss for the period by the weighted-average number of shares of common stock outstanding during the period. Diluted net loss per share gives effect to all potentially dilutive common shares outstanding during the period. For the years ended March 31, 2020 and 2019, 3,177,945 and 1,529,908 outstanding options to purchase common stock were excluded from the calculation of diluted net loss per share because their effect would be anti-dilutive.

Income Taxes

The Company determines deferred tax assets and liabilities based upon the differences between the financial statement and tax bases of the Company's assets and liabilities using tax rates in effect for the year in which the Company expects the differences to affect taxable income. A valuation allowance is established for any deferred tax assets for which it is more likely than not that all or a portion of the deferred tax assets will not be realized. Based on the available information and other factors, management believes it is more likely than not that its federal and state net deferred tax assets will not be fully realized, and the Company has recorded a full valuation allowance.

The Company accounts for uncertain tax positions in accordance with FASB Accounting Standards Codification (ASC) Topic 740, *Income Taxes*. When tax returns are filed, it is likely that some positions taken would be sustained upon examination by the taxing authorities, while others are subject to uncertainty about the merits of the position taken or the amount of the position that would be ultimately sustained. The benefit of a tax position is recognized in the consolidated financial statements in the period during which, based on all available evidence, management believes it is more likely than not that the position will be sustained upon examination, including the resolution of appeals or litigation processes, if any. Tax positions taken are not offset or aggregated with other positions. Tax positions that meet the more-likely-than-not recognition threshold are measured as the largest amount of tax benefit that is more than 50 percent likely of being realized upon settlement with the applicable taxing authority. The portion of the benefits associated with tax positions taken that exceeds the amount measured as described above is reflected as a liability for unrecognized tax benefits in the accompanying consolidated balance sheets along with any associated interest and penalties that would be payable to the taxing authorities upon examination. Interest associated with unrecognized tax benefits is classified as interest expense and penalties are classified in selling, general and administrative expenses in the consolidated statements of income.

The Company files U.S. federal and state income tax returns in jurisdictions with varying statutes of limitations. All tax returns from 2016 to 2019 may be subject to examination by the U.S. federal and state tax authorities. As of March 31, 2020, the Company has not recorded any liability for unrecognized tax benefits related to uncertain tax positions.

Comprehensive Loss

Comprehensive loss represents the changes in equity of an enterprise, other than those resulting from stockholder transactions. Accordingly, comprehensive loss may include certain changes in equity that are excluded from net loss. For the years ended March 31, 2020 and 2019, the Company's comprehensive loss was the same as its net loss.

Recently Adopted Accounting Pronouncements

In 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)* (ASC 842), which sets out the principles for the recognition, measurement, presentation and disclosure of leases. The standard introduces a new lessee model that requires most leases to be recorded on the balance sheet and eliminates the required use of bright-line tests for determining lease classification. In July 2018, the FASB issued the following standards which clarified ASU No. 2016-02 and have the same effective date as the original standard: ASU No. 2018-10, *Codification Improvements to Topic 842*, Leases and ASU No. 2018-11, *Leases (Topic 842): Targeted Improvements*. ASU No. 2018-11 includes an option to not restate comparative periods in transition and elect to use the effective date of ASU No. 2016-02 as the date of initial application of transition. In March 2019, the FASB issued ASU No. 2019-01, *Leases (Topic 842): Codification Improvements,* which clarifies ASU No. 2016-02 and is effective for fiscal years beginning after December 15, 2019 and interim periods within those fiscal years. The Company adopted ASU No. 2016-02, as amended, on April 1, 2019, using the optional transition method provided by the FASB in ASU No. 2018-11. The Company elected to use the practical expedient that allowed it to not reassess: (1) whether any expired or existing contracts are or contain leases, (2) lease classification for any expired or existing leases and (3) initial direct costs for any expired or existing leases as well as the practical expedient that allows lessees to treat the lease and non-lease components of leases as a single lease component for all asset classes. The adoption of this standard did not have a material impact on the Company's balance sheet, results of operations or cash flows. In January 2020, the Company entered into a lease for a new corporate facility and accounted for this lease in accordance with ASC 842. See Note 3 for further information.

In 2018, the FASB issued ASU No. 2018-07 , *Improvements to Nonemployee Share-Based Payment Accounting*. Previously, share-based payments to nonemployees were accounted for under Subtopic 505-50, which significantly differs from the guidance for share-based payments to employees under FASB ASC Topic 718 (Topic 718). This ASU supersedes ASC Subtopic 505-50 by expanding the scope of Topic 718 to include nonemployee awards and generally aligning the accounting for nonemployee awards with the accounting for employee awards. The Company adopted this ASU on April 1, 2019 with no material impact on its results of operations, financial position and cash flows.

NOTE 2 – CONSOLIDATED BALANCE SHEET DETAIL

	March 31,	
Property and equipment, net:	**2020**	**2019**
Leasehold improvements	$ 139,197	$ —
Office equipment	112,198	49,724
Computer equipment and software	51,882	20,565
Machinery and equipment	49,723	21,937
Less: accumulated depreciation	(51,692)	(16,278)
	$ 301,308	$ 75,948

	March 31,	
Accrued expenses	**2020**	**2019**
Accrued bonuses	$ 172,500	$ 25,000
Wages and employee benefits	25,660	4,915
Professional fees and consulting	4,000	3,800
Other	—	6,900
	$ 202,160	$ 40,615

The Company has recorded accrued employee bonuses of $312,500 at March 31, 2020, of which $172,500 was recorded as a current liability and $140,000 as a long-term liability. The current liability amount includes $32,500 of bonuses for non-executive employees that were paid in April 2020. The remaining $280,000 represents a bonus to the Company's chief executive officer, which is payable ratably over the 24 months commencing March 31, 2020, and the Company has recorded the $140,000 payable subsequent to March 31, 2021 as a long-term liability in the consolidated balance sheet.

NOTE 3 – LEASES

As discussed in Note 1, effective April 1, 2019, the Company adopted ASC 842, as amended, using the alternative transition method, which allowed the Company to initially apply the new lease standard at the adoption date (the "effective date method"). In January 2020, the Company executed a lease for a new, larger corporate facility in San Diego, California and paid a $100,000 security deposit. The 39-month lease term commenced on April 1, 2020, and the lease provides for an initial monthly rent of approximately $12,400 with annual rent increases of approximately 3%. In addition to the minimum lease payments, the Company is responsible for property taxes, insurance and certain other operating costs. The right-to-use asset and corresponding liability for the facility lease have been measured at the present value of the future minimum lease payments. A discount rate of 11%, which approximated the Company's incremental borrowing rate, was used to measure the lease asset and liability. Lease expense is recognized on a straight line basis over the lease term.

The Company obtained a right-of-use asset of $270,950 in exchange for is obligations under the operating lease. The landlord also provided a lease incentive of approximately $139,000, which was paid in June 2020, for the Company to make improvements to the leased space.

Future minimum payments under the facility operating lease, net of the lease incentive, as of March 31, 2020 are listed in the table below.

Annual Fiscal Years	Operating lease
2021	$ 136,543
2022	153,432
2023	158,028
2024	40,692
Less:	
Imputed interest	(78,548)
Lease incentive	(139,197)
Present value of lease liabilities	$ 270,950

Rent expense was $35,766 and $36,000 for the years ended March 31, 2020 and 2019, respectively.

NOTE 4 – RELATED PARTY TRANSACTIONS

During the year ended March 31, 2020, the Company entered into consulting agreements with a member of its board of directors. Under the consulting agreements, during the year ended March 31, 2020, the Company paid the director consulting fees of $140,625 in cash, and the director was granted stock options with a fair value of $76,875. The options were for a total of 47,062 shares of common stock, were fully vested on the grant dates and have terms of 10 years. The most recent consulting agreement, which was entered into between the Company and the director in September 2019, was terminated in March 2020. At March 31, 2020, the Company had an outstanding payable to the director of $5,585, which was included in accounts payable in the consolidated balance sheet.

NOTE 5 – STOCK-BASED COMPENSATION

Equity Compensation Plan

In October 2017, the Company's board of directors (the Board) approved the 2017 Equity Incentive Plan (the 2017 Plan) with 3,000,000 shares of common stock reserved for issuance. In January 2020, the Board approved an amendment to the 2017 Plan to increase the number of shares reserved for issuance by 1,000,000 shares. Under the 2017 Plan, eligible employees, directors and consultants may be granted a broad range of awards, including stock options, stock appreciation rights, restricted stock, performance-based awards and restricted stock units. The 2017 Plan is administered by the Board or, in the alternative, a committee designated by the Board.

