

### **SECURITIES & EXCHANGE COMMISSION EDGAR FILING**

# Nemaura Medical Inc.

Form: 10-K

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

FORM 10-K

$\boxtimes$	ANNUAL REPORT PURSUANT TO	SECTION 13 OR 15(d) OF THE S	ECURITIES EXCHAN	GE ACT OF 1934
		For the fiscal year ended <b>M</b>	arch 31, 2019	
		OR		
	TRANSITION REPORT PURSUANT	TO SECTION 13 OR 15(d) OF TH	E SECURITIES EXCH	ANGE ACT OF 1934
	F	For the transition period from	to	
		Commission File Numbe	r 001-38355	
		NEMAURA MEDICA (Exact name of registrant as spe		
	Nevada	(=/dot name of regionant de ope		46-5027260
	(State or other jurisdiction of incorporat	ion or organization)	(I.R.S. Em	ployer Identification No.)
	Lo	Advanced Technology Inno ughborough University Science 5 Oakwood Driv Loughborough, Leice LE11 3QF <u>United Kingdo</u>	and Enterprise Parks /e, stershire <u>m</u>	<b>S</b>
		(Address of principal executive of	offices) (Zip Code)	
	Registra	nt's telephone number, including a	rea code: + 44 1509 2	22912
Secu	rities registered pursuant to Section 1	2(b) of the Act:		
Title	of Each Class	Name of each exchange on	which registered	Trading Symbol
Comr	non Stock, \$0.0001 par value	NASDAQ Capital Market	-	NMRD
Indicat	e by check mark if the registrant is a wel	l-known seasoned issuer, as defin	ed in Rule 405 of the S	Securities Act. Yes □ No ⊠
Indicat	e by check mark if the registrant is not re	equired to file reports pursuant to S	Section 13 or Section 1	5(d) of the Act. Yes □ No ⊠.
1934 (	=	uch shorter period that the registra	-	or 15(d) of the Securities Exchange Act of such reports), and (2) has been subject to
Rule 4			=	File required to be submitted pursuant to orter period that the registrant was required
or an	-	initions of "large accelerated filer,		elerated filer, a smaller reporting company, maller reporting company" and "emerging
Non-a	accelerated filer $\square$ ccelerated filer $\square$ (Do not check if a smaling growth company $\boxtimes$	ller reporting company)	Accelerated filer ⊠ Smaller reporting o	
	merging growth company, indicate by cl w or revised financial accounting standa	=		tended transition period for complying with Act. $\square$
Indicat	e by check mark whether the registrant i	s a shell company (as defined in F	Rule 12b-2 of the Excha	ange Act). Yes □ No ⊠.

The aggregate market value of the registrant's common stock held by non-affiliates computed based on the closing sales price of such stock on

The number of shares outstanding of the registrant's common stock, as of June 9, 2019 was 207,989,304.

September 30, 2018 was \$151,532,841.

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#### DISCLOSURE REGARDING FORWARD-LOOKING STATEMENTS

Certain statements contained in this Annual Report that are not historical facts constitute forward-looking statements, within the meaning of the Private Securities Litigation Reform Act of 1995, and are intended to be covered by the safe harbors created by that Act. Reliance should not be placed on forward-looking statements because they involve known and unknown risks, uncertainties, and other factors, which may cause actual results, performance, or achievements to differ materially from those expressed or implied. Any forward-looking statement speaks only as of the date made. We undertake no obligation to update any forward-looking statements to reflect events or circumstances after the date on which they are made.

The words "believe," "anticipate," "design," "estimate," "plan," "predict," "seek," "expect," "intend," "may," "could," "should," "potential," "likely," "projects," "continue," "will," and "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements are not guarantees of the future as there are a number of meaningful factors that could cause Nemaura Medical Inc.'s ("Nemaura Medical") actual results to vary materially from those indicated by such forward-looking statements. These statements are based on certain assumptions made based on experience, expected future developments and other factors Nemaura Medical believes are appropriate in the circumstances. Factors which could cause actual results to differ from expectations, many of which are beyond Nemaura Medical's control, include, but are not limited to, obtaining regulatory approval for our sugarBEAT device, conducting successful clinical trials, executing agreements required to successfully advance the Company's objectives; retaining the management and scientific team to advance the product; overcoming adverse changes in market conditions and the regulatory environment; obtaining and enforcing intellectual property rights; obtaining adequate financing in the future through product licensing, public or private equity or debt financing or otherwise; dealing with general business conditions and competition; and other factors referenced herein in "Risk Factors." Except as required by law, we do not assume any obligation to update any forward-looking statement. We disclaim any intention or obligation to update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

#### ITEM 1. BUSINESS.

#### **Business Overview**

We are a medical technology company developing sugarBEAT®, a non-invasive, affordable and flexible continuous glucose monitoring system for adjunctive use by persons with diabetes. SugarBEAT consists of a disposable adhesive skin-patch connected to a rechargeable wireless transmitter that displays glucose readings at regular five minute intervals via a mobile app. SugarBEAT works by extracting glucose from the skin into a chamber in the patch that is in direct contact with an electrode-based sensor. The transmitter sends the raw data to a mobile app where it is processed by an algorithm and displayed as a glucose reading, with the ability to track and trend the data over days, weeks and months. While sugarBEAT requires once per day calibration by the patient using a blood sample obtained by a finger stick, we believe sugarBEAT will be adopted by non-insulin dependent persons with diabetes alongside insulin-injecting persons with diabetes who all perform multiple daily finger sticks to manage their disease.

We announced on May 29, 2019 that we had been awarded CE approval to allow sugarBEAT to be legally sold in the European Union. CE approval is disclosed by the use of the CE Mark, a manufacturers' declaration that the product meets the requirements of the applicable European laws. The European clinical trial program for sugarBEAT evaluated 525 patient days across 75 Type 1 and Type 2 diabetic patients and was completed in December 2017. CE approval is the process to achieve a mandatory conformity marking for the sugarBEAT device to allow it to be legally sold in the European Union. It is a manufacturers' declaration that the product meets the requirements of the applicable European laws. We also completed studies required to support a US FDA submission for approval of sugarBEAT as a medical device, and are currently in the process of compiling the application for submission. We previously developed a wristwatch-based version of sugarBEAT for which we obtained CE approval in February 2016. Since then we have developed sugarBEAT using the underlying technology of the wristwatch.

We believe there are additional applications for sugarBEAT and the underlying BEAT technology platform, which may include:

- a web-server accessible by physicians and diabetes professionals to track the condition remotely, thereby reducing healthcare costs and managing the condition more effectively;
- a complete virtual doctor that monitors a person's vital signs and transmits results via the web; and
- other patches using the BEAT technology platform to measure alternative analytes, including lactate, uric acid, lithium and drugs. This
  would be a step-change in the monitoring of conditions, particularly in the hospital setting. Lactate monitoring is currently used to determine
  the relative fitness of professional athletes and we completed preliminary studies demonstrating the application of the BEAT technology for
  continuous lactate monitoring.

#### **Our Business Strategy**

We intend to lead in the discovery, development and commercialization of innovative and targeted diagnostic medical devices that improve disease monitoring, management and overall patient care. Specifically, we intend to focus on the monitoring of molecules that can be drawn out through the skin non-invasively using our technology platform. In addition to glucose, such molecules may include lactic acid monitoring and the monitoring of prescription drugs and blood biomarkers that may help in the diagnosis, prevention or management of diseases, such as diabetes. We plan to take the following steps to implement our broad business strategy. Our key commercial strategies post-approval will first be implemented in Europe and then in parts of the Middle East and Asia, and then the U.S., as follows:

 Commercialize sugarBEAT in the United Kingdom and Republic of Ireland with Dallas Burston Pharma (Jersey) Limited, with whom we have an exclusive marketing rights agreement for these two countries.

We have also signed a full commercial agreement with Dallas Burston Ethitronix (Europe) Limited in May 2018 for all other European territories as part of an equal joint venture agreement. The joint venture intends to seek sub-license rights opportunities to one or more leading companies in the diabetes monitoring space, to leverage their network, infrastructure and resources.

Dallas Burston (Jersey) Limited was founded by Dr. Dallas Burston, MBBS, an entrepreneur who has founded and sold several companies specializing in marketing pharmaceuticals. For example, in 1999, he sold 49% of Ashbourne Pharmaceuticals to HSBC Private Equity for £32 million and Bartholomew-Rhodes to Galen Ltd. for £19.8 million. More recently, in 2015, he sold DB Ashbourne Limited, a provider of off-patent branded pharmaceuticals for the UK market, to Ethypharm. At the time of the sale, DB Ashbourne Limited was estimated to have revenue of approximately £90 million.

- Establish licensing or joint venture agreements with other parties to market sugarBEAT in other geographies. We are in detailed discussions and negotiations with several other parties worldwide for licensing or joint venture agreements for the sale of the sugarBEAT device and have signed commercial agreements with TP MENA for the GCC (Gulf Region), and Al-Danah Medical for Qatar.
- Submit FDA application for approval of sugarBEAT. The application is currently in progress and expected to be submitted in Q2 2019.
- Expand the indications for which the sugarBEAT device may be used. We believe that the sugarBEAT device may offer significant benefits as compared to those found in the non-acute setting for the monitoring of other diseases. This includes monitoring of lactic acid for performance athletics, and the monitoring of drugs. We have completed initial proof of concept for Lactate monitoring and now plan to explore the route to commercialization for well-being applications in athletic performance training, and plan to undertake further clinical programs to support clinical use of the device for lactate monitoring,
- Expand our product pipeline through our proprietary platform technologies, acquisitions and strategic licensing arrangements. We intend to leverage our proprietary platform technologies to grow our portfolio of product candidates for the diagnosis of diabetes and other diseases. In addition, we intend to license our product and acquire products and technologies that are consistent with our research and development and business focus and strategies. This may include drug delivery products for the improved management of diabetes, for example improved insulin injector systems, and/or combination drug products for diabetes related drugs.

#### **Product Development**

Management has extensive experience in regulatory and clinical development of diagnostic medical devices. We intend to take advantage of this experience in the field of diagnostic medical devices in an attempt to increase the probability of product approval. The overall regulatory process for diagnostic medical devices for diabetes is currently similar to those governing other diagnostic devices. The timelines are shorter than, for example, when new drugs or completely invasive diagnostic devices are trialed in clinics. We have successfully tested and evaluated the device for its clinical output, in this case the accuracy and safety with which it can trend blood glucose levels, based on which CE approval was granted by the Notified body BSI, and we are currently in the process of preparing a submission to the US FDA. As we continue to raise funds for marketing the device in some European Union territories, we also intend to seek collaborations with future licensees and marketing partners to achieve our product development and meet our projected milestones.

The table below provides our current estimate of our timeline:

#### **Product Development Timelines**

Milestone	<b>Target Start Date</b>	<b>Target Completion Date</b>
Completion of clinical studies in Type 1 and Type 2 diabetic subjects to define		
final device claims and for submission for CE Mark approval with final device	July 2017	Completed
claims.		
Scale up of commercial sensor/patch manufacturing		
(Scale up means we have started looking at larger scales - sufficient for product	January 2017	Completed
launch in the UK. It refers to the manufacturing process for sensors.)		
Scale up of device (transmitter) manufacturing	January 2017	Ongoing
CE Mark for body worn transmitter device	August 2018	Completed
Commercial launch in the UK, followed by major territories in Europe	Q3 2019	Staggered launch
US FDA Submission	Q2 2019	Q2 2019

#### Market Opportunity for the Company's Products

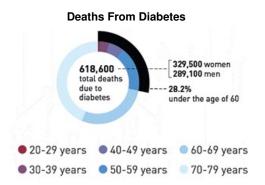
According to the International Diabetes Federation Atlas (the "IDF"), there are approximately 425 million people in the world who had diabetes as of December 2017. The IDF is predicting that by 2035 this will rise to 592 million people. The number of people with Type 2 diabetes is increasing in every country and currently eighty percent (80%) of people with diabetes live in low- and middle-income countries. The greatest number of people with diabetes is between 40 and 59 years of age.

Statistics published by the IDF report that diabetes is a huge and growing problem, and the costs to society are high and escalating. In addition, Europe has the highest prevalence of children with Type 1 diabetes.

#### Statistical Data for Diabetes in Europe

	2013	2035						
Adult population (20-79 years, millions)	659	669						
Diabetes (20 – 79 years)								
Regional prevalence (%)	8.5	10.3						
Comparative prevalence (%)	6.8	7.1						
Number of people with diabetes (millions)	56.3	68.9						
In	npaired Glucose Tolerance (20 – 79 years)							
Regional prevalence (%)	9.2	11.0						
Comparative prevalence (%)	8.1	8.9						
Number of people with IGT (millions)	60.6	73.7						
Type 1 diabetes (0 – 14 years)								
Number of children with Type 1 diabetes (thousands)								
Number of newly diagnosed cases per year (thousands)	20.0	-						

Each year approximately 600,000 people die from diabetes in Europe.



Europe has the highest incidence of children with Type 1 diabetes according to data supplied from IDF.org. The top five countries for the number of people afflicted with diabetes in Europe are listed in the table below.

Top 5 Countries In Europe For People Afflicted With Diabetes 20-79 Years (2013)

Countries/Territories	Millions
Russian Federation	10.9
Germany	7.6
Turkey	7.0
Spain	3.8
Italy	3.6

Type 1 diabetes, once known as juvenile diabetes or insulin-dependent diabetes, is a chronic condition in which the pancreas produces little or no insulin, a hormone needed to allow sugar (glucose) to enter cells to produce energy. The far more common Type 2 diabetes occurs when the body becomes resistant to the effects of insulin or doesn't make enough insulin.

Various factors may contribute to Type 1 diabetes including genetics and exposure to certain viruses. Although Type 1 diabetes typically appears during childhood or adolescence, it also can develop in adults.

Despite active research, Type 1 diabetes has no cure, although it can be managed. With proper treatment, people who have Type 1 diabetes can expect to live longer, healthier lives than they did in the past. Type 1 diabetes includes autoimmune Type 1 diabetes (Type 1a) which is characterized by having positive autoantibodies, as well as idiopathic Type 1 diabetes (Type 1b) where autoantibodies are negative and c-peptide is low. Patients with Type 1 diabetes (insulin dependent) require long term treatment with exogenous insulin and these patients perform self-monitoring of blood glucose (SMBG) to calculate the appropriate dose of insulin. SMBG is done by using blood samples obtained by finger sticks but frequent SMBG does not detect all the significant deviations in blood glucose, specifically in patients who have rapidly fluctuating

Type 2 diabetes, once known as adult-onset or non-insulin-dependent diabetes, is a chronic condition that affects the way your body metabolizes sugar (glucose), your body's main source of fuel. With Type 2 diabetes, your body either resists the effects of insulin, a hormone that regulates the movement of sugar into your cells, or doesn't produce enough insulin to maintain a normal glucose level. Untreated, Type 2 diabetes can be life-threatening.

More common in adults, Type 2 diabetes increasingly affects children as childhood obesity increases. There's no cure for Type 2 diabetes, but it can be managed by eating well, exercising and maintaining a healthy weight. If diet and exercise don't control the blood sugar, diabetes medications or insulin therapy may be required.

Each year, millions of patients undergo diabetes testing in the European Union and in the U.S. The main reason for this testing is to detect and evaluate diabetes in patients with symptoms of diabetes. These studies provide clinical benefit in the initial evaluation of patients with suspected but unproven diabetes, and in those patients in whom a diagnosis of diabetes has been established and information on prognosis or risk is required.

We believe that our market opportunity is a direct function of the number of persons tested, diagnosed and treated for either Type 1 or Type 2 diabetes. The IDF indicates that the total world market opportunity for a continuous glucose monitoring device is in the billions of dollars and is projected to grow annually through the year 2035.

We do not believe it is possible to estimate the number of diabetes patients that undergo finger pricks or other types of invasive glucose monitoring. However, we are unaware of any product currently on the market that may allow for non-invasive continuous glucose monitoring. We believe the sugarBEAT device may be readily adopted by the medical community for the assessment of a patient continuously.

We believe our non-invasive sugarBEAT device possesses many significant advantages and may represent an ideal device for the detection of discordances in an individual's blood sugar levels. If approved for commercialization, we believe the sugarBEAT device may represent a best in class non-invasive continuous glucose monitoring device to reach those afflicted with diabetes. While we cannot estimate the market share that our sugarBEAT device may capture, we believe that the sugarBEAT device will capture a significant share of the non-invasive continuous glucose monitoring market, in-particular the market that has been established by the Abbott Freestyle Libre device for glucose trending, as well as be adopted by non-insulin dependent diabetics who have not historically used continuous glucose monitoring devices due to their invasiveness.

#### Commercialization Plan

We intend to develop our products through the completion of FDA approvals, to verify the claims that the device may be used as an adjunct to a finger-stick measurement, and/or a glucose trending device such as those claims made by the Abbott Freestyle Libre device. We will seek to partner with organizations that may facilitate the further development and distribution of our products at all stages of development. We also intend to seek strategic partners early in the research and development cycle for programs that may fall outside of our core competencies.

#### **Competitive Landscape**

We expect to compete with several medical device manufacturing companies including Dexcom, Abbott, and Senseonics. Our competitors may:

- develop and market products that are less expensive or more effective than our future product;
- commercialize competing products before we or our partners can launch any products developed by us;
- operate larger research and development programs or have substantially greater financial resources than we do;
- initiate or withstand substantial price competition more successfully than we can;
- have greater success in recruiting skilled technical and scientific workers from the limited pool of available talent;
- more effectively negotiate third-party licenses and strategic relationships; and
- take advantage of acquisition or other opportunities more readily than we can.

We will compete for market share against large pharmaceutical and biotechnology companies, smaller companies that are collaborating with larger pharmaceutical companies, new companies, academic institutions, government agencies and other public and private research organizations. Many of these competitors, either alone or together with their partners, may develop new products that will compete with ours, and these competitors may, and in certain cases do, operate larger research and development programs or have substantially greater financial resources than we do.

We anticipate that we will have competition from specific companies. Although it is difficult to analyze our major competitors since currently there are no non-invasive diagnostic medical devices to continuously monitor blood glucose levels, we anticipate that specific companies may compete with us in the future.

Information relating to our competitors is listed in the table below.

	FreeStyle Libre™ <sup>(1)</sup>	Platinum G6®(2)	Platinum G5®(3)	Eversense™ <sup>(4)</sup>	SugarBEAT®
Manufacturer	Abbott	Dexcom	Dexcom	Senseonics	Nemaura Medical
Technology	Inserted Sensor	Inserted Sensor	Inserted Sensor	Implanted Sensor	Non-invasive Sensor
Reliability (Overall MARD)	11.4%	9.8%	9.0%	11.4%	<12%*
Reliability (Clarke Error Grid A+B zone)	99%	Not available	97.0%	99.1%	>95.0%
Patients Studied	72	324	97	44	>75
Patient Days Studies	14	10	9	90	1 to 4
Warm-up Time	1 hour	2 hours	2 hours	NA	30-60 min
Daily Calibration	None	None	2x	2x	1x
Glucose Display Frequency	On manual activation of sensor	Every 5 min	Every 5 min	Every 5 min	Every 5 min
Patch/Senor Life	14 days	10 days	7 days	90 days	1 day
Regulatory Approvals	EU	US	Worldwide	EU	EU
Basis for reimbursement	Finger stick	Not available	CGM	CGM	Finger stick
Daily Avg. Reimbursement Cost	\$2.50 (Germany)	Not available	\$9 (US)	Not available	\$2.50**
Daily Retail Cost UK (exc. VAT)	£3.50 (Patch) £50 (Reader)	Not available	£7.30 (Patch) £475 (Hardware)	Not available	£2** (Daily Patch) £30** (Transmitter)

Sources: (1) Diabetes Technology & Therapeutics, Timothy Bailey, MD, et al., Nov. 2015; (2) Dexcom's press release, Mar. 2018; Dexcom G6 user's guide; (4) SenseonicsHoldings' 8-K, Dec. 2015. \* based on summary data released in August 2018; \*\*Estimated

#### **Regulatory Requirements**

Our device has been electrically safety tested, and all biocompatibility conformance also demonstrated, against the relevant European Medical Device Directives. When new materials are introduced, these undergo a biocompatibility risk assessment, and further testing where necessary. Batches of the device and patches were manufactured for human clinical studies that took place between November 2014 and December 2015. This was a functional watch device with a wire connection to a skin adhered sensor and electrode. Subsequent to studies conducted in India the device received a CE mark approval in February 2016. The device has since been upgraded to include wireless communication from a body worn/adhered transmitter and also to reduce the device size, and with an enhanced sensor system. This miniaturised wireless device achieved CE approval in May 2019, and FDA submission is planned in Q2 2019. An application for CE mark approval requires the Company to have a ISO13485 Quality Management System, covering the design, development and manufacture of a medical device. Nemaura Medical does not have this accreditation, and instead under the terms of a service contract dated 4th April 2018 with Nemaura Pharma Limited, Nemaura Medical has outsourced the CE approval registration process to Nemaura Pharma. Under the terms of the service contract Nemaura Pharma has undertaken all required activities to register the product for CE approval under a fee for service arrangement, whilst Nemaura Medical will retain full title and beneficial ownership of the CE mark, and all related intellectual property without any further payments or royalties becoming due other than the fee for service.

Prior to launching commercial sales of our product, we must complete key material points:

Prepare the body worn transmitter, and sensor-electrode system for manufacturing for commercial sales, i.e., in large volumes. The patches (containing the sensors) and the device have been manufactured in small batches sufficient for clinical studies and laboratory testing. The scale up of the processes have commenced and are being conducted in stages to reflect the market demand based on a staggered launch. This is a continuous process of development, to mass-produce the sensors and patches and the devices in a scale that allows large volume batches to be produced cost effectively. This is necessary to ensure that the manufacturing costs of our products are minimized in order to effectively meet market demands.

#### **Intellectual Property**

We believe that clear and extensive intellectual property relating to our technologies is central to long-term success and we intend to invest accordingly. This applies to both domestic and international patent coverage, and trade secrets, and trademarks.

The SugarBEAT technology is protected by our portfolio of intellectual property comprised of issued and pending patents and trade secrets covering a range of claims, including the methods and apparatus for measuring glucose extracted from human skin in a non-invasive manner, the formula for the cumulative measurement of an analyte, and the formulation and process for preparation of the enzyme solution used in the sensor.

On May 8, 2014, NDM Technologies Limited, a related company, assigned the UK patent application 1208950.4 and International (PCT) patent application PCT/GB2013/051322 entitled "Cumulative Measurement of an Analyte" to Dermal Diagnostics Limited ("DDL") for a nominal consideration.

Two further patents were filed in 2018, that will not be published in the public domain for some months, relating to the sensor and device application, providing further strength to the intellectual property position. Further patents are intended to be filed in the coming months relating to the device and sensor, providing new intellectual property protection, some of which will supersede previous intellectual property.

Additionally, we retain substantial trade secrets relating to the sensor formulation, which have taken over five years to develop, and will prove very difficult to reverse engineer as it consists of formulation components in addition to processing methods in complex combinations that are unique to the final functional sensor. Patents will not be filed on this aspect of the technology to avoid any public dissemination of the know-how.

These patents and know-how cover aspects of the technology platform. Furthermore the trademark BEAT and sugarBEAT has been registered in all major territories globally. Accordingly, all intellectual property essential to the sugarBEAT product is owned by us, and not subject to royalty payments. We intend to take the lead in the preservation and/or prosecution of these patents and patent applications going forward as required. We intend to file additional patents as the development progresses, where deemed to be of value to protecting the technology platform and future modifications and improvements. Where patents cannot be secured, the intellectual property will be limited to know-how and trade secrets, and these will be diligently guarded.

Trade Secrets, Trademarks, and Patents Filed, Granted and Pending

IP: Patent (Core Claim), Know- how, Trademark	Expiration Date	<u>Jurisdictions in which</u> Granted/ Issued	<u>Jurisdictions in which</u> Pending	Ongoing Royalty or Milestone Payments
Patent: Cumulative Measurement of an Analyte*.	May 20, 2032	Australia, France, Germany, Italy, Poland, Spain, Netherlands, UK	Brazil, Canada, China, India, Japan, Qatar, United Arab Emirates, U.S.	None
Patent: Patches for Reverse lontophoresis**	July 1, 2029	Australia, Germany, France, UK, Italy, Netherlands, Switzerland, China, Hong Kong, Japan.	None	None
Know-how: Sensor Formulation	N/A	Trade Secret	N/A	N/A
Two Patents: Sensor and device application.	Filed 2018	First filed in UK	All	None
Trademark: BEAT	Renewal due in 2026	UK, China, EU, India, Japan	Canada	None
Trademark: sugarBEAT	Renewal due in 2025	UK, Australia, Switzerland, China, Egypt, EU, Israel, India, Iran, Japan, North Korea, Morocco, Mexico, Norway, New Zealand, Russia, Singapore, Tunisia, Turkey, USA	Canada	None

<sup>\*</sup> This patent provides a formula for calculating the amount of glucose extracted over a defined period of time by deducting the difference between two readings to allow rapid sensing without needing to deplete the analyte being measured.

<sup>\*\*</sup> This patent provides a reverse iontophoresis patch with means for releasing a conductive medium onto the skin during use and means for transporting analyte to a separate location for analysis.

