



GI Dynamics, Inc. – ASX Announcement

Appendix 4C Quarterly Report Quarter ended 31 March 2014

*GI Dynamics to Hold Briefing Call and Webcast on Financial Results
for First Quarter 2014 on Tuesday, 29 April 2014 at 6 p.m. U.S. EDT
and Wednesday, 30 April 2014 at 8:00 a.m. AEST*

LEXINGTON, Massachusetts, United States and SYDNEY, Australia – 29 April 2014 – GI Dynamics, Inc. (**ASX: GID**) (**GI Dynamics** or the **Company**), a medical device company developing innovative treatments for type 2 diabetes and obesity, is pleased to provide its financial results for the quarter ended 31 March 2014 (**Quarter**). The Appendix 4C, which has been prepared in U.S. dollars, is attached and the results disclosed in the Appendix 4C are unaudited.

“We are pleased with the progress we’ve made this quarter in both self-pay and reimbursed markets,” stated Stuart A. Randle, president and chief executive officer of GI Dynamics. “We are continuing to execute on our global dual-pronged commercial strategy, which aims to drive sales in the near term in self-pay markets, while building for the long-term success and future growth of EndoBarrier® Therapy in reimbursed markets. In the self-pay markets, we expanded patient access to EndoBarrier Therapy in Australia through two high-profile centres located in capital cities, and are currently training physicians at additional centres where we expect to begin treating patients with EndoBarrier soon. In reimbursed markets over the last several months, we achieved important reimbursement milestones on the path to long-term broader reimbursement coverage in Germany, the Netherlands and Israel.”

Business Review & Highlights

Throughout the Quarter, GI Dynamics continued to execute on its global business strategy for EndoBarrier Therapy. The Company’s recent achievements and important milestones are detailed below.

- **Revenues:** The Company increased revenue to US\$0.91 million for the Quarter compared to US\$0.36 million for the corresponding period in 2013, an increase of 154%. The Company experienced increased revenue in Europe, Australia and the Middle East.
- **New Centres:** The Company further expanded the availability of EndoBarrier Therapy in Australia through the addition of two new centres. Physicians at Adelaide Obesity Surgery in Adelaide and Upper GI West in Perth are now treating patients with EndoBarrier Therapy.

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GI Dynamics, Inc., is a corporation incorporated in Delaware, USA, whose stockholders have limited liability. ARBN 151 239 388

- **Reimbursement:** Expanded reimbursement coverage for EndoBarrier Therapy was achieved in key European markets, including:
 - Secured NUB Status 1 designation from InEk, the German Institute for the Hospital Remuneration System. The designation of NUB Status 1 is the highest level available in Germany, and entitles participating hospitals to negotiate with insurance companies for additional funding to cover the cost of procedures.
 - Received preliminary reimbursement coverage from the Dutch Health Care Authority (NZa). Under this ruling, a defined number of EndoBarrier procedures performed between July 2013 – July 2016 at Rijnstate Hospital in Arnhem will be covered by a major regional health insurance fund. The designation of this code allows government authorities in the Netherlands to capture sufficient clinical and economic data for EndoBarrier Therapy over a three-year period.
 - Clalit Health Services, Israel's largest and one of the world's largest health maintenance organizations, has established a reimbursement coverage policy for EndoBarrier Therapy. Clalit Health Services established a reimbursement policy for EndoBarrier Therapy, whereby the approximately 2.7 million people enrolled in a supplementary coverage option are entitled to receive reimbursement for at least 50% of the total agreed-upon charge for EndoBarrier Therapy.

- **Advertising Complaint Determination:** An advertisement that the Australian subsidiary of GI Dynamics placed in an Australian newspaper in September 2013 was the subject of an anonymous complaint to the Therapeutic Goods Administration Complaints Resolution Panel (CRP). The CRP has made a determination against the subsidiary regarding certain aspects of the advertisement (including recommending certain non-monetary sanctions and changes in the content of future advertisements in Australia). GI Dynamics is currently considering avenues to have the determination reviewed and has reserved all of its rights in this regard.

- **Corporate:** GI Dynamics was added to the S&P Dow Jones All Ordinaries Index, which is the largest 500 companies on the ASX with no liquidity restrictions.