The exercise or purchase price of a stock option shall be calculated as follows:

(i) In the case of an incentive stock option, (a) granted to employees, who, at the time of the grant of such incentive stock option own stock representing more than ten percent (10%) of the voting power of all classes of stock of the Company, the per share exercise price shall be not less than one hundred ten percent (110%) of the fair market value per share on the date of grant; or (b) granted to employees, other than to employees, described in the preceding clause, the per share exercise price shall be not less than one hundred percent (100%) of the fair market value per share on the date of grant;

(ii) In the case of a non-qualified stock option, the per share exercise price shall be not less than one hundred percent (100%) of the fair market value per share on the date of grant unless otherwise determined by the Board; and

(iii) In the case of other grants, such price as determined by the Board.

The Board is responsible for determining the consideration to be paid for the shares of common stock to be issued upon exercise or purchase. The 2017 Plan generally does not allow for the transfer of awards, and the Board may amend, suspend or terminate the 2017 Plan at any time.

Stock-Based Compensation Expense

The expense relating to stock options is recognized on a straight-line basis over the requisite service period, usually the vesting period, based on the grant date fair value. The unamortized compensation cost, as of March 31, 2020 was $2,495,385 related to stock options and is expected to be recognized as expense over a weighted-average period of approximately 2.7 years.

During the year ended March 31, 2020, options granted to purchase shares of its common stock to employees, directors and consultants had 10-year terms and a grant-date fair value of $2,839,373. Options to purchase 152,204 shares vested immediately on the grant dates.

The following assumptions were used in the fair-value method calculations:

	Year ended March 31,	
	2020	2019
Risk-free interest rates	0.77% - 2.37%	2.73 - 3.01%
Volatility	86% - 103%	71% - 112%
Expected life (years)	5.0 - 6.0	5.0 - 6.0
Dividend yield	—%	—%

The fair values of options at the grant date were estimated utilizing the Black-Scholes valuation model, which includes simplified methods to establish the fair term of options as well as average volatility of three comparable organizations. The risk-free interest rate was derived from the Daily Treasury Yield Curve Rates, as published by the U.S. Department of the Treasury as of the grant date for terms equal to the expected terms of the options. A dividend yield of zero was applied because the Company has never paid dividends and has no intention to pay dividends in the foreseeable future. In accordance with ASU No. 2016-09, the Company accounts for forfeitures as they occur.

A summary of stock option activity under the 2017 Plan is presented below:

	Shares Available for Grant	Options Outstanding	
		Number of Shares	Weighted Average Exercise Price
Balance at April 1, 2018	3,000,000	—	—
Options granted	(1,529,908)	1,529,908	0.86
Balance at March 31, 2019	1,470,092	1,529,908	0.86
Additional shares authorized under the Plan	1,000,000	—	—
Options granted	(1,717,204)	1,717,204	2.25
Options cancelled and returned to the Plan	69,167	(69,167)	2.25
Balance at March 31, 2020	822,055	3,177,945	1.58

There were no stock options exercised during the years ended March 31, 2020 and 2019.

The following table summarizes the range of outstanding and exercisable options as of March 31, 2020:

	Options Outstanding			Options Exercisable		
Range of Exercise Price	Number Outstanding	Weighted Average Remaining Contractual Life (in Years)	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price	Aggregate Intrinsic value
$0.66 - $2.48	3,177,945	9.08	$ 1.58	1,586,736	$ 0. 92	$ —

The intrinsic value per share is calculated as the excess of the closing price of the common stock on the Company's principal trading market over the exercise price of the option.

The Company is required to present the tax benefits resulting from tax deductions in excess of the compensation cost recognized from the exercise of stock options as financing cash flows in the consolidated statements of cash flows. For the years ended March 31, 2020 and 2019, there were no such tax benefits associated with the exercise of stock options.

NOTE 6 – STOCKHOLDERS' EQUITY

In March 2020, the Company initiated a private placement of shares of its common stock (the 2020 Placement). As of March 31, 2020, the Company sold an aggregate of 321,950 shares of common stock, at a purchase price of $2.87 per share, for aggregate proceeds of approximately $924,000. As the 321,950 shares were issued by the Company's transfer agent subsequent to March 31, 2020, the $924,000 has been recorded as common stock payable in the stockholders' equity section of the consolidated balance sheet at March 31, 2020. Subsequent to March 31, 2020, the Company sold approximately 349,350 shares of common stock for aggregate proceeds of approximately $1,002,600. Under the terms of the common stock purchase agreements between the Company and the investors, the Company must use commercially reasonable efforts to file a registration statement with the SEC within 90 days of the closing of the 2020 Placement to register the shares of common stock sold in the 2020 Placement.

NOTE 7 – INCOME TAXES

The income tax provision (benefit) consisted of the following:

	Year Ended March 31,	
	2020	**2019**
Current portion:		
Federal	$ —	$ —
State	1,600	1,589
	1,600	1,589
Deferred portion:		
Federal	(1,180,434)	(582,782)
State	(391,865)	(193,502)
	(1,572,299)	(776,284)
Change in valuation allowance	1,572,299	776,284
Provision for income taxes	$ 1,600	$ 1,589

As of March 31, 2020, the Company had net operating loss carryforwards (NOLs) of approximately $7,000,000 for federal and state income tax purposes. These NOLs are available to reduce future taxable income and will expire at various times from 2037 through 2040, except federal NOLs from fiscal 2018, 2019 and 2020 which will never expire.

The Company also had federal research and development tax credit carryforwards of approximately $179,000, which will begin expiring at various times from 2038 through 2040, and state research and development credits of approximately $74,000, which do not have an expiration date.

A reconciliation of income taxes provided at the federal statutory rate (21% for fiscal 2020 and 2019) to the actual income tax provision is as follows:

	Year Ended March 31,	
	2020	**2019**
Federal statutory rate	21%	21%
State tax rate, net of federal benefit	7%	7%
Permanent differences	—%	—%
Research and development tax credits	3%	2%
Section 179 assets	—%	1%
Change in valuation allowance	(31)%	(31)%
Effective income tax rate	—%	—%

Significant components of the Company's deferred tax assets and liabilities were:

	March 31,	
	2020	2019
Net operating loss carryforwards	$ 1,965,118	$ 758,799
Stock-based compensation expense	364,989	148,903
Property and equipment	6,842	2,172
Reserves, accruals & other	(7,181)	—
Research and development tax credits	237,716	85,310
Total deferred tax assets	2,567,484	995,184
Less: valuation allowance	(2,567,484)	(995,184)
Deferred tax assets, net	$ —	$ —

Based on the available information and other factors, management believes it is more likely than not that the net deferred tax assets at March 31, 2020 and 2019, will not be fully realizable. Accordingly, management has recorded a full valuation allowance against its net deferred tax assets at March 31, 2020 and 2019. The valuation allowance increased by approximately $776,000 during fiscal 2019.

Management has evaluated and concluded that there were no material uncertain tax positions requiring recognition in the Company's consolidated financial statements at March 31, 2020 and 2019. The Company does not expect any significant changes in its unrecognized tax benefits within twelve months of the reporting date.

NOTE 8 – ROYALTY AGREEMENT

In July 2017, the Company entered into a royalty agreement with its founder, chief executive officer and major shareholder (the Founder). Pursuant to the agreement, the Founder assigned and transferred all of his rights in the intellectual property of Quasuras in return for future royalty payments on the Company's product. The Company is obligated to make royalty payments under the agreement to the Founder on any sales of the royalty product sold or otherwise commercialized by the Company equal to (a) $0.75 on each sale of a royalty product or (b) five percent (5%) of the gross sale price of the royalty product, whichever is less. The royalty payments will cease, and the agreement will terminate, at such time as the total sum of royalty payments actually paid to the Founder, pursuant to the agreement, reaches $10,000,000. The Company has the option to terminate the agreement at any time upon payment, to the Founder, of the difference between total royalty payments actually made to him to date and the sum of $10,000,000. All payments of the royalties, if due, for the preceding quarter, will be made by the Company to the Founder within thirty days after the end of each calendar quarter.

