



Boston, United States
Sydney, Australia
4 January 2019 AEDT

GI Dynamics Appoints Vice President of Clinical and Regulatory Affairs

BOSTON and SYDNEY — 4 January 2019 — GI Dynamics® Inc. (ASX:GID), a medical device company that is developing EndoBarrier® for patients with type 2 diabetes and obesity, is pleased to announce the appointment of Stephen Linhares to the position of vice president of clinical and regulatory affairs.

Linhares' role with GI Dynamics will focus on the pivotal trial of EndoBarrier in the United States ([GID 18-1](#)) and the clinical trial of EndoBarrier in India with [Apollo Sugar](#). He will also lead the company's efforts with its notified body, [Intertek](#), to seek a CE mark for EndoBarrier.

Linhares brings over 30 years of experience in development, regulatory, preclinical and clinical operations, quality and resource management with a focus on medical devices. Prior to joining GI Dynamics, Linhares held the positions of vice president of regulatory, clinical affairs and quality assurance at Neograft Technologies Inc. and leadership roles at Insulet Corporation,¹ Boston Scientific Corporation Inc. and Phase Forward Inc. as well as vice president roles at PLC Medical Systems.

Linhares brings deep knowledge of the diabetes disease space, and the medical device space, where he has led 10 clinical trials, multiple CE mark approvals and numerous 510(k) clearances. Linhares holds nearly 20 United States and international patents and co-author of two peer-reviewed publications.²

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¹ [Insulet Corporation](#), a medical device company specializing in state-of-the-art insulin delivery devices.

² Z. Drozdowicz, R.I. Rudko, S.J. Linhares and B. Lax, "High Gain 4.3 to 4.5 um Optically Pumped CO2 Laser," *IEEE Quantum Electron*, vol. QE-17, pp. 574-1580, 1987.

R.I. Rudko, A. Drozdowicz and S.J. Linhares, "High Repetition-Rate, Recirculating Hydrogen Fluoride/Deuterium Fluoride Laser," *Rev. Sci. Instruments*, vol. 53, pp. 452-457, 1982.



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“GI Dynamics is preparing to launch clinical studies on a product that could disrupt the conventional approaches for the treatment of type 2 diabetes and obesity, and I am very honored and excited to be involved,” said Linhares.

“On behalf of the GI Dynamics board of directors, I am pleased to announce the appointment of Stephen Linhares,” said Scott Schorer, president and chief executive officer of GI Dynamics. “Stephen will join Charles Charter and I on our senior leadership team. Together we are focused on stage 1 of GID 18-1, the clinical trial in India and gaining the EndoBarrier CE mark. Stephen will help lead the company with the necessary expertise, and I am pleased to welcome him to the team.”

About GI Dynamics

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

Forward-Looking Statements

This announcement may contain forward-looking statements. These 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.

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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 raise sufficient additional funds to continue operations and to conduct the pivotal trial of EndoBarrier in the United States (GID 18-1); our ability to execute GID 18-1 under FDA’s Investigational Device Exemption; our ability to enlist clinical trial sites and enroll patients in



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accordance with GID 18-1; the risk that the FDA stops GID 18-1 early as a result of the occurrence of certain safety events or does not approve an expansion of GID 18-1; our ability to maintain compliance with our obligations under our existing convertible note and warrant agreements executed with Crystal Amber Fund Limited, including our obligations to make payment on the relevant note that is due in March 2019; our ability to restructure the terms of the convertible note with Crystal Amber Fund Limited that is due in March 2019 if we are unable to raise sufficient funds to enable us to fully repay such note when due; obtaining and maintaining regulatory approvals required to market and sell our 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 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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