- **Medical Meetings and Congresses:** Data regarding EndoBarrier Therapy continues to be featured at major medical meetings.
 - In March, data were presented during an oral presentation titled “Robust Metabolic Improvement Observed with the Endoscopic, Duodenal-jejunal Bypass Liner: 12 Month Data in Obese Type 2 Diabetes” during the 3rd Latin American Congress on Controversies to Consensus in Diabetes, Obesity and Hypertension (CODHy) in Panama.
 - Data have recently been accepted for presentation at leading medical meetings in the U.S. and additional information will be provided in conjunction with their respective embargo policies, including:
 - Digestive Disease Week, May 3-6, 2014 in Chicago, IL

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- American Association of Clinical Endocrinologists Annual Meeting, May 14-18, 2014 in Las Vegas, NV
 - American Diabetes Association Annual Meeting, June 13-17, 2014 in San Francisco, CA
- **The ENDO Trial:** The Endo Trial is a pivotal clinical trial in the U.S. evaluating the efficacy and safety of EndoBarrier in the treatment of people with type 2 diabetes and obesity. The multi-center, randomized, double-blinded study will enroll 500 patients at as many as 25 sites. The primary endpoint is improvement in diabetes control as measured by HbA1c levels. As of 31 March 2014:
- 22 clinical sites across the U.S. have initiated patient recruitment
 - 18 sites have enrolled a patient into the trial
 - Efforts to accelerate enrollment through expanded recruitment efforts have been successful in referring many more patients to sites for screening and enrollment into the trial.

Financial Review

The Company's key financial results for the Quarter include the following:

- Revenue increased to US\$0.91 million for the Quarter compared to US\$0.36 million for the same period last year, an increase of US\$0.55 million. The increase in the Company's revenue in the Quarter was primarily a result of a 194% increase in revenue from sales in Europe, a 47% increase in revenue from sales in Australia and revenue from sales in the Middle East when there were none in the same period last year.
 - In the fourth quarter of 2013 the Company started to recognize sales in most areas of the world at the time of delivery and to record a corresponding reserve for estimated product returns. During the Quarter, the portion of revenue recorded at the time of delivery was US\$0.73 million compared to US\$0.47 million in the fourth quarter of 2013, an increase of US\$0.26 million.
- The Company had deferred revenue of US\$0.79 million at 31 March 2014 compared to deferred revenue of US\$0.72 million at 31 December 2013.
- Cost of revenue for the Quarter was US\$0.90 million compared to US\$0.62 million for the same period last year. The increase in cost of revenue for the Quarter reflects increased sales volume compared to the same period last year.
- Operating expenses increased to US\$10.10 million for the Quarter compared to US\$8.53 million for the same period last year, an increase of US\$1.57 million.

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- Research and development expenses were US\$5.34 million for the Quarter compared to US\$3.23 million for the same period last year. The increase in research and development expenses was primarily a result of the Company continuing to actively enroll subjects in its U.S. pivotal trial and higher personnel related expenses due to increased headcount to support the Company's clinical and regulatory activities.
- Sales and marketing expenses remained relatively consistent at US\$2.49 million for the Quarter compared to US\$2.46 million for the corresponding period last year, as the Company continues to invest in building the commercial infrastructure in Europe, Australia, the Middle East and South America.
- General and administrative expenses were US\$2.27 million for the Quarter compared to US\$2.84 million for the same period last year, a decrease of US\$0.57 million. The decrease was primarily a result of lower legal expenses and lower non-cash share-based compensation expenses.
- Other income for the Quarter was US\$0.43 million compared to US\$0.07 million for the same period last year. The increase in other income was primarily a result of an increase in foreign exchange gain, due for the most part to changes in the value of the Australian dollar compared to the U.S. dollar and a gain on the remeasurement of the Company's warrant liability.
- As a result, the Company recorded a net loss of US\$9.68 million for the Quarter compared to US\$8.71 million for the same period last year, an increase of US\$0.97 million.
- The Company had cash and cash equivalents of US\$49.49 million at 31 March 2014 compared to US\$58.62 million as of 31 December 2013, a decrease of US\$9.13 million.

Mr. Randle added, "Commercialising a novel medical treatment technology on a global basis in today's healthcare environment is a complex, resource intensive and challenging process. Recent adoption rates and reimbursement decisions are evidence that leading physicians, payors and other healthcare system participants are convinced that EndoBarrier Therapy is a viable alternative for the treatment of type 2 diabetes and obesity. That steady progress and growing support give us confidence that the significant investment that is required to capitalize on this opportunity will be rewarded."

***Briefing Call and Webcast on Financial Results
for First Quarter 2014:***

GI Dynamics, Inc. (ASX: GID) will hold a conference call to discuss the Company's financial results for the quarter ended 31 March 2014, and its business outlook. Stuart Randle, president and chief executive officer, will host the call with Robert Crane, chief financial officer, and Mark Twyman, chief commercial officer.

The briefing call to discuss financial results and business updates will be held at 6 p.m. U.S. EDT on Tuesday, April 29, 2014 (8 a.m. AEST on Wednesday, 30 April 2014).