NOTE 9 – RETIREMENT SAVINGS PLAN

Effective March 2020, the Company adopted the Modular Medical, Inc. 401(k) Plan (the Savings Plan), which qualifies as a thrift plan under Section 401(k) of the Internal Revenue Code. Full-time and part-time employees who are at least 21 years of age are eligible to participate in the Savings Plan at the time of hire. Participants may contribute up to 15% of their earnings to the Savings Plan. The Plan became effective and began accepting participant contributions in April 2020.

NOTE 10 – COMMITMENTS & CONTINGENCIES

Litigations, Claims and Assessments

In the normal course of business, the Company may be involved in legal proceedings, claims and assessments arising in the ordinary course of business. The Company records legal costs associated with loss contingencies as incurred and accrues for all probable and estimable settlements.

Indemnification

In the ordinary course of business, the Company enters into contractual arrangements under which it may agree to indemnify the counterparties from any losses incurred relating to breach of representations and warranties, failure to perform certain covenants, or claims and losses arising from certain events as outlined within the particular contract, which may include, for example, losses arising from litigation or claims relating to past performance. Such indemnification clauses may not be subject to maximum loss clauses. The Company has also entered into indemnification agreements with its officers and directors. No amounts were reflected in the Company's consolidated financial statements for the years ended March 31, 2020 and 2019 related to these indemnifications. The Company has not estimated the maximum potential amount of indemnification liability under these agreements due to the limited history of prior claims and the unique facts and circumstances applicable to each particular agreement. To date, the Company has not made any payments related to these indemnification agreements.

NOTE 11 – SUBSEQUENT EVENTS

Preferred Unit Public Offering

On April 2, 2020, the Company's board of directors authorized the designation of 2,000,000 shares of the Company's preferred stock as 13% Series A Cumulative Redeemable Perpetual Preferred Stock (the Series A Preferred Stock). On April 9, 2020, the Company filed a registration statement on Form S-1 (No. 333-237615) with the SEC, which was declared effective on May 11, 2020, to register 2,000,000 preferred units (the Preferred Units) at a price of $25.00 per unit. Each Preferred Unit consists of (i) one share of Series A Preferred Stock with a $25.00 liquidation preference amount and (ii) three common stock purchase warrants, each to purchase one share of the Company's common stock at an exercise price of $11.00 per share. To date, the Company has not sold any of the Preferred Units.

PPP Loan

On April 24, 2020, the Company received a $368,780 unsecured loan (the PPP Loan) under the Paycheck Protection Program (the PPP), which was established under the U.S. government's Coronavirus Aid, Relief, and Economic Security Act (the CARES Act). The PPP Loan to the Company was made through Silicon Valley Bank (the Lender), and the Company entered into a U.S. Small Business Administration Paycheck Protection Program Note (the Agreement) with the Lender evidencing the PPP Loan.

The term of the PPP Loan is two years. Interest will accrue on the outstanding principal balance of the PPP Loan at a fixed rate of 1.0%, which shall be deferred for the first six months of the term of the PPP Loan. Monthly payments will be due and payable beginning in October 2020 and continue each month thereafter until maturity of the PPP Loan. The Company may prepay principal of the PPP Loan at any time in any amount without penalty. The Agreement contains customary events of default relating to, among other things, payment defaults, breach of representations and warranties or provisions of the PPP Loan. The occurrence of an event of default may result in the repayment of all amounts outstanding, collection of all amounts owing from the Company, and/or filing suit and obtaining judgment against the Company.

The Company may apply to the Lender for forgiveness of the PPP Loan, and the amount which may be forgiven will be equal to the sum of the payroll and benefit costs and covered rent and utility payments incurred by the Company, as calculated in accordance with the terms of the CARES Act. No assurance is provided that the Company will obtain forgiveness of the PPP Loan in whole or in part, but the Company intends to use the proceeds in accordance with the PPP Loan program.

ITEM 9: CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A: CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Disclosure controls and procedures are designed to ensure that information required to be disclosed in the reports filed with or furnished to the Securities and Exchange Commission, or the SEC, under the Securities Exchange Act of 1934, as amended, or the Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed in the reports filed under the Exchange Act is accumulated and communicated to our management, including our Chief Executive Officer, to allow timely decisions regarding required disclosure.

Under the supervision and with the participation of our management, including our Chief Executive Officer, who also serves as our Chief Financial Officer, we conducted an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934 (the Exchange Act). Based on this evaluation, our management concluded that as of March 31, 2020, our disclosure controls and procedures were effective.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management necessarily is required to apply its judgment in evaluating the cost-benefit relationship of possible controls. Internal control over financial reporting is the process designed by, or under the supervision of, our Chief Executive Officer and Chief Financial Officer, and effected by our board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external purposes in accordance with generally accepted accounting principles, and includes those policies and procedures that: (i) pertain to the maintenance of records that in reasonable detail accurately and fairly reflect our transactions and dispositions of assets; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of consolidated financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

Because of its inherent limitations, cost-effective internal controls over financial reporting may not prevent or detect misstatements. All internal control systems, no matter how well designed, have inherent limitations, including the possibility of human error and the circumvention of overriding controls. Accordingly, even effective internal control over financial reporting can provide only reasonable assurance with respect to consolidated financial statement preparation. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Under the supervision and with the participation of our management, including our Chief Executive Officer, we conducted an assessment of the effectiveness of our internal control over financial reporting as of the end of the period covered by this Annual Report on Form 10-K. In making this assessment, we used the criteria based on the framework in *Internal Control—Integrated Framework (2013 Framework)* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on the assessment, our management concluded that our internal control over financial reporting was effective as of March 31, 2020.

Changes in Internal Control over Financial Reporting

As a result of management's assessment of the effectiveness of our internal control over financial reporting as of March 31, 2019, our management concluded that there were material weaknesses and that our internal controls over financial reporting were not effective. A material weakness is a deficiency, or a combination of control deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. The identified material weaknesses related to inadequate internal controls over financial reporting and the lack of segregation of duties in our financial reporting process.

During fiscal 2020, we began implementing a remediation plan to address the material weaknesses identified in our internal controls as of March 31, 2019. These remediation efforts are focused on:

- Enhancing monitoring and review controls over financial reporting and disclosures;
- Ensuring adequate segregation of duties; and
- Retaining personnel with accounting and financial reporting expertise.

As part of our remediation efforts, we have:

- hired a full-time accounting manager to manage our accounting and financial reporting functions;
- engaged an interim chief financial officer (CFO), who has significant experience as a public-company CFO and is a certified public accountant, to have executive responsibility for our accounting, financial reporting and compliance functions;
- expanded our board of directors with the appointment of two new qualified directors, each of whom has been determined to be independent, as determined in accordance with Rule 10A-3 of the Exchange Act;
- formed an audit committee and appointed one of the new directors as the audit committee chairperson and financial expert, as defined by Item 407(d)(5) of Regulation S-K under the Exchange Act;
- formed a compensation committee and appointed the other new, independent director as the compensation committee chairperson;
- initiated audit committee review of our filings with the SEC;
- implemented new management review controls over the preparation of our consolidated financial statements and preparation of the quarterly and annual reports that we file with the SEC; and
- implemented new management review controls over the financial close process, expenditures, payments and payroll processing.

We believe that the addition of these qualified finance professionals and independent directors combined with the internal control procedures implemented during fiscal 2020 has enabled us to remediate the material weaknesses identified as of March 31, 2019 during fiscal 2020. We intend to implement additional controls during fiscal 2021, including formally establishing committee charters, adding additional directors to the committees and establishing additional formally documented policies and procedures.

ITEM 9B: OTHER INFORMATION

Our employment agreement with Paul DiPerna, our chief executive officer, chairman, chief financial officer, secretary and treasurer, dated August 1, 2018, as amended (the Employment Agreement), provides that Mr. DiPerna will receive an annual bonus of $300,000, which is payable at the discretion of our board of directors. Mr. DiPerna has served in these executive capacities since our July 2017 merger with Quasuras, Inc., and, to date, has not received any bonus from us. On June 26, 2020, our board of directors authorized a $280,000 bonus for Mr. DiPerna for fiscal 2020. The bonus will be payable ratably over the 24-month period commencing March 31, 2020.

In addition, on June 26, 2020, our board of directors approved an amendment to the Employment Agreement to provide that Mr. DiPerna's base salary would be paid entirely in cash commencing July 1, 2020. The payment of the additional cash component of Mr. DiPerna's annual base salary ($8,333.33 per month) shall initially be deferred (the Deferred Salary) and accrue for Mr. DiPerna's benefit until the Company has received $5,000,000 of cumulative gross proceeds from its current financing activities. The Deferred Salary shall be paid to Mr. DiPerna after achievement of the $5,000,000 of gross proceeds and the salary deferrals will cease.