#### **Clinical Trials**

Our clinical testing is conducted by contract clinical research organizations in various centers around the world to cover a wide demographic – including Asia and Europe – and is managed by our in-house management team.

We have had 2 pre-submission meetings with the FDA in June 2016, to define the clinical roadmap. As a result, a detailed clinical plan was developed and approved internally and a clinical site in Europe was been selected and audited and approved for commencement of clinical studies using the body worn transmitter device version of the sugarBEAT. The study was completed and the FDA submission is in preparation.

In August 2017, we commenced a European three-stage 75 patient clinical study, consisting of 80% Type 1 and 20% Type 2 diabetics. The study was designed as a single center open-label, single arm, within-subject comparison of sugarBEAT, with blood samples drawn from a venous catheter at corresponding time points, with glucose concentration measured using a laboratory blood glucose analyser, ARCHITECT C8000. The European clinical trial program consisted of a total of 525 patient days, with each patient continuously wearing sugarBEAT for 14 hours on seven consecutive days in a combination of home and clinic settings. Three of the seven days were in-clinic where venous blood samples were taken at 15 minute intervals over a continuous 12 hour period. The clinical study was completed in December 2017. An interim analysis of the data has thus far indicated a precision of 1.07 and accuracy as determined by the Mean Absolute Relative Deviation (MARD) of less than 14%, with no serious or major adverse events. The precision and accuracy of sugarBEAT observed in the study was similar to other CE Mark approved continuous glucose monitors. Data from the clinical study was published on the Nemaura Medical Website, Publications section, in August 2018.

#### Research and development

We spent \$2,296,668 and \$993,833 during the years ended March 31, 2019 and 2018, respectively, on research and development. We anticipate that for the year ending March 2020, research and development expenditures will increase to further develop the device for commercial launch in the UK and Europe.

Development and clinical test costs in support of our current product, as well as costs to file patents and revise and update previous filings on our technologies, will continue to be substantial as we assess the next steps to advance the product.

#### Manufacturing

The manufacture and sale of CE certified medical devices are controlled and governed by guidelines stipulated in the International Organization for Standardization (ISO), more specifically ISO13485; sugarBEAT will be manufactured and marketed according to ISO13485 quality standards.

In preparation for our anticipated commercial launch of sugarBEAT in the UK during the second half of 2019 we worked with our manufacturing partner Nemaura Pharma, to initiate scale-up manufacturing of the various sugarBEAT components alongside facilities for final assembly and packaging. As part of this process, we are expanding our manufacturing and assembly capabilities by occupying additional space within our existing headquarters site at Loughborough Science Park in the UK.

Manufacturers of key components required for our device are:

- Sensors Parlex (a division of Johnson Electrics), based in the Isle of White, UK
- Patches Polarseal Limited, located in Surrey, UK
- Electronics- Datalink Limited located in Loughborough, UK

We expect to enter into the following types of agreements during 2019:

- Manufacturing agreements for the sensor manufacture
- Manufacturing agreements for the patch manufacture
- Manufacturing agreements for the CGM watch device and transmitter device manufacture

#### Sales and Marketing

An Exclusive Marketing Rights agreement for the UK and Republic of Ireland was signed on March 31, 2014 with Dallas Burston Pharma, a Jersey (Channel Island) based company ("DB Pharma") who has pharmaceutical product marketing operations in the UK and has demonstrated a very successful model for the marketing of prescription medical products directly to general practitioners. We received a non-refundable upfront payment of \$1.67 million in return for providing DB Pharma with the exclusive right to sell the sugarBEAT device in the UK and Republic of Ireland, both direct to consumer and through prescriptions by general practitioners. Subsequently, on April 4, 2014, a Letter of Intent was entered into outlining the basic terms of the cost at which the patches and watch will be supplied and minimum order quantities in the first two (2) years. The key terms of the Exclusive Marketing Rights Agreement were concluded in a Commercial Agreement signed in August 2015.

In addition, a joint venture agreement was entered into with Dallas Burston Ethitronix (Europe) in May 2018, whereby we will share equally the costs and net profits of the sales of our sugarBEAT system in all territories in Europe, with the exception of the United Kingdom, which is the subject of a separate agreement with DB Pharma. Commercial agreements were signed in 2018 with TPMENA and Al-Danah Medical, for the Gulf Region (GCC) and Qatar respectively.

#### Regulatory matters

#### Government Regulation

Our business is subject to extensive federal, state, local and foreign laws and regulations, including those relating to the protection of the environment, health and safety. Some of the pertinent laws have not been definitively interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of subjective interpretations. In addition, these laws and their interpretations are subject to change, or new laws may be enacted.

Both federal and state governmental agencies continue to subject the healthcare industry to intense regulatory scrutiny, including heightened civil and criminal enforcement efforts. We believe that we have structured our business operations to comply with all applicable legal requirements. However, it is possible that governmental entities or other third parties could interpret these laws differently and assert otherwise. We discuss below the statutes and regulations that are most relevant to our business.

#### United Kingdom and Wales and the European Union regulations

Government authorities in the United Kingdom and Wales and the European Union as well as other foreign countries extensively regulate, among other things, the research, development, testing, manufacture, labelling, promotion, advertising, distribution, sampling, marketing and import and export of medical devices, including patches and other pharmaceutical products. Our body worn transmitter devices in the United Kingdom and Wales will be subject to strict regulation and require regulatory approval prior to commercial distribution. The process of obtaining governmental approvals and complying with ongoing regulatory requirements requires the expenditure of substantial time and financial resources. In addition, statutes, rules, regulations and policies may change and new legislation or regulations may be issued that could delay such approvals. If we fail to comply with applicable regulatory requirements at any time during the product development process, approval process, or after approval, we may become subject to administrative or judicial sanctions. These sanctions could include the authority's refusal to approve pending applications, withdrawals of approvals, clinical holds, warning letters, product recalls, product seizures, total or partial suspension of our operations, injunctions, fines, civil penalties or criminal prosecution. Any agency enforcement action could have a material adverse effect on us.

The European Commission on Public Health (the "ECPH") provides the regulation for the development and commercialization of new medical diagnostic devices. Any medical device placed on the European market must comply with the relevant legislation, notably with Directive 93/42/EEC, with the active implantable devices Directive 90/385/EEC or with the in vitro devices Directive 98/79/EC. We must first determine whether the device we intend to manufacture or import falls under any of these directives. All medical devices must fulfil the essential requirements set out in the above-mentioned directives. Where available, relevant standards may be used to demonstrate compliance with the essential requirements defined in the devices Directives.

Manufacturers also need to determine the appropriate conformity assessment route. For devices falling under Directive 93/42/EEC, other than custom-made devices and devices intended for clinical investigation, the conformity assessment route depends on the class of the device, to be determined in accordance with certain rules set forth in the directives. Once the applicable class or list has been determined, manufacturers need to follow the appropriate conformity assessment procedure. Subject to the type of the device, this may require manufacturers to have their quality systems and technical documentation reviewed by a Notified Body before they can place their products on the market. A Notified Body is a third-party body that can carry out a conformity assessment recognized by the European Union. The Notified Body will need to assure itself that relevant requirements have been met before issuing relevant certification. Manufacturers can then place the CE marking on their products to demonstrate compliance with the requirements.

The CE approval is the process of achieving a mandatory conformity marking for the sugarBEAT device to allow it to be legally sold in the European Union. It is a manufacturers' declaration that the product meets the requirements of the applicable European laws. The process for the sugarBEAT device CE submission and approval involved the following:

- 1. The device is classified depending on certain categories described by the European Directive with Class I products being low risk (e.g. band aid plasters), through Class III devices being the highest risk. The classes are Class I, IIa, IIb and III. Risk is based upon the potential harm to the patient should a problem arise with a product or its use. The sugarBEAT device is classified as a IIb device.
- 2. A 'technical file' containing all of the information required to demonstrate that the product meets the essential requirements of the European directive will be prepared. This includes information relating to performance and safety of the device such as product specifications, labelling, instructions for use, risk analysis and specific test information/clinical evidence relating to the product that support the claims being made for the product.
- 3. Clinical evidence included in the technical file is expected to demonstrate that the device is safe and meets defined performance requirements. This clinical evidence can be in the form of literature data where substantial published data exists that utilizes the same technique for glucose extraction and measurement (albeit in a different device format), or data from actual clinical studies performed using the sugarBEAT device. The first CE mark submission was based on literature evaluation of 3rd party published clinical data available in the public domain. The final CE mark submission has claims based on the clinical performance of the device, based on clinical studies described earlier herein. The clinical data showed that the sugarBEAT device can trend blood glucose levels in a human subject by taking measurements every 5 minutes. The clinical trial data demonstrates the sugarBEAT device blood glucose trend can be used to supplement normal finger prick measurements.
- 4. The technical file has been assessed by an independent inspector (the Notified Body), regulated by the competent authority, (Medicines and Healthcare products Regulatory Agency, MHRA in the United Kingdom). The Notified Body (an organization in the European Union that has been accredited by a member state to determine whether a medical device complies with the European medical device directives), will then notify The European Commission on Public Health (the "ECPH") of the approval and a certificate will be issued to the Company by the notified body and we will then be able to apply the CE mark to the device, and legally offer the product for sale in the European Economic Area (EEA). The CE mark has been issued as of May 2019 and the company is now able to offer the device for commercial sale in the EU.
- 5. The review of the technical file commenced in August 2018, and the final review and sign off was received in May 2019.

#### U.S. Food and Drug Administration regulation of medical devices.

The FDCA and FDA regulations establish a comprehensive system for the regulation of medical devices intended for human use. sugarBeat is a medical device that is subject to these, as well as other federal, state, local and foreign, laws and regulations. The FDA is responsible for enforcing the laws and regulations governing medical devices in the United States.

The FDA classifies medical devices into one of three classes (Class I, Class II, or Class III) depending on their level of risk and the types of controls that are necessary to ensure device safety and effectiveness. The class assignment is a factor in determining the type of premarketing submission or application, if any, that will be required before marketing in the United States. SugarBeat falls under Class III.

Class I devices present a low risk and are not life-sustaining or life-supporting. The majority of Class I devices are subject only to "general controls" (e.g., prohibition against adulteration and misbranding, registration and listing, good manufacturing practices, labeling, and adverse event reporting. General controls are baseline requirements that apply to all classes of medical devices.)

- Class II devices present a moderate risk and are devices for which general controls alone are not sufficient to provide a reasonable assurance of safety and effectiveness. Devices in Class II are subject to both general controls and "special controls" (e.g., special labeling, compliance with performance standards, and post market surveillance. Unless exempted, Class II devices typically require FDA clearance before marketing, through the premarket notification (510(k)) process.)
- Class III devices present the highest risk. These devices generally are life-sustaining, life-supporting, or for a use that is of substantial importance in preventing impairment of human health, or present a potential unreasonable risk of illness or injury. Class III devices are devices for which general controls, by themselves, are insufficient and for which there is insufficient information to determine that application of special controls would provide a reasonable assurance of safety and effectiveness. Class III devices are subject to general controls and typically require FDA approval of a premarket approval ("PMA") application before marketing.

Unless it is exempt from premarket review requirements, a medical device must receive marketing authorization from the FDA prior to being commercially marketed, distributed or sold in the United States. The most common pathways for obtaining marketing authorization are 510(k) clearance and PMA. After preliminary discussions with the FDA in June 2016 as part of a pre-submission meeting it was determined that the pathway for sugarBeat would be a PMA approval.

#### Premarket approval pathway

The PMA approval process requires an independent demonstration of the safety and effectiveness of a device. PMA is the most stringent type of device marketing application required by the FDA. PMA approval is based on a determination by the FDA that the PMA contains sufficient valid scientific evidence to ensure that the device is safe and effective for its intended use(s). A PMA application generally includes extensive information about the device including the results of clinical testing conducted on the device and a detailed description of the manufacturing process.

After a PMA application is accepted for review, the FDA begins an in-depth review of the submitted information. FDA regulations provide 180 days to review the PMA and make a determination; however, in reality, the review time is normally longer (e.g., 1-3 years). During this review period, the FDA may request additional information or clarification of information already provided. Also during the review period, an advisory panel of experts from outside the FDA may be convened to review and evaluate the data supporting the application and provide recommendations to the FDA as to whether the data provide a reasonable assurance that the device is safe and effective for its intended use. In addition, the FDA generally will conduct a preapproval inspection of the manufacturing facility to ensure compliance with Quality System Regulation, which imposes comprehensive development, testing, control, documentation and other quality assurance requirements for the design and manufacturing of a medical device.

Based on its review, the FDA may (i) issue an order approving the PMA, (ii) issue a letter stating the PMA is "approvable" (e.g., minor additional information is needed), (iii) issue a letter stating the PMA is "not approvable," or (iv) issue an order denying PMA. A company may not market a device subject to PMA review until the FDA issues an order approving the PMA. As part of a PMA approval, the FDA may impose post-approval conditions intended to ensure the continued safety and effectiveness of the device including, among other things, restrictions on labeling, promotion, sale and distribution, and requiring the collection of additional clinical data. Failure to comply with the conditions of approval can result in materially adverse enforcement action, including withdrawal of the approval.

Most modifications to a PMA approved device, including changes to the design, labeling, or manufacturing process, require prior approval before being implemented. Prior approval is obtained through submission of a PMA supplement. The type of information required to support a PMA supplement and the FDA's time for review of a PMA supplement vary depending on the nature of the modification.

The recent De-Novo and subsequent 510(k) by Dexcom provide evidence that current FDA thinking on invasive CGM devices for non-adjunctive use are suitable for Class II classification. The non-invasive nature of sugarBEAT®, as an adjunctive CGM, provides a low level of risk as compared to invasive CGMs. Moreover, the risks to health are understood, and appropriate general and special controls have been applied through the ISO 13485:2016 design controls to provide evidence of assurance of safety and effectiveness. Nemaura is exploring the possibility of submission of a De-Novo application in place of a PMA.

#### Clinical trials

Clinical trials of medical devices in the United States are governed by the FDA's Investigational Device Exemption ("IDE") regulation. This regulation places significant responsibility on the sponsor of the clinical study including, but not limited to, choosing qualified investigators, monitoring the trial, submitting required reports, maintaining required records, and assuring investigators obtain informed consent, comply with the study protocol, control the disposition of the investigational device, submit required reports, etc.

Clinical trials of significant risk devices (e.g., implants, devices used in supporting or sustaining human life, devices of substantial importance in diagnosing, curing, mitigating or treating disease or otherwise preventing impairment of human health) require FDA and Institutional Review Board ("IRB") approval prior to starting the trial. FDA approval is obtained through submission of an IDE application. Clinical trials of non-significant risk ("NSR"), devices (i.e., devices that do not meet the regulatory definition of a significant risk device) only require IRB approval before starting. The clinical trial sponsor is responsible for making the initial determination of whether a clinical study is significant risk or NSR; however, a reviewing IRB and/or FDA may review this decision and disagree with the determination.

An IDE application must be supported by appropriate data, such as performance data, animal and laboratory testing results, showing that it is safe to evaluate the device in humans and that the clinical study protocol is scientifically sound. There is no assurance that submission of an IDE will result in the ability to commence clinical trials. Additionally, after a trial begins, the FDA may place it on hold or terminate it if, among other reasons, it concludes that the clinical subjects are exposed to an unacceptable health risk.

As noted above, the FDA may require a company to collect clinical data on a device in the post-market setting.

The collection of such data may be required as a condition of PMA approval. The FDA also has the authority to order, via a letter, a post-market surveillance study for certain devices at any time after they have been cleared or approved.

#### Pervasive and continuing FDA regulation

After a device is placed on the market, regardless of its classification or premarket pathway, numerous additional FDA requirements generally apply. These include, but are not limited to:

- Establishment registration and device listing requirements;
- Quality System Regulation ("QSR"), which governs the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labelling, storage, installation, and servicing of finished devices;
  - Labelling requirements, which mandate the inclusion of certain content in device labels and labelling, and generally require the label and package of medical devices to include a unique device identifier ("UDI"), and which also prohibit the promotion of products for uncleared or unapproved, i.e., "off-label," uses;
  - Medical Device Reporting ("MDR") regulation, which requires that manufacturers and importers report to the FDA if their device may
    have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or
    serious injury if it were to recur; and
  - Reports of Corrections and Removals regulation, which requires that manufacturers and importers report to the FDA recalls (i.e., corrections or removals) if undertaken to reduce a risk to health posed by the device or to remedy a violation of the Federal Food, Drug and Cosmetic Act that may present a risk to health; manufacturers and importers must keep records of recalls that they determine to be not reportable.

The FDA enforces these requirements by inspection and market surveillance. Failure to comply with applicable regulatory requirements can result in enforcement action by the FDA, which may include, but is not limited to, the following sanctions:

- Untitled letters or warning letters;
- Fines, injunctions and civil penalties;
- Recall or seizure of our products;
- Operating restrictions, partial suspension or total shutdown of production;
- Refusing our request for 510(k) clearance or premarket approval of new products;
- Withdrawing 510(k) clearance or premarket approvals that are already granted; and
- Criminal prosecution.

We would be subject to unannounced device inspections by the FDA, as well as other regulatory agencies overseeing the implementation of and

#### Other Regulation in the United Kingdom and Wales and the EU

#### Healthcare Reimbursement

Government and private sector initiatives to limit the growth of healthcare costs, including price regulation, competitive pricing, coverage and payment policies, and managed-care arrangements, are continuing in many countries where we do business, including the United Kingdom and Wales. These changes are causing the marketplace to put increased emphasis on the delivery of more cost-effective medical products. Government programs, private healthcare insurance and managed-care plans have attempted to control costs by limiting the amount of reimbursement they will pay for particular procedures or treatments. This has created an increasing level of price sensitivity among customers for products. Some third-party payers must also approve coverage for new or innovative devices or therapies before they will reimburse healthcare providers who use the medical devices or therapies. Even though a new medical product may have been cleared for commercial distribution, we may find limited demand for the product until reimbursement approval has been obtained from governmental and private third-party payers.

#### **Environmental Regulation**

We are also subject to various environmental laws and regulations both within and outside the United Kingdom and Wales. Like many other medical device companies, our operations involve the use of substances, including hazardous wastes, which are regulated under environmental laws, primarily manufacturing and sterilization processes. We do not expect that compliance with environmental protection laws will have a material impact on our consolidated results of operations, financial position or cash flow. These laws and regulations are all subject to change, however, and we cannot predict what impact, if any, such changes might have on our business, financial condition or results of operations.

#### Foreign Regulation

Whether or not we obtain regulatory approval for a product, we must obtain approval from the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country, and the time may be longer or shorter than that required for EC approval. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement also vary greatly from country to country.

Under European Union regulatory systems, we may submit marketing authorization applications under a decentralized procedure. The decentralized procedure provides for mutual recognition of national approval decisions. Under this procedure, the holder of a national marketing authorization may submit an application to the remaining member states. Within 90 days of receiving the applications and assessment report, each member state must decide whether to recognize approval. This procedure is referred to as the mutual recognition procedure, or called the MRP.

In addition, regulatory approval of prices is required in most countries other than the United States. We face the risk that the prices which result from the regulatory approval process would be insufficient to generate an acceptable return to us or our collaborators.

#### **EU General Data Protection Regulation**

The EU General Data Protection Regulation (the "GDPR") came into force in all EU Member States from May 25, 2018 and replaced previous EU data privacy laws. Although a number of basic existing principles will remain the same, the GDPR introduces new obligations on data controllers and rights for data subjects, including, among others:

- accountability and transparency requirements, which will require data controllers to demonstrate and record compliance with the GDPR and to provide more detailed information to data subjects regarding processing;
- enhanced data consent requirements, which includes "explicit" consent in relation to the processing of sensitive data;

- obligations to consider data privacy as any new products or services are developed and limit the amount of information collected, processed, stored and its accessibility;
- constraints on using data to profile data subjects;
- providing data subjects with personal data in a useable format on request and erasing personal data in certain circumstances; and
- reporting of breaches without undue delay (72 hours where feasible).

The GDPR also introduces new fines and penalties for a breach of requirements, including fines for serious breaches of up to the higher of 4% of annual worldwide revenue or €20m and fines of up to the higher of 2% of annual worldwide revenue or €10m (whichever is highest) for other specified infringements. The GDPR identifies a list of points to consider when imposing fines (including the nature, gravity and duration of the infringement).

The Company has assessed the implications of the GDPR on all personal data it holds and has implemented measures to ensure that personal data shall be:

- Processed lawfully, fairly and in a transparent manner in relation to the data subject.
- Collected for a specified, explicit and legitimate purpose and not further processed in a manner that is incompatible with those purposes.
- Adequate, relevant and limited to what is necessary in relation to the purposes for which they are processed.
- Kept in a form which permits identification of data subjects for no longer than is necessary for the purposes for which the personal data are
  processed.
- Processed in a manner that ensures appropriate security of the personal data, including protection against unauthorised or unlawful processing and against accidental loss, destruction or damage, using appropriate technical or organisational measures.
- Maintained accurately and up to date and that every reasonable step is taken to ensure that personal data that are inaccurate, having regard to the purposes for which they are processed, are erased or rectified without delay.

At the current stage of the Company's development and, with being pre-revenue at this stage, the scope of data held, and consequently the impact of GDPR, is limited. Increased application of GDPR will be assessed and implemented prior to further Company developments that warrant additional GDPR measures. As the Company progresses with product commercialization, the extent to which GDPR will affect the Company will increase, which will require additional changes to the Company's procedures and policies which could adversely impact operational and compliance costs. Further, there is a risk that the measures will not be implemented correctly or that individuals within the business will not be fully compliant with the new procedures. If there are breaches of these measures, the Company could face significant administrative and monetary sanctions as well as reputational damage which may have a material adverse effect on its operations, financial condition and prospects.

#### **Corporate Information**

Our principal executive offices are located at The Advanced Technology Centre, Oakwood Drive, Loughborough, Leicestershire, LE11 3QF, UK. Our website is located at www.nemauramedical.com and our telephone number is +44 1509 222912. Information found on, or accessible through, our website is not a part of, and is not incorporated into, this Annual Report, and you should not consider it part of the Annual Report.

#### **Employees**

We currently employ 8 personnel. We believe our relationships with our employees and contractors are good.

#### Corporate History and Restructuring

We are a holding corporation that owns one hundred percent (100%) of a diagnostic medical device company specializing in discovering, developing and commercializing specialty medical devices. We were organized on December 24, 2013 under the laws of the State of Nevada. We own one hundred percent (100%) of Region Green Limited, a British Virgin Islands corporation formed on December 12, 2013. Region Green Limited owns one hundred percent (100%) of the stock in Dermal Diagnostic (Holdings) Limited, an England and Wales corporation formed on December 11, 2013. Dermal Diagnostics (Holdings) Limited owns one hundred percent (100%) of the stock in Dermal Diagnostics Limited, an England and Wales corporation formed on January 20, 2009, and one hundred percent (100%) of the stock in Trial Clinic Limited, an England and Wales corporation formed on January 12, 2011.

In December 2013, we restructured the Company and re-domiciled as a domestic corporation in the United States. The corporate re-organization was accomplished to preserve the tax advantages under the laws of the England and Wales tax laws for the benefit of the shareholders of both Dermal Diagnostics Limited ("DDL") and Trial Clinic Limited ("TCL").

DDL is a diagnostic medical device company headquartered in Loughborough, Leicestershire, England. DDL was founded on January 20, 2009 to engage in the discovery, development and commercialization of diagnostic medical devices. The Company's initial focus has been on the development of a novel continuous glucose monitoring (CGM) device.

#### RECENT DEVELOPMENT

On March 27, 2019, we filed a new Registration Statement on Form S-3 (Reg. No. 333-230535), registering up to \$250,000,000 of our common stock, preferred stock, warrants, debt securities and units (the "Form S-3"). The Form S-3 was declared effective by the Securities and Exchange Commission on April 8, 2019. We may offer and sell up to \$250,000,000 in the aggregate of the securities identified from time to time in one or more offerings. The securities may be sold directly by us, through dealers, or agents, designated from time to time, to or through underwriters, or through a combination of these methods as set forth in the "Plan of Distribution" included therein. Each time we offer securities under the prospectus that is part of the Form S-3, we will provide the specific terms of the securities being offered, including the offering price in a prospectus supplement.

#### **CE Approval**

On May 29, 2019 Nemaura Medical announced it had received confirmation of approval of the European Conformity for sugarBEAT which now allows Nemaura to commerce commercialization of the product in to the European Union. The EU currently has in excess of 58 million diabetics which represents an enormous market opportunity that has yet to be fully exploited by other CGM's due primarily to the cost of competitor products whereby a single sensor costs \$10's of dollars as each sensor has to be applied continuously for up to 14 days, whereas with sugarBEAT the sensor is a daily disposable, and therefore the cost of use is limited to a daily cost, and gives the user flexibility over how many days of the month they wear the CGM, to extract very powerful glucose trending data that finger prick testing quite simply cannot provide.

Nemaura has initiated plans to launch the product into the UK market in Q3 of 2019, followed by Germany and other markets. In the UK, Nemaura is working with its licensee DBP (Jersey) Ltd., to launch the product in the UK, and is in discussions with major distributors in Germany through its Joint venture with DB Ethitronix to commence registration and commercial launch into the German market which represents the single largest market in Europe.

