Nemaura Medical

Better Diagnostics for Life

NASDAQ: NMRD

Wellbeing Devices:
US Market, Potential & Regulations
March 2020

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Forward-looking Statements

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 Nemaura Medical Inc.’s (“Nemaura”) 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 Nemaura believes are appropriate in the circumstances. Factors which could cause actual results to differ from expectations, many of which are beyond Nemaura’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 Nemaura’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; and dealing with general business conditions and competition. For a discussion of risks and uncertainties, please refer to the information set forth under “Risk Factors” included in Nemaura’s Annual Report on Form 10--K for the fiscal year ended March 31, 2019, and information contained in subsequent filings with the Securities and Exchange Commission.

Summary: ‘General Wellness’ glucose monitor and digital service – potentially game changing opportunity

There are 34 million people with diabetes and 88 million pre-diabetics in the USA[4] alone

An understanding of how glucose levels fluctuate with lifestyle and dietary factors could help people with diabetes and prediabetes to better manage, reverse and prevent the onset of diabetes by providing actionable insights.

Gathering glucose data and using artificial intelligence to review and sort the data to give the user targeted prompts on their diet and lifestyle is potentially a hugely powerful tool to help people at risk of developing diabetes, or living with pre- or type 2 diabetes by empowering through education.

Such a well--being device would be a potential ‘game changer’ primarily for users but also for healthcare professionals and insurance companies who are increasingly burdened with the costs of treating patients with diabetes and the immeasurable complications it brings.

Medical Monitoring & Wearable Health Technology

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Consumer interest in tracking own health and well--being has never been higher.

19% of Americans currently use a wearable fitness tracker and the same number use a mobile health App. Combining past users nearly half of Americans (45%) have used one or the other[1]

About a third of consumers are interested in using Apps for identifying symptoms and for health coaching for example:

31% are interested in connecting with a live health coach that offers 24/7 text messaging for nutrition, exercise, sleep and stress management.

29% are interested in using an App that uses voice--recognition software to recognize depression or anxiety from changes in the tone of voice. [2]

60% of surveyed consumers said they are willing to share personal health data (generated from wearable devices) with their doctor to improve their health.[2]

Wearable Health Technology Growth

Survey question: In the last 12 months, have you used any technologies – including website/smartphone/tablet app, personal medical device, or fitness monitors – for any of the following health purposes?*

Measure fitness and health improvement goals**

2013	2015	2016	2018
17%	28%	32%	42%

Monitor health issues***

2013	2015	2016	2018
15%	24%	24%	27%

250%+

increase

Consumer use of technology for health and fitness purposes has increased almost two-and-a-half times since 2013[2]

** Chart shows the percentage of respondents who said "Yes". ** Example: Exercise, diet, weight, and sleep. *** Example: Blood sugar, blood pressure, breathing function, mood.*

What is Wearable Technology?

Wearable healthcare technology includes electronic devices that consumers wear (wearables) and which are designed to collect their personal health and exercise data.

World market for wearable devices set to reach $62B by 2025[3]

What is Wearable Technology?

Examples of current wearable devices in healthcare:

Wearable Fitness Trackers – Count steps and keep track of physical activity. Linked to an App the data collected can be used to provide coaching/training plans.

Smart Health Watches – Originally developed to count steps/heart rate, many can now monitor sleep, heart rhythms etc with more functions being added all the time.

Wearable ECG Monitors – Can measure electrocardiograms and send readings to the user's doctor as well as detect atrial fibrillation.

Wearable Blood Pressure Monitors – often look like a smart watch but can measure blood pressure and daily activity such as steps taken and calories burned.

Biosensors – Self-adhesive patches which can collect data on movement, heart rate, temperature and respiratory rate.

Why Monitor Blood Glucose Levels?

For people with diabetes (34 million in the US[4] in 2018), blood sugar levels need to be regularly monitored in order to avoid the damaging extremes (high/low), and for those with type 1 diabetes to effectively manage insulin dosing.

For people with pre--diabetes (88 million in the US in 2015[4]) or those susceptible due to family history/lifestyle, monitoring glucose levels would be a powerful tool in slowing down or even stopping the onset of diabetes by promoting changes in diet/physical activity (which are the two leading modifiable lifestyle behaviors[5])

Health professionals aren't only concerned about chronically elevated blood glucose levels but also about big swings/spikes in blood sugar which can be brought on by certain foods, stress and other lifestyle factors.