Our board of directors approved these actions after reviewing such Employment Agreement with Mr. DiPerna.

PART III

ITEM 10: DIRECTORS, EXECUTIVE OFFICERS, AND CORPORATE GOVERNANCE

The names of our directors and certain information about each of them at March 31, 2020 are set forth below.

Name	Age	Position
Paul DiPerna	61	Chief Executive Officer, Chief Financial Officer, Secretary, Treasurer and Director (Chairman of the Board of Directors)
Liam Burns	54	Director
William J. Febbo(1)	51	Director
Morgan C. Frank	48	Director
Carmen Volkart(2)	59	Director

(1) Member of Compensation Committee
(2) Member of Audit Committee

The principal occupations and positions for at least the past five years of our directors are described below. There are no family relationships among any of our directors or executive officers.

Paul DiPerna. Mr. DiPerna has been our chairman, chief executive officer, chief financial officer, secretary and treasurer since we acquired Quasuras, Inc. (Quasuras) in July 2017. Mr. DiPerna began his career in approximately 1980 as a mechanical design engineer in the automated test equipment industry before moving in approximately 1989 to a start-up in the blood separation sciences industry. This company was eventually acquired in approximately 1991 by Baxter Healthcare (Baxter). Following such acquisition, Mr. DiPerna became employed by Baxter and held various positions during his approximate 12 years at Baxter. While at Baxter, Mr. DiPerna worked on numerous projects and initiatives including leading a team of approximately 50 engineers in developing equipment in the blood separation sciences industry. In approximately 1996, Mr. DiPerna was promoted to General Manager of Baxter's business development group to identify targets for Baxter's expansion opportunities in the medical device industry. While holding such position, Mr. DiPerna led a team researching custom orthopedics, digital dentistry and rapid prototyping. In such role, one of Mr. DiPerna's assignments was identifying synergistic opportunities in the diabetes industry. As a result, Mr. DiPerna developed substantial expertise and knowledge in the diabetes industry and led attempts by Baxter to acquire three insulin pump manufacturers. In 2003, Mr. DiPerna left Baxter and founded what subsequently became Tandem Diabetes Care, Inc. (Tandem). While at Tandem, Mr. DiPerna held various positions, including as director, chief executive officer and chief technology officer and was primarily responsible for the design concept and development of Tandem's initial insulin pump, which subsequently was commercialized by Tandem. Tandem is a medical device company that designs, develops and commercializes products for people with insulin-requiring diabetes. In 2011, Mr. DiPerna resigned from his executive officer position and board seat at Tandem but continued to assist the company through 2013. In early 2012, Mr. DiPerna was the co-inventor with regard to a private company with property rights in a medical device used for blood borne infection control called the "Curos Cap." Curos Cap was acquired by 3M Corporation in 2015. Thereafter, Mr. DiPerna founded a company, Fuel Source Partners, LLC (FSP), where he is the manager of, to incubate early stage medical device products and accumulate technical talent. One of such proposed products was spun-out to Quasuras in March 2015, which we acquired in July 2017. Mr. DiPerna holds a number of patents and patents pending and is a member of the American Diabetes Association. Mr. DiPerna received a Masters in Engineering Management from Northeastern University and a B.S. in Mechanical Engineering from the University of Lowell. In January 2017, Mr. DiPerna joined National Cardiac Incorporated (Cardiac) as its chief executive officer and a board member to leverage Cardiac's technology in the cardiac monitoring space before resigning in 2019 as an executive and 2020 as a member of its board of directors. We believe that Mr. DiPerna is qualified to serve as the chairman of our board of directors due to his extensive knowledge and experience in the medical device industry generally, and, in particular, with regard to insulin pumps and the diabetes industry as well as his management and leadership experience from holding director and senior executive positions in other public and private companies and leading project development teams of medical device companies.

Liam Burns. Mr. Burns was appointed to our board of directors in January 2019. Since that time, he has also been the Chief Executive Officer of Endo-TAGSS, LLC, a privately-held company developing a novel surgical access system for treatment of gastrointestinal diseases. From December 2017 to December 2018, Mr. Burns was the Chief Executive Officer of CuraSeal Inc., a privately-held regenerative medical company. From January 2014 to March 2018, he was the Vice President, Global Sales and Marketing for Dextera Surgical Inc., which marketed the world's smallest surgical stapler. Dextera Surgical Inc. filed for bankruptcy protection on December 11, 2017 and was subsequently sold to B. Braun Aesculap in 2018. From January 2013 to September 2016, Mr. Burns was the managing member and majority interest holder in Bensi Flemington LLC, which operated a restaurant in Flemington, New Jersey. Bensi Flemington LLC filed for bankruptcy protection on August 11, 2015. Prior to that, Mr. Burns held a variety of commercial leadership roles at Ethicon and various early stage medical device companies. Mr. Burns received a B.A. in Economics from the College of the Holy Cross and an Executive MBA from the Weatherhead School of Management at Case Western Reserve University. We believe that Mr. Burns is qualified to serve as a member of our board of directors due to his extensive experience and background in developing and launching new medical technologies, commercial strategy, marketing and branding, as well as his experience in metabolic health.

William J. Febbo. Mr. Febbo was appointed to our board of directors in January 2020. He has served as chief executive officer and a member of the board of directors of OptimizeRx Corporation since February 2016. In 2017, Mr. Febbo became a faculty member of the Massachusetts Institute of Technology's linQ program, which is a collaborative initiative focused on increasing the potential of innovative research to benefit society and the economy. Prior to 2016, he served as chairman and founder of Plexuus, LLC, a payment processing business for medical professionals. From 2007 to 2015, Mr. Febbo served as chief operating officer of Merriman Holdings, Inc., an investment banking firm, and assisted with capital raises in the technology, biotech, cleantech, consumer and resources industries. From 2013 to 2015, he served as chief executive officer and co-founder of Digital Capital Network, Inc., which operated a transaction platform for institutional and accredited investors. Prior to 2007, Mr. Febbo was chief executive officer and co-founder of MedPanel, a provider of market intelligence and communications for the pharmaceutical, biomedical, and medical device industries. He holds a B.A. in international studies and Spanish from Dickinson College. We believe that Mr. Febbo is qualified to serve on our board of directors because of his experience in building and managing health services and financial businesses. In addition, he has expertise in corporate finance and strategy experience gained from his experience as an investment banker.

Morgan C. Frank. Mr. Frank was appointed to our board of directors in April 2017. Mr. Frank has worked with Manchester since May 2002, and prior to such time, he was a founder and managing director at First Principles Group, a boutique consultancy and principal investor specializing in corporate restructuring, restarts, intellectual property assessment and salvage, and spin outs. Prior to such time, Mr. Frank spent approximately five years as an analyst and portfolio manager at Hollis Capital, a San Francisco based hedge fund and prior thereto, Mr. Frank worked for an independent private client group at Paine Webber specializing in primary research to develop investment ideas (particularly short sale ideas) for institutional clients. Prior to his employment at Paine Webber, Mr. Frank was a currency trader for Eastern Vanguard. Mr. Frank holds a BA in Economics and in Political Science from Brown University. We believe that Mr. Frank is qualified to serve as member of our board of directors due to his extensive prior experience conducting financial analysis of public companies (certain of which were in the development stage), including such public companies' management teams, products, including products in the development stage, the potential markets for such products and other factors that could affect the likelihood and timing of success and market penetration of such entities' products as well as his capital raising activities. We believe this provides us with valuable insights into the financial markets and investment criteria of institutional and other investors as well as capital raising activities.

Carmen Volkart. Ms. Volkart was appointed to our board of directors in December 2019. She has served as chief financial officer of Natureworks LLC, an advanced materials company offering a portfolio of renewably-sourced polymers, since October 2018. From October 2012 to July 2018, Ms. Volkart served as chief financial officer and, for a portion of that time, as senior vice president of commercialization for NxThera, Inc., a medical device company pioneering the application of convective radiofrequency thermotherapy to treat endurological conditions. She served as global chief financial officer of Tornier N.V. from 2010 to 2012, and was chief operating and financial officer, corporate secretary, compliance officer and treasurer of Spine Wave, Inc. from 2006 to 2010. Prior to 2006, Ms. Volkart held various executive and financial positions at American Medical, Inc., Medtronic, Inc. and Honeywell, Inc. She holds a B.S. in accounting from the University of North Dakota and an MBA with a concentration in strategic management from the University of Minnesota. Ms. Volkart is qualified to serve on our board of directors because of her substantial financial and public-company experience, as she has served as chief financial officer at multiple medical device and other companies.

