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GI Dynamics, Inc. Provides 2017 Review And 2018 Business Outlook

BOSTON and SYDNEY — 15 January 2018— GI Dynamics®, Inc. (ASX:GID), a medical device company that is developing EndoBarrier® provides shareholders with a review of 2017 activities and its 2018 business outlook.

GI Dynamics is preparing to submit an Investigational Device Exemption (IDE[1]) application to the US Food and Drug Administration (FDA) for a new pivotal trial of the EndoBarrier. In addition, GI Dynamics is focused on taking all appropriate measures to address the withdrawal of the EndoBarrier CE Certificate of Conformity which enabled the company to CE Mark the EndoBarrier and sell the product in Europe and select countries in the Middle East.

GI Dynamics is making efforts to reduce monthly cash expenses and continues to evaluate multiple financing options. As detailed in our recent 10Q filings, GI Dynamics continues to operate with substantial doubt about its ability to continue as a going concern.

CE Mark

GI Dynamics has been working closely with the Medicines and Healthcare Products Regulatory Agency (MHRA[2]) of the United Kingdom and MedPass International[3] in Europe to prioritize patient management during the period following SGS United Kingdom, Limited's (SGS) withdrawal of the EndoBarrier CE Certificate of Conformity.

Investor Relations
United States:
Janell Shields
+1 (781) 357-3280
investor@gidynamics.com

[1] IDE: https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/default.htm
[2] Medicines & Healthcare products Regulatory Agency: https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency
[3] GI Dynamics Authorized Representative MedPass: http://medpass.org/

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Most notably, GI Dynamics expects that all patients with current EndoBarrier implants will be allowed to continue the full twelve-month treatment duration.

GI Dynamics underwent an audit by SGS in October 2017. As part of the audit process, SGS audited GI Dynamics to full ISO 13485:2003[4] and MDD 93/42/EEC[5] standards. GI Dynamics fully passed the ISO 13485:2003 audit and the quality requirements of the MDD 93/42/EEC. The company's contract manufacturer Proven Process Medical Devices, Inc. (PPMD) also successfully participated in the audit. Despite passing the positive results of the quality system audit, SGS did not consider that GI Dynamics fulfilled revised clinical evaluation obligations.

GI Dynamics is evaluating legal remedies to protect its rights and those of its shareholders.

The company has been in contact with other notified bodies in Europe, with the intent of obtaining a new CE Certificate of Conformity for EndoBarrier.

2017 Highlights

Financing

In mid-January 2017, GI Dynamics closed out its Security Purchase Plan that commenced in December 2016, raising a total of approximately US $0.2 million under that plan. In June 2017, GI Dynamics entered into a US $5 million convertible note financing arrangement with its major shareholder, Crystal Amber Fund Ltd.

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investor@gidynamics.com

[4] ISO 13485:2003: http://www.sgs.com/en/life-sciences/medical-devices/audit-certification-and-verification/certification/iso-13485-2003
[5] MDD 93/42/EEC: http://www.sgs.com/en/life-sciences/medical-devices/audit-certification-and-verification/certification/93-42-eec-medical-devices-directive-ce-marking-for-europe

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Board of Directors

Dr. Oern Stuge, MD, MBA and Ms. Juliet Thompson were added to the Board of Directors. Since their respective appointments to the Board, Dr. Stuge has become the chair of the Nominating & Corporate Governance Committee, and Ms. Thompson has become the chair of the Audit Committee.

Dr. Stuge brings significant experience in medical devices and specifically in type 2 diabetes and obesity. He has also lead successful clinical development programs and global commercialization efforts and has held executive and board positions with numerous medical device companies over the past 30 years, such as Medtronic Plc and Abbott Laboratories, Inc. As a director, he has helped lead several successful company exits, raised significant capital and launched an IPO.

Ms. Thompson has advised and raised capital for healthcare companies for more than 20 years and founded Code Securities, a healthcare investment banking firm that was sold to Nomura. In addition to GI Dynamics, Ms. Thompson also serves as NED for Nexstim Limited, NED for Novacyt SA, and is the chair of Premier Veterinary Group Plc.