The Company ordered 12,500 sugarBEAT devices in July 2018 in anticipation of CE approval, and these devices are currently being assembled and programmed with the updated software for the planned launch in Germany and the UK, and they are in discussions with their UK licensee with regards to taking orders for additional quantities to support product launch for the next 12 months.

Nemaura also plans to commence activities with respect to registering the CGM product based on the CE Mark in the GCC countries with their respective licensees in that region, Al-Danah Medical and TPMena in the coming weeks.

1. https://www.idf.org/aboutdiabetes/what-is-diabetes/facts-figures.html

#### **Management Team Hire**

Nemaura plans to further strengthen its operational and management team with the hire of Chris Avery, Vice President Business Operations. Chris has an impeccable track record of over 32 years in the diabetes industry including 9 years at Hypoguard, 5 years at Lifescan and 15 years at Nipro Diagnostics where he served as the UK Managing Director from 2010-14, and most recently was Senior VP Global Business Development at DB Ethitronix., where over a period of 2 years he was appointed to oversee the development of sugarBEAT and its commercialization strategy. Chris is expected to oversee the global operational management, handle investor updates on the technical and commercial development, as well as help broaden the global market reach of the product through the implementation of novel strategies based on the opportunities sugarBEAT presents that no other CGM is currently able to offer to date, due to its flexible wear time of sugarBEAT.

#### **Advisory Board**

Nemaura plans to further strengthen its advisory board through the appointment of Jafar Hamid who is a Private banking professional with over 25 years in the Investment Banking Industry, including with UBS, Credit Suisse and Citibank, and most recently J P Morgan. His expertise includes advising ultra High Net Worth individuals and family offices in the Healthcare and Pharmaceuticals areas. Mr. Hamid is expected to act as an adviser to the board.

#### ITEM 1A. — RISK FACTORS

If any of the following risks actually occur, they could materially adversely affect our business, financial condition or operating results. In that case, the trading price of our common stock could decline.

#### Risks Related to Our Product Candidate and Operation

We are largely dependent on the success of our sole product candidate, the sugarBEAT device, and we may not be able to successfully commercialize this potential product.

We have incurred and will continue to incur significant costs relating to the development and marketing of our sole product candidate, the sugarBEAT device. We have obtained approval to market this product in the EU, but it is not guaranteed that we will achieve this in any jurisdiction and we may never be able to obtain approval or, if approvals are obtained, to commercialize this product successfully in other territories.

If we fail to successfully commercialize our product(s) in multiple territories, we may be unable to generate sufficient revenue to sustain and grow our business, and our business, financial condition and results of operations will be adversely affected

If we fail to obtain regulatory approval of the sugarBEAT device or any of our other future products, we will be unable to commercialize these potential products.

The development, testing, manufacturing and marketing of our product is subject to extensive regulation by governmental authorities in Great Britain and the European Union. In particular, the process of obtaining CE approval by a Notified Body, a third party that can carry out a conformity assessment recognized by the European Union, is costly and time consuming, and the time required for such approval is uncertain. Our product must undergo rigorous preclinical and clinical testing and an extensive regulatory approval process mandated for the CE. Such regulatory review includes the determination of manufacturing capability and product performance. We have received CE approval on sugarBEAT wireless body worn device in May 2019.

There can be no assurance that all necessary approvals will be granted for future products or that CE review or actions will not involve delays caused by requests for additional information or testing that could adversely affect the time to market for and sale of our product. Further failure to comply with applicable regulatory requirements can, among other things; result in the suspension of regulatory approval as well as possible civil and criminal sanctions.

#### Failure to enroll patients in our clinical trials may cause delays in developing the sugarBEAT device or any of our future products.

We may encounter delays in the development and commercialization, or fail to obtain marketing approval, of the sugarBEAT device or any other future products if we are unable to enroll enough patients to complete clinical trials. Our ability to enroll sufficient numbers of patients in our clinical trials depends on many factors, including the severity of illness of the population, the size of the patient population, the nature of the clinical protocol, the proximity of patients to clinical sites, and the eligibility criteria for the trial and competing clinical trials. Delays in any possible future patient enrolment, based on request by local regulatory agencies to conduct studies in their territory, may result in increased costs and harm our ability to complete our clinical trials and obtain regulatory approval.

#### Delays in clinical testing could result in increased costs to us and delay our ability to generate revenue.

Significant delays in clinical testing could materially adversely impact our product development costs. We do not know whether planned clinical trials will begin on time, will need to be restructured or will be completed on schedule, if at all. Clinical trials can be delayed for a variety of reasons, including delays in obtaining regulatory approval to commence and continue a study, delays in reaching agreement on acceptable clinical study terms with prospective sites, delays in obtaining institutional review board approval to conduct a study at a prospective site and delays in recruiting patients to participate in a study.

Significant delays in testing or regulatory approvals for any of our current or future products, including the sugarBEAT device, could prevent or cause delays in the commercialization of such product candidates, reduce potential revenues from the sale of such product candidates and cause our costs to increase.

Our clinical trials for any of our current or future products may produce negative or inconclusive results and we may decide, or regulators may require us, to conduct additional clinical and/or preclinical testing for these products or cease our trials.

We will only receive regulatory approval to commercialize a product candidate if we can demonstrate to the satisfaction of the applicable regulatory agency that the product is safe and effective. We do not know whether our future clinical trials will demonstrate safety and efficacy sufficiently to result in marketable products. Because our clinical trials for the sugarBEAT device may produce negative or inconclusive results, we may decide, or regulators may require us, to conduct additional clinical and/or preclinical testing for this product or cease our clinical trials. If this occurs, we may not be able to obtain approval for this product or our anticipated time to market for this product may be substantially delayed and we may also experience significant additional development costs. We may also be required to undertake additional clinical testing if we change or expand the indications for our product.

If approved, the commercialization of our product, the sugarBEAT device, may not be profitable due to the need to develop sales, marketing and distribution capabilities, or make arrangements with a third party to perform these functions.

In order for the commercialization of our potential product to be profitable, our product must be cost-effective and economical to manufacture on a commercial scale. Subject to regulatory approval, we expect to incur significant sales, marketing, distribution, and to the extent we do not outsource manufacturing, manufacturing expenses in connection with the commercialization of the sugarBEAT device and our other potential products. We do not currently have a dedicated sales force or manufacturing capability, and we have no experience in the sales, marketing and distribution of medical diagnostic device products. In order to commercialize the sugarBEAT device or any of our other potential products that we may develop, we must develop sales, marketing and distribution capabilities or make arrangements with a third party to perform these functions. Developing a sales force is expensive and time-consuming, and we may not be able to develop this capacity. If we are unable to establish adequate sales, marketing and distribution capabilities, independently or with others, we may not be able to generate significant revenue and may not become profitable. Our future profitability will depend on many factors, including, but not limited to:

- the costs and timing of developing a commercial scale manufacturing facility or the costs of outsourcing the manufacturing of the sugarBEAT device;
- receipt of regulatory approval of the sugarBEAT device;
- the terms of any marketing restrictions or post-marketing commitments imposed as a condition of approval by regulatory authorities;

- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- costs of establishing sales, marketing and distribution capabilities;
- the effect of competing technological and market developments; and
- the terms and timing of any collaborative, licensing and other arrangements that we may establish.

Even if we receive regulatory approval for the sugarBEAT device or any other product candidates, we may never receive significant revenues from any of them. To the extent that we are not successful in commercializing our potential products, we will incur significant additional losses if we do not successfully commercialize our products.

Our proprietary rights may not adequately protect our intellectual property and product and if we cannot obtain adequate protection of our intellectual property and product, we may not be able to successfully market our product.

Our commercial success will depend in part on obtaining and maintaining intellectual property protection for our technologies and product. We will only be able to protect our technologies and product from unauthorized use by third parties to the extent that valid and enforceable patents cover them, or that other market exclusionary rights apply. While we have issued enforceable patents covering the sugarBEAT device, the patent positions of companies like ours can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in such companies' patents has emerged to date in Great Britain and the European Union. The general patent environment outside the United States involves significant uncertainty. Accordingly, we cannot predict the breadth of claims that may be allowed or that the scope of these patent rights would provide a sufficient degree of future protection that would permit us to gain or keep our competitive advantage with respect to this product and technology. Additionally, companies like ours are dependent on creating a pipeline of products. We may not be able to develop additional proprietary technologies or products that produce commercially viable products or that are themselves patentable.

Our issued patents may be subject to challenge and possibly invalidated by third parties. Changes in either the patent laws or in the interpretations of patent laws in Great Britain or the European Union or other countries may diminish the market exclusionary ability of our intellectual property.

In addition, others may independently develop similar or alternative technologies that may be outside the scope of our intellectual property. Should third parties obtain patent rights to similar technology, this may have an adverse effect on our business.

To the extent that consultants or key employees apply technological information independently developed by them or by others to our product, disputes may arise as to the proprietary rights of the information, which may not be resolved in our favour. Consultants and key employees that work with our confidential and proprietary technologies are required to assign all intellectual property rights in their discoveries to us. However, these consultants or key employees may terminate their relationship with us, and we cannot preclude them indefinitely from dealing with our competitors. If our trade secrets become known to competitors with greater experience and financial resources, the competitors may copy or use our trade secrets and other proprietary information in the advancement of their products, methods or technologies. If we were to prosecute a claim that a third party had illegally obtained and was using our trade secrets, it would be expensive and time consuming and the outcome would be unpredictable. In addition, courts in Great Britain and the European Union are sometimes less willing to protect trade secrets than courts in the United States. Moreover, if our competitors independently develop equivalent knowledge, we would lack any contractual claim to this information, and our business could be harmed.

Our ability to commercialize our product will depend on our ability to sell such products without infringing the patent or proprietary rights of third parties. If we are sued for infringing intellectual property rights of third parties, such litigation 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 will depend on our ability to sell such products without infringing the patents or other proprietary rights of third parties. Third-party intellectual property in the field of diagnostic medical devices is complicated, and third-party intellectual property rights in this field are continuously evolving. We have not performed searches for third-party intellectual property rights that may raise freedom-to-operate issues, and we have not obtained legal opinions regarding commercialization of our product other than patent research prior to the filing of our patent applications, and search and examination reports from the respective patent examination offices.

In addition, because patent applications are published months after their filing, and because applications can take several years to issue, there may be currently pending third-party patent applications that are unknown to us, which may later result in issued patents. If a third-party claims that we infringe on its patents or other proprietary rights, we could face a number of issues that could seriously harm our competitive position, including:

- infringement claims that, with or without merit, can be costly and time consuming to litigate, can delay the regulatory approval process and can divert management's attention from our core business strategy;
- substantial damages for past infringement which we may have to pay if a court determines that our products or technologies infringe upon a competitor's patent or other proprietary rights;
- 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; and
- Re-designing our process so that it does not infringe the third-party intellectual property, which may not be possible, or which may require substantial time and expense including delays in bringing our own products to market.

Such actions could harm our competitive position and our ability to generate revenue and could result in increased costs.

#### Nemaura Medical Inc. is an Emerging Growth Company (EGC) as defined under the Jumpstart Our Business Startups (JOBS) Act.

An "emerging growth company" is an issuer whose initial public offering was or will be completed after December 8, 2011, and had total annual gross revenues of less than \$1 billion during its most recently completed fiscal year. An issuer's EGC status terminates on the earliest of:

- The last day of the first fiscal year of the issuer during which it had total annual gross revenues of \$1 billion or more;
- The last day of the fiscal year of the issuer following the fifth anniversary of the date of the issuer's initial public offering;
- The date on which such issuer has issued more than \$1 billion in non-convertible debt securities during the prior three-year period determined on a rolling basis; or
- The date on which the issuer is deemed to be a "large accelerated filer" under the Exchange Act, which means, among other things, that it has a public float in excess of \$700 million.

We expect our Emerging Growth Company status to expire on March 31, 2020.

Pursuant to the JOBS Act of 2012, as an emerging growth company the Company can elect to opt out of the extended transition period for any new or revised accounting standards that may be issued by the PCAOB or the SEC. The Company has elected not to opt out of such extended transition period which means that when a standard is issued or revised and it has different application dates for public or private companies, the Company, as an emerging growth company, can adopt the standard for the private company. This may make comparison of the Company's financial statements with any other public company which is not either an emerging growth company nor an emerging growth company which has opted out of using the extended transition period difficult or impossible as possible different or revised standards may be used.

The Company has elected to use the extended transition period for complying with new or revised financial accounting standards available under Section 102(b)(2)(B) of the Act. Among other things, this means that the Company's independent registered public accounting firm will not be required to provide an attestation report on the effectiveness of the Company's internal control over financial reporting so long as it qualifies as an emerging growth company, which may increase the risk that weaknesses or deficiencies in the internal control over financial reporting go undetected. Likewise, so long as it qualifies as an emerging growth company, the Company may elect not to provide certain information, including certain financial information and certain information regarding compensation of executive officers that would otherwise have been required to provide in filings with the SEC, which may make it more difficult for investors and securities analysts to evaluate the Company. As a result, investor confidence in the Company and the market price of its common stock may be adversely affected.

If our product, the sugarBEAT device, does not gain market acceptance among physicians, patients and the medical community, we will be unable to generate significant revenue, if any.

The sugarBEAT device that we developed may not achieve market acceptance among physicians, patients, third-party payers and others in the medical community. If we receive the regulatory approvals necessary for commercialization, the degree of market acceptance will depend upon a number of factors, including:

- limited indications of regulatory approvals;
- the establishment and demonstration in the medical community of the clinical efficacy and safety of our product and its potential advantages over existing diagnostic medical devices;
- the prevalence and severity of any side effects;
- our ability to offer our product at an acceptable price;
- the relative convenience and ease of use of our product;
- the strength of marketing and distribution support; and
- sufficient third-party coverage or reimbursement.

The market may not accept the sugarBEAT device based on any number of the above factors. If the sugarBEAT device is approved, there may be other therapies available which directly compete for the same target market. The market may choose to continue utilizing the existing products for any number of reasons, including familiarity with or pricing of these existing products. The failure of any of our product to gain market acceptance could impair our ability to generate revenue, which could have a material adverse effect on our future business.

We have outsourced the bulk of the commercial manufacturing operations for the various components of the sugarBEAT, with the exception of the Sensor chemistry which is being conducted in-house. The failure to find manufacturing partners or expand our internal manufacturing facility could have an adverse impact on our ability to grow our business.

We are largely dependent on third parties to supply our product according to our specifications, in sufficient quantities, on time, in compliance with appropriate regulatory standards and at competitive prices. We cannot be sure that we will be able to obtain an adequate supply of our product candidates on acceptable terms, or at all.

Manufacturers supplying diagnostic medical devices must comply with regulations which require, among other things, compliance with evolving regulations under Medical Device Directives stipulated under ISO13485. The manufacturing of products at any facility will be subject to strict quality control, testing and record keeping requirements, and continuing obligations regarding the submission of safety reports and other post-market information. Both the sensor and patch manufacturing facilities for the sugarBEAT device are currently ISO13485 certified. We cannot guarantee that the facilities will continue to pass regulatory inspection, or that future changes to ISO13485 standards will not also affect the manufactures of the sensors and patches.

If we fail to attract and retain senior management, consultants, advisors and scientific and technical personnel, our product development and commercialization efforts could be impaired.

Our performance is substantially dependent on the performance of our senior management and key scientific and technical personnel, particularly Dr. Dewan Fazlul Hoque Chowdhury, President, Chairman and Chief Executive Officer. The loss of the services of any member of our senior management or our scientific or technical staff may significantly delay or prevent the development of our product and other business objectives by diverting management's attention to transition matters and identification of suitable replacements, if any, and could have a material adverse effect on our business, operating results and financial condition.

We also rely on consultants and advisors to assist us in formulating our research and development strategy. All of our consultants and advisors are either self-employed or employed by other organizations, and they may have conflicts of interest or other commitments, such as consulting or advisory contracts with other organizations, that may affect their ability to contribute to us.

In addition, we believe that we will need to recruit additional executive management and scientific and technical personnel. There is currently intense competition for skilled executives and employees with relevant scientific and technical expertise, and this competition is likely to continue. The inability to attract and retain sufficient scientific, technical and managerial personnel could limit or delay our product development efforts, which would adversely affect the development of our product and commercialization of our potential product and growth of our business.

We expect to expand our research, development, clinical research and marketing capabilities and, as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

We expect to have significant growth in expenditures, the number of our employees and the scope of our operations, in particular with respect to those potential products that we elect to commercialize independently or together with others. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to train qualified personnel. Due to our limited resources, we may not be able to effectively manage the expansion of our operations or train additional qualified personnel. The physical expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plan or disrupt our operations.

We will need to raise additional funds in order to finance the anticipated commercialization of our product by incurring indebtedness, through collaboration and licensing arrangements, or by issuing securities which may cause dilution to existing stockholders, or require us to relinquish rights to our technologies and our product.

Developing our product, conducting clinical trials, establishing manufacturing facilities and developing marketing and distribution capabilities is expensive. We will need to finance future cash needs through additional public or private equity offerings, debt financings or corporate collaboration and licensing arrangements. We cannot be certain that additional funding will be available to us on acceptable terms, or at all. If adequate funds are not available, we may be required to delay, reduce the scope of, or eliminate one or more of our research or development programs or our commercialization efforts. To the extent that we raise additional funds by issuing equity securities, our stockholders may experience dilution. To the extent that we raise additional funds through collaboration and licensing arrangements, it may be necessary to relinquish some rights to our technologies or our product or grant licenses on terms that are not favorable to us.

# We have a limited operating history and you should not rely on our historical financial data as an indicator of our future financial performance.

We have a limited operating history in the medical device industry. You should consider our business and prospects in light of the risks and difficulties we face with our limited operating history and should not rely on our past results as an indication of our future performance. In particular, we may face challenges in planning our growth strategy and forecasting market demand accurately as a result of our limited historical data and limited experience in implementing and evaluating our business strategies. If we are unable to successfully address these risks, difficulties and challenges as a result of our limited operating history, our ability to implement our strategic initiatives could be adversely affected, which may in turn have a material adverse effect on our business, financial condition, results of operations and prospects.

#### We have a history of losses and may not achieve or maintain profitability.

We have incurred net losses every year since our inception in 2009 and have not generated revenue from the period of our inception from product sales or licenses to date. As of March 31, 2019, we had an accumulated deficit of approximately \$13.4 million. We may expect to incur losses for the next several years and cannot be certain that we will ever achieve profitability. As a result, our business is subject to all of the risks inherent in the development of a new business enterprise, such as the risk that we may not obtain substantial additional capital needed to support the expenses of developing our technology and commercializing our potential products; develop a market for our potential products; successfully transition from a company with a research focus to a company capable of either manufacturing and selling potential products or profitably licensing our potential products to others; and/or attract and retain qualified management, technical and scientific staff.

#### We currently have not generated any revenue from product sales and may never become profitable.

To date, we have generated no revenue for product sales and we do not know when or if our product will generate revenue. Our ability to generate revenue depends on a number of factors, including our ability to successfully complete clinical trials for the sugarBEAT device and obtain regulatory approval to commercialize these potential products. Even then, we will need to establish and maintain sales, marketing, distribution and to the extent we do not outsource manufacturing, manufacturing capabilities. We plan to rely on one or more strategic collaborators to help generate revenues in markets outside of Great Britain however, we cannot be sure that our collaborators, if any, will be successful. Our ability to generate revenue will also be impacted by certain challenges, risks and uncertainties frequently encountered in the establishment of new technologies and products in emerging markets and evolving industries. These challenges include our ability to:

- execute our business model;
- create brand recognition;
- manage growth in our operations;
- create a customer base cost-effectively;
- retain customers;
- access additional capital when required; and
- attract and retain key personnel.

We cannot be certain that our business model will be successful or that it will successfully address these and other challenges, risks and uncertainties. If we are unable to generate significant revenue, we may not become profitable, and we may be unable to continue our operations. Even if we are able to commercialize the sugarBEAT device, we may not achieve profitability for at least several years, if at all, after generating material revenue.

#### Fluctuations in foreign exchange rates may adversely affect our financial condition and results of operations.

Our functional currency is the Great Britain Pound Sterling ("GBP"). The reporting currency is the United States dollar (US\$). Income and expenditures are translated at the average exchange rates prevailing during the reporting period. Assets and liabilities are translated at the exchange rates as of balance sheet date. Stockholders' equity is translated into United States dollars from GBP at historical exchange rates. Currency fluctuations and restrictions on currency exchange may adversely affect our business, including limiting our ability to convert GBP into foreign currencies and, if the GBP were to decline in value, reducing our revenue in U.S. dollar terms. To the extent the U.S. dollar strengthens against foreign currencies, the translation of these foreign currencies denominated transactions results in reduced revenue, operating expenses and net income for our international operations. Similarly, to the extent the U.S. dollar weakens against foreign currencies, the translation of these foreign currency denominated transactions results in increased revenue, operating expenses and net income for our international operations. We are also exposed to foreign exchange rate fluctuations as we convert the financial statements of our foreign subsidiaries into U.S. dollars in consolidation. If there is a change in foreign currency exchange rates, the conversion of the foreign subsidiaries' financial statements into U.S. dollars will lead to a translation gain or loss which is recorded as a component of other comprehensive income (loss). We have not entered into agreements or purchased instruments to hedge our exchange rate risks. The availability and effectiveness of any hedging transaction may be limited and we may not be able to successfully hedge our exchange rate risks.

In addition, following the UK's Brexit vote to leave the EU, there has been a weakening of GBP against many currencies. We expect to have to pay some of our service providers and vendors in USD and we will pay approximately 10% more at present than we would have done prior to the Brexit vote. The currency exchange rate continues to be very unstable and therefore the future impact or further weakening of GBP is not known at this time.

#### **Risks Related to Our Industry**

Our competitors may develop products that are less expensive, safer or more effective, which may diminish or eliminate the commercial success of any potential products that we may commercialize.

If our competitors market products that are less expensive, safer or more effective than our future products developed from our product candidates, or that reach the market before our products, we may not achieve commercial success. For example, if approved, the sugarBEAT device's primary competition in the glucose monitoring device setting will be companies such as Dexcom, Abbott, and Senseonics who produce glucose monitoring devices. The market may choose to continue utilizing the existing products for any number of reasons, including familiarity with or pricing of these existing products. The failure of our product to compete with products marketed by our competitors would impair our ability to generate revenue, which would have a material adverse effect on our future business, financial condition and results of operations.

We expect to compete with several companies including Dexcom, Abbott, and Senseonics, and our competitors may:

- develop and market products that are less expensive or more effective than our future product;
- commercialize competing products before we can launch any products developed from our product candidate;
- operate larger research and development programs or have substantially greater financial resources than we do:
- initiate or withstand substantial price competition more successfully than we can;
- have greater success in recruiting skilled technical and scientific workers from the limited pool of available talent;
- more effectively negotiate third-party licenses and strategic relationships; and
- take advantage of acquisition or other opportunities more readily than we can.

We expect to compete for market share against large medical diagnostic device manufacturing companies, smaller companies that are collaborating with larger companies, new companies, and other public and private research organizations.

In addition, our industry is characterized by rapid technological change. Because our research approach integrates many technologies, it may be difficult for us to stay abreast of the rapid changes in each technology. If we fail to stay at the forefront of technological change, we may be unable to compete effectively. Our competitors may render our technologies obsolete by advances in existing technological approaches or the development of new or different approaches, potentially eliminating the advantages in our product discovery process that we believe we derive from our research approach and proprietary technologies.

#### The use of hazardous materials in our operations may subject us to environmental claims or liabilities.

Our research and development activities involve the use of hazardous chemical materials. Injury or contamination from these materials may occur and we could be held liable for any damages, which could exceed our available financial resources. This liability could materially adversely affect our business, financial condition and results of operations.

We are subject to laws and regulations governing the use, manufacture, storage, handling and disposal of hazardous materials and waste products. We may be required to incur significant costs to comply with environmental laws and regulations in the future that could materially adversely affect our business, financial condition and results of operations.

If we fail to comply with extensive regulations enforced by regulatory agencies with respect to diagnostic medical device products, the commercialization of our product could be prevented, delayed or halted.

Research, preclinical development, clinical trials, manufacturing and marketing of our product is subject to extensive regulation by various government authorities. We have not received marketing approval for the sugarBEAT device. The process of obtaining the required regulatory approvals is lengthy and expensive, and the time required for such approvals is uncertain. The approval process is affected by such factors as:

- the indication and claims of the diagnostic device;
- the quality of submission relating to the product;
- the product's clinical efficacy and safety;
- the manufacturing facility compliance;
- the availability of alternative devices;
- the risks and benefits demonstrated in clinical trials; and
- the patent status and marketing exclusivity rights of certain innovative products.

Any regulatory approvals that we or our partners receive for our product may also be subject to limitations on the indicated uses for which the product may be marketed or contain requirements for potentially costly post-marketing follow-up studies. The subsequent discovery of previously unknown problems with the product, including adverse events of unanticipated severity or frequency, may result in restrictions on the marketing of the product and withdrawal of the product from the market.

Manufacturing, labelling, storage and distribution activities also are subject to strict regulation and licensing by government authorities. The manufacturing facilities for our product will be subject to periodic inspection by the regulatory authorities and from time to time, these agencies may send notice of deficiencies as a result of such inspections. Our failure or the failure of our manufacturing facilities, to continue to meet regulatory standards or to remedy any deficiencies could result in corrective action by the authorities, including the interruption or prevention of marketing, closure of our manufacturing facilities, and fines or penalties.