The names of our executive officers and certain information about them are set forth either above or below:

Name	Age	Position
Paul DiPerna	61	Chief Executive Officer, Chief Financial Officer, Secretary, Treasurer and Director (Chairman of the Board of Directors)
Stephen Daly	52	Chief Commercial Officer

Stephen Daly. Mr. Daly became our Chief Commercial Officer in March 2020. From December 2014 until February 2020, he served as U.S. General Manager for Adocia, a clinical-stage, French biotechnology company. Before joining Adocia, Mr. Daly served in senior roles for the commercialization of therapeutics in the diabetes and metabolism fields at companies such as Halozyme, Amylin Pharmaceuticals and Affymax. Prior to his industry-specific experience in diabetes and metabolism, he held portfolio planning and commercialization roles in the generic and biosimilar marketplace for Baxter International and Sicor, a division of Teva Pharmaceuticals. Mr. Daly holds a Bachelor of Science in business administration (finance and information systems) from Northeastern University.

Involvement in Legal Proceedings

Except with regard to Mr. Burns, to our knowledge, none of our executive officers or our directors has, during the last ten years:

- had any bankruptcy petition filed by or against the business or property of the person, or of any partnership, corporation or business association of which he was a general partner or executive officer, either at the time of the bankruptcy filing or within two years prior to that time;

- been subject to any order, judgment, or decree, not subsequently reversed, suspended or vacated, of any court of competent jurisdiction or federal or state authority, permanently or temporarily enjoining, barring, suspending or otherwise limiting, his involvement in any type of business, securities, futures, commodities, investment, banking, savings and loan, or insurance activities, or to be associated with persons engaged in any such activity;

- been found by a court of competent jurisdiction in a civil action or by the SEC or the Commodity Futures Trading Commission to have violated a federal or state securities or commodities law, and the judgment has not been reversed, suspended, or vacated;

- been the subject of, or a party to, any federal or state judicial or administrative order, judgment, decree, or finding, not subsequently reversed, suspended or vacated (not including any settlement of a civil proceeding among private litigants), relating to an alleged violation of any federal or state securities or commodities law or regulation, any law or regulation respecting financial institutions or insurance companies including, but not limited to, a temporary or permanent injunction, order of disgorgement or restitution, civil money penalty or temporary or permanent cease-and-desist order, or removal or prohibition order, or any law or regulation prohibiting mail or wire fraud or fraud in connection with any business entity; or

- been the subject of, or a party to, any sanction or order, not subsequently reversed, suspended or vacated, of any self-regulatory organization (as defined in Section 3(a)(26) of the Exchange Act), any registered entity (as defined in Section 1(a)(29) of the Commodity Exchange Act), or any equivalent exchange, association, entity or organization that has disciplinary authority over its members or persons associated with a member.

To our knowledge, there are no material proceedings to which any director, officer or affiliate of ours, any owner of record or beneficially of more than 5% of any class of voting securities of us, or any associate of any such director, officer, affiliate of ours, or security holder is a party adverse to us or any of our subsidiaries or has a material interest adverse to us or any of our subsidiaries.

Arrangements for Appointment of Directors and Officers

Until July 24, 2022, our board of directors shall consist of no more than five and no less than two directors of which (i) Manchester has the right to appoint two directors, pursuant to which Manchester appointed Mr. Frank and Ms. Volkart and (ii) Mr. DiPerna, in addition to being our chairman of the board, has the right to appoint 2 additional directors, pursuant to which he appointed Messrs. Burns and Febbo. See "Risk Factor - *If the beneficial ownership of our common stock continues to be highly concentrated, it may prevent you and other shareholders from influencing significant corporate decisions; agreement to elect directors*."

The DiPerna Employment and Related Agreements

We entered into an employment agreement dated August 1, 2018, with Mr. DiPerna pursuant to which Mr. DiPerna is employed by us as our Chief Executive Officer and President for an initial 2-year term with automatic one-year renewals. Pursuant to such agreement, we have agreed to pay Mr. DiPerna: i) an annual salary of $200,000 in cash, ii) $100,000 per year in fully-vested stock options granted monthly at an exercise price determined by the board of directors in its sole discretion and iii) an annual bonus of $300,000, payable at the discretion of the board of directors in its sole discretion, either in shares of stock or in cash. If the Board chooses to pay the bonus in shares of stock, such shares will be valued at a price determined by the board of directors. In addition, pursuant to our employment agreement with Mr. DiPerna, in the event that we terminate Mr. DiPerna's employment without cause or he resigns with good reason, we will pay Mr. DiPerna a lump sum of $200,000. In the event that we terminate Mr. DiPerna's employment for cause, we are not obligated to make any severance payment and Mr. DiPerna will receive only his base compensation through the last day of his employment. In the event of Mr. DiPerna's death or disability, he will receive his base compensation through the last day of his employment and will remain eligible for all applicable benefits relative to death or disability pursuant to any plans that we have in place at such time. If a "change of control" (as defined in the employment agreement) occurred, under his employment agreement, Mr. DiPerna will be paid a lump sum of $100,000 within sixty days of the time at which such change of control takes place.

If a change of control occurred on March 31, 2020, under his employment agreement, Mr. DiPerna would be entitled to the following:

- payment of a lump sum of $100,000 within 60 days of the time at which such change of control takes place; and
- accelerated vesting of 275,000 shares of common stock under an unvested stock option. The value of the shares subject to accelerated vesting is calculated as the intrinsic value per share multiplied by the number of shares that would become fully vested upon a change of control. The intrinsic value per share would be calculated as the excess of the closing price of the common stock of $0.24 on the OTC Pink Open Market on March 31, 2020 over the exercise price of the option. If the value is less than zero, which it is as of March 31, 2020, it is deemed to be zero for the purposes of this calculation.

In May 2020, we amended our employment agreement with Mr. DiPerna to provide that in the event of a change in control:

- within 60 days of the date the change of control occurs, Mr. DiPerna shall be paid by us or our successor in interest a lump sum cash payment equal to 12 months of Mr. DiPerna's then annual Base Compensation (as defined in the employment agreement); and
- immediately prior to such change of control, any unvested stock options or other unvested securities of ours issued to Mr. DiPerna shall automatically accelerate and immediately become fully vested and exercisable.

In connection with our acquisition of Quasuras, we entered into an Intellectual Property Transfer Agreement dated as of July 24, 2017, with Quasuras and Mr. DiPerna (the IP Transfer Agreement), pursuant to which Mr. DiPerna transferred to us all intellectual property rights owned directly and/or indirectly by him related to our business.

Separately, we agreed to pay Mr. DiPerna, as part of his compensation for services to be performed for us, pursuant to a royalty agreement (the Royalty Agreement), certain fees based upon future sales, if any, of our potential product subject to a maximum $10,000,000 cap on the aggregate amount of fees that Mr. DiPerna could earn from such arrangement.

Communications with our Board of Directors

Our stockholders may send correspondence to our board of directors c/o the corporate secretary at the address set forth on the cover page of this Annual Report on Form 10-K. Our corporate secretary will forward stockholder communications to our board of directors prior to the board of director's next scheduled meeting following the receipt of the communication.

Corporate Governance

Board Leadership Structure and Role in Risk Oversight

Due to the small size and early stage of the Company, we have not adopted a formal policy on whether the chairman and chief executive officer positions should be separate or combined. Our board of directors has oversight responsibility for our risk management processes. Our board of directors receives and reviews periodic reports from management, auditors, legal counsel, and others, as considered appropriate, regarding our assessment of risks. Our board of directors will focus on the most significant risks facing us and our general risk management strategy, and also ensure that risks undertaken by us are consistent with our appetite for risk. While our board of directors oversees our risk management processes, management is responsible for day-to-day risk management processes. We believe this division of responsibilities is the most effective approach for addressing the risks facing us and that the leadership structure of our board of directors supports this approach.

