

Nemaura Medical Inc

01:30 29 Mar 2019

Nemaura on track for FDA's De Novo submission for sugarBEAT glucose monitor in 2Q

Nemaura Medical Inc (NASDAQ:NMRD) CEO Faz Chowdhury told investors Thursday that the company has "successfully completed" the clinical studies needed to support a De Novo submission to the US Food & Drug Administration (FDA) for approval of sugarBEAT, the world's first painless non-invasive glucose monitor.

Chowdhury told investors that the company plans to apply to the FDA in the second quarter of 2019, which could speed up sugarBEAT's arrival on American shores.

READ: Nemaura rises after supply deal for its SugarBEAT glucose monitor in Mideast

For certain low-risk novel devices, the FDA's De Novo pathway offers a swifter route to market.

The FDA created the De Novo process in 1997 as an alternative pathway for companies bringing novel Class I and Class II devices to market via the pathway. The goal is to bring more transparency and predictability for manufacturers.

SugarBEAT is targeted at people with Type I and Type II diabetes, as well as for screening prediabetic patients.

De Novo submission to FDA

"We are currently preparing our dossier for FDA submission," Chowdhury told investors in a letter to shareholders.

He added that clinical studies to support the upcoming FDA De Novo submission was split between Type I and Type II diabetics and consisted of 75 patients who were monitored over 225 days. The studies generated over 12,000 paired data points, with blood samples taken via a 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 meetings Nemaura held with the FDA, ensuring the study was sufficiently powered to provide statistically valid results. Overall the clinical study results indicated a mean absolute relative difference (MARD) of 11.92% (with a lower figure denoting greater accuracy) for 95.95% of the paired data points, using a single point finger prick calibration. There was no device-related adverse event.

Progress towards CE Mark

SugarBEAT, which has been honed and perfected over seven years is expected to receive CE approval in the UK soon. It will launch first in the UK and then the rest of Europe and Qatar.

"We continue to make significant progress towards completion of our CE Mark," said Chowdhury. "The clinical review was completed in December 2018, and based on the ongoing dialogue, we are now in the final stages of the review process, after which Nemaura expects CE approval will be issued."

Price: 5.01

Market Cap: \$104.25 m

1 Year Share Price Graph



December 2018 June 2019 December 20

Share Information

Code: NMRD

Listing: NASDAQ

52 week High Low
19.9 4.206

Sector: Medical technology & services

Website: www.nemauramedical.com

Company Synopsis:

Nemaura Medical Inc. is a medical technology company which has developed sugarBEAT® as a non-invasive, affordable and flexible continuous glucose monitor (CGM) designed to improve glucose management for all people with diabetes and pre-diabetics.

action@proactiveinvestors.com.au

The company said it had made further enhancements to sugarBEAT with a sign-off from the British Standards Institute.

A predecessor sugarBEAT device from Nemaura, which was based on a wired wrist-watch form factor, received CE Mark approval in 2016.

Healthy outlook

"The outlook for the business is extremely encouraging and we are confident in our ability to secure regulatory approval," said Chowdhury.

The global addressable market for continuous glucose monitoring devices is estimated at \$82 billion annually, and over \$13 billion in the US alone.

According to the Centers for Disease Control and Prevention, more than 100 million Americans have diabetes or prediabetes, the precursor to diabetes marked by higher than normal blood sugar levels.

Market disruptor

Since sugarBEAT doesn't require needles or insertion, it is likely to disrupt the continuous glucose monitor (CGM) device market. It will challenge entrenched players like DexCom Inc (NASDAQ:DXCM), which markets the Dexcom G6 and Abbott Laboratories (NYSE:ABT) Libre System.

SugarBEAT consists of a daily disposable adhesive skin-patch connected to a rechargeable transmitter, with an app displaying glucose readings at five-minute intervals for periods up to 24 hours. The innovation of sugarBEAT lies in its groundbreaking skin-patch technology, which allows for better glucose management.

"Our product includes significant and unique features that the competition does not provide, in particular the non-invasive nature of the device and the flexible wear period," said Chowdhury. "We believe these advantages will allow SugarBEAT to become adopted by a very large and diverse patient and user group."

Chowdhury, a serial inventor and entrepreneur, is the brains behind sugarBEAT. The pharmaceutical scientist received his PhD in Nanomedicine from the University of Oxford. Today, Chowdhury holds 50 patents on drug delivery systems and sensors, across 15 technology platforms.

Contact Uttara Choudhury at uttara@proactiveinvestors.com

Follow her on Twitter: [@UttaraProactive](https://twitter.com/UttaraProactive)

Proactive Investors facilitate the largest global investor network across 4 continents in 4 languages. With a team of analysts journalists & professional investors Proactive produce independent coverage on 1000's of companies across every sector for private investors, private client brokers, fund managers and international investor communities.

Contact us +61 (0)2 9280 0700 action@proactiveinvestors.com.au

No investment advice

The Company is a publisher. You understand and agree that no content published on the Site constitutes a recommendation that any particular security, portfolio of securities, transaction, or investment strategy is suitable or advisable for any specific person. You understand that the Content on the Site is provided for information purposes only, and none of the information contained on the Site constitutes an offer, solicitation or recommendation to buy or sell a security. You understand that the Company receives either monetary or securities compensation for our services. We stand to benefit from any volume which any Content on the Site may generate.

You further understand that none of the information providers or their affiliates will advise you personally concerning the nature, potential, advisability, value, suitability or profitability of any particular security, portfolio of securities, transaction, investment, investment strategy, or other matter.

You understand that the Site may contain opinions from time to time with regard to securities mentioned in other products, including Company-related products, and that those opinions may be different from those obtained by using another product related to the Company. You understand and agree that contributors may write about securities in which they or their firms have a position, and that they may trade such securities for their own account. In cases where the position is held at the time of publication and such position is known to the Company, appropriate disclosure is made. However, you understand and agree that at the time of any transaction that you make, one or more contributors may have a position in the securities written about. You understand that price

and other data is supplied by sources believed to be reliable, that the calculations herein are made using such data, and that neither such data nor such calculations are guaranteed by these sources, the Company, the information providers or any other person or entity, and may not be complete or accurate.

From time to time, reference may be made in our marketing materials to prior articles and opinions we have published. These references may be selective, may reference only a portion of an article or recommendation, and are likely not to be current. As markets change continuously, previously published information and data may not be current and should not be relied upon.

The Site does not, and is not intended to, provide investment, tax, accounting, legal or insurance advice, and is not and should not be construed as providing any of the foregoing. You should consult an attorney or other relevant professional regarding your specific legal, tax, investment or other needs as tailored to your specific situation.

In exchange for publishing services rendered by the Company on behalf of Nemauro Medical Inc named herein, including the promotion by the Company of Nemauro Medical Inc in any Content on the Site, the Company receives from said issuer annual aggregate cash compensation in the amount up to Twenty Five Thousand dollars (\$25,000).