Regulatory authorities also will require post-marketing surveillance to monitor and report potential adverse effects of our product. If approved, any of our products' subsequent failure to comply with applicable regulatory requirements could, among other things, result in warning letters, fines, suspension or revocation of regulatory approvals, product recalls or seizures, operating restrictions, injunctions and criminal prosecutions.

Government policies may change and additional government regulations may be enacted that could prevent or delay regulatory approval of our product. We cannot predict the likelihood, nature or extent of adverse government regulation that may arise from future legislation or administrative action. If we are not able to maintain regulatory compliance, we might not be permitted to market our product and our business could suffer.

# In the future, we hope to distribute and sell our product outside of the United Kingdom and the European Union, which will subject us to further regulatory risk.

In addition to seeking approval from the United Kingdom and the European Union for the sugarBEAT device, we may seek regulatory approval from Saudi Arabia and the United Arab Emirates, Hong Kong, Australia, and the USA, to market the sugarBEAT device, however, there is no guarantee we will do so. We may in the future also seek approvals for additional countries. The regulatory review process varies from country to country, and approval by foreign government authorities is unpredictable, uncertain and generally expensive. The ability to market our product could be substantially limited due to delays in receipt of, or failure to receive, the necessary approvals or clearances. Marketing of our product in these countries, and in most other countries, is not permitted until we have obtained required approvals or exemptions in each individual country. Failure to obtain necessary regulatory approvals could impair our ability to generate revenue from international sources.

#### Market acceptance of our product will be limited if users are unable to obtain adequate reimbursement from third-party payers.

Government health administration authorities, private health insurers and other organizations generally provide reimbursement for products like our product and our commercial success will depend in part on these third-party payers agreeing to reimburse patients for the costs of our product. Even if we succeed in bringing our product to market, we cannot assure you that third-party payers will consider our product cost effective or provide reimbursement in whole or in part for its use.

Significant uncertainty exists as to the reimbursement status of newly approved health care products. Our product is intended to replace or alter existing therapies or procedures. These third-party payers may conclude that our product is less safe, effective or cost-effective than existing therapies or procedures. Therefore, third-party payers may not approve our product for reimbursement.

If third-party payers do not approve our product for reimbursement or fail to reimburse for them adequately, sales will suffer as some physicians or their patients will opt for a competing product that is approved for reimbursement or is adequately reimbursed. Even if third-party payers make reimbursement available, these payers' reimbursement policies may adversely affect our ability and the ability of our potential collaborators to sell our product on a profitable basis.

The trend toward managed healthcare, the growth of organizations such as health maintenance organizations and legislative proposals to reform healthcare and government insurance programs could significantly influence the purchase of healthcare services and products, resulting in lower prices and reduced demand for our product which could adversely affect our business, financial condition and results of operations.

In addition, legislation and regulations affecting the pricing of our product may change in ways adverse to us before or after the regulatory agencies approve our product for marketing. While we cannot predict the likelihood of any of these legislative or regulatory proposals, if any government or regulatory agencies adopt these proposals, they could materially adversely affect our business, financial condition and results of operations.

## Product liability claims may damage our reputation and, if insurance proves inadequate, the product liability claims may harm our business.

We may be exposed to the risk of product liability claims that is inherent in the diagnostic medical device. A product liability claim may damage our reputation by raising questions about our product's safety and efficacy and could limit our ability to sell our product by preventing or interfering with commercialization of our product.

In addition, product liability insurance for our industry is generally expensive to the extent it is available at all. There can be no assurance that we will be able to obtain and maintain such insurance on acceptable terms or that we will be able to secure increased coverage if the commercialization of our product progresses, or that future claims against us will be covered by our product liability insurance. Moreover, there can be no assurance that any product liability coverage from any insurance policy and/or any rights of indemnification and contribution that we may have will offset any future claims. We currently do not maintain product liability insurance. A successful claim against us with respect to uninsured liabilities and not subject to any indemnification or contribution could have a material adverse effect on our business, financial condition and results of operations.

We could be negatively impacted by the application or enforcement of fraud and abuse laws, including anti-kickback laws and other anti-referral laws.

We are not aware of any current business practice which is in violation of any fraud and abuse law. However, continued vigilance to assure compliance with all potentially applicable laws will be a necessary expense associated with product development. For example, all product marketing efforts must be strictly scrutinized to assure that they are not associated with improper remunerations to referral sources in violation of any anti-kickback statutes. Remunerations may include potential future activities for our product, including discounts, rebates and bundled sales, which must be appropriately structured to take advantage of statutory and regulatory "safe harbors." From time to time we may engage physicians in consulting activities. In addition, we may decide to sponsor continuing medical education activities for physicians or other medical personnel. We also may award or sponsor study grants to physicians from time to time. All relationships with physicians, including consulting arrangements, continuing medical education and study grants, must be similarly reviewed for compliance with any anti-kickback statute to assure that remuneration is not provided in return for referrals. Patient inducements may also be unlawful. Inaccurate reports of product pricing, or a failure to provide a product at an appropriate price to various governmental entities, could also serve as a basis for an enforcement action under various theories.

Claims which are "tainted" by virtue of kickbacks or a violation of self-referral rules may be alleged as false claims if other elements of a violation are established. Because our potential customers may seek payments from healthcare programs for our product, even during the clinical trial stages, we must assure that we take no actions which could result in the submission of false claims. For example, free product samples which are knowingly or with reckless disregard billed to healthcare programs could constitute false claims. If the practice was facilitated or fostered by us, we could be liable. Moreover, inadequate accounting for or a misuse of grant funds used for product research and development could be alleged as a violation of relevant statutes.

The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations, and additional legal or regulatory change.

#### **Risks Related to Our Common Stock**

#### Our stock price may be volatile.

The stock market, particularly in recent years, has experienced significant volatility particularly with respect to pharmaceutical, biotechnology and other diagnostic medical device company stocks. The volatility of pharmaceutical, biotechnology and other diagnostic medical device company stocks often does not relate to the operating performance of the companies represented by the stock. Factors that could cause this volatility in the market price of our Common Stock include:

- results from and any delays in our clinical trials;
- failure or delays in entering our product into clinical trials;
- failure or discontinuation of any of our research programs;
- delays in establishing new strategic relationships;
- delays in the development or commercialization of our product;
- market conditions in the diagnostic medical device sectors and issuance of new or changed securities analysts' reports or recommendations;
- actual and anticipated fluctuations in our financial and operating results;
- developments or disputes concerning our intellectual property or other proprietary rights;
- introduction of technological innovations or new commercial products by us or our competitors;
- issues in manufacturing our product;
- market acceptance of our product;
- third-party healthcare reimbursement policies;
- regulatory actions affecting us or our industry;
- litigation or public concern about the safety of our product; and
- additions or departures of key personnel.

These and other external factors may cause the market price and demand for our Common Stock to fluctuate substantially, which may limit or prevent investors from readily selling their shares of Common Stock and may otherwise negatively affect the liquidity of our Common Stock. In the past, when the market price of a stock has been volatile, holders of that stock have instituted securities class action litigation against the company that issued the stock. If any of our stockholders brought a lawsuit against us, we could incur substantial costs defending the lawsuit. Such a lawsuit could also divert the time and attention of our management.

#### We have not paid and may not pay any dividends on our Common Stock.

We have paid no dividends on our Common Stock to date and may not pay dividends to holders of our Common Stock in the foreseeable future. While our future dividend policy will be based on the operating results and capital needs of the business, it is currently anticipated that any earnings will be retained to finance our future expansion and for the implementation of our business plan. As an investor, you should take note of the fact that a lack of a dividend can further affect the market value of our stock, and could significantly affect the value of any investment in our Company.

We are subject to the reporting requirements of federal securities laws. This can be expensive and may divert resources from other projects, and thus impairing our ability to grow.

We are subject to the information and reporting requirements of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and other federal securities laws, including compliance with the Sarbanes-Oxley Act of 2002 (the "Sarbanes-Oxley Act"). The costs of preparing and filing annual and quarterly reports, proxy statements and other information with the SEC (including reporting of any Merger that may occur in the future) and furnishing audited reports to stockholders will cause our expenses to be higher than they would have been if we had remained privately held.

If we fail to establish and maintain an effective system of internal control, we may not be able to report our financial results accurately or to prevent fraud. Any inability to report and file our financial results accurately and timely could harm our reputation and adversely impact the trading price of our Common Stock.

We are subject to reporting obligations under the U.S. securities laws. The Securities and Exchange Commission, or the SEC, as required by Section 404 of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, adopted rules requiring every public company to include a management report on such company's internal control over financial reporting in its annual report, which contains management's assessment of the effectiveness of the company's internal control over financial reporting. Our management has concluded that our internal control over our financial reporting is not effective. Our reporting obligations as a public company will place a significant strain on our management, operational and financial resources and systems for the foreseeable future.

Prior to 2014, we were a private company with a short operating history and limited accounting personnel and other resources with which to address our internal control and procedures over financial reporting. We have identified material weaknesses, which include (i) our size has prevented us from being able to employ sufficient resources to enable us to have an adequate level of supervision and segregation of duties within our internal control system, (ii) a lack of adequate financial expertise related to the assessment of complex transactions and a lack of adequate resources to review out of the ordinary transactions and arrangements of the Company, (iii) limited policies and procedures over related party transactions. We will continue to implement measures to remedy these material weaknesses as well as other deficiencies. If we fail to timely achieve and maintain the adequacy of our internal controls, we may not be able to conclude that we have effective internal control over financial reporting. Moreover, effective internal control over financial reporting is necessary for us to produce reliable financial reports and is important to help prevent fraud. As a result, our failure to achieve and maintain effective internal control over financial reporting could result in the loss of investor confidence in the reliability of our financial statements, which in turn could harm our business and negatively impact the market price of our common stock.

Effective internal control is necessary for us to provide reliable financial reports and prevent fraud. If we cannot provide reliable financial reports or prevent fraud, we may not be able to manage our business as effectively as we would if an effective control environment existed, and our business and reputation with investors may be harmed. As a result, our small size and any current internal control deficiencies may adversely affect our financial condition, results of operation and access to capital. We have not performed an in-depth analysis to determine if historical undiscovered failures of internal controls exist and may in the future discover areas of our internal control that need improvement.

We have disclosed a material weakness in our internal control over financial reporting which could have an adverse effect on our ability to report our financial condition, results of operations or cash flows accurately and on a timely basis.

We have disclosed a material weakness in our internal control over financial reporting due to (i) our size has prevented us from being able to employ sufficient resources to enable us to have an adequate level of supervision and segregation of duties within our internal control system, (ii) a lack of adequate financial expertise related to the assessment of complex transactions and a lack of adequate resources to review out of the ordinary transactions and arrangements of the Company, and (iii) limited policies and procedures over related party transactions. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the Company's annual or interim financial statements will not be prevented or detected on a timely basis. We have determined that further improvements are required in our accounting processes and personnel before we can consider the material weakness remediated. Management's procedures and testing identified errors that, although not material to the consolidated financial statements, led management to conclude that control deficiencies exist related to the timely production and filing of financial information. As a result of these deficiencies, it is reasonably possible that internal controls over financial reporting may not have prevented or detected errors from occurring that could have been material, either individually or in the aggregate.

A material weakness in our internal control over financial reporting could adversely impact our ability to provide timely and accurate financial information. While considerable actions have been taken and are underway to improve our internal controls in response to the identified material weaknesses and further action steps to strengthen controls have been taken, additional work continues to address and remediate the identified material weaknesses. If we are unsuccessful in implementing or following our remediation plan, we may not be able to timely or accurately report our financial condition, results of operations or cash flows or maintain effective internal controls over financial reporting. If we are unable to report financial information timely and accurately or to maintain effective disclosure controls and procedures, we could be subject to, among other things, regulatory or enforcement actions by the SEC, which could adversely affect the valuation of our common stock and could adversely affect our business prospects.

#### Public company compliance may make it more difficult to attract and retain officers and directors.

The Sarbanes-Oxley Act and new rules subsequently implemented by the SEC have required changes in corporate governance practices of public companies. As a public company, we expect these new rules and regulations to increase our compliance costs in 2019 and beyond and to make certain activities more time consuming and costly. As a public company, we also expect that these new rules and regulations may make it more difficult and expensive for us to obtain director and officer liability insurance in the future and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified persons to serve on our board of directors or as executive officers.

#### Our Common Stock will be deemed a "penny stock," which makes it more difficult for our investors to sell their shares.

Our Common Stock will be subject to the "penny stock" rules adopted under Section 15(g) of the Exchange Act. The penny stock rules generally apply to companies whose common stock is not listed on The Nasdaq Stock Market or other national securities exchange and trades at less than \$5.00 per share, other than companies that have had average revenue of at least \$6,000,000 for the last three years or that have tangible net worth of at least \$5,000,000 (\$2,000,000 if the company has been operating for three or more years). These rules require, among other things, that brokers who trade penny stock to persons other than "established customers" complete certain documentation, make suitability inquiries of investors and provide investors with certain information concerning trading in the security, including a risk disclosure document and quote information under certain circumstances. Many brokers have decided not to trade penny stocks because of the requirements of the penny stock rules and, as a result, the number of broker-dealers willing to act as market makers in such securities is limited. If we remain subject to the penny stock rules for any significant period, it could have an adverse effect on the market, if any, for our securities. If our securities are subject to the penny stock rules, investors will find it more difficult to dispose of our securities.

# Offers or availability for sale of a substantial number of shares of our Common Stock may cause the price of our Common Stock to decline.

If our stockholders sell substantial amounts of our Common Stock in the public market upon the expiration of any statutory holding period, under Rule 144, or issued upon the exercise of outstanding options or warrants, it could create a circumstance commonly referred to as an "overhang" and in anticipation of which the market price of our Common Stock could fall. The existence of an overhang, whether or not sales have occurred or are occurring, also could make more difficult our ability to raise additional financing through the sale of equity or equity-related securities in the future at a time and price that we deem reasonable or appropriate.

The interests of Dr. D.F. Chowdhury, or the controlling shareholders, may not always coincide with the interests of us and our other shareholders, and the controlling shareholders may exert significant control or substantial influence over us and may take actions that are not in, or may conflict with, public shareholders' best interests.

The controlling shareholders control the exercise of voting rights of over 50 % of the shares eligible to vote in any of our annual or special meeting. Therefore, these controlling shareholders will be able to exercise significant influence over all matters that require us to obtain shareholder approval, including the election of directors to our board and approval of significant corporate transactions that we may consider, such as a merger or other sale of our company or its assets. The controlling shareholders may cause us to take actions that are not in, or may conflict with, the interests of us or the public shareholders. In the case where the interests of the controlling shareholders conflict with those of our other shareholders, or if the controlling shareholders choose to cause us to pursue objectives that would conflict with the interests of our other shareholders, such other shareholders could be left in a disadvantageous position by such actions caused by the controlling shareholders and the price of our common stock could be adversely affected.

We are subject to the anti-takeover provisions of the Nevada Revised Statutes governing business combinations and control share acquisition.

Applicability of the Nevada business combination statute would discourage parties interested in taking control of our company if they cannot obtain the approval of our board of directors. These provisions could prohibit or delay a merger or other takeover or change in control attempt and, accordingly, may discourage attempts to acquire our company even though such a transaction may offer our stockholders the opportunity to sell their stock at a price above the prevailing market price.

The effect of the Nevada control share statute is that the acquiring person, and those acting in association with the acquiring person, will obtain only such voting rights in the control shares as are conferred by a resolution of the stockholders at an annual or special meeting of the stockholders. The Nevada control share law, if applicable, could have the effect of discouraging takeovers of our company based on our organizational structure.

We are subject to compliance with multiple tax jurisdictions.

As we transact out of both the UK and United States we must comply with tax filing requirements in both jurisdictions.

We may not manage to implement changes to our control environment within the timeframes required.

We have identified changes that we need to make to our control environment in order to move to SOX compliance. While we have an action plan in place, it may not be possible for us to implement all of the changes required by the required date.

#### ITEM 1B. UNRESOLVED STAFF COMMENTS.

None.

#### ITEM 2. PROPERTIES.

Our offices are located at ATIC Building, 5 Oakwood Drive, Loughborough, Leicestershire, United Kingdom. The offices house our headquarters and offices. The monthly rent is \$2,410. The lease is on a three-year term which commenced on August 1, 2017. The terms of the lease provide a break option allowing both landlord and tenant to terminate the lease on provision of not less than one month's prior written notice. We believe that we will be able to continue on a year to year lease for as long as necessary.

#### ITEM 3. LEGAL PROCEEDINGS.

We do not know of any material, active, pending or threatened proceeding against us or our subsidiaries, nor are we, or any subsidiary, involved as a plaintiff or defendant in any material proceeding or pending litigation.

#### ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable

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

#### **Market Information**

Our common stock began quotation on the OTCBB under the symbol "NMRD" on November 4, 2014. On June 30, 2017, our common stock began quotation on the OTCQB.

On January 25, 2018, the Company's common stock commenced trading on the NASDAQ Capital Market under its existing trading symbol, "NMRD". For the periods indicated, the following table sets forth the high and low bid prices per share of common stock. The following quotations reflect the high and low bids for our shares of common stock based on inter-dealer prices, without retail mark-up, mark-down or commission and may not represent actual transactions.

Fiscal Year 2018	High Bid	Low Bid
First Quarter	9.00	2.00
Second Quarter	6.99	4.04
Third Quarter	6.49	4.20
Fourth Quarter	6.80	4.50
Fiscal Year 2019	High Bid	Low Bid
First Quarter	5.00	2.51
Second Quarter	3.98	2.05
Third Quarter	2.50	0.80
Fourth Quarter	1.93	0.90
Fiscal Year 2020	High Bid	Low Bid
First Quarter (through June 1, 2019)	1.48	0.80

As of June 9, 2019, we had approximately 92 holders on record of our common stock.

#### **Dividends**

Since incorporation, we have not paid any dividend on any class of equity securities. We anticipate that for the foreseeable future all earnings will be retained for use in our business and no cash dividends will be paid to stockholders. Any payment of cash dividends in the future on the Company's common stock or preferred stock, will be dependent upon our financial condition, results of operations, current and anticipated cash requirements, plans for expansion, as well as other factors that the Board of Directors deems relevant.

#### Securities Authorized for Issuance Under Equity Compensation Plans

We have not adopted an equity compensation plan.

#### **Unregistered Sales of Securities**

None.

#### Purchases of Equity Securities by the Registrant and Affiliated Purchasers

We have not repurchased any shares of our common stock during the fiscal year ended March 31, 2019.

#### ITEM 6. SELECTED FINANCIAL DATA.

#### Financial highlights

Year Ended March 31,	_	2019	 2018	_	2017	 2016	_	2015
Net loss	\$	(4,452,797)	\$ (1,820,449)	\$	(1,551,266)	\$ (1,539,637)	\$	(1,319,840)
Diluted loss per share	\$	(0.02)	\$ (0.01)	\$	*	\$ *	\$	*
Cash, cash equivalents, and short-term								
investments	\$	3,740,664	\$ 5,733,886	\$	2,779,309	\$ 9,403,965	\$	354,749
Total assets	\$	4,763,715	\$ 6,255,402	\$	7,401,906	\$ 9,732,783	\$	913,108
Long-term obligations	\$	_	\$ _	\$	_	\$ _	\$	(170,000)
Non-current portion of Deferred Revenue	\$	1,237,850	\$ 1,333,128	\$	1,183,035	\$ 1,396,005	\$	1,538,300
Stockholders' equity/(deficit)	\$	2,226,904	\$ 4,110,965	\$	5,366,500	\$ 7,678,765	\$	(917,411)

<sup>\*</sup> less than \$0.01

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

The discussion and analysis below includes certain forward-looking statements that are subject to risks, uncertainties and other factors, as described in "Risk Factors" and elsewhere in this Annual Report on Form 10-K, that could cause our actual growth, results of operations, performance, financial position and business prospects and opportunities for this fiscal year and the periods that follow to differ materially from those expressed in, or implied by, those forward-looking statements.

#### **Corporate Overview**

Since inception we have devoted substantially all of our efforts establishing a new business and while operations have commenced we have generated no revenue from our limited operations. We are a holding corporation for a diagnostic medical device company and a clinical trial company specializing in discovering, developing and commercializing diagnostic medical devices with initial applications in the area of diabetes.

We are a holding corporation that owns one hundred percent (100%) of a diagnostic medical device company specializing in discovering, developing and commercializing specialty medical devices. We were organized on December 24, 2013 under the laws of the State of Nevada. We own one hundred percent (100%) of Region Green Limited, a British Virgin Islands corporation formed on December 12, 2013. Region Green Limited owns one hundred percent (100%) of the stock in Dermal Diagnostic (Holdings) Limited, an England and Wales corporation formed on December 11, 2013. Dermal Diagnostics (Holdings) Limited owns one hundred percent (100%) of the stock in DDL, an England and Wales corporation formed on January 20, 2009, and one hundred percent (100%) of the stock in Trial Clinic Limited, an England and Wales corporation formed on January 12, 2011.

In December 2013, we restructured the Company and re-domiciled as a domestic corporation in the United States. The corporate re-organization was accomplished to preserve the tax advantages under the laws of the England and Wales tax laws for the benefit of the shareholders of both DDL and TCL.

#### **Affiliated Company Relationships**

Nemaura Pharma Ltd (Pharma) was incorporated in November 2005. Through October 2013, all technology development and related transactions were incurred by Pharma. As new technology platforms were invented and developed, additional companies were set up to contain these new technology platforms to aid in the process of raising further investments to progress the development of these subsequent technologies. However, due to the small size of the operations, low number of employees and laboratory and office space required, initially, only one payroll was maintained and invoices were posted in Pharma and recharges were made as required. Prior to the year ended March 31, 2016, recharges included a proportion of the overhead allocated based on management's assessment. On April 4, 2018 a service agreement was put into place between Pharma and DDL. This covered the development of SugarBeat under Pharma's ISO13485 Accreditation. In lieu of these services, DDL invoices Pharma on a periodic basis for said services. Services are provided at cost plus a service surcharge amounting to less than 10% of the total costs incurred. This agreement includes all aspects of the development, registration and manufacture of sugarBEAT. Full legal title and beneficial ownership of the CE Mark and all related intellectual property remains with Nemaura Medical under the terms of the service contract.

Dr. D.F. Chowdhury and Mr. Bashir Timol are officers of Pharma. However, Pharma plans a management restructuring and a new management team is planned to be recruited in due course, aligned with commercial launch plans. The current management at DDL, including Dr. D. F. Chowdhury will allocate 15%-20% of their time to oversee the current operations at Pharma and the implementation of the new management team and to provide ongoing support in an advisory role. Pharma is a drug delivery company, which means that its activities are entirely related to the delivery of drugs to the body of a human or animal subject. DDL is a diagnostic company, which means it is entirely focused on extracting molecules from the human or animal subject and analyzing it to make a diagnosis or to monitor the level of a particular molecule such as glucose. These are two independent businesses engaged in different activities, therefore there is no conflict of interest between the two and management does not see any conflicts arising from the allocations of some of DDL management time to overseeing the operations of Pharma.

Payments made solely for work that Dr. D.F. Chowdhury performed/performs for Pharma in his capacity as Manager are not recharged to Nemaura Medical Inc. and are not included in our financial statements.

## **RESULTS OF OPERATIONS**

## Management's plans and basis of presentation

The Company has experienced recurring losses and negative cash flows from operations. At March 31, 2019, the Company had approximate cash balances of \$3,740,664, working capital of \$3,216,199, total stockholders' equity of \$2,226,904 and an accumulated deficit of \$13,425,879. To date, the Company has in large part relied on equity financing to fund its operations. Initially additional funding also came from related party contributions. The Company expects to continue to incur losses from operations for the near-term and these losses could be significant as product development, regulatory activities, clinical trials and other commercial and product development related expenses are incurred.

Management's strategic assessment includes the following potential options:

- obtaining regulatory approval for the sugarBEAT device: CE mark review and approval in Europe was received in May 2019, and FDA submission is planned for Q2 2019.
- pursuing additional capital raising opportunities;
- exploring licensing opportunities; and
- undertaking manufacturing development and scale-up of the sugarBEAT device for commercialization.

# **Results of Operations**

### Year Ended March 31, 2019 Compared To The Year Ended March 31, 2018

# Revenue

There was no revenue recognized in the years ended March 31, 2019 and March 31, 2018. In 2014, we received an upfront non-refundable cash payment of £1 million (approximately \$1.30 million at March 31, 2019) in connection with an Exclusive Marketing Rights Agreement with an unrelated third party that provides the third party the exclusive right to market and promote the sugarBEAT device and related patch under its own brand in the United Kingdom and the Republic of Ireland. We have deferred this licensing revenue until we complete our continuing performance obligations, which include securing successful CE marking of the sugarBEAT patch (received in May 2019), and we expect to record the revenue in income over an approximately 10-year term after CE marking approval is obtained. Although the revenue is deferred at March 31, 2019 and 2018, the cash payment became immediately available and was being used to fund our operations, including research and development costs associated with obtaining the CE marking approval.