Audit Committee

Our board of directors established an audit committee on December 31, 2019 for the purpose of overseeing the accounting and financial reporting processes and audits of our consolidated financial statements. During fiscal 2021, our board of directors intends to implement a formal audit committee charter and appoint additional directors to this committee. Ms. Volkart serves as the chairperson and has been designated by the board of directors as the "audit committee financial expert," as defined by Item 407(d)(5) of Regulation S-K under the Securities Act of 1933, as amended, and the Exchange Act. That status does not impose duties, liabilities or obligations that are greater than the duties, liabilities or obligations otherwise imposed on her as a member of the audit committee and the board of directors, however. Our board of directors has determined that she is an independent director, as determined in accordance with Rule 10A-3 of the Securities Exchange Act of 1934, as amended (the Exchange Act). Ms. Volkart is responsible for review and pre-approval of services proposed to be provided by our independent registered public accounting firm.

Compensation Committee

Our board of directors established a compensation committee in January 2020 for the purpose of reviewing, recommending and approving our compensation policies and benefits, including the compensation of all of our executive officers and directors. Our compensation committee also has the principal responsibility for the administration of our equity incentive plan. During fiscal 2021, our board of directors will approve a formal compensation committee charter and appoint additional directors to this committee. Mr. Febbo serves as the chairman, and our board of directors has determined that he is an independent director, as determined in accordance with the Exchange Act.

Nominations Process

We do not have a nominating committee, as we are a small company and Manchester and Mr. DiPerna have the right to appoint directors to our board of directors, as discussed above. Instead of having such a committee, Messrs. DiPerna and Frank identify and evaluate qualified individuals to become nominees for director and board committee members. When new candidates for our board of directors are sought, our board of directors evaluates each candidate for nomination as a director within the context of the needs and the composition of the board of directors as a whole. Our board of directors conduct any appropriate and necessary inquiries into the backgrounds and qualifications of candidates. When evaluating director nominees, our board of directors generally seeks to identify individuals with diverse, yet complementary business backgrounds. Although we have no formal policy regarding diversity, our directors consider both the personal characteristics and experience of director nominees, including each nominee's independence, diversity, age, skills, expertise, time availability and industry background in the context of the needs of the board of directors and the Company. The board of directors believes that director nominees should exhibit proven leadership capabilities and experience at a high level of responsibility within their chosen fields, and must have the experience and ability to analyze the complex business issues facing us, and specifically, the issues inherent in the medical device industry. In addition to business expertise, the board of directors requires that director nominees have the highest personal and professional ethics, integrity and values and, above all, are committed to representing the long-term interests of our stockholders and other stakeholders.

Delinquent Section 16(a) Reports

Section 16(a) of the Exchange Act requires our directors, executive officers and persons who own more than 10% of a registered class of our equity securities to file with the SEC initial reports of ownership and reports of changes in ownership of common stock and other equity securities of ours. Directors, executive officers and greater than 10% holders are required by SEC regulation to furnish us with copies of all Section 16(a) reports they file. Based on our review of Forms 3 and 4 filed during fiscal 2020 (and any written representations to us by such persons), we believe that all directors, executive officers and 10% stockholders complied with all applicable Section 16(a) filing requirements during fiscal 2020 except that:

- Mr. DiPerna failed to timely file 13 Form 4s;
- Mr. Burns failed to timely file 12 Form 4s and one Form 5;
- Ms. Volkart failed to timely file a Form 3 and a Form 4; and
- Mr. Daly failed to timely file a Form 3 and Form 4.

ITEM 11. EXECUTIVE COMPENSATION

SUMMARY COMPENSATION TABLE

The following table sets forth compensation information for fiscal 2020 and 2019 for each of our named executive officers.

Name and Principal Position	Year	Salary ($)	Stock Awards ($)	Option Awards ($)(1)	Non-Equity Incentive Plan Compensation ($)	All Other Compensation ($)	Total ($)
Paul DiPerna CEO, CFO, Secretary,	2020	200,000	—	584,200	—	280,000(3)	1,064,200
Treasurer and Director (2)	2019	192,500	—	67,761	—	—	260,261
Stephen Daly Chief Commercial Officer (4)	2020	20,833	—	355,240	—	—	376,073

(1) Award amounts reflect the aggregate grant date fair value with respect to awards granted, as determined pursuant to FASB ASC Topic 718. The assumptions used to calculate the aggregate grant date fair value of option awards are set forth in the notes to the consolidated financial statements included in item 8 of this Report. These amounts do not reflect actual compensation earned or to be earned by our named executive officers.

(2) Mr. DiPerna's annual salary base was increased from $180,000 to $300,000 in August 2018, under the terms of an employment agreement between us and Mr. DiPerna. Mr. DiPerna's $300,000 annual salary is paid $200,000 in cash and $100,000 in fully-vested stock options granted monthly. Our board of directors amended the salary payment composition subsequent to March 31, 2020, as disclosed in item 9B of this Report.

(3) Earned as a bonus, which will be paid over the 24-month period commencing on March 31, 2020.

(4) Mr. Daly became our Chief Commercial Officer in March 2020 at an annual base salary of $250,000.

Outstanding Equity Awards at Fiscal Year-End

The following table shows certain information regarding outstanding equity awards held by our named executive officers as of March 31, 2020.

Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price($)	Option Expiration Date(1)
Paul DiPerna	4,979(2)	—	2.48	3/2/2030
	5,235(3)	—	2.48	2/1/2030
	5,181(4)	—	2.48	1/1/2030
	5,424(5)	—	2.25	12/1/2029
	5,431(6)	—	2.25	11/1/2029
	5,161(7)	—	2.25	10/1/2029
	4,986(8)	—	2.25	9/15/2029
	4,998(9)	—	2.25	8/15/2029
	4,979(10)	—	2.25	7/15/2029
	4,948(11)	—	2.25	6/15/2029
	5,028(12)	—	2.25	5/15/2029
	4,869(13)	—	2.25	4/15/2029
	5,082(14)	—	2.25	3/15/2029
	4,921(15)	—	2.25	2/15/2029
	4,808(16)	—	2.25	1/15/2029
	5,324(17)	—	2.25	12/28/2028
	5,324(18)	—	2.25	11/14/2028
	18,013(19)	—	0.66	10/14/2028
	18,013(20)	—	0.66	09/14/2028
	18,013(21)	—	0.66	08/14/2028
	25,000(22)	275,000	2.25	11/25/2029
Stephen Daly	—(23)	200,000	2.25	3/3/2030

(1) The standard option term is ten years, but all of the options expire automatically unless exercised within 90 days after the cessation of service as an employee, director or consultant.
(2) The option was granted on March 2, 2020, and the shares subject to this option were fully vested on the grant date.
(3) The option was granted on February 1,2020, and the shares subject to this option were fully vested on the grant date.
(4) The option was granted on January 1, 2020, and the shares subject to this option were fully vested on the grant date.
(5) The option was granted on December 1, 2019, and the shares subject to this option were fully vested on the grant date.
(6) The option was granted on November 1, 2019, and the shares subject to this option were fully vested on the grant date.
(7) The option was granted on October 1, 2019, and the shares subject to this option were fully vested on the grant date.
(8) The option was granted on September 15, 2019, and the shares subject to this option were fully vested on the grant date.
(9) The option was granted on August 15, 2019, and the shares subject to this option were fully vested on the grant date.
(10) The option was granted on July 15, 2019, and the shares subject to this option were fully vested on the grant date.
(11) The option was granted on June 15, 2019, and the shares subject to this option were fully vested on the grant date.
(12) The option was granted on May 15, 2019, and the shares subject to this option were fully vested on the grant date.
(13) The option was granted on April 15, 2019, and the shares subject to this option were fully vested on the grant date.
(14) The option was granted on March 15, 2019, and the shares subject to this option were fully vested on the grant date.
(15) The option was granted on February 15, 2019, and the shares subject to this option were fully vested on the grant date.
(16) The option was granted on January 15, 2019, and the shares subject to this option were fully vested on the grant date.
(17) The option was granted on December 15, 2018, and the shares subject to this option were fully vested on the grant date.
(18) The option was granted on November 15, 2018, and the shares subject to this option were fully vested on the grant date.
(19) The option was granted on October 15, 2018, and the shares subject to this option were fully vested on the grant date.
(20) The option was granted on September 15, 2018, and the shares subject to this option were fully vested on the grant date.
(21) The option was granted on August 15, 2018, and the shares subject to this option were fully vested on the grant date.
(22) The option was granted on November 25, 2019, and the shares subject to this option vest monthly over three years commencing January 1, 2020, subject to continued service as an employee, director or consultant.
(23) This option was granted on March 3, 2020, and the shares subject to this option vest will as to 1/3rd of the shares on March 2, 2021 and as to 1/36th of the shares subject to the option monthly thereafter, subject to continued service as an employee, director or consultant .

