



G Medical Innovations Holdings Ltd
ARBN 617 204 743

ASX Announcement

30 April 2020

Quarterly activities report: strong foundation set for growth

- **Clinical trials completed to progress China NMPA approval for Prizma device**
- **Taiwan FDA approval granted with permit licence obtained – unlocks large potential opportunity**
- **Distribution agreement unlocks European market entry – Prizma units being shipped to partner in Italy**
- **Significant increase in demand witnessed for GMV solutions – Company remains well placed to deliver on near term growth catalysts**
- **Crucial milestones achieved following quarter end include FDA OTC approval, NASDAQ IPO progress and distribution agreements in the USA and Australia**

Mobile and e-Health company **G Medical Innovations (ASX: GMV) (“G Medical” or the “Company”)** is pleased to provide the following update to shareholders on its progress for the three month period ended 31 March 2020 (Q1 2020). The Company delivered on a number of key milestones, which provide a strong foundation for growth across the coming quarters.

Clinical trials completed to progress China NMPA approval process:

G Medical successfully completed the required clinical trials to obtain National Medical Products Administration (NMPA) (formerly China Food and Drug Administration or CFDA) approval for the use of its Prizma device in the People’s Republic of China.

GMV has completed the additional trials with 208 patients across three partner hospitals. Trials included measurements for electrocardiography (ECG), blood-oxygen saturation (SPO2) and body temperature using the Prizma device benchmarked against the relevant ‘gold standard’ hospital diagnostic equipment.

The Company continues to interpret the vast amount of statistical data generated from the exercise. Once finalised GMV will lodge a dossier of results with the NMPA in a push to gain NMPA approval for the device.

NMPA approval would allow for the commencement of commercial sales and services activities within the China market. Approval will also allow the Company to accelerate existing distribution and services arrangements with its China partners being; Beijing SilverLake Investment Co., Ltd (“SilverLake”) and Shandong Boletong Information S&T Co. Ltd (“Boletong”), underpinning multiple potential revenue streams (in accordance with requirements to the respective agreements as previously announced).

Taiwan FDA approval granted for Prizma:

In a major milestone, GMV received notification through its partner First Channel Ltd (“FCL”), that its Prizma medical device has been granted regulatory approval by the Taiwan Food and Drug Administration (“FDA”). Subsequent to the end of the period, FCL also secured the required permit licence from the Taiwan FDA (refer ASX announcement: 4 April 2020).

Following receipt of the approval and licence and in accordance with the existing non-exclusive memorandum of understanding between the companies, G Medical and FCL have commenced discussions Taiwanese market entry.

As previously advised, distribution of GMV's products by FCL remains subject to FCL finalising and entering into additional definitive agreements with FCL's third party partners.

G Medical intends to explore additional partnerships within Taiwan. The Company will update shareholders as developments progress.

Distribution agreement unlocks European market entry:

G Medical secured a 12-month, non-exclusive agreement with leading European telemedicine provider Meditel srl ("Meditel") (www.meditelitalia.it) to promote and sell G Medical's Prizma device and Extended Holter in Italy.

Meditel is based in Milan and promotes and delivers telemedicine services through web based call centres in Italy. It delivers these offerings through agreements with third party developers, which has allowed it to activate telemedicine service delivery points in over 500 pharmacies across Italy. Services can also be utilised on a pay per use basis, for individuals who wish to manage clinical tests directly.

Meditel has also developed the Lifechart platform, used for home monitoring of chronic patients. This web-based service was developed to defray costs for hospitals and healthcare facilities. Lifechart is certified to deliver electrocardiogram (ECG) monitoring services and provides a large potential opportunity for G Medical.

Under the agreement, Meditel will promote, sell and distribute the Prizma device and Extended Holter in Italy. Both parties will also explore ways to implement G Medical's devices and its monitoring capabilities into Meditel's existing telemedicine offerings.

The Company advises that first units of the Prizma device are being delivered to Meditel. The Company expects to update shareholders on in country progress in the coming weeks.