#### Research and Development Expenses

Research and development expenses were \$2,296,668 and \$993,833 for the years ended March 31, 2019 and 2018, respectively. This increase was driven by the increased level of activity as the Company draws closer to commercialization. This amount related to clinical trials and improvements made to the sugarBEAT device, and expenditures included sub-contractor activities, and consultant's fees and wages. We expect research and development expenses to continue to be a significant cost in future periods as we continue our clinical studies of our sugarBEAT device and pursue strategic opportunities.

# General and Administrative Expenses

General and administrative expenses were \$2,180,056 and \$915,132 for the years ended March 31, 2019 and 2018, respectively. This increase is due to higher insurance costs and fees for professional services. These consisted primarily of legal, professional and audit fees plus wages and charitable contributions. General and administrative expenses will be expected to significantly increase as we commence product manufacture and commercialization.

# Other Comprehensive Income

For the years ended March 31, 2019 and 2018 other comprehensive income/(loss) was (\$299,263) and \$564,914, respectively, arising from foreign currency translation adjustments.

# Year Ended March 31, 2018 Compared To The Year Ended March 31, 2017

#### Revenue

There was no revenue recognized in the years ended March 31, 2018 and March 31, 2017. In 2014, we received an upfront non-refundable cash payment of £1 million (approximately \$1.40 million at March 31, 2018) in connection with an Exclusive Marketing Rights Agreement with an unrelated third party that provides the third party the exclusive right to market and promote the sugarBEAT device and related patch under its own brand in the United Kingdom and the Republic of Ireland. We have deferred this licensing revenue until we complete our continuing performance obligations, which include securing successful CE marking of the sugarBEAT patch, and we expect to record the revenue in income over an approximately 10 year term after CE marking approval is obtained. Although the revenue is deferred at March 31, 2018 and 2017, the cash payment became immediately available and was being used to fund our operations, including research and development costs associated with obtaining the CE marking approval.

# Research and Development Expenses

Research and development expenses were \$993,833 and \$1,034,605 for the years ended March 31, 2018 and 2017, respectively. This amount related to clinical trials and improvements made to the sugarBEAT device, and expenditures included sub-contractor activities, and consultancy fees and wages. We expect research and development expenses to continue to be a significant cost in future periods as we continue our clinical studies of our sugarBEAT device and pursue strategic opportunities.

# General and Administrative Expenses

General and administrative expenses were \$915,132 and \$516,661 for the years ended March 31, 2018 and 2017, respectively. These consisted primarily of legal, professional and audit fees plus wages and charitable contributions. General and administrative expenses will be expected to significantly increase as we commence product manufacture and commercialization.

# Other Comprehensive Income

For the years ended March 31, 2018 and 2017 other comprehensive income/(loss) was \$564,914 and (\$760,999), respectively, arising from foreign currency translation adjustments.

#### **Liquidity and Capital Resources**

We have experienced net losses and negative cash flows from operations since our inception. We have sustained cumulative losses of \$13,425,879 through March 31, 2019. We have historically financed our operations through the issuances of equity, UK government grants and contributions of services from related entities.

At March 31, 2019, the Company had net working capital of \$ 3,216,199 which included cash account balances of \$3,740,664. The Company reported a net loss of \$4,452,797 for the year ended March 31, 2019.

We have completed clinical studies required for FDA submission and plan to submit an application to the FDA for approval of the device in Q2 2019, and therefore will not incur any further research and development costs for glucose monitoring for the foreseeable future. We are scaling-up our manufacturing operations to support product launch in EU now that CE mark approval has been received. Our long-term business plan will require further funds to support commercialization and large scale manufacture, and is therefore contingent upon our ability to raise additional funds. This may include a combination of debt, equity and licensing fees. We are currently in discussions with two of the largest shareholders in the company with respect to potentially securing non-dilutive conventional interest bearing loans from these shareholders, now that the company is expected to become revenue generating through licensing and product sales in Europe following the recent CE approval.

We believe the cash position as of March 31, 2019 is adequate for our current level of operations through June 2020, and for the achievement of certain of our product development milestones. Our plan is to utilize the cash on hand to continue establishing commercial manufacturing operations for the commercial supply of the sugarBEAT device and patches now that CE mark approval has been received.

#### **Cash Flows**

Net cash used by our operating activities for the year ended March 31, 2019 was \$3,560,952 which reflected our net loss of \$4,452,797, increased by an increase in prepaid expenses and other receivables of \$456,125 and increase in inventory of \$37,396. This was offset by stock-based compensation \$429,610, an increase in accounts payable of \$98,118, an increase in liability due to related parties \$697,182, an increase in accrued expenses and other liabilities \$21,494 and a decrease in accrued interest receivable of \$70,759. This was further offset by depreciation and amortization of \$33,407 and a loss on disposal of \$34,796.

Net cash used by our operating activities for the year ended March 31, 2018 was \$2,136,977 which reflected our net loss of \$1,820,449, increased by an increase in accounts payable, an increase in prepayments, a decrease in liability due to related parties and an increase in accrued interest receivable of \$452,535, and offset by an increase in accruals of \$106,751.

Net cash used by our operating activities for the year ended March 31, 2017 was \$1,192,828 which reflected our net loss of \$1,551,266, and offset by a net increase in accounts payable, liability due to related parties and accrued expenses of \$252,638, and by a decrease in prepayments and other receivables of \$85,367.

Net cash provided by investing activities was \$4,403,855 for the year ended March 31, 2019, which reflected \$4,483,852 returned from the maturity of a fixed rate savings account but reduced by the expenditures made in developing intellectual property, primarily related to patent fillings of \$20,331 and the purchase of capital equipment of \$59,666.

Net cash generated by investing activities was \$1,949,215 for the year ended March 31, 2018, which reflected the cash received from the maturity of a fixed rate savings account of \$1,994,475 offset by expenditures made in developing intellectual property, primarily related to patent fillings of \$45,260.

Net cash used in investing activities was \$6,306,089 for the year ended March 31, 2017, which reflected the expenditures made in developing intellectual property, primarily related to patent filings of \$73,070, property and equipment of \$6,519 and \$6,226,500 invested in fixed rate savings account.

Net cash provided by financing activities for the year ended March 31, 2019 was \$2,049,855. Proceeds from the sale of the Company's common stock and warrants were \$2,539,258, the majority of this reflected the December 2018 public offering which generated gross proceeds of \$2,019,743 and the ATM facility which delivered gross proceeds of \$455,105. In addition, \$100 was raised in relation to a unit purchase option and \$64,311 was raised in connection with the exercise of warrants. Cash costs relating to these offerings were \$489,404; \$328,302 of cash costs related to the December public offering and \$161,102 related to the ATM.

For the years ended March 31, 2018 and 2017, there were no financing activities.

#### **Off-Balance Sheet Arrangements**

We have no off-balance sheet arrangements, including unrecorded derivative instruments that have or are reasonably likely to have a current or future material effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources.

## **Contractual Obligations**

None

### Critical Accounting Policies

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America (GAAP) requires management to make estimates and assumptions about future events that affect the amounts reported in the financial statements and accompanying notes. Future events and their effects cannot be determined with absolute certainty. Therefore, the determination of estimates requires the exercise of judgment. Actual results inevitably will differ from those estimates, and such differences may be material to the financial statements. The most significant accounting estimates inherent in the preparation of our financial statements include estimates associated with research and development, income taxes and intangible assets, revenue recognition and stock-based compensation.

The Company's financial position, results of operations and cash flows are impacted by the accounting policies the Company has adopted. In order to get a full understanding of the Company's financial statements, one must have a clear understanding of the accounting policies employed. A summary of the Company's critical accounting policies follows:

Research and Development Expenses: The Company charges research and development expenses to operations as incurred. Research and development expenses primarily consist of salaries and related expenses for personnel and outside contractor and consulting services. Other research and development expenses include the costs of materials and supplies used in research and development, prototype manufacturing, clinical studies, related information technology and an allocation of facilities costs.

**Income taxes**: Income taxes are accounted for under the asset and liability method. Deferred income tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases, and operating loss carry forwards. Deferred income tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the year in which those temporary differences are expected to be recovered or settled. The effect on deferred income tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. A valuation allowance is provided to reduce the carrying amount of deferred income tax assets if it is considered more likely than not that some portion, or all, of the deferred income tax assets will not be realized.

The Company recognizes the effect of income tax positions only if those positions are more likely than not of being sustained. Recognized income tax positions are measured at the largest amount that is greater than 50% likely of being realized. Changes in recognition or measurement are reflected in the period in which the change in judgment occurs. The Company has elected to classify interest and penalties related to unrecognized tax benefits as part of income tax expense in the consolidated statements of comprehensive loss.

Intangible Assets: Intangible assets consist of licenses and patents associated with the sugarBEAT device and are amortized on a straight-line basis, generally over their legal lives of up to 20 years and are reviewed for impairment. Costs capitalized relate to invoices received from third parties and not any internal costs. The Company evaluates its intangible assets (all have finite lives) and other long-lived assets for impairment whenever events or circumstances indicate that they may not be recoverable, or at least annually. Recoverability of finite and other long-lived assets is measured by comparing the carrying amount of an asset group to the future undiscounted net cash flows expected to be generated by that asset group. The Company groups assets for purposes of such review at the lowest level for which identifiable cash flows of the asset group are largely independent of the cash flows of the other groups of assets and liabilities. The amount of impairment to be recognized for finite and other long-lived assets is calculated as the difference between the carrying value and the fair value of the asset group, generally measured by discounting estimated future cash flows. There were no impairment indicators present during the years ended March 31 2019, 2018 or 2017.

Revenue Recognition: While the Company is not currently recognizing revenue, we have considered the guidelines within ASC Topic 606, Revenue from Contracts with Customers.. This standard applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments. Under ASC Topic 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration that the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC Topic 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of ASC Topic 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations, and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

The Company may enter into product development and other agreements with collaborative partners. The terms of the agreements may include non-refundable signing and licensing fees, milestone payments and royalties on any product sales derived from collaborations.

The Company has entered into license agreements and for these, recognizes up front license payments as revenue upon delivery of the license only if the license has stand-alone value to the customer. However, where further performance criteria must be met, revenue is deferred and recognized on a straight-line basis over the period the Company is expected to complete its performance obligations.

Royalty revenue will be recognized upon the sale of the related products provided the Company has no remaining performance obligations under the agreement.

**Stock-based compensation:** For stock options granted as consideration for services rendered by non-employees, the Company recognizes compensation expense in accordance with the requirements of FASB ASC Topic 505-50 ("ASC 505-50"), "Equity Based Payments to Non-Employees." Non-employee restricted common stock and stock option grants that do not vest immediately upon grant, and whose terms are known, are recorded as an expense over the vesting period of the underlying instrument granted. At the end of each financial reporting period prior to vesting, the value of the instruments granted, will be re-measured using the fair value of the Company's common stock and the stock-based compensation recognized during the period will be adjusted accordingly.

For restricted common stock and stock option awards that have performance-based conditions, the Company recognizes the stock-based compensation expense at the fair value of the award based on the date that the performance conditions have been met. The Company calculates the fair value of the stock options using the Black Scholes option pricing model. The fair value of restricted common stock awards is based on the closing price of the Company's common stock on the applicable measurement date.

The assumptions used in calculating the fair value of stock-based awards represent management's best estimates and involve inherent uncertainties and the application of management's judgment.

To date, the Company has not granted any stock-based compensation awards to employees.

In June 2018, the FASB issued ASU 2018-07, *Improvements to Nonemployee Share-Based Payment Accounting*, or ASU 2018-07. ASU 2018-07 simplifies the accounting for share-based payments to nonemployees by aligning it with the accounting for share-based payments to employees, with certain exceptions. The Company will adopt ASU 2018-07 prospectively as of April 1, 2019. The adoption of ASU 2018-07 is not expected to have a material impact on the Company's financial position, results of operations or related disclosures.

## ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

#### **Interest Rate Risk**

The Company's exposure to interest rate risk is minimal. We have no bank borrowings and, although we have placed funds on deposit to earn interest during the year, these are of fixed-term and fixed-rate and therefore offer little exposure to interest rate risk. The long term fixed rate account held matured in December, 2018 and all interest accrued was received.

# Foreign Exchange Risk

Our foreign currency exposure gives rise to market risk associated with exchange rate movements against the US dollar, our reporting currency. Currently, the majority of our expenses and cash and fixed rate deposits are denominated in Pounds Sterling, with the remaining portion denominated in US dollars. Fluctuations in exchange rates, primarily the US dollar against the Pound Sterling, will affect our financial position. At March 31, 2019, the Company held approximately USD 2.5 million in GBP-denominated bank accounts. Based on this balance, a 1% depreciation of the Pound against the US dollar would cause an approximate USD 25,000 reduction in cash and fixed rate deposit account balances.

We have not utilized any hedging instruments in order to mitigate the foreign currency risk.

#### Inflation

Historically, with UK inflation rates having been low in recent years, inflation has not had a significant effect on our business in the UK, the location of the substantial part of our activities. Due to uncertainty surrounding Brexit, it is possible that UK inflation may be more volatile in the future.

# NEMAURA MEDICAL INC. INDEX TO CONSOLIDATED FINANCIAL STATEMENTS MARCH 31, 2019 AND 2018

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## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Stockholders and the Board of Directors of Nemaura Medical Inc. Loughborough, United Kingdom

#### **Opinion on the Financial Statements**

We have audited the accompanying consolidated balance sheet of Nemaura Medical, Inc. (the "Company") as of March 31, 2019, the related consolidated statements of comprehensive loss, changes in stockholders' equity, and cash flows for the year 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, 2019, and the results of its operations and its cash flows for the year then ended, in conformity with accounting principles generally accepted in the United States of America.

## **Basis for Opinion**

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audit. 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 audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit 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 audit included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audit provides a reasonable basis for our opinion.

# /s/ Mayer Hoffman McCann P.C.

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

Denver, Colorado June 14, 2019

#### REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Stockholders and the Board of Directors of Nemaura Medical Inc. Loughborough, United Kingdom

## **Opinion on the Financial Statements**

We have audited the accompanying consolidated balance sheet of Nemaura Medical Inc. (the "Company") as of March 31, 2018, the related consolidated statements of comprehensive loss, changes in stockholders' equity (deficit), and cash flows for each of the two years in the period ended March 31, 2018, 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, 2018, and the results of its operations and its cash flows for each of the two years in the period ended March 31, 2018, in conformity with accounting principles generally accepted in the United States of America.

# **Basis for Opinion**

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

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting in accordance with the standards of the PCAOB. 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 in accordance with the standards of the PCAOB.

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

# **Emphasis of Matter - Related Party Transactions**

The Company has significant transactions and relationships with related parties that are described in Note 7 to the consolidated financial statements.

/s/ Crowe LLP.

We have served as the Company's auditor since 2017.

Denver, Colorado June 12, 2018

# NEMAURA MEDICAL INC. CONSOLIDATED BALANCE SHEETS

	As of March 31, 2019 (\$)	As of March 31, 2018 (\$)
ASSETS		
Current assets:		
Cash	3,740,664	822,335
Fixed rate cash account	<del>-</del>	4,911,551
Prepaid expenses and other receivables	736,460	187,139
Accrued interest receivable	_	77,508
Inventory	38,036	_
Total current assets	4,515,160	5,998,533
Other assets:		
Property and equipment, net of accumulated depreciation	56,871	5,770
Intangible assets, net of accumulated amortization	191,684	251,099
intallyble assets, her or accumulated amortization		
	248,555	256,869
Total assets	4,763,715	6,255,402
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	161,348	49,912
Liability due to related party	964,679	613,818
Other liabilities and accrued expenses	107,759	77,414
Deferred revenue	65,175	70,165
Total current liabilities	1,298,961	811,309
Non-current portion of deferred revenue	1,237,850	1,333,128
Total liabilities	2,536,811	2,144,437
Commitments and contingencies		
Stockholders' equity:		
Series A convertible preferred stock, \$0.001 par value, 200,000 shares authorized; 0 and		
137,324 outstanding at March 31, 2019 and March 31, 2018, respectively.	_	137
Common stock, \$0.001 par value, 420,000,000 shares authorized and 207,655,916 shares		
issued and outstanding at March 31, 2019 (420,000,000 shares authorized and 67,676,000		
shares issued and outstanding at March 31, 2018 )	207,656	67,676
Additional paid in capital	15,785,015	13,056,859
Accumulated deficit	(13,425,879)	(8,973,082)
Accumulated other comprehensive loss	(339,888)	(40,625)
Total stockholders' equity	2,226,904	4,110,965
Total liabilities and stockholders' equity	4,763,715	6,255,402
· · · · · · · · · · · · · · · · ·	,100,110	5,255,462

# NEMAURA MEDICAL INC CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

	Year Ended March 31,			
	2019	2018	2017	
	(\$)	(\$)	(\$)	
Revenues				
Total revenues	=	_	_	
Operating expenses:				
Research and development	2,296,668	993,833	1,034,605	
General and administrative	2,180,056	915,132	516,661	
Total operating expenses	4,476,724	1,908,965	1,551,266	
Loss from operations	(4,476,724)	(1,908,965)	(1,551,266)	
	,		,	
Interest income	23,927	88,516	_	
Net loss	(4,452,797)	(1,820,449)	(1,551,266)	
Other comprehensive income/ (loss)				
Foreign currency translation adjustment, net of tax	(299,263)	564,914	(760,999)	
Comprehensive loss	(4,752,060)	(1,255,535)	(2,312,265)	
Loss per share				
Basic and diluted	(0.02)	(0.01)	*	
Weighted average number of common shares outstanding	180,903,839	150,070,400	205,000,000	

<sup>\*</sup> less than \$0.01

See notes to consolidated financial statements

# NEMAURA MEDICAL INC. CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY YEARS ENDED MARCH 31, 2019, 2018, 2017

Accumulated

	Common	Stock	Convertible preferred	Additional Paid in	Accumulated	Other Comprehensive Income	Total Stockholders'
	Shares	Amount (\$)	stock (\$)	Capital (\$)	Deficit (\$)	(Loss) (\$)	Equity (\$)
Balance at April 1, 2016	005 000 000	005 000		40.040.070	(F CO4 OC7)	455.400	7 670 765
Net loss	205,000,000	205,000		12,919,672	(5,601,367) (1,551,266)	155,460	<b>7,678,765</b> (1,551,266)
Other comprehensive income - foreign currency	_	_	_	_	(1,331,200)	_	(1,551,200)
translation loss						(760,999)	(760,999)
Balance at							
March 31, 2017	205,000,000	205,000	<u></u>	12,919,672	(7,152,633)	(605,539)	5,366,500
Cancellation of common stock and issue of convertible					(1,132,033)	(003,339)	3,300,300
preferred stock Net loss	(137,324,000)	(137,324)	137	137,187	— (1,820,449)	_	— (4 000 440)
Other comprehensive income - foreign currency translation				_	(1,020,770)		(1,820,449)
gain	_	_	_	_	_	564,914	564,914
Balance at							
March 31, 2018	67,676,000	67,676	137	13,056,859	(8,973,082)	(40,625)	4,110,965
Conversion of preferred stock into common							
stock	137,324,000	137,324	(137)	(137,187)	_	_	_
Issuance of stock – exercise of Invictus							
warrants	50,000	50	_	450	_		500
Issuance of common shares under ATM financing net of offering costs of							
\$161,102 Issuance of common shares and warrants under public offering -net of offering costs of	234,998	235	_	293,768	_	_	294,003
\$328,302	1,942,061	1,942	_	1,689,499	_	_	1,691,441

related party  Balance at  March 31,  2019	207,655,916	207,656		302,819	(13,425,879)	(339,888)	302,819 <b>2,226,904</b>
Forgiveness of payable by a						(255,255)	(200,200)
Other comprehensive income - foreign currency translation loss	_	_	_	_	<u> </u>	(299,263)	(299,263)
stock-based compensation to investor relations and Management consultants Net loss	367,500 —	368 —	<u>-</u>	514,957 —	— (4,452,797)	<u>-</u>	515,325 (4,452,797)
Restricted shares and warrants issued as							
Underwriter purchase of option to purchase units		_	_	100	_	_	100
Exercise of warrants under public offering	61,357	61	_	63,750	_	_	63,811

See notes to consolidated financial statements

# NEMAURA MEDICAL INC. CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended March 31		
	2019	2018	2017
	(\$)	(\$)	(\$)
Cash Flows from Operating Activities:			
Net loss	(4,452,797)	(1,820,449)	(1,551,266)
Adjustments to reconcile net loss to net cash used in operating			
activities:			
Depreciation and amortization	33,407	29,256	20,433
Stock Based Compensation	429,610		
Other non-cash expenses	34,796	_	_
Changes in assets and liabilities:	5 1,1 0 0		
Prepaid expenses and other receivables	(456,125)	(138,859)	85,367
Accrued interest receivable	70,759	(73,441)	, 
Increase in inventory	(37,396)	· - '	_
Accounts payable	98,118	(31,247)	2,522
Liability due to related party	697,182	(162,644)	270,975
Other liabilities and accrued expenses	21,494	60,407	(20,859)
Net cash used in operating activities	(3,560,952)	(2,136,977)	(1,192,828)
		<u> </u>	
Cash Flows from Investing Activities:			
Capitalized patent costs	(20,331)	(45,260)	(73,070)
Purchase of property and equipment	(59,666)		(6,519)
Fixed rate savings account	4,483,852	1,994,475	(6,226,500)
Net cash provided by/ (used in) investing activities	4,403,855	1,949,215	(6,306,089)
Cash Flows from Financing Activities:			
Costs incurred in relation to ATM Financing	(161,102)	_	_
Costs incurred in relation to public offering	(328,302)	_	_
Gross proceeds from issuance of common stock in relation to			
ATM financing	455,105	_	_
Gross proceeds from public offering	2,019,743	_	_
Gross proceeds from warrant exercise	64,311	_	_
Gross proceeds from unit purchase option	100	_	_
Net cash provided by financing activities	2,049,855		
Net increase/(decrease)/ in cash	2,892,758	(187,762)	(7,498,917)
Effect of exchange rate changes on cash	25,571	98,738	(993,689)
Cash at beginning of year	822,335	911,359	9,403,965
Cash at end of year	3,740,664	822,335	911,359
Supplemental displaying of new cook financing activities:			
Supplemental disclosure of non-cash financing activities:	107.004		
Conversion of Series A preferred stock to common stock	137,324	<del>_</del>	_
Prepayment of equity compensation	85,715	_	_
Forgiveness of payable from a related party	302,819	_	_

See notes to consolidated financial statements

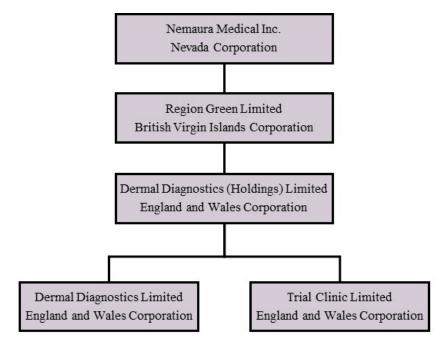
#### NOTE 1 - ORGANIZATION, PRINCIPAL ACTIVITIES AND MANAGEMENT'S PLANS

Nemaura Medical Inc. ("Nemaura" or the "Company"), through its operating subsidiaries, performs medical device research and manufacturing of a continuous glucose monitoring system ("CGM"), named sugarBEAT. The sugarBEAT device is a non-invasive, wireless device for use by persons with Type I and Type II diabetes and may also be used to screen pre-diabetic patients. The sugarBEAT device extracts analytes, such as glucose, to the surface of the skin in a non-invasive manner where it is measured using unique sensors and interpreted using a unique algorithm.

Nemaura is a Nevada holding company organized in 2013. Nemaura owns one hundred percent (100%) of Region Green Limited, a British Virgin Islands corporation ("RGL") formed on December 12, 2013. RGL owns one hundred percent (100%) of the stock in Dermal Diagnostic (Holdings) Limited, an England and Wales corporation ("DDHL") formed on December 11, 2013, which in turn owns one hundred percent (100%) of Dermal Diagnostics Limited, an England and Wales corporation formed on January 20, 2009 ("DDL"), and one hundred percent (100%) of Trial Clinic Limited, an England and Wales corporation formed on January 12, 2011 ("TCL").

DDL is a diagnostic medical device company headquartered in Loughborough, Leicestershire, England, and is engaged in the discovery, development and commercialization of diagnostic medical devices. The Company's initial focus has been on the development of the sugarBEAT device, which consists of a disposable patch containing a sensor, and a non-disposable miniature electronic watch with a re-chargeable power source, which is designed to enable trending or tracking of blood glucose levels. All the Company's operations and assets are located in England.

The following diagram illustrates Nemaura's corporate and shareholder structure as of March 31, 2019:



The Company was incorporated in 2013 since which period there has been recurring losses from operations and an accumulated deficit of \$13,425,879 as of March 31, 2019. These operations have resulted in the successful completion of clinical programs to support a European CE mark approval, as well as a US Food and Drug Administration submission. The Company expects to continue to incur losses from operations until revenues are generated through licensing fees or product sales. However, given the completion of the requisite clinical programs, these losses are expected to be reduced over time. Management has entered into licensing agreements with unrelated third parties relating to the United Kingdom, Europe, Qatar, all countries in the Gulf Cooperation Council, Management has evaluated the expected expenses to be incurred along with its available cash and has determined that the Company has the ability to continue as a going concern for at least one year subsequent to the date of issuance of these consolidated financial statements. The Company has \$3,740,664 of readily available cash on hand at March 31, 2019.