Employment Agreements

We have entered into our standard form of employment, confidential information and invention assignment agreement with each of our named executive officers.

We also have entered into agreements to indemnify our directors and certain executive officers, in addition to the indemnification provided for in our certificate of incorporation and bylaws. These agreements, among other things, provide for indemnification of our directors and certain executive officers for many expenses, including attorneys' fees, judgments, fines and settlement amounts incurred by any such person in any action or proceeding, including any action by or in the right of the Company, arising out of such person's services as a director or executive officer of ours, any subsidiary of ours or any other company or enterprise to which the person provided services at our request.

Director Compensation

The following table summarizes the compensation we paid to our non-employee directors in fiscal 2020:

Name	Fee Compensation ($)	Restricted Stock Awards ($)	Option Awards ($)(1)(2)	All Other Compensation	Total ($)
Liam Burns(3)	10,000	—	179,000	—	189,000
William Febbo(4)	2,500	—	344,960	—	347,460
Carmen Volkart(5)	2,500	—	258,510	—	261,010

(1) Award amounts reflect the aggregate grant date fair value with respect to awards granted, as determined pursuant to FASB ASC Topic 718. The assumptions used to calculate the aggregate grant date fair value of option awards are set forth in the notes to the consolidated financial statements included in Item 8 of this Annual Report on Form 10-K. These amounts do not reflect actual compensation earned or to be earned by our directors.

(2) As of March 31, 2020, our non-employee directors each held outstanding options to purchase the following number of shares of our common stock: Liam Burns, 197,062; William Febbo, 200,000; Carmen Volkart, 150,000.

(3) Mr. Burns was granted an option to purchase 60,000 shares of our common stock in January 2020.

(4) Mr. Febbo joined our board of directors in January 2020 and was granted an option to purchase 200,000 shares of our common stock.

(5) Ms. Volkart joined our board of directors in December 2019 and was granted options to purchase a total of 150,000 shares of our common stock.

Our board of directors has authorized an annual cash retainer fee of $10,000, payable in quarterly installments, for our non-employee directors, with the exception of Mr. Frank, as compensation for their service.

In addition, upon appointment to our board of directors, we award our non-employee directors a stock option grant under our Amended 2017 Equity Incentive Plan (the 2017 Plan) ranging from 150,000 to 200,000 shares of our common stock. These options vest annually over three years from the date of appointment to our board of directors.

ITEM 12: SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The following table sets forth certain information as of June 15, 2020 concerning the ownership of our common stock by:

- each shareholder known by us to be the beneficial owner of more than 5% of the outstanding shares of our common stock (currently our only class of voting securities);
- each of our directors;
- each of our executive officers; and
- all directors and executive officers as a group.

Beneficial ownership is determined in accordance with Rule 13d-3 of the Exchange Act, and includes all shares over which the beneficial owner exercises voting or investment power. Shares that are issuable upon the exercise of options, warrants and other rights to acquire common stock that are presently exercisable or exercisable within 60 days of June 15, 2020 are reflected in a separate column in the table below. These shares are taken into account in the calculation of the total number of shares beneficially owned by a particular holder and the total number of shares outstanding for the purpose of calculating percentage ownership of the particular holder. We have relied on information supplied by our officers, directors and certain stockholders and on information contained in filings with the SEC. Except as otherwise indicated, and subject to community property laws where applicable, we believe, based on information provided by these persons, that the persons named in the table have sole voting and investment power with respect to all shares of common stock shown as beneficially owned by them. The percentage of beneficial ownership is based on 18,454,459 shares of common stock outstanding as of June 15, 2020.

Unless otherwise stated, the business address of each of our directors and executive officers listed in the table is 16772 West Bernardo Drive, San Diego, California 92127.

Name and principal position	Number of Shares Beneficially Owned (Excluding Outstanding Options)(1)	Number of Shares Issuable on Exercise of Outstanding Options(2)	Percent of Class
James Besser	6,384,691(3)	—	34.60%
JEB Partners, L.P.	6,384,691(3)	—	34.60%
Manchester Explorer L.P.	6,384,691(3)	—	34.60%
Manchester Management LLC	6,384,691(3)	—	34.60%
Directors and Officers:			
Paul DiPerna	7,523,430(4)	186,610	41.36%
Liam Burns	—	77,062	*
Stephen Daly	—	—	*
William J. Febbo	—	—	*
Morgan C. Frank	6,384,691(3)	—	34.60%
Carmen Volkart	—	—	*
All current directors and executive officers as a group (6 persons)	13,908,121	263,672	76.37%

* Represents less than 1%

(1) Excludes shares subject to outstanding options to acquire common stock that are exercisable within 60 days of June 15, 2020.

(2) Represents the number of shares subject to outstanding options to acquire common stock that are exercisable within 60 days of June 15, 2020.

(3) Includes (i) 180,830 shares directly held by Mr. Besser, which shares were received in the Acquisition in exchange for Mr. Besser's shares of Quasuras; (ii) 88,889 shares directly held by Mr. Besser who purchased such shares in the 2018 Placement; (iii) 4,545,455 shares held by Manchester Explorer L.P. (Manchester) which purchased such shares in a 2017 private placement (the 2017 Placement); (iv) 471,111 shares held by Manchester who purchased such shares in a 2018 private placement (the 2018 Placement); (v) 757,576 shares held by JEB Partners L.P. (JEB) purchased in the 2017 Placement; (vi) 160,000 shares held by JEB who purchased such shares in the 2018 Placement; and (vii) 180,830 shares held by Mr. Frank, which shares were received in the Acquisition in exchange for Mr. Frank's shares of Quasuras. Mr. Besser as the managing member and Mr. Frank as the portfolio manager and consultant to Manchester Management, LLC (MMC), the general partner of Manchester and JEB, have shared voting and dispositive power over shares held by Manchester and JEB. The address for Messrs. Besser and Frank is c/o Manchester Management, LLC 2 Calle Candina, No. 1701, San Juan, Puerto Rico 00907. Such person disclaims beneficial ownership of all shares not held directly by such person, except to the extent of such person's pecuniary interest therein.

(4) Includes (i) 303,030 shares held directly by the Paul DiPerna Trust, which shares were purchased by the Paul DiPerna Trust in the 2017 Placement and (ii) 7,220,400 shares acquired by Mr. DiPerna in the Acquisition in exchange for his shares of Quasuras. Mr. DiPerna is the Chairman of our board of directors, and also serves as our Chief Executive Officer, Chief Financial Officer Treasurer and Secretary. Such person disclaims beneficial ownership of all shares not held directly by such person, except to the extent of such person's pecuniary interest therein.

ITEM 13: CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

Transactions with Related Persons

As disclosed elsewhere in this Annual Report on Form 10-K, Mr. DiPerna, is a party to related party transactions with us, see *Item 10. Directors, Executive Officers and Corporate Governance*.

During fiscal 2020, we entered into consulting agreements with Liam Burns, a member of our board of directors. Under the consulting agreements, during the year ended March 31, 2020, we paid Mr. Burns consulting fees of $140,625 in cash, and Mr. Burns was granted stock options with a fair value of $76,875. The options were for a total of 47,062 shares of common stock, were fully vested on the grant dates and have terms of 10 years. The most recent consulting agreement, which was entered into between Mr. Burns and us in September 2019, was terminated in March 2020. As of March 31, 2020, we had an outstanding payable to Mr. Burns of $5,585.

Director Independence

See Item 10. Directors, Executive Officers and Corporate Governance.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The following table shows the fees billed to us by Farber Haas Hurley LLP, or Farber, our independent registered public accounting firm, for the audit of our consolidated financial statements and other services provided.

	2020	2019
Audit fees(1)	$ 28,900	$ 23,500
Audit-related fees(2)	7,600	—
Total(3)	$ 36,500	$ 23,500

(1) Audit fees consisted of fees for professional services rendered for the audit of our annual consolidated financial statements, review of our quarterly consolidated financial statements and services provided in connection with our issuance of SEC registration statements.

(2) Audit-related fees consisted of fees for assurance and related services that are reasonably related to the performance of the audit or review of our consolidated financial statements fees and primarily related to the issuance of SEC registration statements.

(3) Farber did not provide any non-audit or other services other than those reported under “Audit fees” and “Audit-related fees.”

