



G Medical Innovations Holdings Ltd
ARBN 617 204 743

ASX Announcement

14 April 2020

Corporate and Business Update

- **Recent regulatory approvals in USA, Italy and Taiwan leave G Medical well positioned for growth**
- **GMV has commenced the fulfilment of Prizma units to its partner in Italy**

Mobile and e-Health Company **G Medical Innovations Holdings Ltd** (“**G Medical**” or the “**Company**”) (ASX: GMV) provides the following update on the Company’s activities. G Medical has achieved a number of key milestones in relation to its Prizma medical device in the recent months, leaving the Company well positioned to capitalise on a number of near term, value-enhancing opportunities.

FDA grants Prizma Over-the-Counter approval authorisation

The Company achieved a major milestone following Over-the-Counter (OTC) authorisation being granted for its Prizma device in the USA by the US Food & Drug Administration (FDA) (refer to the ASX announcement dated 8 April 2020 for further details).

The authorisation followed discussions with the FDA following the release of a guidance document (Policy) issued by the organisation on 20 March 2020 in response to the COVID-19 pandemic.

G Medical directly contacted the FDA seeking acknowledgement that the Prizma medical device satisfied the Policy scope for authorisation defined as “non-invasive remote monitoring devices that measure or detect common physiological parameters and that are used to support patient monitoring during the COVID-19 public health emergency”ⁱ.

The FDA subsequently confirmed that the Prizma satisfied the policy scope. Following this authorisation the FDA expanded the use of the Prizma from prescription to OTC. This is a change in classification and allows for the device to be sold directly to consumers, without a prescription.

The Company is confident that the Prizma has the ability to assist in alleviating the current pressure on the US healthcare system, which is facing capacity challenges due to the COVID-19 public health emergency. Further, the device can assist in the management of unrelated medical conditions, which provide additional burden on the healthcare system and its professionals.

G Medical considers that the USA presents a tremendous opportunity for the Company and is presently in ongoing discussions with number of parties to expedite the device launch. The Company will provide shareholders with an update in respect to its progress by way of further ASX announcements.

Italian market entry progress

G Medical has made progress in Italy following the registration of its Prizma device on the Italian Health Ministry’s Database of Health products (registration number: RDM 1938127) (refer to the ASX announcement dated 6 April 2020), which allows for the Prizma to be distributed in Italy. This provides the Company with another opportunity, as Italy’s healthcare system is currently experiencing significant challenges and overburden due to Covid-19.

G Medical will work with its distribution partner in the region, Meditel (refer to the ASX announcement dated 6 February 2020), to offer and provide access to medically certified devices and unique, sophisticated telehealth technologies and service solutions to assist patients in Italy.

G Medical has commenced the fulfilment of Prizma units to Meditel. The Company will continue to progress its Italian market entry and will update shareholders on these developments, by way of ASX announcements, as they progress.

Permit license for Prizma received from Taiwan FDA

The Company has, through its partners, First Channel Ltd (FCL), received a permit license for the Prizma device in Taiwan (refer to the ASX announcement dated 6 April 2020).

The permit license was granted by the Taiwan Food and Drug Administration ("FDA") following the provision of ancillary product information (including packaging and labelling) from FCL (refer to the ASX announcement dated 20 January 2020).

Discussions with FCL remain ongoing in regards to a commercial strategy for the Taiwanese market and the commencement of any distribution agreement of the Company's products via FCL remains subject to FCL finalising and entering into additional definitive agreements with FCL's third party partners (refer to the ASX announcement dated 10 November 2017).

The Company will provide shareholders with an update in respect to its progress in Taiwan by way of further ASX announcements.

NASDAQ Listing

The Company wishes to advise shareholders that it is re-considering a listing on the NASDAQ Stock Exchange (NASDAQ) to unlock additional value for shareholders (refer to the ASX announcement dated 23 August 2019). The Company has commenced preliminary discussions with various third parties in respect to a proposed NASDAQ listing. As at the date of this announcement, there is no certainty that the NASDAQ listing will proceed and the Company will provide shareholders with an update by way of further ASX announcements.

Management commentary

CEO and Executive Director Dr Yacov Geva said: "G Medical has achieved a number of pivotal milestones in the recent months, leaving it well placed for growth and optimistic for the remainder of 2020.

"The Prizma device can be used to monitor systems associated with infection, chronic disease and acute illness and has been recognised by some world's leading authorities, including the US Food & Drug Administration.

"These recent approvals, coupled with our devices capabilities and a global push towards telehealth solutions, leave G Medical incredibly well placed to unlock value for shareholders.

"The Company is progressing initiatives on a number of fronts in Italy, the USA and Taiwan and we look forward to updating shareholders on its progress in the near term."

-Ends-

Authorised for release by Yacov Geva, Managing Director.

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About G Medical Innovations:

G Medical (ASX: GMV) was founded in August 2014, aiming to be at the forefront of the digital health revolution, developing the next generation of mobile health (mHealth) technologies. The Company leverages the experience and expertise of its Board to deliver best-in-class solutions to address this global opportunity.

The Company specialises in innovative next generation mobile and e-health solutions using its suite of proprietary devices and software solutions, as well as patient service operations, with a view to driving multiple and recurring revenue streams, across numerous verticals and territories.

For more information on G Medical, please visit www.gmedinnovations.com

About G Medical products:

G Medical offers a suite of consumer and professional clinical-grade products (with regulatory approval) that are positioned to streamline healthcare services, improve remote access to medical data, reduce costs, improve quality of care, and make healthcare more personalized and precise. Currently the Company is focusing on two main verticals.

The 'Prizma' Medical Smartphone Case is one of two key products developed by G Medical and is aimed at everyday consumers focused on their medical health and wellbeing. The 'Prizma' allows consumers to turn their smartphone into a mobile medical monitor to measure a wide range of vital signs, with the added advantage that users are able to store their medical data in the cloud and share it with third parties such as healthcare professionals and family members.

G Medical also offers a professional real-time patient continuous monitoring solution, G Medical's Vital Signs Monitoring System (VSMS) and G Medical Patch (GMP). This modular solution measures a wide range of vital signs that are automatically presented in a call centre (IDTF) or a hospital setting. The GMP assists in diagnosing patient complaints and conditions remotely, from pre-hospitalisation, hospitalisation and through to post discharge home-based settings.

ⁱ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-non-invasive-remote-monitoring-devices-used-support-patient-monitoring-during>