Management's strategic plans include the following:

- obtaining further regulatory approval for the sugarBEAT device in other countries such as the USA;
- pursuing additional capital raising opportunities, in addition to the Equity Distribution Agreement entered into on October 19, 2018 by the Company and Maxim pursuant to which the Company may offer and sell, from time to time, through Maxim, up to \$20,000,000 in shares of the Company's common stock.
- exploring licensing opportunities; and
- developing the sugarBEAT device for commercialization for other applications.

## **NOTE 2 – BASIS OF PRESENTATION**

# (a) Basis of presentation

The accompanying consolidated financial statements include the accounts of the Company and the Company's subsidiaries, DDL, TCL, DDHL and RGL. The consolidated financial statements are prepared in accordance with accounting principles generally accepted in the United States of America, and all significant intercompany balances and transactions have been eliminated in consolidation.

The functional currency for the majority of the Company's operations is the Great Britain Pound Sterling ("GBP"), and the reporting currency is the US Dollar.

# **NOTE 3 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

# (a) Cash and cash equivalents

The Company considers all highly liquid investments purchased with original maturities of three months or less to be cash equivalents. Cash and cash equivalents consist primarily of cash deposits maintained in the United Kingdom. From time to time, the Company's cash account balances exceed amounts covered by the Financial Services Compensation Scheme. The Company has never suffered a loss due to such excess balances.

# (b) Fixed rate cash accounts

From time to time the Company may invest funds in fixed rate cash savings accounts. Customarily, these accounts, at the time of the initial investment, provide a higher interest rate than other bank accounts, and require the Company to maintain the funds in the accounts for a certain period of time. As of March 31, 2019, the Company does not hold any cash reserves in any such savings accounts.

#### (c) Fair value of financial instruments

The Company's financial instruments primarily consist of cash, fixed rate cash accounts, accounts payable and other current liabilities. The estimated fair values of non-related party financial instruments approximates their carrying values as presented, due to their short maturities. The fair value of amounts payable to related parties are not practicable to estimate due to the related party nature of the underlying transactions.

# (d) Property and equipment

Property and equipment is stated at cost and depreciated using the straight-line method over the estimated useful lives of the assets, generally four years. This is charged to operating expenses.

## (e) Intangible assets

Intangible assets consist of licenses and patents associated with the sugarBEAT device and are amortized on a straight-line basis, generally over their legal lives of up to 20 years and are reviewed for impairment. Costs capitalized relate to invoices received from third parties and not any internal costs. The Company evaluates its intangible assets (all have finite lives) and other long-lived assets for impairment whenever events or circumstances indicate that they may not be recoverable, or at least annually. Recoverability of finite and other long-lived assets is measured by comparing the carrying amount of an asset group to the future undiscounted net cash flows expected to be generated by that asset group. The Company groups assets for purposes of such review at the lowest level for which identifiable cash flows of the asset group are largely independent of the cash flows of the other groups of assets and liabilities. The amount of impairment to be recognized for finite and other long-lived assets is calculated as the difference between the carrying value and the fair value of the asset group, generally measured by discounting estimated future cash flows. There were no impairment indicators present during the years ended March 31 2019, 2018 or 2017.

# (f) Revenue Recognition

While the Company is not currently recognizing revenue, we have considered the guidelines within ASC Topic 606, Revenue from Contracts with Customers, which is effective for the Company beginning April 1, 2019. This standard applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments. Under ASC Topic 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration that the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC Topic 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of ASC Topic 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations, and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

The Company may enter into product development and other agreements with collaborative partners. The terms of the agreements may include non-refundable signing and licensing fees, milestone payments and royalties on any product sales derived from collaborations.

The Company has entered into license agreements and for these, recognizes up front license payments as revenue upon delivery of the license only if the license has stand-alone value to the customer. However, where further performance criteria must be met, revenue is deferred and recognized on a straight-line basis over the period the Company is expected to complete its performance obligations.

Royalty revenue will be recognized upon the sale of the related products provided the Company has no remaining performance obligations under the agreement.

#### (g) Research and development expenses

The Company charges research and development expenses to operations as incurred. Research and development expenses primarily consist of salaries and related expenses for personnel and outside contractor and consulting services. Other research and development expenses include the costs of materials and supplies used in research and development, prototype manufacturing, clinical studies, related information technology and an allocation of facilities costs. The CE mark has now been granted and the FDA submission is planned in Q2 2019. Research and Development costs will therefore decrease significantly for the glucose monitoring application given these major milestones have been achieved and FDA submission is imminent.

# (h) Inventory

Inventories are stated at the lower of cost or net realizable value, with cost determined on a first-in first-out basis. At present all inventory relates to raw materials.

#### (i) Income taxes

Income taxes are accounted for under the asset and liability method. Deferred income tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases, and operating loss carry forwards. Deferred income tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred income tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. A valuation allowance is provided to reduce the carrying amount of deferred income tax assets if it is considered more likely than not that some portion, or all, of the deferred income tax assets will not be realized.

The Company recognizes the effect of income tax positions only if those positions are more likely than not of being sustained. Recognized income tax positions are measured at the largest amount that is greater than 50% likely of being realized. Changes in recognition or measurement are reflected in the period in which the change in judgment occurs. The Company has elected to classify interest and penalties related to unrecognized tax benefits as part of income tax expense in the consolidated statements of comprehensive loss. The Company does not have any accrued interest or penalties associated with any unrecognized tax benefits, nor was any interest expense related to unrecognized tax benefits recognized for the three years ended March 31, 2019.

In December 2017, the US Tax Cuts and Jobs Act was signed into law. Generally, this Act reduces corporate rates from a top rate of 35% to a top rate of 21%, effective January 1, 2018. As the Company's US operations are minimal, and all deferred tax assets maintain a full valuation allowance, there is no significant impact to the Company as of and for the year ended March 31, 2019.

#### (j) Earnings (loss) per share

Basic earnings (loss) per share is computed by dividing income (loss) available to common stockholders by the weighted-average number of common shares outstanding during the period. For the years ended March 31, 2019, 2018, and 2017, warrants to purchase 10 million shares of common stock were anti-dilutive and were excluded from the calculation of diluted loss per share. For the year ended March 31, 2019, warrants to purchase 1,880,704 shares of common stock and a unit purchase option to purchase 97,103 shares of common stock as well as 97,103 warrants were considered anti-dilutive and were also excluded from the calculation of diluted loss per share. For the years ended March 31, 2018 and 2017 preferred stock convertible to 137,324,000 shares of common stock were anti-dilutive and were excluded from the calculation of diluted loss per share.

# (k) Use of estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America 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 financial statements and the reported amounts of revenues and expenses during the periods presented. Actual results may differ from those estimates.

#### (I) Foreign currency translation

The functional currency of the Company is the Great Britain Pound Sterling ("GBP"). The reporting currency is the United States dollar (US\$). Stockholders' equity is translated into United States dollars from GBP at historical exchange rates. Assets and liabilities are translated at the exchange rates as of the balance sheet date. Income and expenses are translated at the average exchange rates prevailing during the reporting period.

The translation rates are as follows:

	2019	2018	2017
Year end GBP : US\$ exchange rate	1:1.3030	1:1.4033	1:1.2453
Average period/yearly GBP: US\$ exchange rate	1:1.3026	1:1.3305	1:1.3146

Adjustments resulting from translating the financial statements into the United States dollar are recorded as a separate component of accumulated other comprehensive loss in stockholders' equity.

# (m) Stock-based compensation

For stock options granted as consideration for services rendered by non-employees, the company recognizes compensation expense in accordance with the requirements of FASB ASC Topic 505-50 ("ASC 505-50"), "Equity Based Payments to Non-Employees." Non-employee restricted common stock and stock option grants that do not vest immediately upon grant, and whose terms are known, are recorded as an expense over the vesting period of the underlying instrument granted. At the end of each financial reporting period prior to vesting, the value of the instruments granted, will be re-measured using the fair value of the Company's common stock and the stock-based compensation recognized during the period will be adjusted accordingly.

For restricted common stock and stock option awards that have performance-based conditions, the Company recognizes the stock-based compensation expense at the fair value of the award based on the date that the performance conditions have been met. The Company calculates the fair value of the stock options using the Black Scholes option pricing model. The fair value of restricted common stock awards is based on the closing price of the Company's common stock on the applicable measurement date.

The assumptions used in calculating the fair value of stock-based awards represent management's best estimates and involve inherent uncertainties and the application of management's judgment.

To date, the Company has not granted any stock-based compensation awards to employees.

## (n) Direct costs incurred for equity financing

The Company includes all direct costs incurred in connection with successful equity financings as a component of additional paid-in capital. Direct costs incurred for equity financings that are unsuccessful are expensed.

#### (o) Recent accounting pronouncements

The Company continually assesses any new accounting pronouncements to determine their applicability. When it is determined that a new accounting pronouncement affects the Company's financial reporting, the Company undertakes a study to determine the consequences of the change to its consolidated financial statements and assures that there are proper controls in place to ascertain that the Company's consolidated financial statements properly reflect the change.

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Updates ("ASU") No. 2014-09, Revenue from Contracts with Customers. ASU 2014-09 has been modified multiple times since its initial release. This ASU outlines a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers and will replace most existing revenue recognition guidance in U.S. GAAP when it becomes effective. ASU 2014-09, as amended, becomes effective for annual reporting periods beginning after December 15, 2017. Early adoption is permitted. As an Emerging Growth Company (we expect our Emerging Growth Company status to expire on March 31, 2020), the Company is allowed to adopt new, or updated, accounting standards using the same time frame that applies to private companies. The Company will adopt this standard on April 1, 2019. Management is currently evaluating the impact of adoption of this ASU on the Company's consolidated financial statements.

In March 2016, the FASB issued ASU No. 2016-02, Leases. The main difference between the provisions of ASU No. 2016-02 and previous U.S. GAAP is the recognition of right-of-use assets and lease liabilities by lessees for those leases classified as operating leases under previous U.S. GAAP. ASU No. 2016-02 retains a distinction between finance leases and operating leases, and the recognition, measurement, and presentation of expenses and cash flows arising from a lease by a lessee have not significantly changed from previous U.S. GAAP. For leases with a term of 12 months or less, a lessee is permitted to make an accounting policy election by class of underlying asset not to recognize right-of-use assets and lease liabilities. The accounting applied by a lessor is largely unchanged from that applied under previous U.S. GAAP. In transition, lessees and lessors are required to recognize and measure leases at the beginning of the earliest period presented using a modified retrospective approach. This ASU is effective for public business entities in fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018. Early adoption is permitted as of the beginning of any interim or annual reporting period. As an Emerging Growth Company, the Company is allowed to adopt new, or updated, accounting standards using the same time frame that applies to private companies. The Company will adopt this standard on April 1, 2020. Management is currently evaluating the impact of adoption of this ASU on the Company's consolidated financial statements.

In June 2018, the FASB issued ASU 2018-07, *Improvements to Nonemployee Share-Based Payment Accounting*, or ASU 2018-07. ASU 2018-07 simplifies the accounting for share-based payments to nonemployees by aligning it with the accounting for share-based payments to employees, with certain exceptions. The Company will adopt ASU 2018-07 prospectively as of April 1, 2019. The adoption of ASU 2018-07 is not expected to have a material impact on the Company's financial position, results of operations or related disclosures.

In August 2018, the FASB issued ASU No. 2018-13, Fair Value Measurement: Disclosure Framework – Changes to the Disclosure Requirements for Fair Value Measurement (ASU 2018-13), which adds and modifies certain disclosure requirements for fair value measurements. Under the new guidance, entities will no longer be required to disclose the amount and reasons for transfers between Level 1 and Level 2 of the fair value hierarchy, or valuation processes for Level 3 fair value measurements. However, public business entities will be required to disclose the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements, and related changes in unrealized gains and losses included in other comprehensive income. ASU 2018-13 is effective for public business entities for fiscal years beginning after December 15, 2019, including interim periods. Management is currently evaluating the impact that this guidance will have on the Company's consolidated financial statements.

# (p) Risks and Uncertainties:

The Company is in the commercialization stage for sugarBEAT in the EU now that CE mark approval (European Union approval of the product) has been received. The Company has entered into sales and marketing agreements for the product. It has also placed orders for the first commercial batch of transmitter devices with the electronics manufacturer Datalink Limited. It has not entered into exclusive manufacturing agreements with any of its contract manufacturers. Uncertainties still exist with regards to regulatory acceptance of the Company's primary product development efforts in territories outside of Europe.

#### (q) Preferred shares

On October 5, 2017, the Company entered into common stock exchange agreements with each of its three largest shareholders, to exchange, in the aggregate, 137,324,000 shares of the Company's common stock for 137,324 shares of Series A Convertible Preferred Stock (the "Series A Preferred"). Each share of Series A Preferred is convertible into 1,000 shares of the Company's common stock, automatically upon the occurrence of all of certain triggering events, as set forth in the Certificate of Designation for the Series A Preferred, namely (a) the sugarBEAT® device to be commercialized has CE regulatory approval; (b) retail sales having commenced; and (c) retail sales exceeding USD\$5 million, inclusive of advanced sales or voluntarily by the holder after February 7, 2018, if these triggering events have not occurred. Each holder of issued and outstanding Series A Preferred is entitled to a number of votes equal to the number of shares of common stock into which the Series A Preferred is convertible. Holders of Series A Preferred are entitled to vote on any and all matters presented to stockholders of the Company, except as provided by law. The Series A Preferred has no preference to the common stock as to dividends or distributions of assets upon liquidation or winding up of the Company (which has been agreed to by the holders of the Series A Preferred). The Company determined that the fair value of the shares of Series A Preferred issued for the shares of common stock was equivalent to the fair value of the shares of common stock exchanged.

On November 6, 2017, the transactions contemplated by the exchange agreements were consummated and 137,324,000 shares of common stock were cancelled. As a result, the Company had 67,676,000 shares of common stock issued and outstanding as of March 31, 2018.

On June 5, 2018, the three holders of the Company's Series A Preferred each delivered notices of conversion to voluntarily convert their Series A Preferred, in the aggregate amount of 137,324 of Series A Preferred shares, into 137,324,000 shares of common stock. The holders had the right to voluntarily convert each share of Series A Preferred into 1,000 shares of common stock of the Company.

## (r) Subsequent events

## S-3 Registration

Prior to the year end, the Company filed a new Registration Statement on Form S-3, registering up to \$250,000,000 of our common stock, preferred stock, warrants, debt securities and units (the "Form S-3"). The Form S-3 was declared effective by the Securities and Exchange Commission on April 8, 2019. We may offer and sell up to \$250,000,000 in the aggregate of the securities identified from time to time in one or more offerings. The securities may be sold directly by us, through dealers, or agents, designated from time to time, to or through underwriters, or through a combination of these methods as set forth in the "Plan of Distribution" included therein. Each time we offer securities under the prospectus that is part of the Form S-3, we will provide the specific terms of the securities being offered, including the offering price in a prospectus supplement.

On April 10, 2019, the Company re-started the ATM offering, with Maxim Group LLC, as sales agent ("Maxim"), pursuant to which the Company may offer and sell, from time to time, through Maxim (the "Offering"), up to \$19,544,895 in shares of its common stock (the "Shares").

# CE Approval

On May 29, 2019 Nemaura Medical announced it had received confirmation of approval of the European Conformity for sugarBEAT which now allows Nemaura to commence commercialization of the product in to the European Union.

Nemaura has initiated plans to launch the product into the UK market in Q3 of 2019, followed by Germany and other markets. In the UK, Nemaura is working with its licensee DBP (Jersey) Ltd., to launch the product in the UK, and is working with its joint venture partner DB Ethitronix to commence registration and commercial launch into the German market.

The Company ordered 12,500 sugarBEAT devices in July 2018 in anticipation of CE approval, and these devices are currently being assembled and programmed with the updated software for the planned launch in Germany and the UK, and they are in discussions with their UK licensee with regards to taking orders for additional quantities to support product launch for the next 12 months.

Nemaura has also commenced activities with respect to registering the CGM product based on the CE Mark in the GCC countries with their respective licensees in that region, Al-Danah Medical and TPMena.

# (s) Reclassifications

To conform to the current year's presentation, as of March 31, 2018, the Company reclassified \$70,165 from other liabilities and accrued expenses to current portion of deferred revenue. There was no impact on total assets, total liabilities, net loss or total equity.

#### **NOTE 4 – LICENSING AGREEMENTS**

# United Kingdom and the Republic of Ireland, the Channel Islands and the Isle of Man

In March 2014, the Company entered into an Exclusive Marketing Rights Agreement with an unrelated third party that granted to the third party the exclusive right to market and promote the sugarBEAT device and related patches under its own brand in the United Kingdom and the Republic of Ireland, the Channel Islands and the Isle of Man. The Company received a non-refundable, up-front cash payment of GBP 1,000,000 (approximately \$1.303 million and \$1.403 million as of March 31, 2019 and 2018, respectively), which was wholly non-refundable, upon signing the agreement.

As the Company has continuing performance obligations under the agreement, the up-front fees received from this agreement have been deferred and will be recorded as income over the term of the commercial licensing agreement beginning from the date of clinical evaluation approval. As the Company expects commercialization of the sugarBEAT device to occur in the year ending March 31, 2020, approximately \$65,000 of the deferred revenue has been classified as a current liability as of March 31, 2019.

In April 2014, a Letter of Intent was signed with a third party which specified a 10-year term and in November 2015, a License, Supply and Distribution Agreement with an initial 5-year term was executed. Pursuant to this agreement, the Company grants the exclusive right to market and promote its product in the United Kingdom and purchase the product at specified prices.

# Other European territories

In May 2018, the Company signed a commercial agreement with Dallas Burston Ethitronix Limited (DBEE) for all other European territories as part of an equal joint collaboration agreement. The joint collaboration agreement intends to seek sub-license rights opportunities to one or more leading companies in the diabetes monitoring space, in order to leverage their network, infrastructure and resources. The Company and DBEE agreed that they shall share proceeds equally from sales of the Company's sugarBEAT products. In consideration of the sub-license rights granted, DBEE shall pay to the Company the sum of approximately \$1 if demanded and, except as described elsewhere in the Agreement, no commission, royalties or other payments shall be due to the Company from DBEE. The initial term of the Agreement is for five years, which may be terminated at the end of such five-year initial term by either party upon at least 12 months' prior written notice. If such notice of termination is not provided by either party during the initial term, the Agreement shall automatically continue until terminated by either party upon 12 months' prior written notice. In the event the Agreement is terminated as provided above, the non-terminating party shall receive an exit payment equal to 50% of the open market value of the joint collaboration business as defined in the collaboration agreement and as agreed to by the parties at the time of termination. The parties may also terminate the Agreement if the other party commits a material breach of the terms of the Agreement which is not remedied within 30 days of written notification of such breach, or the other party dissolves or goes bankrupt. Commercialization is expected to occur in the second half of 2019. As of March 31, 2019 no payments have been made or received or are due or receivable under the terms of the collaboration agreement.

#### Qatar

In November 2018, the Company signed a commercial agreement with Al-Danah Medical Company for the exclusive license and distribution of the sugarBEAT device in Qatar. This agreement gives Al-Danah Medical Company the exclusive rights to sell and market the Company's products in Qatar. The Company will sell devices to Al-Danah Medical Company at a specified price and with minimum order quantities which will be set post product launch. The Company's responsibility is limited to the supply of the device and related consumables. Al-Danah Medical Company is responsible for ensuring compliance with all local regulation related to registering and selling the device within Qatar. Product launch in Qatar is expected to take place after the initial commercialization of the sugarBEAT device which is expected to occur in the second half of 2019.

## Gulf Cooperation Council (GCC) excluding Qatar

In February 2019, the Company signed a commercial agreement with The Principals Mena DMCC (TPM), for the exclusive licence and distribution of the sugarBEAT device in all countries of the Gulf Cooperation Council (GCC) excluding Qatar. This agreement gives TPM the exclusive rights to sell and market the Company's products in the GCC subject to mutual agreement on minimum order quantities and supply price which are to be determined pre-launch in the territory. The Company's responsibility is limited to the supply of the device and related consumables, and maintenance of the mobile phone Application. TPM is responsible for ensuring compliance with all local regulations related to registering and selling the device within the GCC, and marketing and sales. Product launch in the GCC is expected to take place after the initial commercialization of the sugarBEAT device in Europe.

#### **NOTE 5 - PROPERTY AND EQUIPMENT**

As of March 31, 2019, and March 31, 2018 property and equipment is summarized as follows.

	March 31, 2019	March 31, 2018
	(\$)	(\$)
Property and equipment	77,597	18,213
Less accumulated depreciation	(20,726)	(12,443)
	56,871	5,770

Depreciation expense related to property and equipment for the years ended March 31, 2019, 2018 and 2017 was approximately \$9,000, \$4,000 and \$4,000 respectively.

#### **NOTE 6 - INTANGIBLE ASSETS**

As of March 31, 2019, and March 31, 2018 intangible assets are summarized as follows:

	March 31, 2019 (\$)	March 31, 2018 (\$)
Patents and licenses	261,938	323,987
Less accumulated amortization	(70,254)	(72,888)
	191,684	251,099

Estimated amortization expense is approximately \$19,000 for each of the next five years.

# **NOTE 7 – RELATED PARTY TRANSACTIONS**

Nemaura Pharma Limited (Pharma), Black and White Health Care Limited (B&W) and NDM Technologies Limited (NDM) are entities controlled by the Company's chief executive officer, interim chief financial officer, and majority shareholder, Dewan F.H. Chowdhury.

In accordance with the United States Securities and Exchange Commission (SEC) Staff Accounting Bulletin 55, these financial statements are intended to reflect all costs associated with all operations of Nemaura Medical and its subsidiaries Pharma has a service agreement with DDL, to undertake development, manufacture and regulatory approvals under Pharma's ISO13485 Accreditation. In lieu of these services, Pharma invoices DDL on a periodic basis for said services. Services are provided at cost plus a service surcharge amounting to less than 10% of the total costs incurred.

Following is a summary of activity between the Company and Pharma, B&W and NDM for the years ended March 31, 2019, 2018 and 2017. These amounts are unsecured, interest free, and payable on demand.

	Year Ended March 31, 2019 (\$)	Year Ended March 31, 2018 (\$)	Year Ended March 31, 2017 (\$)
Balance due to Pharma and NDM at beginning of period	613,818	687,609	494,145
Amounts received from Pharma	<del>_</del>	145,214	2,480
Amounts invoiced by Pharma to DDL, NM and TCL (1)	2,312,412	842,739	577,481
Amounts invoiced by DDL to Pharma	(977)	_	(15,305)
Amounts repaid by DDL to Pharma	(1,569,496)	(1,096,767)	(249,060)
Amounts paid by DDL on behalf of Pharma	<del>_</del>	(19,889)	(42,403)
Amounts invoiced by B&W to DDL	2,206	_	_
Amounts repaid by DDL to B&W	(5,622)	_	_
Foreign exchange differences	(84,843)	54,912	(79,729)
Forgiveness of payable accounted for as equity contribution	(302,819)	_	_
Net balance due to Pharma and NDM at end of the period	964,679	613,818	687,609

(1) These amounts are included primarily in research and development expenses.

All related party transactions relate to operating activities in the years ended March 31, 2019, 2018 and 2017.

Total costs charged to the Company by Pharma and NDM were \$2,312,412, \$842,739, and \$577,481 for the years ended March 31, 2019, 2018 and 2017, respectively.

In the year ended March 31, 2019, consultancy services totalling \$2,160 relating to the preparation of tax advice was provided by Diagnostax Limited, a company of which Mr. T. Johnson is a director. Mr. T. Johnson is a non-executive director of the Company.

# **NOTE 8 - INCOME TAXES**

The Company and its subsidiaries file separate income tax returns.

# The United States of America

The Company is incorporated in the US and is subject to a US federal corporate income tax rate of 21% for the year ended March 31, 2019. As a result of the US Tax Cuts and Jobs Act, the Company was subject to a US federal corporate income tax blended rate of 30.79% for the year ended March 31, 2018 and 35% for the year ended March 31, 2017.

# **British Virgin Islands**

RGL is incorporated in the British Virgin Islands ("BVI"). Under the current laws of the BVI, RGL is not subject to tax on income or capital gains. In addition, upon payments of dividends by RGL, no BVI withholding tax is imposed. During the years ended March 31, 2019, 2018 and 2017, there was no income or expenses in the BVI.

# UK

DDL, TCL and DDHL are all incorporated in the United Kingdom (UK) and the applicable UK statutory income tax rate for these companies is 19%.

