



G Medical Innovations Holdings Ltd
ARBN 617 204 743



ASX Announcement

30 July 2019

COMPANY UPDATE

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.

United Kingdom

The Company wholly owned subsidiary G Medical Innovations UK Ltd (GMedUK) has established its UK headquarters, and employed 3 additional staff, after successfully completing its pilot programs for its CE approved G Medical Proprietary Patch (extended Holter monitor) (Patch). The UK market for GMedUK comprises of the NHS (both primary and secondary), private hospital groups, nursing and aged care facilities as well as other market participants. The healthcare system and reimbursement regime in the UK is very complimentary and compatible with the Company’s business model and services, and is an important territory for deployment, given both the Prizma and the Patch are already regulatory approved for use within the UK.

Reimbursement rates for typical services range from ~£500 and £700, varying from site to site and depending upon the insurance company’s reimbursement rates.

The Company is pleased update its shareholders that it has seven (7) accounts that have successfully trialled the Patch, with the view to forming definitive arrangements. The typical value of each of these accounts is ~£256,000 per annum. Further, GMedUK, via invitation, is also currently trialling the Patch at an additional three (3) sites with one of the UK’s largest private hospital groups. GMedUK has received strong clinician feedback, for the simple ease of use of the Patch, and importantly citing exceptional clinical data capture and quality within the final reports received. Patient compliance is very high, and the Company “Patched” its youngest ever patient last week (1 Year old) at the Great Ormond Street Hospital in London.

The Company looks forward to updating its shareholders on the outcome of the continued Patch implementation pilot programs and any additional material developments as they unfold.

US Provider Agreements

During the past quarter the Company announced the execution of Provider Participation Agreements (PPAs) with Prime Health Services, Inc (PHS) and Ancillary Care Services (ACS) Network in the US territory, with its wholly owned subsidiary G Medical Diagnostic Services Inc. (GMEDx). The Provider Participation Agreements have significantly increased GMEDx’s footprint in the healthcare delivery system of cardiac monitoring and has provided more exposure to our future patient base and third-party payer populations as well as having secured additional access to Medicare reimbursements for the Covered Services rendered to Covered Persons for all applicable programs associated under the PPA with PHS and ACS.

Additionally, the Company has executed the following Provider Agreements:

- 1) **Humana Military** (Entity partners with the US Department of Defence for the administration of TRICARE health programs)
 - (a) **Covered Lives of millions** of military members, retirees and their families across the United States. The Agreement covers all GMEDx services for MCT (Auto Detect Auto Send real-time monitoring), AECG (extended Holter), CEM and HOLTER monitor.

- 2) **Molina Health Care of Texas (Molina), for ~423,000 Covered Lives:**
 Molina products included in the Provider Agreement include;
 - (a) Medicaid Star, Medicaid Star+ PLUS, Medicaid STAR Kids, and all other future Molina Medicaid Health Plans;
 - (b) Molina Medicare Advantage including Molina Medicare Options, Molina Medicare Options Plus and all future Molina Medicare Advantage programs;
 - (c) Molina Health Insurance Marketplace; and
 - (d) Molina Medicare-Medicaid program, including the Star+PLUS Medicare-Medicaid program, and CHIP including Chip MCO, CHIP Perinatal, CHIP RSA and all other future developed programs.
 The Agreement covers GMEDx services dependent on the type of Molina product held by the insured individual.

- 3) **Molina Health Care of Ohio (Molina), for ~302,000 Covered Lives:**
 Molina products included in the Provider Agreement include;
 - (a) Medicaid;
 - (b) Medicare;
 - (c) MyCare Ohio;
 - (d) Health Insurance Marketplace; and
 - (e) Molina Dual Options (includes insurance with both Medicare and Medicaid).
 The Agreement covers GMEDx services dependent on the type of Molina product held by the insured individual.

IDTF Operations in the USA (GMEDx)

Recently, both individually and since acquisition and amalgamation, the Company's IDTF operations has seen consistent month on month new patient enrolment, with the most profitable services provided being MCT (Auto Detect Auto Send – real time service) and AECG (Extended Holter).

The enrolment data outlined below are the total enrollment numbers per month through the Company's wholly owned IDFT services.

Patient Enrolments	Jan-19	Feb-19	Mar-19	Apr-19	May-19	Jun-19	Total
Total	2,336	2,536	2,465	2,677	2,532	2,244	14,790
<i>Selling days</i>	21	19	21	22	22	20	

Once enrolled, patients will commence an individualized service, which generally range from a 24-hour monitoring service to 30 days of service, and with Prizma to potentially years for chronic care services. The services outlined above equate to approximately ~US\$500,000 per month for the half-year 2019 for new patient enrolments.

GMEDx timing on receipts for services are dependent on the duration of service to completion and receipt of funds from the provider/s, with realized revenues being further apparent over approximately 90 days.

