

Nemaura Medical Inc

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Nemaura Medical's stock flies ahead of De Novo FDA submission for sugarBEAT glucose monitor

Nemaura Medical Inc's (NASDAQ:NMRD) stock soared Monday after the medtech company said it was tapping industry veteran Dr Fred Schaebsdau to "advance the commercial strategy" for its launch of SugarBEAT, the world's first painless, non-invasive glucose monitor, in Europe.

He will also advise the company on the upcoming De-Novo 510(k) submission to the Food and Drug Administration.

Investors sent shares in the UK-based company up 17.5% to \$1.21 in midday trade.

READ: Nemaura publishes positive data for De Novo FDA submission, prices \$2.5M offering ahead of sugarBEAT launches
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.

In addition to leading strategy and business development, Schaebsdau will be a part of Nemaura's scientific advisory board.

"We are moving rapidly towards the launch of SugarBEAT in Europe and we are looking to accelerate our entrance into the US market," said Nemaura Medical CEO Faz Chowdhury. "We are planning our submission to the FDA Human Factors Premarket Evaluation team. We are honored that Dr Schaebsdau has agreed to lead our European launch and assist us with the FDA 510(k)."

The annual addressable market for continuous glucose monitors for diabetics is estimated at \$82 billion, with the US market estimated at \$13 billion.

In December, Nemaura published positive clinical data from clinical studies supporting a De Novo submission to the FDA for approval of sugarBEAT. The studies were 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.

READ: Nemaura is a red hot medtech stock with a winner in its painless sugarBEAT glucose monitor
Nemaura plans to apply to the FDA during the first quarter of 2019, following the completion of a non-clinical human factors study with 15 end users.

Meanwhile, Nemaura is all set to launch sugarBEAT, which has been honed and perfected over seven years, in the UK once the device receives CE approval.

The CE mark will not only kick off sugarBeat's launch in the UK, but help its passage through the rest of Europe and

Price: \$0.79
Market Cap: \$163.29 m

Share Information

Code: NMRD
Listing: NASDAQ
52 week **High** **Low**
3.25 0.7

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.

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"We are confident that Dr Schaebdsau will help us advance our sales platform in Europe and that his oversight will help us to expedite our FDA submission," said Chowdhury. "We look forward to leveraging his expertise as we move towards commercialization and navigate the scientific and regulatory environments."

Schaebdsau has more than 15 years of experience in the continuous glucose monitoring (CGM) and insulin delivery industries. He was the general manager of Dexcom Germany which achieved triple-digit revenue and new patient growth every year. During his tenure, two generations of CGM devices — the G5 and G6 — were successfully launched.

In September 2015, Schaebdsau founded his own firm, which became an exclusive distributor in Europe, the Middle East and Africa for UniStrip, the world's first generic blood glucose test strip.

Schaebdsau studied medicine at the University of Giessen and completed residencies in urology and surgery at the University of Chicago, University of Hannover and University of Freiburg. He received an MBA from Wharton at the University of Pennsylvania.

"The non-invasive, flexible and affordable nature of SugarBEAT has the potential to really open up the CGM market to all diabetics, pre-diabetics and non-diabetics seeking to better manage their diet, weight and physical fitness," said Schaebdsau. "Nemaura's approach is innovative and the addressable market is global and enormous."

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