Prizma product development initiatives:

As part of its ongoing research and development initiatives, G Medical successfully integrated a blood glucose module into the Prizma device. This is a monumental achievement for the Company and continues GMV's efforts in creating the next generation of the Prizma.

Known as the Prizma Generation 3 ("G3"), the Company is aiming to create a mobile laboratory, which will allow the Prizma to undertake an array of chemical, laboratory and diagnostic tests. The additional feature sets will become an appealing diagnostic and management tool for both patients and individuals with specific chronic illnesses, as well as those wanting more convenient and reliable access to a broader spectrum of personal physiological and biochemical data and analysis.

Prizma G3's chemical tests are automatically synced and stored into the Prizma's existing platform and recorded on the individual's personal electronic medical record ("EMR"). As with the current Prizma's EMR functionality, the G3's EMR can also be shared digitally and instantaneously with the patient's physician, health care provider and/or guardian on election, as well as provide in-APP guidance on the analysis.

GMV will conduct third party clinical studies as required by the regulatory for any specific territory it decides to enter. The Company looks forward to updating shareholders on progress with the Prizma G3.

Corporate:

Receipts from customers were \$1,232,000 for the period, with the majority of sales generated from remote independent diagnostics testing facility services. The Company advises that revenue decreased slightly on the previous quarter (Q4 2019: ~\$1.4m) due to the outbreak of COVID-19. Due to lockdown restrictions put in place, G Medical sales representatives were forced to shift initiatives online.

To deal with the effects of the pandemic, G Medical has implemented a number of cost cutting initiatives and will remain vigilant on expenditure.

Despite volatile market conditions, G Medical has begun to witness increased interest in its products and solutions from parties in the USA, Europe and Australia. The Company is confident that it can deliver on a number near term value catalysts, which will unlock considerable value for shareholders.

FDA grants Prizma over-the-counter (OTC) authorisation:

Subsequent to the end of the period, the Company achieved a major milestone when it was granted OTC approval for its Prizma device in the USA by the US Food & Drug Administration (FDA). Authorisation following discussions with the FDA following the release of a guidance document issued by the organisation in response to the COVID-19 pandemic.

GMV contacted the FDA directly to seek acknowledgement that the Prizma satisfied the scope of the guidance document for authorisation defined at ‘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 guidance documents scope and expanded the use of the Prizma from prescription to OTC. The change in classification and allows for the device to be sold directly to consumers, without a prescription.

The development allows GMV to target the US market more aggressively. OTC classification will allow for broader uptake of the Prizma device by consumers more broadly. The Company is working to expedite a device launch and will update shareholders on progress as soon as possible.

Distribution agreement with remote patient solutions company LiveCare:

GMV entered into a three-year non-exclusive distribution agreement with LiveCare Corp. (“LiveCare”) (www.livecareusa.com), under which LiveCare will promote the sale and distribute the Prizma device in the USA. As part of the agreement, GMV will work with LiveCare to integrate the Prizma into the Link+ platform, which will be offered directly to US consumers.

Life+ 4G Smart Home Gateway that integrates an array of medical devices into a patient’s home using a simple, touch-free syncing process. The Link+ helps monitor chronic care patients, offers better patient outcomes, reduces healthcare costs and lowers readmission rates.

Once a patient uses the home monitoring service or a connected device, all data is transmitted through the Link+ directly to the FDA cleared, LiveCare HIPAA cloud. If there is a decline in the patient’s condition, the system will automatically generate an alert to a call centre, which can be escalated as required.

LiveCare has an established distribution footprint in the USA and is the preferred provider to the Independent Physician Association of America (TIPAAA), the leading trade association serving independent and integrated physician associations. TIPAAA currently represents approximately 700 organisation and affiliates in 39 states and more than 300,000 physicians.