Policy on Audit Committee Pre-Approval of Audit and Permissible Non-Audit Services of Independent Auditors

In December 2020, our board of directors formed an audit committee, and appointed Ms. Volkart to serve as it chairperson. We are in the process of developing a charter for and adding additional directors to the audit committee. While we have not yet implemented a formal policy, Ms. Volkart pre-approves the fees for any services to be provided to us by Farber.

PART IV

ITEM 15: EXHIBITS

(a)(1) *Consolidated financial statements*. See the audited consolidated financial statements for the year ended March 31, 2020 contained in Item 8 of this Report which are incorporated herein by this reference.

(2) *Financial statement schedule*s. Omitted because they are not required, not applicable or because the required information is shown in the consolidated financial statements or notes thereto

(3) *Exhibits*. Required exhibits are incorporated by reference or are filed with this Report.

No.	Description
2.1(1)	Reorganization and Share Exchange Agreement dated as of July 24, 2017, by and among the Registrants, Quasuras, Inc., Paul DiPerna and the other stockholders of Quasuras, Inc.
3.1(2)	Second Amended and Restated Articles of Incorporation, as filed with the Secretary of State of Nevada on June 27, 2017
3.1.1(3)	Certificate of Designation of Preferences, Rights and Limitations of Series A Cumulative Redeemable Perpetual Preferred Stock
3.2(4)	Amended Bylaws
4.1(5) +	2017 Equity Incentive Plan, as amended
4.2(3)	Form of Common Stock Purchase Warrant
4.3(3)	Form of Warrant Agent Agreement
4.4(3)	Form of Subscription Agreement
4.5(3)	Form of Subscription Escrow Agreement
4.6(3)	Form of Dividend Payment Escrow Agreement
10.1(6)	Common Stock Purchase Agreement, dated as of April 5, 2017, by and among Bear Lake Recreation, Inc., Manchester Explorer, LP, a Delaware limited partnership, and certain persons named therein
10.2(1)	Form of Common Stock Purchase Agreement, dated as of July 24, 2017, by and between the Registrant and the purchaser named therein
10.3(7)	Form of Common Stock Purchase Agreement dated as of November 19, 2018 among the Registrant and the Investors named therein
10.4(8)+	Employment Agreement dated August 1, 2018, by and between the Registrant and Paul DiPerna
10.5(1)	Intellectual Property Assignment Agreement dated July 24, 2017, by and between the Registrant, Quasuras, Inc. and Paul DiPerna
10.6(1)+	Technology Royalty Agreement dated as of July 24, 2017, by and between the Registrant, Quasuras, Inc. and Paul DiPerna
10.7(8)	Service Agreement effective January 16, 2019 between the Registrant and Liam Burns
10.8(8)	Standard Sublease Agreement, dated August 21, 2017, between the Registrant and Western Education Corporation
10.9(9)	Lease between MCP Socal Industrial – Bernardo, LLC and the Registrant dated January 10, 2020
10.10(9)	Consulting Agreement between the Registrant and Liam Burns dated April 15, 2019
10.11(9)	Consulting Agreement between the Registrant and Liam Burns dated July 15, 2019
10.12(9)	Consulting Agreement between the Registrant and Liam Burns dated September 3, 2019
10.13(9)	Service Agreement effective December 31, 2019 between the Registrant and Carmen Volkart
10.14(9)	Service Agreement effective January 23, 2020 between the Registrant and William Febbo
10.15(9)	Form of Indemnification Agreement between the Registrant and each of its directors and officers used from January 23, 2020
10.16(9) +	Form of Notice of Stock Option Grant and Stock Option Agreement under the Amended 2017 Equity Incentive Plan
10.17(3)	Form of Common Stock Purchase Agreement dated March 2020 by and between the Registrant and the Investors named therein
10.18(10) +	First Amendment to Employment Agreement between the Registrant and Paul DiPerna effective as of May 12, 2020
10.19(11)	U.S. Small Business Administration Paycheck Protection Program Note dated April 23, 2020
21.1	Sole Subsidiary of the Registrant (as disclosed in the Notes to Consolidated Financial Statements as of March 31, 2020 in Item 8 of this Report)
24.1	Power of Attorney (see signature page of this Report)
31.1	Certification of Paul M. DiPerna pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32	Certification of Paul M. DiPerna pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema
101.CAL	XBRL Taxonomy Extension Calculation Linkbase
101.DEF	XBRL Taxonomy Extension Definition Linkbase
101.LAB	XBRL Taxonomy Extension Label Linkbase
101.PRE	XBRL Taxonomy Extension Presentation Linkbase

(1) As filed with the Registrant's Current Report on Form 8-K filed July 28, 2017, and incorporated herein by reference.
(2) As filed with the Registrant's Current Report on Form 8-K filed June 29, 2017, and incorporated herein by reference.
(3) As filed with the Registrant's Registration Statement on Form S-1, as amended, originally filed April 9, 2020, declared effective May 11, 2020 (Commission file No. 333-237615), and incorporated herein by reference.
(4) As filed with the Registrant's Annual Report on Form 10-K/A for the year ended June 30, 2008, and incorporated herein by reference.
(5) As filed with the Registrant's Annual Report on Form 10-K filed June 29, 2018, and incorporated herein by reference.
(6) As filed with the Registrant's Current Report on Form 8-K filed April 5, 2017, and incorporated herein by reference.
(7) As filed with the Registrant's Current Report on Form 8-K filed November 20, 2018 and incorporated herein by reference.
(8) As filed with the Registrant's Registration Statement on Form S-1, as amended, originally filed June 27, 2019, declared effective October 22, 2019 (Commission file No. 333-232377), and incorporated herein by reference.
(9) As filed with the Registrant's Quarterly Report on Form 10-Q for the quarter ended December 31, 2019, and incorporated herein by reference.
(10) As filed with the Registrant's Current Report on Form 8-K filed May 27, 2020, and incorporated herein by reference.
(11) As filed with the Registrant's Current Report on Form 8-K filed May 12, 2020, and incorporated herein by reference.

+ Management contract, compensatory plan or arrangement.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, on the 29th day of June, 2020.

MODULAR MEDICAL, INC.

By: */s/* Paul M. DiPerna
Paul M. DiPerna
Chief Executive Officer, Chief Financial Officer,
Secretary, Treasurer and Director
(principal executive, financial and accounting officer)

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Paul DiPerna as true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution, for her and him and in her or his name, place and stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorney-in- fact and agent, or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Name	**Title**	**Date**
/s/ Paul M. DiPerna Paul M. DiPerna	Chief Executive Officer, Chief Financial Officer, Secretary, Treasurer, (principal financial and accounting officer) and Director (Chairman of the Board)	June 29, 2020
/s/ Liam Burns Liam Burns	Director	June 29, 2020
/s/ William Febbo William Febbo	Director	June 29, 2020
/s/ Morgan Frank Morgan Frank	Director	June 29, 2020
/s/ Carmen Volkart Carmen Volkart	Director	June 29, 2020

Exhibit 31.1

CERTIFICATION PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Paul M. DiPerna, certify that:

1. I have reviewed this Annual Report on Form 10-K of Modular Medical, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Registrant as of, and for, the periods presented in this report;

4. The Registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rule 13a-15(f) and 15d-15(f)) for the Registrant and have:

a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) evaluated the effectiveness of the Registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) disclosed in this report any change in the Registrant's internal control over financial reporting that occurred during the Registrant's most recent fiscal quarter (the Registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the Registrant's internal control over financial reporting; and

5. The Registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Registrant's auditors and the audit committee of the Registrant's board of directors (or persons performing the equivalent functions);

a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Registrant's ability to record, process, summarize and report financial information; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the Registrant's internal control over financial reporting.

Date: *June 29, 2020*

By: */s/ Paul M. DiPerna*
Chief Executive Officer, Chief Financial Officer,
Secretary, Treasurer and Director
(principal executive, financial and accounting officer)

Exhibit 32

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Modular Medical, Inc. (the "Registrant") on Form 10-K for the period ending March 31, 2020, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Paul M. DiPerna, in my capacity as Chief Executive Officer, Chief Financial Officer, Secretary and Treasurer of the Registrant, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company for the period covered by the report.

Date: *June 29, 2020*

By: */s/ Paul M. DiPerna*
Chief Executive Officer, Chief Financial Officer,
Secretary, Treasurer and Director
(principal executive, financial and accounting officer)