As part of the growth strategy to the Company's GMEDx division, GMEDx will gradually increase its sales force to provide for continued increase in patient enrollments within the market, as well to push Prizma from POC to full commercialization.

The Company is very pleased with the increasing revenue profile GMEDx has achieved in the short time since CardioStaff and Telerhythmic were acquired and amalgamated into GMEDx, with the **revenue growth having increased ~200% from ~US\$0.98M for H1 2018 to ~US\$3M for H1 2019.**



Image 1: G Medical IDTF Centre

Hygea Purchase Orders and Implementation

As announced 30 January 2019, the Company executed a significant purchase order with Hygea Holdings Corp and two subsidiaries of Hygea, Palm Medical Group and AllCare Management Services, Inc. The Company through its wholly owned GMEDx subsidiary has continued with the implementation of its IDTF services across several Hygea's wholly owned accounts. Further the IDTF is currently providing its cardiac monitoring services to Hygea utilising GMEDx's existing third-party devices, whilst the G Medical proprietary patch continues to finalise the requirements for its FDA approval process.

Hygea's Integrated Physician Association (IPA) network will allow potentially for more than 250 Cardiologists, representing more than 400,000 patients, to have access to the new Patch technology.

The Company has implemented a number of account programs for the Prizma within Hygea’s wholly owned Independent Group Practices (IPG) and with accounts currently within the GMEDx IDTF network, for the remote patients monitoring program. For these accounts, the Prizma device is being issued at no cost, and GMEDx is in the process of charging an ongoing monthly service fee from the insurance companies (in example, Medicare reimburses for Prizma services in accordance with new CPT codes for patient monitoring services announced in November 2018). Prizma, on fully implementation across the IPA network, will have a potentially qualified user base of more than 2500 physicians treating approximately 3.3 million patients.

Hygea has advised the Company that it has commenced an internal management and organisational restructuring. During this time, the Company has agreed with Hygea to defer the purchase order aspect of the Company’s medical devices as outlined in the existing Agreement between the parties, to allow for the restructuring to be finalised. During this period, product implementation and service provisions as outlined in this section will continue. The Company views Hygea as a strong strategic partner within its US expansion strategy and has been very pleased with the collective and dynamic implementation efforts between the two groups to date.

FDA Approvals

The G Medical Proprietary Patch (GMP) which is granted regulatory approved CE Mark for the European territory (and counties which recognise such), continues to process its separate FDA filing. To meet newly established requirements as an Extended Holter monitor for the US territory, the Company has taken the vision and opportunity to add further features as a second-generation type G Medical Patch, being an Extended Holter with Auto Detect Auto Send (real-time MCT service) features. The additional design and feature set includes the following stages and its anticipated to be approved by the FDA during Q1 2020:

- Protection circuit for defibrillator compatibility;
- Mechanical design alterations;
- Algorithm upgrades;
- Testing and submission;
- FDA approval.



Image 2: G Medical IDTF Centre

The Company is pleased to advise that no further clinical trials are required for the second-generation Patch, and that when approved will be one of the most advanced devices available on the market.

The FDA approval process for Over the Counter (OTC) classification for the Prizma continues, and the Company confirms that no additional clinical trials are required.



Image 3: G Medical Proprietary Patch

Dr Yacov Geva Loan Conversion and Share Purchases

On 23 May 2019, CEO, Dr Yacov Geva, converted US\$3,317,500 of his US\$10M Company loan (Loan Facility) to 14,706,719 ordinary shares; as approved at the General Meeting of 24 April 2019. Further, at the Annual General Meeting held on 24 May 2019, shareholders approved the conversion of an additional US\$2,000,000 from Dr Geva's Loan Facility for 14,532,771 ordinary shares. During the quarter ended 30 June 2019 Dr Geva purchased an additional 742,168 shares on-market to the value of \$182,566 (\$0.246 per share) (see Appendix 3Y released 13 June 2019). The Board of Directors once again thanks Dr Geva who continues to demonstrate his continued support and faith in the future of the Company.

NASDAQ listing

During the 30 June 2019 quarter the Company announced the release of its prospectus for its NASDAQ public offering, to be dual listed. The Company has commenced investor meetings in the US, and investor meetings continue in both the US and Hong Kong with groups deemed strategic to the Company's operations as well as those to its proposed listing of its Chinese subsidiary on the Hong Kong Stock Exchange (HKSE). The Company continues to work with its US Advisors surrounding its preferred go public date and the quantum and pricing of the associated capital raising, with consideration to its parallel HKSE Listing process, and other key operational factors.

HKSE Listing

During the 30 June 2019 quarter the Company filed with the Stock Exchange of Hong Kong Limited (HKSE), its “Suitability for Listing under Chapter 18A of the Rules” application, for its Chinese subsidiary. The Company has now received correspondence from the HKSE that it can now proceed to formally file its A1 Prospectus Listing application, with the anticipated IPO in Q4 2019 - Q1 2020.