Fosun Hani Securities Limited and Boustead Securities engaged as financial and listing advisors to NASDAQ IPO

Both Fosun Hani and Boustead Securities have been engaged as joint financial and listing advisors to G Medical’s planned NASDAQ IPO. The Company is aiming to progress to IPO during Q3 2020.

Fosun Hani is a wholly owned subsidiary of Fosun International Limited (HKEx: 00656) (“Fosun Group”), a leading global investment group. Fosun Hani is based in Hong Kong and acts as Fosun Group’s integrated financial hub and primary investment arm. Established in 1987, it has a strong track-record across a broad range of sectors and is a participant member of The Stock Exchange of Hong Kong Limited.

Boustead is a California based investment banking firm that specialises in IPOs, M&A, capital raises and restructuring assignments in a wide array of industries and geographies. Its core value proposition is to create opportunity through innovative solutions and tenacious execution. Boustead has an experienced management team in the United States and has considerable experience with NASDAQ related transactions.

Both parties bring strong investor networks and extensive expertise that G Medicals will be able to leverage when progressing its NASDAQ listing.

Distribution agreement with HomeStay Care Limited (ASX:HSC):

The Company executed a non-exclusive agreement with smart home solutions provider HomeStay Care Limited for the distribution of its Prizma device in Australia and New Zealand. Further, GMV and HomeStay Care will work collaboratively to integrate Prizma into HomeStay's IoT platform. Integration will provide remote vital signs monitoring capabilities to HSC's uVue telehealth platform ("uVue") and a 24-hour monitoring response to users in Australia and New Zealand. Following integration, the Prizma device will be made available primarily using the uVue telehealth platform as the communication delivery system.

uVue is a cloud-based system telehealth platform that is connected to a client's television. It is used by a large number of aged care providers that have challenges communicating effectively with the elderly due to the technology gap experienced by seniors.

The distribution agreement provides G Medical with another established partner in a key market. The Company looks forward to progressing opportunities with HomeStay Care and other providers in Australia.

Management commentary:

CEO and Executive Director Dr Yacov Geva said: "While the quarter was challenging given restriction put in place by COVID-19, G Medical has been able to lay a strong foundation for growth through a number of critical regulatory and operational milestones.

"The momentum generated during Q1 has continued well into the current period and G Medical remains incredibly well positioned to capitalise despite a volatile market. We look forward to updating shareholders on a number of initiatives in the coming weeks, that will unlock considerable near term value."

Ends

Authorised for release by Yacov Geva, Managing Director.

Released through: Henry Jordan, Six Degrees Investor Relations: +61 (0) 431 271 538

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>

Appendix 4C

Quarterly cash flow report for entities subject to Listing Rule 4.7B

Name of entity

G Medical Innovations Holdings Ltd

ABN

617 204 743

Quarter ended ("current quarter")

31 March 2020

Consolidated statement of cash flows	Current quarter \$US'000	Year to date (3 months) \$US'000
1. Cash flows from operating activities		
1.1 Receipts from customers	1,232	1,232
1.2 Payments for		
(a) research and development	(62)	(62)
(b) product manufacturing and operating costs	(338)	(338)
(c) advertising and marketing	(45)	(45)
(d) leased assets	-	-
(e) staff costs	(1,232)	(1,232)
(f) administration and corporate costs	(236)	(236)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	-	-
1.5 Interest and other costs of finance paid	(12)	(12)
1.6 Income taxes paid		
1.7 Government grants and tax incentives	-	-
1.8 Other (provide details if material)	28	28
1.9 Net cash from / (used in) operating activities	(665)	(665)
2. Cash flows from investing activities		
2.1 Payments to acquire:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	(7)	(7)
(d) investments	-	-
(e) intellectual property	-	-
(f) other non-current assets	(30)	(30)

Consolidated statement of cash flows		Current quarter \$US'000	Year to date (3 months) \$US'000
2.2	Proceeds from disposal of:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	-	-
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	-
2.3	Cash flows from loans to other entities	-	-
2.4	Dividends received (see note 3)	-	-
2.5	Other (provide details if material)	38	38
2.6	Net cash from / (used in) investing activities	1	1