Studies including one from Stanford University[6] have shown that severe glucose variability can happen in non--diabetic patients after eating certain foods suggesting that monitoring (or being able to predict) glycemic variability based on food types alone could be a lot more informative than fasting glucose values.

A device capable of providing an understanding of how specific foods, exercise and stress levels can impact blood sugar response could empower people to create a personalized diet/lifestyle regimen that could lead to better blood sugar control.

"90% of people who are prediabetic have no idea they are prediabetic and up to 70% will go on to develop type 2. If you can see what's happening before you lose glucose control, you can figure out ways to manage it before it's too late." – *Michael Synder – Stanford University*

Who Will Pay For General Wellness devices & Services?

Healthcare insurers around the world are already paying for mobile phone apps that encourage weight loss and promote better health and help prevent diabetes or help reverse Type 2 diabetes. Examples include:

- UK National health service low carb program[9]
- German Health insurers are due to start prescribing health apps commencing 2020[10]

The US currently has 88 million pre--diabetics and 34 million[4] people with diabetes. It would appear to be in the interest of healthcare insurers to fund services that could potentially prevent 88 million people from becoming diabetic and therefore mitigate the cost burden associated with managing such vast numbers of patients, in the same way their European counterparts have already embraced digital wellness products.

Device Regulations In the USA

Any medical device will be regulated by FDA if it meets the definition in Section 201(h) of the Food, Drug, and Cosmetic Act[7]:

Per Section 201(h) of the Food, Drug, and Cosmetic Act, a device is:

An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:

1. *Recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,*
2. *Intended for use in the diagnosis of disease, in man or other animals, or*
3. *Intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and*

Which does not achieve its primary intended purpose through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes. The term "device" does not include software functions excluded pursuant to Section 520(0)

Device Regulations In the USA

Medical Devices in the US currently fall into three categories:

Class I – Low risk to user. General controls are adequate to control it.

Class II – Medium risk to user. General controls plus special (specific) controls required.

Class III – High risk to user. General controls and Pre-- Market Approval (PMA) required.

Device Regulations In the USA

FDA classifies medical devices on the intended use of the device and its indications for use. As an example a scalpel is intended to cut tissue but a scalpel designed to cut cornea tissue will require different and more stringent controls than a standard scalpel.

All three classes generally require **prior approval** from FDA before marketing via PMA, 510(k) or ‘De Novo’ application route but there are **exceptions** eg. ‘General Wellness Products’.

What Is A ‘General Wellness Product’?

FDA policy is not to assess low risk general wellness products[8].

A general wellness product is one that meets the following two criteria:

1. Intended only for general wellness use
2. Presents a low risk to the safety of users and other persons.

What is ‘General Wellness Use’?

‘(1) An intended use that relates to maintaining or encouraging a general state of health or a healthy activity, or

(2) An intended use that relates the role of healthy lifestyle with helping to reduce the risk or impact of certain chronic diseases or condi2ons and where it is well understood and accepted that healthy lifestyle choices may play an important role in health outcomes for the disease or condition.’[8]

What Is A ‘General Wellness Product’?

Examples of claims for products under category (1):

- Weight management e.g. Claims to promote healthy eating or assist in weight loss goals
- Sleep Management e.g. promote better sleep by tracking sleep trends

Examples of claims for products under category (2):

- Intended to promote, track or encourage choices which as part of a healthy lifestyle may help to reduce the risk of certain chronic diseases or conditions
- Intended to promote, track or encourage choices which as part of a healthy lifestyle may help living with certain chronic diseases or conditions

Claims that healthy lifestyle may play an important role in health outcomes of the chronic diseases should be well accepted. Examples of chronic conditions provided in FDA guidance include heart disease, high blood pressure and Type 2 diabetes.

What Is A ‘General Wellness Product’?

Examples for category 2:

- Product promotes physical activity which as part of a healthy lifestyle may help reduce the risk of high blood pressure
- Product promotes healthy sleep patterns which as part of a healthy lifestyle may help reduce the risk of developing type 2 diabetes

General Wellness Products must also be low risk:

Must not be implanted or invasive and not involve technology that without controls could pose a risk to the safety of users and/or other persons.

References

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