

SECURITIES & EXCHANGE COMMISSION EDGAR FILING

Nemaura Medical Inc.

Form: 8-K

Date Filed: 2019-04-23

Corporate Issuer CIK: 1602078

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): **April 23, 2019**

NEMAURA MEDICAL, INC.

(Exact name of registrant as specified in charter)

Nevada

(State or other jurisdiction of incorporation)

000-55283

(Commission File Number)

46-5027260

(IRS Employer Identification No.)

Advanced Technology Innovation Centre,
Loughborough University Science and Enterprise Parks,
5 Oakwood Drive,
Loughborough, Leicestershire
LE11 3QF
United Kingdom

(Address of principal executive offices)

N/A

(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 April 23, 2019, Nemauro Medical, Inc. issued a press release announcing it successfully completed two Summative human factors usability studies for SugarBEAT®. 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 April 23, 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.

Nemauro Medical, Inc.

Dated: April 23, 2019

By: /s/ Dewan F H Chowdhury

Name: Dewan F H Chowdhury

Title: Chief Executive Officer

Exhibit List

Exhibit No. Description

99.1 Press Release, dated April 23, 2019

Nemaura Announces Successful Completion of Summative Human Factors Usability Study for SugarBEAT®

Final step required prior to filing de novo application to the U.S. Food and Drug Administration

Loughborough, England – April 23, 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 successfully completed two summative human factors usability studies for SugarBEAT®. The usability studies were conducted according to the U.S. Food and Drug Administration (FDA) guidance on ‘Applying Human Factors and Engineering to Medical Devices,’ in preparation for submission of its medical device application to the FDA for SugarBEAT®.

The two studies consisted of 16 participants each, including both Type I and Type II diabetics. Participants in the first and second study ranged from ages 18-50 and 51-70, respectively. The studies were designed to ensure adequate information was captured for the diverse age groups expected to use SugarBEAT®. The objective of the two studies was to confirm that the user interface aspects of SugarBEAT® met the FDA guidelines for medical devices.

Dr. Faz Chowdhury, CEO of Nemaura, commented, “We are pleased to have successfully completed these important studies and we are preparing our FDA filing at this time. We anticipate broader adoption of SugarBEAT® as compared with competitive offerings given SugarBEAT® is non-invasive with flexible wear time, and will be attractively priced.”

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.

Contact:

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