



Boston, United States  
Sydney, Australia  
1 May 2020 AEST

## Quarterly Activities Report – Q1 2020

**BOSTON and SYDNEY — 1 May 2020** — GI Dynamics® Inc. (ASX:GID) (GID or the Company), a medical device company that is developing EndoBarrier® for patients with type 2 diabetes and obesity, is presenting its quarterly activities report for Q1 2020 further to filing the Appendix 4C on 28 April 2020.

### Operational

On 15 January 2020, the Company announced the publication of positive EndoBarrier data from a study conducted by the University of Freiburg in Germany which indicated improvements of cardiovascular (CV) risk biomarkers and predicted 4-year risk of major CV events. The study “Duodenal-jejunal Bypass Liner (DJBL) Improves Cardiovascular Risk Biomarkers and Predicted 4-Year Risk of Major CV Events in Patients with Type 2 Diabetes and Metabolic Syndrome,” published by Natascha Roehlen, MD, of the University of Freiburg, demonstrates CV risk decreased significantly during EndoBarrier implantation and sustained improvements within 6 months after explantation

On 28 January 2020, the Company announced that it had enrolled its first patient in the United States STEP-1 clinical trial of EndoBarrier at Michigan Medicine in Ann Arbor, Michigan. This represented the first of 67 patients expected to be enrolled into Stage 1 of the STEP-1 trial. Results from the STEP-1 trial will support the Company’s pre-market approval application for EndoBarrier to the U.S. Food and Drug Administration (FDA).

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### Corporate

On 2 March 2020, the Company announced the appointment of Praveen Tyle, PhD, to its Board of Directors (the Board) as a Class III director to serve until the 2020 Annual Meeting of Stockholders and thereafter in accordance with the Company’s bylaws. Then on 30 March 2020, the Company announced the resignation of Timothy Barberich from the Board and the appointment of Dr. Tyle to replace Mr. Barberich as compensation committee chairman and audit committee member.



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## **Fundraising**

On 14 January 2020, the Company confirmed that funding had been provided by Crystal Amber Fund Limited (Crystal Amber) under the convertible note dated 22 August 2019 (2019 Note) and that the Company had also issued a warrant to Crystal Amber in connection with the 2019 Note.

On 23 March 2020, the Company announced that it had lodged a draft proxy statement with SEC and ASX noting that it was seeking to secure further funding through the issue of new CDIs and potentially warrants to sophisticated and professional investors in one or more private placement transactions. The Company also advised that it had appointed a non-U.S. financial advisor to assist the Company with its proposed fundraising activities outside of the United States. Finally, the Company announced that it may be seeking to amend some of the existing terms under notes and warrants on issue to Crystal Amber as part of any new fundraising activity.

## **Post Period Activity**

On 1 April 2020, the Company announced that Crystal Amber had agreed to extend the maturity date of the 2017 Senior Secured Convertible Promissory Note from 31 March 2020 to 1 May 2020.

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This announcement has been authorized for release by Charles Carter, chief financial officer and company secretary of GI Dynamics.

## **About GI Dynamics**

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GI Dynamics®, Inc. (ASX:GID) is the developer of EndoBarrier®, the first endoscopically-delivered medical device for the treatment of type 2 diabetes and the reduction of obesity. EndoBarrier is not approved for sale and is limited by federal law to investigational use only. EndoBarrier is subject to an Investigational Device Exemption



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by the FDA in the United States and is entering concurrent pivotal trials in the United States and India.

Founded in 2003, GI Dynamics is headquartered in Boston, Massachusetts. For more information please visit the Company website at [www.gidynamics.com](http://www.gidynamics.com).

### **Forward-Looking Statements**

This announcement may contain forward-looking statements. These statements are based on management's current estimates and expectations of future events as of the date of the press release. Furthermore, the estimates are subject to several risks and uncertainties that could cause actual results to differ materially and adversely from those indicated in or implied by such forward-looking statements.

These risks and uncertainties include, but are not limited to, risks associated with the ability of the Company, its critical vendors, and key regulatory agencies to resume operational capabilities subsequent to the removal of COVID-19 pandemic restrictions; the Company's ability to continue to operate as a going concern; the Company's ability to raise sufficient additional funds to continue operations and to conduct the planned pivotal trial of EndoBarrier in the United States (STEP-1); the Company's ability to maintain compliance with its obligations under its existing convertible note and warrant agreements executed with Crystal Amber, including its obligations to make payment on the convertible note that is due on 1 May 2020 and its ability to restructure the terms of the convertible note with Crystal Amber that is due on 1 May 2020 if the Company is unable to raise sufficient funds to enable it to fully repay such convertible note when due; the Company's ability to execute STEP-1 under the FDA's Investigational Device Exemption; the Company's ability to enlist clinical trial sites and enroll patients in accordance with STEP-1; the risk that the FDA stops STEP-1 early as a result of the occurrence of certain safety events or does not approve an expansion of STEP-1; the Company's ability to enroll patients in accordance with I-STEP; the Company's ability to secure a CE Mark; the Company's obtaining and maintaining regulatory approvals

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required to market and sell the Company's products; the possibility that future clinical trials will not be successful or confirm earlier results; the timing and costs of clinical trials; the timing of regulatory submissions; the timing, receipt and maintenance of regulatory approvals; the timing and amount of other expenses; the timing and extent of third-party reimbursement; intellectual-property risk; risks related to excess inventory; risks related to assumptions regarding the size of the available market; the benefits of the Company's products; product pricing; timing of product launches; future financial results; and other factors, including those described in the Company's filings with the SEC.

Given these uncertainties, one should not place undue reliance on these forward-looking statements. The Company does not assume any obligation to publicly update or revise any forward-looking statements, whether as a result of new information or future events or otherwise, unless it is required to do so by law.

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