CFDA (now known as NMPA)

As previously announced, the Company has been undergoing an accelerated “Green Channel” process with the regulator. During the 30 June 2019 quarter, the Company lost its independent Chief Principal Investigator (PI) to its NMPA clinical trial process, who sadly and unexpectedly passed away. The NMPA Committee has sought to nominate and approve a new PI to the Company’s remaining clinical trial process in which the Company understands there may be up to a 3-month process to the appointment.

During the ongoing trial process, additional measurements surrounding the single biometric indication being “temperature” has been required to identify and test outlier patients within a specific clinical range for completion of the trial data. The previous guidance for the anticipated completion time of this trial being May 2019, is revised due to limited qualified patients presenting obligatory symptoms during the Summer period in this territory.

The Company has been working closely with its partner hospitals to identify and recruit suitable patients, and through its trial facilitators have now sourced eligible in-patients in the coldest Northern regions and expect that the data collection will be completed within 4-6 weeks.

Further to the very stringent data set requirements in accordance with NMPA, the Company has been now required to source and recruit 12 volunteers who will undergo a clinically induced and controlled reduction in their SPO2 levels to a threshold of 72% SPO2; for the expressed purposes of final clinical verification of the Prizma’s advanced SPO2 biometric capabilities. Candidates are currently being prepared for this trial by the Company’s trial facilitator and partnered hospitals, and in accordance with the regulatory body requirements.

Further the Company is very pleased to advise it has formally received notification that it has passed all requirements of the NMPA during the regulators mid-term auditing process, being a key milestone in the NMPA approval process that limited other trial peers passed with ease.

In consideration of the above, the NMPA approval for the Prizma is anticipated to be received during 2HY 2019. In parallel, the company continues to progress the NMPA regulatory processes for the G Medical Patch (VSMS extended Holter), with significant activity for this process being over the last 4 months, including final assembly line for the product at the Company’s Guangzhou Production Facility and submission of NMPA testing samples.



Image 4: G Medical Proprietary Patch – China Territory Packaging

Guangzhou Yimei Innovative Medical Science and Technology Co., Ltd

The Company is pleased to provide an update on the in-territory activities within its Chinese subsidiary, Guangzhou Yimei Innovative Medical Science and Technology Co., Ltd (“Yimei”), including;

Research and Development

- Obtained Chinese software copyright registration certification for Prizma APP;
- Released Chinese version Prizma Android APP to Tencent APP Store;
- Chinese version Prizma User Portal has been released and is live;
- Chinese version Prizma IOS APP passed SQA test and is ready for release to China Apple Store;
- Commenced hardware design for medical smart watch;
- Commenced software requirement analysis for blood pressure measurement.

Business Development

The Company has showcased at a number of exhibits and has a continuous schedule of exhibitions and events for the remainder of the calendar year. Preparation is underway for an in-territory Prizma launch, which includes a multi-faceted marketing approach purposefully designed for territory and demographic appropriateness, including Company and product website localization.

In parallel, the Company continues its identification and discussions with potential direct sales partners (such as private and public hospital, aged care facilities, insurance providers etc) and distributors, both physical and online.



Image 5: Yimei Facility, Guangzhou China



Image 6: Yimei Facility, Guangzhou China

Memorandums of Understanding (MoU)

G Medical's business model is to provide innovative next generation mobile and e-health solutions as well as patient services utilising its suite of proprietary devices and software solutions to integrate into existing patient networks via partnership arrangement and/or through the acquisition of existing infrastructure and Provider Contracts; with the view to driving multiple and recurring revenue streams, over and above singular device and product sales revenue, and across numerous verticals and worldwide territories.

Since listing, the Company has executed several MoU's in various territories in accordance with this strategy of establishing partnerships in both medical infrastructure and services, and device and product sales. The details surrounding each MoU have been outlined in the Company's previous ASX announcements and within the Company's listing prospectus. The Company has formally cancelled the MoU with Medtl Medical Technologies Ltd (announced 2 October 2017) for the territory of Greece and Cyprus effective as at 29 July 2019 due to non-performance in accordance with the MoU.

The Company confirms that unless otherwise announced to the market, that all MoUs remain in good standing, and that the Company will evaluate the commercial viability of each arrangement to proceed to a binding agreement, with consideration to the party to any such agreement being able to deliver a beneficial outcome in accordance with the Company aforementioned business model; including the provision of the necessary ancillary services to the Company's proprietary devices.

The Company will continue to explore partnerships in all territories satisfying its current expansion plans, with a focus on the US, China and UK territories, whereby it already has existing infrastructure and operations as well as healthcare regimes compatible and complementary to its current service provisions.

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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 and services using its suite of devices and software solutions 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.