For the years ended March 31, 2019, 2018 and 2017 loss before income tax expense (benefit) arose in the UK and U.S. as follows:

		Year Ended March 31,				
	2019	2018	2017			
	\$	\$	\$			
Loss before income taxes arising in UK	(2,726,862)	(1,353,243)	(1,251,870)			
Loss before income taxes arising in United States	(1,725,935)	(467,206)	(299,396)			
Total loss before income tax	(4,452,797)	(1,820,449)	(1,551,266)			

Reconciliation of our effective tax rate to loss to the statutory U.S federal tax rate is as follows:

	Year Ended March 31,					
	2019		2018	8	2017	7
	\$		\$		\$	
Loss before income taxes	(4,452,797)		(1,820,449)		(1,551,266)	
Expected tax benefit	(935,000)	(21%)	(561,000)	(31%)	(527,000)	(34%)
Foreign tax differential	55,000	1%	36,000	2%	270,000	17%
Enhanced research and development	(297,000)	(7%)	(215,000)	(12%)	(198,000)	(13%)
Other	1,000	0%	35,000	2%	_	_
Change in valuation allowance	1,176,000	26%	705,000	39%	455,000	29%
Actual income tax benefit						_

The tax effects of the temporary differences that give rise to significant portions of deferred income tax assets are presented below:

	Year Ended March 31,				
	2019	2018			
	\$	\$			
Net operating tax loss carried forwards	2,641,000	1,627,000			
Research and development enhancement	867,000	602,000			
Other items	(103,000)	_			
Valuation allowance	(3,405,000)	(2,229,000)			
		_			
Net deferred tax assets		_			

For each of the years ended March 31, 2019, 2018 and 2017, the Company did not have unrecognized tax benefits, and therefore no interest or penalties related to unrecognized tax benefits were accrued. Management does not expect that the amount of unrecognized tax benefits will change significantly within the next twelve months.

The Company mainly files income tax returns in the United States and the UK. The Company is subject to U.S. federal income tax examination by tax authorities for tax years beginning in 2015. The UK tax returns for the Company's UK subsidiaries are open to examination by the UK tax authorities for the tax years beginning in April 1, 2013.

As of March 31, 2019, the Company has net operating losses (NOLs) of approximately \$3.2 million in the U.S. and \$11.5 million in the UK. NOLs may be carried forward indefinitely. Additionally, the Company has a research and development enhancement deduction carry forward of approximately \$5.1 million for purposes of UK income tax fillings.

# **NOTE 9 - STOCKHOLDERS' EQUITY**

In November 2015, the Company issued 5 million shares of common stock and warrants to purchase 10 million shares of common stock for total proceeds of \$10 million. The warrants are exercisable at \$0.50 per share through to the fifth anniversary of the listing of the Company on a national exchange. The Company listed to the Nasdaq exchange on January 25, 2018.

On October 19, 2018, the Company entered into an Equity Distribution Agreement (the "Distribution Agreement") with Maxim Group LLC, as sales agent ("Maxim"), pursuant to which the Company may offer and sell, from time to time, through Maxim (the "Offering"), up to \$20,000,000 in shares of its common stock (the "Shares"). Between October 31, 2018, and March 31, 2019, the Company issued 234,998 shares of its common stock through the Distribution Agreement and received gross proceeds of \$455,105. \$161,102 of costs were incurred in relation to this transaction. As of March 31, 2019, the Company may sell, from time to time, the remaining \$19,544,895 under the distribution agreement.

On December 18, 2018, the Company entered into a placement agency agreement with Dawson James Securities, Inc. with respect to the issuance and sale of an aggregate of up to 2,400,000 units, each unit consisting of one share of common stock, par value \$0.001 per share, together with one warrant to purchase one share of common stock at an exercise price equal to \$1.04 per share, in a public offering. The warrants offered in the public offering will terminate on the fifth anniversary of the date of issuance. The public offering price for each unit was \$1.04.

The closing of the offering occurred on December 20, 2018 and at such closing the Company sold 1,942,061 shares of common stock and 1,942,061 warrants for gross proceeds of \$2,019,743. The net proceeds to the Company from the sale of the shares of common stock and the warrants was \$1,691,541, after deducting \$328,302 of placement agent commissions and other offering expenses payable by the Company. As at March 31, 2019 61,357 of the warrants had been exercised, generating \$63,811 of additional funds. At the end of March 31, 2019, there were 1,880,704 warrants outstanding.

Effective December 18, 2018, the Company issued a unit purchase option to the placement agent to purchase 97,103 shares and 97,103 warrants. The Company has classified this option as equity. The unit purchase option has a term of three years and an exercise price of \$1.30.

# **NOTE 10 - QUARTERLY FINANCIAL INFORMATION (UNAUDITED)**

The following is a summary of consolidated quarterly financial information:

	 Quarter Ended						
2019	 June 30		Sept. 30		Dec. 31		March 31
Total revenue	\$ 	\$		\$		\$	_
Loss from operations	\$ (771,963)	\$	(1,147,357)	\$	(932,925)	\$	(1,624,479)
Net loss	\$ (763,154)	\$	(1,139,275)	\$	(925,889)	\$	(1,624,479)
Basic and diluted loss per share	\$ (0.01)	\$	(0.01)	\$	*	\$	(0.01)
Weighted average number of shares outstanding	105,821,556		205,003,261		205,407,088		207,561,482

	 Quarter Ended						
2018	 June 30		Sept. 30		Dec. 31		March 31
Total revenue	\$ 	\$		\$		\$	_
Loss from operations	\$ (417,320)	\$	(447,516)	\$	(476,353)	\$	(567,776)
Net loss	\$ (407,787)	\$	(393,031)	\$	(466,365)	\$	(553,266)
Basic and diluted loss per share	\$ *	\$	*	\$	*	\$	*
Weighted average number of shares outstanding	205,000,000		205,000,000		121,411,478		150,070,400

	 Quarter Ended						
2017	June 30		Sept. 30		Dec. 31		March 31
Total revenue	\$ 	\$		\$		\$	_
Loss from operations	\$ (494, 183)	\$	(322,482)	\$	(375,366)	\$	(359,235)
Net loss	\$ (494,183)	\$	(322,482)	\$	(375,366)	\$	(359,235)
Basic and diluted loss per share	\$ *	\$	*	\$	*	\$	*
Weighted average number of shares outstanding	205,000,000		205,000,000		205,000,000		205,000,000

<sup>\*</sup> less than \$0.01

# **NOTE 11 – OTHER ITEMS**

# (a) Investor relations agreements

The Company currently has contracts with several investor relations specialists to help support the ongoing financing activities of the business.

On June 27, 2018, the Company entered into a Master Services Agreement with investor relations company 1, pursuant to which for an initial three month term, the third party shall provide services related to advising and assisting the Company in developing and implementing appropriate plans and materials for presenting the Company and its business plans, strategy and personnel to the financial community, introducing the Company to the financial community through the use of social media, digital media and other online awareness campaigns. The aggregate fees in the amount of \$160,000 are payable to the third party during the initial three-month term. On July 23, 2018 the Board of Directors approved the issuance of a warrant to the third party exercisable for 75,000 shares of common stock at an exercise price of \$0.01 per share. As of September 30, 2018, the Company recognized \$114,500 of stock-based compensation expense related to the 50,000 warrants that had vested as of that date based on a fair value of \$2.29 per warrant. On October 9, 2018, 50,000 shares of common stock were issued to the third party, as a result of the third party's exercise of 50,000 warrants on September 24, 2018. At March 31, 2019, all liabilities for share based compensation were considered fully settled. It was agreed by both parties that there is no further obligation to issue the remaining 25,000 warrants.

On August 31, 2018, the Company entered into an agreement to receive investor relations services from investor relations company 2. The term of the agreement was 1 year, although cancellable after 3 months if certain performance-based conditions are not met, including if the share trade volumes fail to meet an average of 100,000 shares per day minimum. Compensation is partly in cash and partly in restricted stock, 40,000 shares of restricted stock due on the 3-month anniversary and the final 40,000 due on the one-year anniversary, provided performance conditions are met as per the agreement. On November 30, 2018, 20,000 shares of common stock were issued to investor relations company 2 in compensation for services performed over the previous 3 months. A fair value of \$1.90 was established based on the closing price of the common stock on November 30, 2018 and \$38,000 was expensed. This fulfilled all liabilities in relation to this agreement and as of November 30, 2018 the agreement was terminated.

On December 1, 2018 a new agreement was entered into to receive investor relations services from investor relations company 2. The term of the agreement is 1 year, although cancellable at the end of each three-month period if certain performance obligations are not met, including if the share trade volumes fail to meet an average of 100,000 shares per day minimum. Compensation is partly in cash and partly in restricted stock. A cash payment of \$22,500 will be made at the beginning of each quarter and 12,500 shares of restricted common stock will be issued at the end of each quarter dependent on the performance obligations being met.

On March 1, 2019, the existing agreement with investor relations company 2 was cancelled and replaced with a rolling monthly contract. At this point it was agreed that there was no obligation to issue the 12,500 shares that were part of the compensation for the December 1, 2018 contract. Compensation for the new agreement is a rolling contract in the form of a \$5,000 payment made at the beginning of each month. There is no stock based compensation included in this agreement.

On December 11, 2018 the Company entered into an agreement to receive investor relations services from investor relations company 3. The term of this agreement is 3 months. Compensation is partly in cash and partly in restricted common stock. At the beginning of each month a cash payment of \$10,000 will be made and 15,000 shares of restricted stock will be issued. As a result of this agreement a total of 45,000 shares were issued with an average fair value of \$1.05, \$47,400 was expensed in relation to this agreement.

On March 18, 2019 the Company cancelled its existing agreement and entered into a new agreement with investor relations company 3. The term of this contract has been agreed to be on a month to month basis. Compensation is partly in cash and partly in restricted common stock. At the beginning of each monthly term a cash payment of \$5,000 will be made and 7,500 shares of restricted stock will be issued. At March 31, 2019 7,500 shares had been issued in relation to this contract. A fair value of \$1.03 with a total value of \$7,725, \$3,240 of this cost has been treated as a prepayment as the contract length spans the month end.

# (b) Management Consulting Agreement

On December 3, 2018, the Company entered into an agreement to receive management consulting advice from management consulting company 1. The term of this agreement is 12 months but is cancellable prior to this date on written notice to the other party. Compensation is partly in cash and partly in restricted stock. A cash payment of \$25,000 together with the issuance of 12,500 shares of restricted common stock was made at the inception of the agreement and will be made at the beginning of each subsequent quarter. A fair value of \$1.90 was established for the shares issued in December based on the closing price of common stock on December 3, 2018 with a total of \$23,750 being expensed. A fair value of \$1.14 was established for the shares issued on March 2019, based on the closing price of common stock on March 4, 2019. \$9,500 of the total \$14,250 expense was treated as a pre-payment as of March 31, 2019.

On February 4, 2019, the Company signed an addendum to the contract with management consulting company 1. This extended the range of services from this company. Compensation for the initial 120-day period will be in the form of a cash payment of \$20,000 and the issuance of 20,000 restricted shares of common stock. Compensation for subsequent 90-day periods will be comprised of a cash payment of \$15,000 and the issuance of 15,000 restricted shares of common stock. The contract is on a rolling 90-day period and can be cancelled at the end of each three-month period and at the end of the initial 120-day period. A fair value of \$1.11 was established based on the closing price of common stock on February 4, 2019. \$11,100 of the total \$22,200 expense was treated as a pre-payment as of March 31, 2019.

On January 7, 2019 the Company entered into a six-month contract with management consulting company 2 for the provision of specialist consulting services. Compensation is wholly through the issue of 250,000 restricted shares of common stock which will be issued on commencement of the contract and 150,000 additional restricted shares which will be issued on the fourth month after commencement of the contract. If the contract has been terminated prior to the fourth month, the additional restricted shares will not be payable. A fair value of was based on the closing price of common stock on January 7, 2019, of \$0.99 per common share. \$61,875 of the total \$247,500 expense was treated as a pre-payment at March 31, 2019.

During the year ended March 31, 2019, the Company issued a total of 367,500 restricted common shares and warrants to purchase 50,000 common shares to investor relations and management consultants. The equity instruments were valued at \$515,325 of which \$429,610 was expensed and \$85,715 is included in prepaid expenses as at March 31, 2019.

#### 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**

Dr. Dewan F.H. Chowdhury, our Chief Executive Officer and Interim Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures as of the end of the period covered by this Annual Report on Form 10-K. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to a company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost benefit relationship of possible controls and procedures. Based on this evaluation, management concluded that our disclosure controls and procedures were not effective as of March 31, 2019, at the reasonable assurance level due to a material weakness in our internal control over financial reporting, which is described below.

## 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 defined in Exchange Act Rule 13a-15(f). Our internal control system is a process designed by, or under the supervision of, our principal executive and principal financial officer, or persons performing similar functions, 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 financial statements for external purposes in accordance with U.S. generally accepted accounting principles ("U.S. GAAP").

Our internal control over financial reporting includes policies and procedures that pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect transactions and dispositions of assets; provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with U.S. GAAP, and that receipts and expenditures are being made only in accordance with the authorization of our management and directors; and provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on our consolidated financial statements.

Because of our inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Management assessed the effectiveness of our internal control over financial reporting as of March 31, 2019. In making this assessment we used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in *Internal Control – Integrated Framework* (2013). As a result of its assessment, management identified material weaknesses in our internal control over financial reporting. During fiscal year 2019, significant work has been done to address these weaknesses, but this is not yet fully complete and further formal testing is planned for later in 2019. On this basis, management concluded that our internal control over financial reporting was not effective as of March 31, 2019.

A material weakness is a deficiency, or combination of 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 summary below details the material weaknesses in internal control that were identified over financial reporting due to lack of formal testing are still deemed to be in place as of March 31, 2019.

- · Our size has prevented us from being able to employ sufficient resources to enable us to have an adequate level of supervision and segregation of duties within our internal control system. This has resulted in a number of internal control deficiencies. Specifically,
  - there is a lack of segregation of duties in the processing of financial transactions which could result in inappropriate initiation, processing
    and review of transactions and the financial reporting of such transactions whether due to errors or fraud;
  - there is a lack of review and approval of journal entries which could result in the improper initiation and reporting of transactions; and
  - there is a lack of access controls and documentation over the Company's IT applications which could result in the improper initiation and reporting of significant transactions.
- · Management has identified that there is a lack of adequate financial expertise related to the assessment of complex transactions and a lack of adequate resources to review out of the ordinary transactions and arrangements of the Company. This could result in the improper reporting of significant transactions or arrangements.
- · Related party transactions. Specifically, there are limited policies and procedures to ensure that financial statement disclosures reconcile fully to the underlying accounting records and that Board approval of these transactions is not documented.

In addition, during the three-month period September 30, 2018, material weaknesses were identified for the accounting and reporting in the following complex areas:

- Deferred offering costs and cutoff for accrued expenses were not properly accounted for.
- Stock based compensation was not properly accounted for.
- Preparation of condensed consolidated financial statements.

The material weaknesses that occurred in the three-month period ended September 30, 2018 related to complex accounting issues and supported the view that there is a lack of adequate financial expertise related to the assessment of complex transactions and a lack of adequate resources to review out of the ordinary transactions and arrangements of the Company.

Since the September 2018 quarter end the Company has enhanced the quarterly financial reporting process by taking the following actions:

- External advice from a specialized third-party provider has been sought to provide technical guidance on accounting for December 2018 Public offering and related costs.
- Additional training for accounting personnel on the proper accounting and reporting for stock-based compensation and complex equity transactions.
- The month end process has been enhanced and additional controls such as full balance sheet reconciliations have been implemented.
- In addition, the increased size of the finance team has enabled and increased level of segregation of duties and enhanced opportunity for review.

Notwithstanding the identified material weaknesses, management believes the consolidated financial statements included in this Annual Report on Form 10-K fairly represent in all material respects our financial condition, results of operations and cash flows at and for the periods presented in accordance with U.S. GAAP.

#### **Remediation of Material Weaknesses**

We are in the process of implementing improvements and remedial measures in response to the material weaknesses. During fiscal year 2019, we have continued to engage with a third-party consulting firm to help us to assess our current internal controls over financial reporting against COSO 2013. They have completed specific gap analysis, suggested improvements in controls, and assisted us in testing our control systems. They have completed specific testing of our IT general controls, purchasing processes, payment processes and month end closing procedures. Their recommendations have led to a number of the actions below, and we will continue to work with them through fiscal year 2020 to complete formal testing of the revised procedures. Key actions taken in fiscal year 2019 to remediate the identified weaknesses are detailed below:

- The Company has increased the size of the finance function and restructured responsibilities to ensure greater segregation of duties within the purchase to pay process.
- Greater visibility of bank transactions and enhanced use of the accounting system are allowing more accurate and efficient debt management.
- The addition of an assistant management accountant in October 2018, allows better segregation of duties within the month end process.
- Balance sheets are reconciled on a monthly basis to ensure controls are working correctly.
- The Company continues to look at the development of the existing accounting system.
- IT processes have been strengthened and controls implemented around user access and systems installation.
- An engagement letter has been signed with a specialized third-party provider for the provision of technical guidance on accounting for specialized transactions such as the December 2018 Public offering and related costs.
- During this financial year, the Company has strengthened internal controls over related party transactions by putting in place a service contract between Nemaura Pharma and the Company. All costs are now invoiced between the two parties on a monthly basis, and outstanding balances are reported as a disclosure in the guarterly reporting.
- Continuing to develop and formalize the activities of the audit committee. The committee will be helped by an outsourced internal audit department to review our internal control processes, policies and procedures to ensure compliance with the Sarbanes-Oxley Act of 2002.

In order to build on the work done in fiscal year 2019, in fiscal year 2020 we intend to take the following actions:

- Assembling a team from our finance department to be responsible for the preparation of financial statements under U.S. securities laws, including hiring additional gualified personnel such as a CFO with US listed company experience.
- The Company intends to continue to strengthen controls through enhanced use of our accounting system and further strengthening of standard processes and procedures.
- Requiring our finance personnel to participate in regular US GAAP training courses;
- Continued testing of the operating effectiveness of the controls that have been identified and implemented in order to prevent misstatement
  of the financial statements. In addition, the Company will focus on the design and implementation of Key Performance Indicators (KPIs) to
  measure the quality of the processes in place, and the efficiency of the controls.
- As the SugarBeat product reaches the commercialization stage, new processes such as stock management and revenue recognition will
  come into scope. We intend to take external advice as required to ensure that processes implemented are sufficient to ensure compliance
  with the Sarbanes-Oxley Act of 2002.

# ITEM 9B. OTHER INFORMATION.

None.

#### **PART III**

# ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE.

The following persons are our executive officers and directors, and hold the positions set forth opposite their respective names as of the date hereof.

Name	Age	Position	Date of Appointment
Dewan Fazlul Hoque	46	Chief Executive Officer,	December 24, 2013
Chowdhury		Interim Chief Financial	
		Officer, President and	
		Director	
Bashir Timol	44	Director	December 24, 2013
		Chief Business Officer	April 9, 2018
Thomas Moore	55	Independent Director	August 3, 2017
Dr. Salim Natha	52	Independent Director	July 26, 2017
Timothy Johnson	35	Independent Director	July 17, 2017

Our directors hold office until the earlier of their death, resignation or removal or until their successors have been qualified.

**Dewan Fazlul Hoque Chowdhury.** Dr. D.F. Chowdhury has been our President, Chief Executive Officer and a member of our board of directors since our incorporation on January 20, 2009. Dr. D.F. Chowdhury is also currently acting as interim Chief Financial Officer. He is in charge of research and development of our core technologies, product development, innovation and commercialization. He also coordinates and oversees legal compliance; development of the company mission; policy and planning. Prior to establishing the Company, Dr. D.F. Chowdhury was the founder and CEO of Microneedle Technologies and Nemaura Pharma Limited where he played a pivotal role in the development, manufacture and launch of a microneedle device used in skin clinics, which is also currently being evaluated for skin cancer drug delivery. Dr. D.F. Chowdhury has been responsible for negotiating licensing deals for a transdermal patch to treat Alzheimer's disease. Additionally, he was involved in negotiations for out-licensing patches to treat Parkinson's and Hypertension, and in-licensing complementary technologies.

Dr. D.F. Chowdhury originally trained as a pharmaceutical scientist and has an MSc in Microsystems and Nanotechnology from Cranfield University, and a Doctorate from the University of Oxford on nano-drug delivery. His experience in the Pharmaceutical Industry includes product development; manufacturing; and technical and corporate management.

**Bashir Timol**. Mr. Timol has been a Director since Nemaura Medical Inc. was organized on December 24, 2013. He has been a director of Dermal Diagnostics Limited from October 30, 2013. On April 9, 2018 Mr Timol was appointed to the role of Chief Business Officer. Mr. Timol possesses over 10 years' experience in food and beverage, franchise, and logistic operations. His experience includes constructing sales contracts and having the responsibility for overseeing the key managers in the operation of a large scale retail food chain. He has experience as an entrepreneur investing in and operating a number of retail food chains in the UK, including DIXY Chicken and Costa Coffee. Prior to joining Nemaura Mr. Timol has been employed as a director at SABT 1 Ltd. since March of 2009 and One-E Group since January of 2007. Mr. Timol holds a bachelor degree in Economics from the University of Central Lancashire, UK.

**Timothy Johnson**. Mr. Johnson was elected as a director in July 2017. He is currently serving in executive positions in Diagnostax advisory, EQIQ. Mr. Johnson received his first class Masters of Science in Mathematics and Physics from the University of Manchester, UK.

**Dr. Salim Natha.** Dr. Natha was elected as a director in July 2017. He is currently practicing as an Eye Surgeon in the UK National Health Service (NHS), and is the clinical lead for a retinopathy screening program for over 20,000 diabetics in the Ashton, Wigan and Leigh region. He has published several articles in the medical literature and is a peer reviewer for the English National Diabetic Retinopathy Screening Program. Dr. Natha graduated with honors from the University of Liverpool Medical School.

**Thomas Moore.** Mr. Moore was elected as a director in August 2017. He is currently working as a management consultant, having built up three decades of experience in accounting and consulting fields at leading accounting firms including Grant Thornton, KPMG and PricewaterhouseCoopers. He is a practicing Chartered Tax Adviser and earned his first class Bachelor of Arts in French and Russian from the University of Northumbria, UK.

#### Family Relationships

There are no family relationships between any of our directors or executive officers.

# Involvement in Certain Legal Proceedings.

None.

#### **Board of Directors**

All directors hold office until the next Annual Meeting of shareholders and until their successors have been duly elected and qualified. Directors are elected at the annual meetings to serve for one-year terms. Officers are elected by, and serve at the discretion of, the Board of Directors. Our Board of Directors shall hold meetings on at least a quarterly basis.

The Board of Directors complies with the NASDAQ Listing Rules with respect to corporate governance matters. Under the NASDAQ rules we are required to maintain a board of directors comprised of at least 50% independent directors, and an audit committee of at least two members, comprised solely of independent directors who also meet the requirements of Rule 10A-3 under the Securities Exchange Act of 1934.

# **Director Independence**

The board of directors has reviewed the independence of our directors, applying the NASDAQ independence standards. Based on this review, the board of directors determined that each of Thomas Moore, Dr. Salim Natha and Timothy Johnson are independent within the meaning of the NASDAQ rules. In making this determination, our board of directors considered the relationships that each of these non-employee directors has with us and all other facts and circumstances our board of directors deemed relevant in determining their independence. As required under applicable NASDAQ rules, we anticipate that our independent directors will meet on a regular basis as often as necessary to fulfil their responsibilities, including at least annually in executive session without the presence of non-independent directors and management.

## **Board Committees**

Our board of directors has established standing committees in connection with the discharge of its responsibilities. These committees include an Audit Committee, a Compensation Committee and a Nominating and Corporate Governance Committee. Our board of directors has adopted written charters for each of these committees. Copies of the charters are available on our website. Our board of directors may establish other committees as it deems necessary or appropriate from time to time.

# **Audit Committee**

Our Audit Committee was established on July 26, 2017 and is comprised of our independent directors: Thomas Moore, Dr. Salim Natha and Timothy Johnson. Mr. Johnson qualifies as the Audit Committee financial expert as defined in Item 407(d)(5) of Regulation S-K promulgated under the Securities Act.

According to its charter, the Audit Committee consists of at least three members, each of whom shall be a non-employee director who has been determined by the Board to meet the independence requirements of NASDAQ, and also Rule 10A-3(b)(1) of the SEC, subject to the exemptions provided in Rule 10A-3(c). The Audit Committee Charter describes the primary functions of the Audit Committee, including the following:

- Oversee the Company's accounting and financial reporting processes;
- Oversee audits of the Company's financial statements;
- Discuss policies with respect to risk assessment and risk management, and discuss the Company's major financial risk exposures and the steps management has taken to monitor and control such exposures;

- Review and discuss with management the Company's audited financial statements and review with management and the Company's independent registered public accounting firm the Company's financial statements prior to the filing with the SEC of any report containing such financial statements.
- Recommend to the board that the Company's audited financial statements be included in its annual report on Form 10-K for the last fiscal year;
- Meet separately, periodically, with management, with the Company's internal auditors (or other personnel responsible for the internal audit function) and with the Company's independent registered public accounting firm;
- Be directly responsible for the appointment, compensation, retention and oversight of the work of any independent registered public accounting firm engaged to prepare or issue an audit report for the Company;
- Take, or recommend that the board take, appropriate action to oversee and ensure the independence of the Company's independent registered public accounting firm; and
- Review major changes to the Company's auditing and accounting principles and practices as suggested by the Company's independent registered public accounting firm, internal auditors or management.

#### **Compensation Committee**

The Compensation Committee is responsible for, among other matters:

- reviewing and approving, or recommending to the board of directors to approve the compensation of our CEO and other executive officers and directors reviewing key employee compensation goals, policies, plans and programs;
- administering incentive and equity-based compensation;
- reviewing and approving employment agreements and other similar arrangements between us and our executive officers; and
- appointing and overseeing any compensation consultants or advisors.

