

SECURITIES & EXCHANGE COMMISSION EDGAR FILING

Nemaura Medical Inc.

Form: 8-K

Date Filed: 2020-08-19

Corporate Issuer CIK: 1602078

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): **August 19, 2020**

NEMAURA MEDICAL INC.

(Exact name of registrant as specified in its charter)

Nevada

(State or other jurisdiction of
incorporation or organization)

001-38355

(Commission
File Number)

46-5027260

(I.R.S. Employer
Identification Number)

57 West 57th Street
Manhattan, NY

(Address of principal executive offices)

10019

(Zip Code)

Registrant's telephone number, including area code:

(646) 416-8000

N/A

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	NMRD	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

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

Item 7.01. Regulation FD Disclosure.

On August 19, 2020, Nemauro Medical Inc. (the "Company") issued a press release and presentation outlining how continuous glucose monitoring is being used by quarantined and hospitalized COVID-19 patients. Copies of the press release and presentation are attached as Exhibits 99.1 and 99.2, respectively, to this Current Report on Form 8-K.

The information included in this Current Report on Form 8-K, including Exhibits 99.1 and 99.2, shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall such information be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing. The information set forth under this Item 7.01 shall not be deemed an admission as to the materiality of any information in this Current Report on Form 8-K that is required to be disclosed solely to satisfy the requirements of Regulation FD.

DISCLOSURE REGARDING FORWARD-LOOKING STATEMENTS

Certain statements contained in this Current Report on Form 8-K, including on Exhibits 99.1 and 99.2 hereto, that are not historical facts constitute forward-looking statements, within the meaning of the Private Securities Litigation Reform Act of 1995. 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 the Company's 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 the Company believes are appropriate in the circumstances. Factors which could cause actual results to differ from expectations, many of which are beyond the Company'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 in the Company's filings with the Securities and Exchange Commission, including in the "Risk Factors" section of the Company's Annual Report on Form 10-K for the fiscal year ended March 31, 2020. 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 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press release issued by the registrant on August 19, 2020.
99.2	Presentation of the registrant dated August 19, 2020.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: August 19, 2020

NEMAURA MEDICAL INC.

By: /s/ Dewan F. H. Chowdhury

Name: Dewan F. H. Chowdhury

Title: Chief Executive Officer

AUGUST 19, 2020

Nemaura Medical issues Presentation Pertaining to the use of Continuous Glucose Monitoring in COVID-19 Patients

Loughborough, England, August 19, 2020 – Nemaura Medical, Inc. (NASDAQ: NMRD) (“Nemaura” or the “Company”), a medical technology company focused on developing micro-systems-based wearable diagnostic devices and currently commercializing sugarBEAT®, its non-invasive and flexible continuous glucose monitor (“CGM”), together with BEAT™ diabetes, a planned health subscription service designed to help people with Type 2 diabetes and prediabetes through personalized lifestyle coaching, today issued a presentation outlining how CGM is being used by quarantined and hospitalised COVID-19 patients.

The Company has previously reported the uses of continuous lactate measurements for the monitoring of diseases progression in COVID-19 patients. Today the company issued a report outlining how CGM has been used as an effective tool for the monitoring of disease progression in both quarantined and hospitalised COVID-19 patients. This includes improvement in glycaemic control in persons with Type 2 diabetes, monitoring and managing hyperglycaemia in patients with COVID-19, and remote monitoring of glucose levels in hospitalised COVID-19 patients leading to improved quality of care without compromising the safety of medical professionals.

Both the CGM and CLM (continuous lactate monitoring) products are based on Nemaura’s BEAT™ platform, which is designed to non-invasively extract a number of analytes through the skin. By adapting the sensor chemistry, algorithm and mobile app interface initially developed for sugarBEAT®, the BEAT™ platform has the potential to be utilized for several markets beyond glucose monitoring and diabetes. Nemaura is evaluating the timelines for bringing the CLM to market as a Class 2 approved Medical Device, and the CGM device is a CE mark approved Class 2b medical device planned for launch this calendar year in the UK and Germany.