The company saw the departures of directors Mike Carusi, Graham Bradley and Anne Keating.

Clinical Data

EndoBarrier was the subject of multiple studies released during Digestive Disease Week 2017 in Chicago, Illinois, the American Diabetes Association's 77th Scientific Sessions in San Diego, California, and the 53rd Annual Meeting of the European Association for the Study of Diabetes in Lisbon, Portugal.

The clinical data sourced from multiple investigator-initiated clinical trials, two ongoing registries, and a recent comprehensive meta-analysis continues to underscore

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EndoBarrier positive risk: benefit profile. The clinical data focuses on expanding studies on the use of EndoBarrier within the type 2 diabetes and obesity population, reports post-removal efficacy, studies the effects on non-alcoholic fatty liver disease[6] patients, evaluates serial EndoBarrier treatment, and releases the first data on an adolescent obesity study.

More detailed clinical information is further summarized at the end of this press release.

SAB

GI Dynamics formed a Scientific Advisory Board (SAB) of world-renowned physicians and scientists specializing in endocrinology, gastroenterology and metabolic surgery to advance the evidence-based understanding of EndoBarrier and support its optimal usage.

The GI Dynamics SAB was created to help the company advance the body of evidence supporting clinical use of EndoBarrier, ask and answer relevant questions about the treatment paradigm and advance the state of patient care for type 2 diabetes and obesity.

PPMD

The company announced the selection of Proven Process Medical Devices, Inc. (PPMD) as its contract manufacturing partner for EndoBarrier in July of 2017. Since then, PPMD has been validated by GI Dynamics for the manufacture of EndoBarrier and passed the ISO/MDD audit in October of 2017.

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United States:
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[6] NAFLD or NASH: https://www.niddk.nih.gov/health-information/liver-disease/nafld-nash

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Patents

GI Dynamics continued to build its intellectual property protection around EndoBarrier. The company was granted a total of seven patents from the United States Patent and Trademark Office, two patents from the European Patent Office, and two in China.

Priorities for 2018

- Work towards FDA approval for a new IDE pivotal study and initiate enrollment in the new clinical study in the United States
- Continue to work with European regulators and MedPass International to ensure the safe removal of all current EndoBarrier implants after treatment duration of twelve months
- Continue to consider possibilities of raising capital to fund operations
- Identify alternate notified bodies in Europe with the intent of obtaining a new CE Certificate of Conformity for EndoBarrier
- Continue to work with its Scientific Advisory Board (SAB) to continually improve the company's efforts to treat type 2 diabetes and obesity with EndoBarrier
- Seek to bolster the efficacy and safety profile for EndoBarrier with new clinical data

Closing Remarks

"While significant progress was made across all fronts in 2017 including conducting a comprehensive analysis of the science around EndoBarrier and moving towards an IDE filing, we did not achieve the desired outcome of continuing to CE Mark the EndoBarrier in Europe. Despite this issue, EndoBarrier continues to produce significant clinical data through numerous clinical studies," said Scott Schorer, president and chief executive officer. "We have taken necessary steps to further reduce cash burn and are focused on appropriately capitalizing the company."

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"EndoBarrier has the potential to remain the most advanced treatment for patients with type 2 diabetes and obesity who are not adequately managed by pharmacotherapy alone," Schorer continued, "The leadership team, employees, and directors of GI Dynamics remain resolved in our commitment to continue to develop EndoBarrier for the millions of patients who have no viable treatment option for the type 2 diabetes and obesity."

Further Details of Released Studies

Meta-Analysis:

At Digestive Disease Week® 2017 Pichamol Jirapinyo, M.D., Division of Gastroenterology, Hepatology and Endoscopy at Brigham and Women's Hospital and Harvard Medical School in Boston, presented "The Effect of the Duodenal-Jejunal Bypass Liner on Glycemic Control in Type-2 Diabetic Patients with Obesity: A Meta-Analysis with Secondary Analysis on Weight Loss and Hormonal Changes." The study analyzed publicly available data from 14 studies as part of the most comprehensive meta-analysis of EndoBarrier to date.