Our Compensation Committee was established on July 26, 2017, and currently consists of Thomas Moore, Dr. Salim Natha and Timothy Johnson. Dr. Salim Natha serves as chair of the Compensation Committee.

# **Corporate Governance and Nominating Committee**

The Corporate Governance and Nominating Committee is responsible for, among other matters:

- selecting or recommending for selection candidates for directorships;
- evaluating the independence of directors and director nominees;
- reviewing and making recommendations regarding the structure and composition of our board and the board committees;
- developing and recommending to the board corporate governance principles and practices;
- reviewing and monitoring the Company's Code of Ethics; and
- overseeing the evaluation of the Company's management.

Our Corporate Governance and Nominating Committee was established on July 26, 2017, and currently consists of Thomas Moore, Dr. Salim Natha and Timothy Johnson. Mr. Johnson serves as chair of the Corporate Governance and Nominating Committee.

#### Material Changes to Procedures by which Security Holders May Recommend Board Nominees

None.

## Board Leadership Structure and Role in Risk Oversight

Dr. Chowdhury holds the positions of chief executive officer, interim chief financial officer, and chairman of the board of the Company. The board believes that Dr. Chowdhury's services as both chief executive officer, chairman of the board and interim Chief Financial Officer is in the best interest of the Company and its shareholders. Dr. Chowdhury possesses detailed and in-depth knowledge of the issues, opportunities and challenges facing the Company in its business and is thus best positioned to develop agendas that ensure that the Board's time and attention are focused on the most critical matters relating to the business of the Company. His combined role enables decisive leadership, ensures clear accountability, and enhances the Company's ability to communicate its message and strategy clearly and consistently to the Company's shareholders, employees and customers.

The board has not designated a lead director. Given the limited number of directors comprising the Board, the independent directors call and plan their executive sessions collaboratively and, between meetings of the Board, communicate with management and one another directly. Under these circumstances, the directors believe designating a lead director to take on responsibility for functions in which they all currently participate might detract from rather than enhance performance of their responsibilities as directors.

Management is responsible for assessing and managing risk, subject to oversight by the board of directors. The board oversees our risk management policies and risk appetite, including operational risks and risks relating to our business strategy and transactions. Various committees of the board assist the board in this oversight responsibility in their respective areas of expertise.

- The Audit Committee assists the board with the oversight of our financial reporting, independent auditors and internal controls. It is charged with identifying any flaws in business management and recommending remedies, detecting fraud risks and implementing antifraud measures. The audit committee further discusses Nemaura's policies with respect to risk assessment and management with respect to financial reporting.
- The Compensation Committee oversees compensation, retention, succession and other human resources-related issues and risks.
- The Corporate Governance and Nominating Committee overviews risks relating to our governance policies and initiatives.

#### Delinquent Section 16(a) Reports

To the Company's knowledge, based solely on a review of copies of such reports furnished to the Company during and/or with respect to year ended March 31, 2019, the Company is not aware of any delinquent filings required under Section 16(a) of the Exchange Act.

## Code of Ethics

We have adopted a Code of Ethics that applies to our principal executive officer, principal financial officer and other persons performing similar functions. A copy of our Code of Ethics is available on our website. We intend to post amendments to, or waivers from a provision of, our Code of Ethics that apply to our principal executive officer, principal financial officer or persons performing similar functions on our website.

#### ITEM 11. EXECUTIVE COMPENSATION.

## **Summary Compensation Table**

This table provides disclosure, for fiscal years 2019 and 2018, of the compensation paid to our named executive officers.

Named Executive Officer				All Other	
and Principal Position	Year	Salary	Bonus	Compensation	Total
		\$	\$	\$	\$
Dr. D.F.H. Chowdhury Chief Executive Officer					
(Principal Executive Officer) Interim Chief					
Financial Officer (Interim Principal Financial and					
Accounting Officer)	2019	104,208	_	1,050	105,208
	2018	106,440	_	390	106,830
lain Anderson					
Chief Financial Officer (Principal Financial					
Officer)*	2019	52,178	_	737	52,915
	2018	57,938	_	297	58,235

<sup>\*</sup> Mr. Anderson resigned effective immediately on February 8, 2019.

## Dr. D.F. Chowdhury

We entered into an employment agreement with Dr. D.F. Chowdhury on November 2, 2013. Dr. D.F. Chowdhury's contract is for an unspecified period. He may leave the Company with notice or the Company may terminate his contract with notice. Termination may be with or without cause. Dr. D.F. Chowdhury receives an annual salary of £80,000 pounds sterling or \$104,000 USD. Our contract with Dr. D.F. Chowdhury does not include any provision for stock options or equity incentives.

Under the executive employment agreement Dr. D.F. Chowdhury's annual salary was adjusted on a pro rata basis to reflect only work that was performed for Nemaura Medical Inc. The disclosure set forth in the table reflects his pro rata compensation from April 1, 2017 through March 31, 2019.

#### Mr. Anderson

We did not have a written employment contract with our Chief Financial Officer, Iain Anderson. Mr Anderson had an annual salary of £100,000 (approximately \$143,000). These amounts have been prorated for the 2018 and 2019 fiscal years based on actual time working for the Company. Our contract with Mr. Anderson did not include any provision for stock options or equity incentives. Mr. Anderson resigned from his position as Chief Financial Officer on February 8, 2019 and left the company with immediate effect.

## **Outstanding Equity Awards for 2019**

We have not currently granted any stock based compensation to employees of the Company.

## Potential payments upon termination or change-in-control.

None. Upon termination by us or Dr D.F.H.. Chowdhury, officers shall only be entitled to receive their base salary through the date of termination

#### **Director Compensation**

Each of our independent directors receive annual fees of £5,000 pounds sterling or \$6,513 USD for their service on our board of directors and committees. We currently have no plan for compensating our executive directors for their services in their capacity as directors. Although we have agreements with each of our independent directors to serve on our board, in which we provide for the grant of options, at this time no such option grants have been made and no equity compensation plan has been approved.

Name	Fees Earned or paid in Cash (\$US)	Non-Equity Incentive Plan Compensation (\$US)	All other Compensation (\$US)	Total (\$US)
Timothy Johnson	6,513			6,513
Dr. Salim Natha	6,513	<del>-</del>	<del>_</del>	6,513
Thomas Moore	6,513	_	_	6,513

## Compensation Committee Interlocks and Insider Participation

No member of our Compensation Committee has at any time been an officer or employee of ours or our subsidiaries. No interlocking relationship exists between our Board of Directors or Compensation Committee and the Board of Directors or Compensation Committee of any other company, nor has any interlocking relationship existed in the past.

# ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCK HOLDER MATTERS.

The following tables set forth certain information as of March 31, 2019 regarding the beneficial ownership of our Common Stock, by (i) each person or entity who, to our knowledge, owns more than 5% of our Common Stock; (ii) our executive officers; (iii) each director; and (iv) all of our executive officers and directors as a group.

Unless otherwise indicated in the footnotes to the following table, each person named in the table has sole voting and investment power and that person's address is c/o NEMAURA MEDICAL INC., Advanced Technology Innovation Centre, 5 Oakwood Drive, Loughborough, Leicestershire, United Kingdom LE11 3QF.

## **Beneficial Ownership**

		Percentage
Name of Beneficial Owner	<b>Shares Beneficially Owned</b>	Total Voting Power <sup>1</sup>
Dr. D.F.H. Chowdhury	87,537,000	42%
Bashir Timol	27,082,100	13%
Timothy Johnson	_	_
Dr. Salim Natha	4,193,889	2%
Thomas Moore	_	_
Total Officers and Directors as a Group	118,812,989	57%
Holders of 5% or more of our Common Stock		
Ismail, Sufyan	22,705,250	11%

<sup>&</sup>lt;sup>1</sup> Based upon 207,655,916 shares of our Common Stock outstanding at March 31, 2019.

## ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE.

Nemaura Pharma Limited (Pharma) and NDM Technologies Limited (NDM) are entities controlled by our Chief Executive Officer, President, Chairman of the Board and majority shareholder, Dr. D.F.H. Chowdhury.

Pharma has invoiced our subsidiaries, Dermal Diagnostics Limited (DDL) and Trial Clinical Limited (TCL) for research and development services. In addition, certain operating expenses of DDL and TCL were incurred and paid by Pharma and NDM which have been invoiced to us. Certain costs incurred by Pharma and NDM are directly attributable to DDL and TCL and such costs were billed to us.

Total costs charged to us by Pharma and NDM were \$2,312,412 for the year ended March 31, 2019.

Following is a summary of activity between the Company and Pharma and NDM for the years ended March 31, 2019 and 2018. These amounts are unsecured, interest free, and payable on demand.

	Year Ended March 31, 2019 (\$)	Year Ended March 31, 2018 (\$)
Balance due from Pharma and NDM at beginning of year	613,818	687,609
Amounts received from Pharma	_	145,214
Amounts invoiced by Pharma to DDL, NM and TCL (1)	2,312,412	842,739
Amounts invoiced by DDL to Pharma	(977)	_
Amounts repaid by DDL to Pharma	(1,569,496)	(1,096,767)
Amounts paid by DDL on behalf of Pharma	_	(19,889)
Amounts invoiced by B&W to DDL	2,206	_
Amounts repaid by DDL to B&W	(5,622)	_
Foreign exchange differences	(84,843)	54,912
Forgiveness of debt by a related party transferred to APIC	(302,819)	
Net balance due to Pharma and NDM at end of the year	964,679	613,818

(1) These amounts are included primarily in research and development expenses.

## REVIEW, APPROVAL OR RATIFICATION OF TRANSACTIONS WITH RELATED PERSONS

It is Company policy to not enter any transaction (other than compensation arrangements in the ordinary course) with any director, executive officer, employee, or principal stockholder or party related to them, unless authorized by a majority of the directors having no interest in the transaction, upon a favourable recommendation by the Audit Committee (or a majority of its disinterested members).

## ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The following table sets forth the aggregate fees billed to us for the fiscal years ended March 31, 2019 and 2018 by Crowe LLP and Mayer Hoffman McCann P.C.

## Fees relating to Crowe LLP

	2019	2018
Audit Fees	\$ 40,000	\$ 106,000
Audit Related Fees	\$ 107,719	\$ _
Tax Fees	\$ _	\$ 6,765
Other Fees	\$ _	\$ _
Totals	\$ 147,719	\$ 112,765

## Fees relating to Mayer Hoffman McCann P.C.

	2019	2018
Audit Fees	\$ 98,000	\$ _
Audit Related Fees	\$ 88,850	\$ 
Tax Fees	\$ 10,000	\$ _
Other Fees	\$ _	\$ _
Totals	\$ 196,850	\$ _

Audit fees represent amounts billed for professional services rendered or expected to be rendered for the audit of our annual financial statements.

Audit-related fees represent professional services rendered or expected to be rendered for assurance and related services by the accounting firm that are reasonably related to the performance of the audit or review of our financial statements that are not reported under audit fees.

Tax fees represent professional services rendered by the accounting firm for tax compliance.

The Audit Committee approves all auditing services and the terms thereof and non-audit services (other than non-audit services published under Section 10A(g) of the Exchange Act or the applicable rules of the SEC or the Pubic Company Accounting Oversight Board) to be provided to us

by the independent auditor; provided, however, the pre-approval requirement is waived with respect to the provisions of non-audit services for us if the "de minimus" provisions of Section 10A(i)(1)(B) of the Exchange Act are satisfied.

## **Audit Committee Pre-Approval Policy**

Under provisions of the Sarbanes-Oxley Act of 2002, our principal accountant may not be engaged to provide non-audit services that are prohibited by law or regulation to be provided by it, and the Audit Committee must pre-approve the engagement of the our principal accountant to provide audit and permissible non-audit services. The Audit Committee has not established any policies or procedures other than those required by applicable laws and regulations.

Our independent auditors, Mayer Hoffman McCann P.C., leases substantially all of its personnel who work under the control of Mayer Hoffman McCann P.C shareholders, from wholly owned subsidiaries of CBIZ, Inc., in an alternative practice structure.

# **PART IV**

# ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES.

(a) Exhibits:

Exhibit No.	Description
3.1	Articles of Incorporation December 24, 2013 (Incorporated by reference from the registrant's registration statement on
	Form S-1 (File No. 333-194857))
3.1(a)	Certificate of Amendment to the Articles of Incorporation Incorporated by reference from the registrant's Annual Report on
511 (a)	Form 10-K for the fiscal year ended March 31, 2018, filed June 12, 2018)
3.2	Certificate of Designation for Series A Convertible Preferred Stock (Incorporated by reference from the registrant's Annual Report on Form 10-K for the fiscal year ended March 31, 2018, filed with the SEC on June 12, 2018)
	1.0ps/1.017-0111-10-11-10-11-10-11-00-11-01-11-01-0
3.3	Bylaws (incorporated by reference from the Registrant's Registration Statement on Form S-1 (File No. 333-194857), filed
	<u>March 28, 2014)</u>
3.4	Amended and Restated Company By-laws (Incorporated by reference from the registrant's Annual Report on Form 10-K
	for the fiscal year ended March 31, 2018, filed June 12, 2018)
4.1	Form of Subscription Agreement (incorporated by reference from the Registrant's Current Report on Form 8-K filed on
	December 2, 2015)
4.2	Common Stock Purchase Warrant by and between Nemaura Medical, Inc. and Dr. Dallas John Burston, dated November 26, 2015 (Incorporated by reference from the registrant's Current Report on Form 8-K filed with the SEC on December 2,
	2015
4.3*	Description of Registrant's Securities
10.1	Employment Agreement dated November 1, 2013 between the Company and Dewan F.H. Chowdhury (incorporated by
	reference from the Registrant's Registration Statement on Form S-1 (File No. 333-194857), filed March 28, 2014)
10.2	Exclusive Rights License Agreement between Dallas Burston Pharma (DBP) Jersey Limited and Dermal Diagnostics
10.2	Limited, dated March 31, 2014 (incorporated by reference from the Registrant's Registration Statement on Form S-1 (File
	No. 333-194857), filed July 11, 2014)
10.3	Assignment Agreement between NDM Technologies Limited and Dermal Diagnostics Limited, dated May 8, 2014
	(incorporated by reference from the Registrant's Registration Statement on Form S-1 (File No. 333-194857), filed July 30,
	<u>2014)</u>
10.4	Assignment Agreement between Nemaura Pharma Limited and Dermal Diagnostics Limited, dated May 8, 2014
	(incorporated by reference from the Registrant's Registration Statement on Form S-1 (File No. 333-194857), filed July 30,
	<u>2014)</u>
10.5+	License, Supply and Distribution Agreement (incorporated by reference from the Registrant's Current Report on Form 8-K
	filed on December 2, 2015)
10.6	Form of Common Stock Exchange Agreement (incorporated by reference from the Registrant's Current Report on Form 8-
10.6	K filed on November 7, 2017)
10.7+	Joint Collaboration Agreement', between Dallas Burston Ethitronix (Europe) Limited and Nemaura Medical Inc., dated May 21, 2018 (incorporated by reference from the Registrant's Current Report on Form 8-K filed on May 25, 2018)
	21, 2016 (incorporated by reference from the negistrant's Current neport on Form 6-K lifed on May 25, 2016)
14.1	Code of Ethics adopted by the Board of Directors (incorporated by reference from the Registrant's Registration Statement
	on Form S-1 (File No. 333-194857), filed March 28, 2014)
21.1*	<u>Subsidiaries</u>
23.1*	Consent of Crowe LLP
23.2*	Consent of Mayer Hoffman McCann P.C.

31.1*	Rule 13a-14(a)/15d-14(a) - Certification of Chief Executive Officer
31.2*	Rule 13a-14(a)/15d-14(a) - Certification of Interim Chief Financial Officer
32.1*	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2*	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101	Interactive data files pursuant to Rule 405 of Regulation S-T: (i) the Balance Sheets, (ii) the Statements of Comprehensive
	Loss, (iii) Statements of Stockholders Equity, (iv) the Statement of Cash Flows and (v) the Notes to the Financial
	Statements

<sup>· \*</sup>Filed herewith

 $<sup>\</sup>cdot$  +Portions of this Exhibit have been omitted pursuant to a request for confidential treatment.

## **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 on June 14, 2019 by the undersigned thereunto duly authorized.

## **NEMAURA MEDICAL INC.**

By: /s/ Dr D.F.H, Chowdhury

Dr D.F.H, Chowdhury

President, Chief Executive Officer (Principal Executive Officer) and

Interim Chief Financial Officer

Pursuant to the requirements of the Securities and Exchange Act of 1934, this Report has been signed below by the following persons on behalf of the Registrant on xxx , 2019, in the capacities indicated.

Signature	Title	Date		
/s/ D.F.H, Chowdhury	President, Chief Executive Officer (Principal Executive Officer) Interim Chief Financial Officer	June 14, 2019		
D.F.H, Chowdhury				
/s/ B. Timol	Director	June 14, 2019		
B. Timol				
/s/ T. Johnson	Independent Director	June 14, 2019		
T. Johnson				
/s/ S. Natha	Independent Director	June 14, 2019		
S. Natha				
/s/ Thomas Moore	Independent Director	June 14, 2019		
Thomas Moore				

#### Capital Stock

#### General

The following descriptions of common and preferred stock summarizes the material terms and provisions of our common stock and preferred stock, but is not intended to be complete. For the full terms of our common and preferred stock, please refer to our articles of incorporation, as amended from time to time, and our bylaws, as amended from time to time. The Nevada Revised Statutes may also affect the terms of these securities.

As of March 31, 2019, our authorized capital stock consists of 420,000,000 shares of common stock, par value \$0.001 per share, of which 207,655,916 shares were issued and outstanding as of March 31, 2019, and 200,000 shares of preferred stock, par value \$0.01, of which no shares were issued and outstanding as of March 31, 2019. The authorized and unissued shares of both common and preferred stock are available for issuance without further action by our stockholders, unless such action is required by applicable law, the NASDAQ Capital Market, or the rules of any other stock exchange on which our securities may be listed. Unless approval of our stockholders is so required, our board of directors will not seek stockholder approval for the issuance and sale of either our common stock or preferred stock.

#### Common Stock

The holders of our common stock are entitled to one vote per share. Any action required to be taken by the holders of our common stock at a meeting may, without prior notice, by taken by written consent in lieu of a meeting if the consent has been signed by the minimum number of holders of common stock required to approve such action.

In addition, the holders of our common stock will be entitled to receive ratably such dividends, if any, as may be declared by our board of directors out of legally available funds; however, the current policy of our board of directors is to retain earnings, if any, for operations and growth. Upon liquidation, dissolution or winding-up, the holders of our common stock will be entitled to share ratably in all assets that are legally available for distribution. The holders of our common stock will have no pre-emptive, subscription, redemption or conversion rights. The holders of our common stock do not have cumulative rights in the election of directors. The rights, preferences and privileges of holders of our common stock are subject to, and may be adversely affected by, the rights of the holders of our preferred stock.

Our common stock is listed on the NASDAQ Capital Market under the symbol "NMRD." The transfer agent and registrar for our common stock is Island Stock Transfer, Inc. Its address is 15500 Roosevelt Blvd., Suite 301, Clearwater, FL 33760, and its telephone number is 727-289-0010.

## Preferred Stock

Our board of directors may determine, in its sole discretion, the powers, designations, preferences, and relative participation, optional or other rights, if any, and the qualifications, limitations or restrictions thereof, including dividend rights, conversion rights, voting rights, redemption rights, liquidation preference, sinking fund terms and the number of shares. The rights, preferences, privileges and restrictions of the preferred stock of each series will be fixed by the certificate of designation relating to that series.

In October 2017, we filed with the Nevada Secretary of State a Certificate of Designation for up to 200,000 shares of Series A convertible preferred stock. The holders of the Series A preferred stock have rights superior to the holders of our common stock as to the distributions of assets upon our liquidation, dissolution or winding up, whether voluntary or involuntary. The Series A convertible preferred stock shall automatically convert to shares of common stock at a ratio of 1000-for-1, i.e. each share of Series A preferred stock shall convert into 1000 shares of common stock, when the following conditions are met: (a) the sugarBEAT® device has received CE regulatory approval; (b) retail sales of sugarBEAT® have commenced and (c) such retail sales have exceeded \$5 million. Holders of Series A preferred stock may voluntarily convert their shares after February 7, 2018 at the conversion ratio then in effect, subject to adjustment for any stock splits, combinations, dividends, distributions, or mergers and acquisitions.

The holders of the Series A convertible preferred stock are entitled to vote, as a class, on matters on all matters voted on by the holders of our common stock. Each share of Series A convertible preferred stock is entitled to that number of votes equal to the number of shares of common stock the Series A preferred stock is convertible into at the time the vote is taken. The holders of the Series A convertible preferred stock shall also vote, as a class, on all matters that may adversely impact their rights and preferences. The Series A convertible preferred stock is not eligible for dividend payments and we have no right to redeem these preferred shares. Holders of the Series A convertible preferred stock may transfer their shares without our consent.

As of March 31, 2019, there were no shares of Series A convertible preferred stock issued and outstanding.

With respect to any future series of preferred stock to be authorized, we will file a certificate of designation with the Secretary of State of the State of Nevada that will specify the following: the maximum number of shares; the designation of the shares; the annual dividend rate, if any, and whether the dividend is fixed or variable; the price and terms and conditions for redemption, if any; the liquidation preference, if any; any sinking fund or similar provision; the terms and conditions, if any, for conversion and exchange of the preferred stock into any other class or classes of our capital stock or any other of our securities or assets; and voting rights.

The future issuance of shares of preferred stock will affect, perhaps adversely, the rights of holders of our common stock. While we cannot state

the actual effects of such issuance until our board of directors determines the specific rights attached to the preferred stock to be issued, these effects could include: restricting dividends on the common stock; diluting the voting power of the common stock; impairing the liquidation rights of our common stock; and delaying or preventing changes in our control or management.

As of March 31, 2019, we had warrants outstanding to purchase 10,000,000 and 1,880,704 shares of our common stock at exercise prices of \$0.50 per share and \$1.04 per share, respectively. The warrants will terminate on the five-year anniversary of the date of issuance.

# **SUBSIDIARIES**

Region Green Limited

**Dermal Diagnostics (Holdings) Limited** 

**Dermal Diagnostics Limited** 

**Trial Clinic Limited** 

# CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement #333-230535 on Form S-3 of Nemaura Medical Inc. of our report dated June 12, 2018, on the consolidated balance sheet of Nemaura Medical Inc. as of March 31, 2018 and the related consolidated statements of comprehensive loss, changes in stockholders' equity (deficit) and cash flows for each of the two years in the period ended March 31, 2018, which appears in this Annual Report on Form 10-K.

/s/ Crowe LLP

Oak Brook, Illinois June 14, 2019



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# CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

As an independent registered public accounting firm, we hereby consent to the incorporation by reference in Nemaura Medical Inc.'s Registration Statement on Form S-3 (File No. 333-230535) of our report dated June 14, 2019, with respect to the consolidated financial statements of Nemaura Medical Inc., as of March 31, 2019 and for the year then ended included in this Annual Report on Form 10-K of Nemaura Medical Inc. for the year ended March 31, 2019.

/s/ Mayer Hoffman McCann P.C.

June 14, 2019 Denver, Colorado

#### CERTIFICATION

- I, Dr. D.F.H. Chowdhury, certify that:
- 1. I have reviewed this Annual Report on Form 10-K of Nemaura Medical Inc. and its subsidiaries;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 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 fourth fiscal quarter 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 14, 2019 By: /s/ Dr. D.F.H. Chowdhury

Name: Dr. D.F.H. Chowdhury

Title: Chief Executive Officer (Principal Executive Officer)

#### CERTIFICATION

- I, Dr. D.F.H Chowdhury, certify that:
- 1. I have reviewed this Annual Report on Form 10-K of Nemaura Medical Inc. and its subsidiaries;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report:
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 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 fourth fiscal quarter 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 14, 2019 By: /s/ Dr. D.F.H. Chowdhury

Name: Dr. D.F.H. Chowdhury

Title: Interim Chief Financial Officer (Principal Financial and Accounting

Officer)

# WRITTEN STATEMENT PURSUANT TO 18 U.S.C. SECTION 1350

In connection with Annual Report of Nemaura Medical Inc. and its subsidiaries (the "Company") on Form 10-K for the year ended March 31, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Dr. D.F.H. Chowdhury, Chief Executive Officer (Principal Executive Officer) of the Company, certifies, 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 13a-14(b) or 15d-14(b) 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.

Dated: June 14, 2019 By: /s/ Dr. D.F.H. Chowdhury

Name: Dr. D.F.H. Chowdhury

Title: Chief Executive Officer (Principal Executive Officer)

# WRITTEN STATEMENT PURSUANT TO 18 U.S.C. SECTION 1350

In connection with Annual Report of Nemaura Medical Inc. and its subsidiaries (the "Company") on Form 10-K for the year ended March 31, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Dr. D.F.H. Chowdhury, Interim Chief Financial Officer (Principal Financial Officer) of the Company, certifies, 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 13a-14(b) or 15d-14(b) 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.

Dated: June 14, 2019 By: /s/ Dr. D. F.H. Chowdhury

Name: Dr. D. F.H. Chowdhury

Title: Interim Chief Financial Officer (Principal Financial Officer)