SECURITIES & EXCHANGE COMMISSION EDGAR FILING

Nemaura Medical Inc.

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SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

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

Date of Report (Date of earliest event reported):**May 29, 2019**

NEMAURA MEDICAL, INC.
(Exact name of registrant as specified in charter)

Nevada
(State or other jurisdiction of incorporation)

000-55283	**46-5027260**
(Commission File Number)	(IRS Employer Identification No.)
Advanced Technology Innovation Centre, Loughborough University Science and Enterprise Parks, 5 Oakwood Drive, Loughborough, Leicestershire LE11 3QF United Kingdom	N/A
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: **00 44 1509 222912**

_____

(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 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(b) under the Exchange Act (17 CFR 240.14a-12(b))

[_] 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))
Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

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 provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01. Other Events

On May 29, 2019, Nemaura Medical Inc. issued a press release announcing CE Mark approval of SugarBEAT®, as the world's first non-invasive continuous glucose monitor. A copy of the press release is attached to this Current Report on Form 8-K as Exhibit 99.1.

Item 9.01 Financial Statements and Exhibits

(d) **Exhibits**

Exhibit No.	Description
99.1	Press Release, dated May 29, 2019

SIGNATURES

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

Nemaura Medical, Inc.

By: /s/ Dewan F H Chowdhury
Name: Dewan F H Chowdhury
Title: Chief Executive Officer

Dated: May 29, 2019

Exhibit List

Exhibit No.	Description
99.1	Press Release, dated May 29, 2019

Nemaura Announces CE Mark Approval of SugarBEAT®

SugarBEAT® is the World's First Non-Invasive Continuous Glucose Monitor

Loughborough, England – May 29, 2019 –Nemaura Medical, Inc. (NASDAQ: NMRD), a medical technology company focused on the development of SugarBEAT® as a non-invasive, affordable and flexible Continuous Glucose Monitor (CGM) for use by diabetics and pre-diabetics, today announced that it has received CE Mark approval for SugarBEAT®. With this Approval, Nemaura is permitted to commence sales of SugarBEAT® throughout the European Union.

Key Highlights:

- SugarBEAT® consists of a non-invasive, needle-free, disposable adhesive skin-patch connected to a rechargeable transmitter
- Lowest priced CGM in the industry
- Enables users to spend more time in range (TIR) by providing an ambulatory glucose profile (AGP) chart
- Targeting $179 billion global market opportunity including insulin and non-insulin dependent diabetics, pre-diabetics, and wearable health-tech markets
- On track to submit U.S. Food and Drug Administration (FDA) application in mid-2019
- Dedicated SugarBEAT® Symposia planned for the European Association for the Study of Diabetes (EASD) Barcelona Congress in September 2019, where key opinion leader data and end-user feedback are to be presented
- CE Mark approval issued by British Standards Institute (BSI), including newly added predictive alert and alarm functionality
- Product launch in United Kingdom and Germany planned for next quarter
- Dr. Fred Schaebsdau, MD, PhD, MBA, former General Manager of Dexcom Germany, to advise on SugarBEAT® launch

Dr. Faz Chowdhury, CEO of Nemaura, said, "We are very pleased to report CE Mark approval in Europe for SugarBEAT®, which is the world's first non-invasive, needle-free, continuous glucose monitor (CGM). Importantly, as a daily disposable adhesive skin-patch that sits on the surface of the skin, SugarBEAT® is painless, and versatile in terms of wear time. Given these benefits, we look forward to aggressively entering both the multi-billion-dollar diabetic (insulin and non-insulin dependent) and pre-diabetic markets. In addition, we plan to target the wearable health tech market for health-conscious consumers, which is experiencing explosive growth. Due to the non-invasive nature of the sensor patch and connection to a rechargeable transmitter, SugarBEAT® will allow users the freedom to decide when, and for how long to wear the patch. Moreover, we have a unique competitive advantage, which we believe will make SugarBEAT® the lowest priced CGM device in the industry. SugarBEAT® is protected by a solid IP portfolio with over 30 issued and pending patents across multiple patent families."