This meta-analysis reviewed randomized, controlled trials and cohort studies found in MEDLINE, EMBASE and Web of Science published through 1 November 2016 that assessed outcomes of EndoBarrier in patients with type 2 diabetes and obesity. Data was pooled using a mixed-effect model or a random-effect model for high heterogeneity. Of 593 eligible studies, 18 were included and seven studies provided additional data.

The Meta-Analysis showed a mean reduction in HbA1c of 1.3% from baseline to removal, a mean reduction in HbA1c of 1.0% from baseline to six months post removal, a mean 12.6kg and 14% reduction in body weight, and other significant hormonal measures.

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Treatment Durability:

During the American Diabetes Association's 77th Scientific Sessions Bob Ryder, M.D., Consultant Diabetologist of Sandwell and West Birmingham Hospitals' National Health Service Trust presented a poster titled, "Maintenance of Efficacy After EndoBarrier in UK 1st National Health Service (NHS) EndoBarrier Service." The data demonstrated that metabolic improvements made by patients while implanted with EndoBarrier were sustained for six months after EndoBarrier was explanted.

Twelve patients completed a 12-month implantation of EndoBarrier and were evaluated six months following explantation; 75 percent of patients (nine out of the 12) sustained considerable metabolic improvements, including weight loss, body mass index reduction and lower glucose levels.

EndoBarrier Compared to Gastric Plication:

At the 53rd Annual Meeting of the European Association for the Study of Diabetes Anna Cinkajzlova, M.D., from the Centre for Experimental Medicine, Institute for Clinical and Experimental Medicine presented "Circulating Lipopolysaccharide and Gut Permeability in Obese Subjects with Type 2 Diabetes: The Influence of Surgical and Endoscopic Interventions," an analysis that compared gastric plication to EndoBarrier.

Cinkajzlova conducted a basic scientific assessment of circulatory levels of lipopolysaccharide binding protein, fatty acid binding protein 2 and sCD14 following assigned weight-reducing treatments combined with quantification of adipose tissue macrophages. In addition, the study compared clinical outcomes across multiple health metrics and biomarkers between surgical gastric plication, a form of gastric restriction, and EndoBarrier.

Re-implantation of EndoBarrier:

At the German Diabetes Congress 2017 in Hamburg, Germany, the primary investigator, Jürgen Stein, M.D., presented data from an observational study titled "Is Re-Implantation of the Duodenal-Jejunal Bypass Liner Viable?." The study explored

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whether it is technically feasible to re-implant EndoBarrier in patients who previously had the device implanted and explanted, as well as whether the re-implantation would achieve similar weight and metabolic effects as on patients who had received prior EndoBarrier implantation.

Five patients participated in this study. Each patient completed an initial course of EndoBarrier treatment for a 12-month period. The device was explanted and the patients were monitored for four months. A second EndoBarrier was then implanted for a 12-month course of treatment and subsequently removed.

About GI Dynamics

GI Dynamics, Inc. (ASX:GID), is the developer of EndoBarrier, the first endoscopically-delivered device therapy approved for the treatment of type 2 diabetes and obesity. EndoBarrier is not approved for sale in the United States and is limited by federal law to investigational use only in the United States. Founded in 2003, GI Dynamics is headquartered in Boston, Massachusetts. For more information, please visit www.gidynamics.com.

Forward-Looking Statements

This announcement contains forward-looking statements. These forward-looking statements are based on GI Dynamics management's current estimates and expectations of future events as of the date of this announcement. 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 our ability to continue to operate as a going concern, our ability to maintain compliance with our obligations under the Convertible Loan Note executed with Crystal Amber Fund Limited, obtaining and maintaining regulatory approvals required to market and sell our products; obtaining funding from third parties; the

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consequences of stopping the ENDO trial and 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; risks associated with commercial product sales, including product performance, competition, market acceptance of products, intellectual-property risk; risks related to excess inventory; and risks related to assumptions regarding the size of the available market, the benefits of our products, product pricing, timing of product launches, future financial results and other factors, including those described in our filings with the U.S. Securities and Exchange Commission. Given these uncertainties, one should not place undue reliance on these forward-looking statements. We do 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 we are required to do so by law.

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