The presentation may be accessed on the link below:

<https://nemauramedical.com/wp-content/uploads/2020/08/Glucose-monitoring-in-Covid19-August.pdf>

About Nemaura Medical, Inc.:

Nemaura Medical Inc. (NMRD) is a medical technology company developing micro-systems-based wearable diagnostic devices and currently commercializing sugarBEAT®, and proBEAT™. sugarBEAT®, a CE mark approved Class IIb medical device, is a non-invasive and flexible continuous glucose monitor (CGM) providing actionable insights derived from real time glucose measurements and daily glucose trend data, which may help people with diabetes and pre-diabetes to better manage, reverse and prevent the onset of diabetes. Nemaura has also submitted a PMA application for sugarBEAT® to the U.S. FDA. proBEAT™ comprises a non-invasive glucose monitor and a digital healthcare subscription service and is due to be launched in the US as a general wellness product.

For more information visit: www.NemauraMedical.com.

Cautionary Statement Regarding Forward-Looking Statements:

The statements in this press release that are not historical facts may constitute forward-looking statements that are based on current expectations and are subject to risks and uncertainties that could cause actual future results to differ materially from those expressed or implied by such statements. Those risks and uncertainties include, but are not limited to, the launch of proBEAT™ in the U.S., risks related to regulatory status and the failure of future development and preliminary marketing efforts, Nemaura's ability to secure additional commercial partnering arrangements, risks and uncertainties relating to Nemaura and its partners' ability to develop, market and sell proBEAT™, the availability of substantial additional equity or debt capital to support its research, development and product commercialization activities, and the success of its research, development, regulatory approval, marketing and distribution plans and strategies, including those plans and strategies related to both proBEAT™ digital health, and sugarBEAT®. There can be no assurance that the company will be able to reach a part of or any of the global market for CGM with its products/services. The FDA reserves the right to re-evaluate their decision that proBEAT™ qualifies as a general wellness product should it become aware of any issues such as skin irritation or other adverse events from the device, as well as any misuse impacting patient safety, and any other reason as the FDA may see fit at its discretion to determine the product does not fit the definition of a general wellness product. These and other risks and uncertainties are identified and described in more detail in Nemaura's filings with the United States Securities and Exchange Commission, including, without limitation, its Annual Report on Form 10-K for the most recently completed fiscal year, its Quarterly Reports on Form 10-Q, and its Current Reports on Form 8-K. Nemaura undertakes no obligation to publicly update or revise any forward-looking statements.

Contacts

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NASDAQ: NMRD

Better Diagnostics for Life

**Continuous Glucose Monitoring
in Hospitalised and Quarantined Patients
with COVID-19**

August 2020

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

- This presentation may contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), that are subject to risks and uncertainties that could cause actual future results to differ materially from those expressed or implied by such statements. All statements, other than statements of historical fact, included in this presentation regarding development of our strategy, future operations, future financial position, projected costs, prospects, plans and objectives of management are forward-looking statements. Forward-looking statements may include, but are not limited to, statements about:
 - any statements of the plans, strategies and objectives of management for future operations;
 - any statements concerning proposed new products, services or developments;
 - any statements regarding future economic conditions or performance;
 - our ability to protect our intellectual property and operate our business without infringing upon the intellectual property rights of others;
 - our estimates regarding the sufficiency of our cash resources and our need for additional funding;
 - any statement that our business, financial condition and results of operations may be materially adversely affected by global health epidemics, including the recent COVID-19; and
 - any statement regarding the effectiveness of our continuous temperature monitoring system to assist with the diagnosis and monitoring of symptoms of COVID-19 or the effectiveness of our continuous lactate monitoring system (CLM) to monitor disease progression in COVID-19 patients.
- 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. Forward-looking statements reflect our current views with respect to future events, are based on assumptions and are subject to risks and uncertainties. We cannot guarantee that we actually will achieve the plans, intentions or expectations expressed in our forward-looking statements and you should not place undue reliance on these statements.
- There are a number of important factors that could cause our actual results to differ materially from those indicated or implied by forward-looking statements. These factors and the other cautionary statements made in this presentation should be read as being applicable to all related forward-looking statements whenever they appear herein. These and other risks and uncertainties are identified and described in more detail in our filings with the United States Securities and Exchange Commission, including, without limitation, our Annual Report on Form 10-K for the most recently completed fiscal year, our Quarterly Reports on Form 10-Q, and our Current Reports on Form 8-K. 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.

Authors

- Dr Moiz Khan, *Pharm.D, MBA*
- Stephen Willmor, BSc

Overview

This presentation highlights the potential applications and benefits of Continuous Glucose Monitoring (CGM) in monitoring disease progression and improving outcomes in patients infected with COVID-19.