Continuous Glucose Monitoring has transformed diabetes management by providing real-time, continuous glucose readings, typically at 5 min intervals (12 per hour) which accumulate to provide an Ambulatory Glucose Profile (AGP) whereby glucose profiles over multiple days can be overlaid to observe trends, patterns, and the extent of fluctuations and out of range glucose profiles.

Dr. Chowdhury continued, “SugarBEAT® is unique in that it can be worn on non-continuous days, enhancing the flexibility and price savings. As a result, we plan to initially target the Type II diabetes market (95% of diabetics) who have traditionally relied on periodic A1c readings (every 3-6 months) to manage glucose levels. A1c measurements have significant limitations in that they are derived from a lab blood test providing a single value representing the average glucose level over the past 60-90 days. In contrast, CGM transforms glucose control by widening the focus from the limited ‘gold standard’ A1c metric to more meaningful ‘time in range’ (TIR) metric—measuring how much time per day glucose is kept within the normal range. The SugarBEAT® smartphone app displays glucose readings every five minutes for the duration of wear. Independent studies have shown that diabetes can be put into remission if glucose levels are consistently maintained in range. SugarBEAT® may also reduce the frequency of daily ‘finger prick’ tests utilized by many diabetics.”

The CE Mark approval includes recently added predictive alerts to the product design, which provide visual indication when glucose levels are falling or rising above minimum and maximum thresholds. Additional audible alerts or physical vibration of the Bluetooth-enabled mobile phone connected to SugarBEAT® occur in instances where glucose levels are deemed to fall to dangerously low levels, until switched off by the user.

“The inclusion of our new predictive alert capabilities will also have particular appeal to Type I diabetics who are at higher risk of hypoglycemia, or very low glucose levels. Insulin users can adjunctively use SugarBEAT® when calibrated with a finger-stick glucose reading. In addition, given the flexibility and non-invasive nature of the device, we look forward to targeting the growing $60 billion wearable health tech market through partnerships with leading smartphone and wearable manufacturers. Researchers, physicians and health-conscious consumers are increasingly recognizing the importance of maintaining glucose within appropriate ranges to minimize long-term health complications,” added Dr. Chowdhury.

The Company’s clinical studies were split between Type I and Type II diabetics and consisted of 75 patients over 225 patient days. The studies generated over 12,000 paired data points, with blood samples taken via catheter every 15 minutes over a 12-hour period for three non-consecutive days for each patient. The study design was based on two previous pre-sub meetings Nemaura held with the FDA, ensuring that the study would provide statistically valid results. The clinical study results indicated a MARD (Mean Absolute Relative Difference) of 11.92% (with a lower figure denoting greater accuracy), using a single point finger stick calibration. No device-related adverse events were noted. The Company remains on track to apply for FDA approval in mid-2019.

To view a video of SugarBEAT®, please visit http://sugarbeat.com/introducing-sugarbeat/

About Nemaura Medical, Inc.:

Nemaura Medical, Inc. (NASDAQ: NMRD), is a medical technology company developing SugarBEAT® as a non-invasive, affordable and flexible Continuous Glucose Monitor (CGM) designed to help people with diabetes and pre-diabetics better manage their glucose levels by spending more time in range. Insulin users can adjunctively use SugarBEAT® when calibrated by a finger stick reading. SugarBEAT® consists of a daily, disposable adhesive skin-patch connected to a small form factor rechargeable transmitter, connected via Bluetooth to a specially designed mobile application, which displays glucose readings at five-minute intervals throughout the day.

For more information visit:

www.NemauraMedical.com

www.SugarBEAT.com

Cautionary Statement Regarding Forward Looking Statements:

The statements in this press release that are not historical facts, and 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, risks related to regulatory approvals and the success of Nemaura's ongoing studies, including the safety and efficacy of Nemaura's SugarBEAT® system, 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 SugarBEAT®, 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 SugarBEAT®. These and other risks and uncertainties are identified and described in more detail in Nemaura's filings with the Securities and Exchange Commission, including, without limitation, its Annual Report on Form 10-K for the current 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.

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