3.	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	845	845
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	-	-
3.4	Transaction costs related to issues of equity securities or convertible debt securities	-	-
3.5	Proceeds from borrowings	206	206
3.6	Repayment of borrowings	(109)	(109)
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other (provide details if material)	-	-
3.10	Net cash from / (used in) financing activities	942	942

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	(93)	(93)
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(665)	(665)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	1	1

Consolidated statement of cash flows		Current quarter \$US'000	Year to date (3 months) \$US'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	942	942
4.5	Effect of movement in exchange rates on cash held		
4.6	Cash and cash equivalents at end of period	185	185

5.	Reconciliation of cash and cash equivalents at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	Current quarter \$US'000	Previous quarter \$US'000
5.1	Bank balances	185	185
5.2	Call deposits		
5.3	Bank overdrafts		
5.4	Other (provide details)		
5.5	Cash and cash equivalents at end of quarter (should equal item 4.6 above)	185	185

6. Payments to related parties of the entity and their associates

6.1 Aggregate amount of payments to related parties and their associates included in item 1

6.2 Aggregate amount of payments to related parties and their associates included in item 2

Current quarter \$US'000
-
-

Note: if any amounts are shown in items 6.1 or 6.2, your quarterly activity report must include a description of, and an explanation for, such payments

7. Financing facilities

Note: the term "facility" includes all forms of financing arrangements available to the entity.

Add notes as necessary for an understanding of the sources of finance available to the entity.

	Total facility amount at quarter end \$US'000	Amount drawn at quarter end \$US'000
7.1 Loan facilities		
7.2 Credit standby arrangements	2,290	2,290
7.3 Other – Loans from controlling shareholder	2,043	2,043
Other – Convertible Notes	777	777
Other – Funding facility	(*) 18,279	567
7.4 Total financing facilities	23,389	5,677

(*) A\$ 30,000,000

7.5 Unused financing facilities available at quarter end

17,712

7.6 Include in the box below a description of each facility above, including the lender, interest rate, maturity date and whether it is secured or unsecured. If any additional financing facilities have been entered into or are proposed to be entered into after quarter end, include a note providing details of those facilities as well.

7.1- The Company received several loans from Bank Mizrahi Tfahot in Israel. As of March 31, 2020, the total amount of these loans is: US\$ 1.084 M.

The loans are denominated in US Dollars and NIS and bear interest rates of Libor + (2.5%) and prime+ (0.5%- 0.85%) per annum.

The Company's major shareholder provides a guarantee for part of these loans payments.

Upon CardioStaff acquisition, additional long- term loans were added to the Company balance. As of December 31, 2019, the total amount of these loans is US\$ 1.206 M and include mainly loans from private people/institutions and bear interest of 4%-12% per annum.

7.3- Loans from controlling shareholder (Yacov Geva) - Yacov Geva has entered into a credit line agreement in May 2018, to provide the Company up to US\$ 3 M. The agreement was amended and effective as of October 1, 2018 the aggregate amount available to the company is US\$ 10 M.

On April 24, 2019 our shareholders approved the conversion of approx. US\$ 3.3 million that had been drawn from the 2016 and 2018 credit line into an aggregate of 14,706,719 shares.

On June 24, 2019 our shareholders approved additional conversion of US\$ 2 M that had been drawn from the 2018 credit line into an aggregate of 14,532,771 shares.

On March 19, 2020 our shareholders approved additional conversion of US\$ 5.0 million that had been drawn from the credit line into 93,339,307 shares.

As of March 31, 2020, the amount drawn of Yacov Geva loans totalled at US\$ 2.043 M.

Convertible Notes -

The Company issued, in the last quarter of 2018, 4,050,000 Convertible Notes at a face value of US\$ 4.455 M. Until March 31 2020, the company redeemed 998,331 Convertible Notes and terminated some of the Convertible Notes in exchange for a financial commitment that amounted to US\$ 3.566 as of March 31, 2020. The Convertible Notes remaining as of March 31, 2020 is US\$ 776,667. The Fixed conversion price is A\$ 0.3362, the maturity date is 18 months after the purchase date and the payment is 115% of the face value.