The following areas have been looked at:

- Recent reports of the effect of monitoring Glucose levels in COVID-19 patients
- Recent report of the usefulness of monitoring Lactate levels in COVID-19 patients
- Monitoring Glucose Levels in hospitalised and quarantined patients

Multi-centred study of 7,337 cases of COVID-19 in Hubei Province, China, among which 952 had pre-existing T2D¹

Table 1. Characteristics of Patients in the Well-Controlled and Poorly Controlled BG Groups Before and After Propensity Score Matching

Parameters	Unmatched		SD	Matched (1:1)		SD
	Well Controlled (n = 282)	Poorly Controlled (n = 528)		Well Controlled (n = 250)	Poorly Controlled (n = 250)	
Clinical Characteristics on Admission						
Age, median (IQR)	62 (55-67)	63 (56-68)	-0.094	62 (55-67)	63 (54-68)	0.008
Male gender, n (%)	136 (48.2%)	298 (56.4%)	-0.165	126 (50.4%)	126 (50.4%)	0.000
Female gender, n (%)	146 (51.8%)	230 (43.6%)	0.165	124 (49.6%)	124 (49.6%)	0.000
Heart rate, median (IQR), bpm	84.0 (77.0-95.0)	85.0 (76.3-97.0)	-0.103	84.0 (75.5-93.5)	83.0 (76.0-96.0)	-0.048
Respiratory rate, median (IQR), bpm	20.0 (18.0-20.0)	20.0 (19.0-21.0)	-0.180	20.0 (18.0-20.0)	20.0 (19.0-21.0)	0.008
SBP, median (IQR), mmHg	130.0 (120.0-142.0)	130.0 (120.0-142.0)	0.073	130.0 (120.0-142.0)	130.0 (120.0-142.0)	0.085
DBP, median (IQR), mmHg	80.0 (73.0-89.0)	80.0 (72.0-86.0)	0.074	80.0 (73.0-86.5)	80.0 (72.0-86.0)	0.025
Symptom onset to admission, median (IQR), day	13.0 (7.0-23.0)	10.0 (6.0-17.0)	0.261	12.0 (7.0-20.0)	10.0 (6.0-18.8)	0.177
Fever, n (%)	182 (64.5%)	381 (72.2%)	-0.164	166 (66.4%)	171 (68.4%)	-0.043
Cough, n (%)	169 (59.9%)	350 (66.3%)	-0.132	155 (62.0%)	153 (61.2%)	0.016
Fatigue, n (%)	90 (31.9%)	218 (41.3%)	-0.196	87 (34.8%)	90 (36.0%)	-0.025
Dyspnea, n (%)	48 (17.0%)	117 (22.2%)	-0.130	44 (17.6%)	39 (15.6%)	0.054



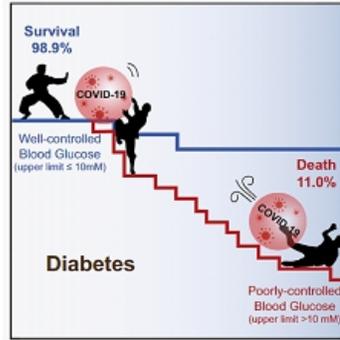
Multi-centred study of 7,337 cases of COVID-19 in Hubei Province, China, among which 952 had pre-existing T2D

Summary:

- Patients with T2D required more medical interventions and had a significantly higher mortality (7.8% versus 2.7%) and multiple organ injury than the non-diabetic individuals
- Well-controlled BG (glycaemic variability within 3.9 to 10.0 mmol/L) was associated with markedly lower mortality compared to individuals with poorly controlled BG (upper limit of glycaemic variability exceeding 10.0 mmol/L) during hospitalization.

Conclusion:

Findings provide clinical evidence correlating improved glycaemic control with better outcomes in patients with COVID-19 and pre-existing T2D.



The Chinese Centre for Disease Control and Prevention: largest case series to date of COVID-19²

Summary

- The Chinese Centre for Disease Control and Prevention published the largest case series to date of coronavirus disease 2019 (COVID-19) in mainland China (72,314 cases).
- The case fatality rate (CFR) was 49.0% among critical cases.
- The CFR was elevated among those with pre-existing comorbid conditions; an increase of 7.3% for patients with diabetes.

Conclusion:

- Persons with diabetes are more at risk of fatality if contracting COVID-19 than general population. As such routine monitoring of blood glucose and better control of diabetes could improve chances of survival.



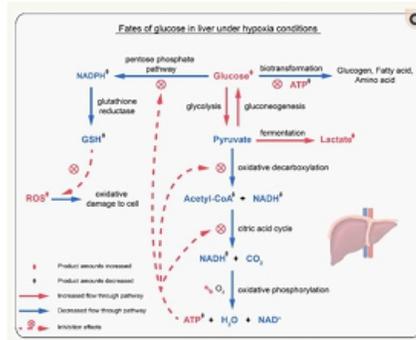
Blood glucose monitoring are crucial for quarantined COVID-19 patients³

Summary:

- Patients critically ill with COVID-19 often have compromised lung function which can result in reduced oxygen levels and hypoxia.
- COVID-19 patients are likely to develop hyperglycaemia under such a persistent state of hypoxia
- Acceleration in the anaerobic glycolysis process of glucose forms large amount of lactate in these cases.

Conclusion:

- Large proportion of COVID-19 patients present with hyperglycaemia and increased blood lactate concentrations along with disease aggravation.
- This study strongly suggests that adequate oxygen intake and blood glucose monitoring should be introduced for patients under home quarantine to manage / monitor their condition and prevent further deterioration.



Sheba Medical Centre - Government Hospital in Israel⁴

Summary:

- The care of diabetic patients with COVID-19 in isolation presents a challenge in terms of staff exposure to potential infection.
- To prevent patient-staff transmission, monitoring of glucose levels remotely from outside the designated isolated rooms is required.

Conclusion:

- CGM system offers a novel tool for inpatient diabetes control in COVID-19 isolation facilities and minimises the risk of staff exposure and burden.



Emerging Considerations for Remote Glucose Monitoring during the COVID-19 Pandemic⁵

Summary:

- Changes in hospital patient care have been made to address critical supply shortages, most notably the lack of personal protective equipment (PPE) available to healthcare workers (HCW).
- The traditional approach to care for patients with diabetes in the hospital is complex and requires portable glucose monitors for frequent point-of-care (POC) testing with finger sticks and associated technical and comfort limitations.
- The emerging need to transition to CGM to care for patients with diabetes and COVID-19 under extreme conditions has revealed the impracticality of the previously used (or 'current') glucose monitoring strategies in hospitals.
- The appropriate implementation of CGM technology may significantly decrease the burden of glucose monitoring for patients and providers during and post the pandemic.

Conclusion:

- CGM is likely to become a widely accepted form of continuous monitoring in the hospital setting. During the pandemic, this technology can be used to immediately address the emerging needs for remote / self-monitoring when there is a high demand for both nursing staff and PPE.

Overall Conclusions

- CGM can be used as part of a system to monitor disease progression in patients with COVID-19.
- People with diabetes are more prone to developing critical condition / dying after infection with COVID-19 than general population so monitoring blood glucose levels to control their diabetes becomes more important than ever.
- Up until recently CGM has mainly been used in non-healthcare environments. However due to the need for isolation / to reduce contact between staff and patients during the pandemic it has been used and shown to be effective in a hospital setting too.

References

- ¹ Association of Blood Glucose Control and Outcomes in Patients with COVID-19 and Pre-existing Type 2 Diabetes (<https://www.sciencedirect.com/science/article/pii/S1550413120302382>)
- ² Characteristics of and Important Lessons From the Coronavirus Disease 2019 (COVID-19) Outbreak in China: Summary of a Report of 72 314 Cases From the Chinese Center for Disease Control and Prevention (<https://jamanetwork.com/journals/jama/article-abstract/2762130>)
- ³ From the insight of glucose metabolism disorder: Oxygen therapy and blood glucose monitoring are crucial for quarantined COVID-19 patients (<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7151413/>)
- ⁴ Remote Glucose Monitoring of Hospitalized, Quarantined Patients With Diabetes and COVID-19 (<https://care.diabetesjournals.org/content/43/7/e75.full>)
- ⁵ Implementation of Continuous Glucose Monitoring in the Hospital: Emergent Considerations for Remote Glucose Monitoring During the COVID-19 Pandemic (<https://journals.sagepub.com/doi/full/10.1177/1932296820932903>)