Funding facility -

The company has secured capital commitments of up to A\$30 million (~ US\$ 18 million) over a three year period from Luxembourg based GEM Global Yield LLC SCS .

Subject to the terms of a Capital Commitment Agreement, the Company may choose to, on one or more occasions within the three year period, subject to conditions precedent draw down on the facility by giving GEM 15 trading days' notice to subscribe for fully paid ordinary shares in the Company. The number of shares which GMV may draw down under a notice is capped at 1,000% of the average daily number of GMV shares traded on ASX during the 15 trading days prior to that draw down notice, subject to adjustments.

If the Company issues a draw down notice, the subscription price of the shares to be issued to GEM (or its nominees) will be 90% of the higher of:

- the average closing bid price of GMV shares as quoted by ASX over the pricing period, being the 15 consecutive trading days after GMV gives the draw down notice to GEM (subject to certain adjustments); or
- a fixed floor price nominated by the Company in its draw down notice.

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8. Estimated cash available for future operating activities	\$US'000
8.1 Net cash from / (used in) operating activities (Item 1.9)	(675)
8.2 Cash and cash equivalents at quarter end (Item 4.6)	185
8.3 Unused finance facilities available at quarter end (Item 7.5)	17,712
8.4 Total available funding (Item 8.2 + Item 8.3)	17,897
8.5 Estimated quarters of funding available (Item 8.4 divided by Item 8.1)	27

8.6 If Item 8.5 is less than 2 quarters, please provide answers to the following questions:

1. Does the entity expect that it will continue to have the current level of net operating cash flows for the time being and, if not, why not?

Answer:

2. Has the entity taken any steps, or does it propose to take any steps, to raise further cash to fund its operations and, if so, what are those steps and how likely does it believe that they will be successful?

Answer:

3. Does the entity expect to be able to continue its operations and to meet its business objectives and, if so, on what basis?

Answer:

Compliance statement

- 1 This statement has been prepared in accordance with accounting standards and policies which comply with Listing Rule 19.11A.
- 2 This statement gives a true and fair view of the matters disclosed.

April 30, 2020

Date:

Yacov Geva

Authorised by:
 (Name of body or officer authorising release – see note 4)

Notes

1. This quarterly cash flow report and the accompanying activity report provide a basis for informing the market about the entity's activities for the past quarter, how they have been financed and the effect this has had on its cash position. An entity that wishes to disclose additional information over and above the minimum required under the Listing Rules is encouraged to do so.
2. If this quarterly cash flow report has been prepared in accordance with Australian Accounting Standards, the definitions in, and provisions of, *AASB 107: Statement of Cash Flows* apply to this report. If this quarterly cash flow report has been prepared in accordance with other accounting standards agreed by ASX pursuant to Listing Rule 19.11A, the corresponding equivalent standard applies to this report.

3. Dividends received may be classified either as cash flows from operating activities or cash flows from investing activities, depending on the accounting policy of the entity.
4. If this report has been authorised for release to the market by your board of directors, you can insert here: "By the board". If it has been authorised for release to the market by a committee of your board of directors, you can insert here: "By the [name of board committee – eg Audit and Risk Committee]". If it has been authorised for release to the market by a disclosure committee, you can insert here: "By the Disclosure Committee".
5. If this report has been authorised for release to the market by your board of directors and you wish to hold yourself out as complying with recommendation 4.2 of the ASX Corporate Governance Council's *Corporate Governance Principles and Recommendations*, the board should have received a declaration from its CEO and CFO that, in their opinion, the financial records of the entity have been properly maintained, that this report complies with the appropriate accounting standards and gives a true and fair view of the cash flows of the entity, and that their opinion has been formed on the basis of a sound system of risk management and internal control which is operating effectively.