Accessing the Briefing Call via Webcast:

A live webcast of the call will be available on the GI Dynamics website at investor.gidynamics.com. The webcast can be directly accessed at: <http://edge.media-server.com/m/p/8tnfj6ga/lan/en>.

Accessing the Briefing Call via Telephone:

For those preferring to listen by telephone, please dial in five minutes prior to the start of the call and provide the **passcode 37084535**. Regional dial-in numbers are as follows:

- **United States** callers please dial toll-free **1 (888) 771-4371**
- **Australia** callers please dial toll-free **1 (800) 507-265**
- **International** callers please dial **1 (847) 585-4405**

**Robert Crane
Chief Financial Officer & Company Secretary**

About GI Dynamics

GI Dynamics, Inc. (ASX: GID) is the developer and marketer of EndoBarrier[®], a breakthrough device that represents an entirely new class of non-surgical, non-pharmaceutical therapy for the treatment of type 2 diabetes and/or obesity. EndoBarrier is approved and commercially available in multiple countries outside the U.S. EndoBarrier is not approved for sale in the U.S. and is limited by federal law to investigational use only in the United States. GI Dynamics is conducting a pivotal clinical trial of EndoBarrier in the U.S. for the treatment of patients who have uncontrolled type 2 diabetes and are obese. Founded in 2003, GI Dynamics is headquartered in Lexington, Massachusetts. For more information, please visit www.gidynamics.com.

Forward-Looking Statements

This announcement contains forward-looking statements concerning: our development and commercialization plans; our potential revenues, costs, profitability and financial performance; our ability to obtain reimbursement for our products; our clinical trials, and associated regulatory submissions and approvals; the number and location of commercial centres offering the EndoBarrier[®]; and our intellectual property position. These forward-looking statements are based on the current estimates and expectations of future events by the management of GI Dynamics, Inc. as of the date of this announcement and are subject to a number of 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 possibility that clinical trials will not be successful or confirm earlier results; risks associated with obtaining funding from third parties; risks relating to the timing and costs of clinical trials, results of clinical trials, the timing of regulatory submissions, the timing and receipt of regulatory approvals, the timing and amount of other expenses; execution risks;

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competition; risks related to market acceptance of products; intellectual property risks; and assumptions regarding the size of the available market, benefits of our products, product pricing, timing of product launches, future financial results and other factors. Given these uncertainties, you 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, future events or otherwise, unless required by law.

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Appendix 4C

Quarterly report for entities admitted on the basis of commitments

Introduced 31/03/00 Amended 30/09/01, 24/10/05, 17/12/10

Name of entity

GI Dynamics, Inc.

ABN

151 239 388

Quarter ended ("current quarter")

31 March 2014

Consolidated statement of cash flows

Cash flows related to operating activities	Current quarter (Q1) \$'000 USD	Year to date (3 months) \$'000 USD
1.1 Receipts from customers	906	906
1.2 Payments for		
(a) staff costs	(3,508)	(3,508)
(b) advertising and marketing	(1,185)	(1,185)
(c) research and development	(3,477)	(3,477)
(d) leased assets	—	—
(e) other working capital	(2,495)	(2,495)
1.3 Dividends received	—	—
1.4 Interest and other items of a similar nature received	52	52
1.5 Interest and other costs of finance paid	(1)	(1)
1.6 Income taxes paid	(10)	(10)
1.7 Other (provide details if material)	—	—
Net operating cash flows	(9,718)	(9,718)

+ See chapter 19 for defined terms.

Appendix 4C
Quarterly report for entities
admitted on the basis of commitments

	Current quarter (Q1) \$'000 USD	Year to date (3 months) \$'000 USD
1.8 Net operating cash flows (carried forward)	(9,718)	(9,718)
Cash flows related to investing activities		
1.9 Payment for acquisition of:		
(a) businesses (item 5)	—	—
(b) equity investments	—	—
(c) intellectual property	—	—
(d) physical non-current assets	(80)	(80)
(e) other non-current assets	—	—
1.10 Proceeds from disposal of:		
(a) businesses (item 5)	—	—
(b) equity investments	—	—
(c) intellectual property	—	—
(d) physical non-current assets	—	—
(e) other non-current assets	—	—
1.11 Loans to other entities	—	—
1.12 Loans repaid by other entities	—	—
1.13 Other (provide details if material)	—	—
Net investing cash flows	(80)	(80)
1.14 Total operating and investing cash flows	(9,798)	(9,798)
Cash flows related to financing activities		
1.15 Proceeds from issues of shares, options, etc.	484	484
1.16 Proceeds from sale of forfeited shares	—	—
1.17 Proceeds from borrowings	—	—
1.18 Repayment of borrowings	(19)	(19)
1.19 Dividends paid	—	—
1.20 Other	—	—
Net financing cash flows	465	465
Net increase (decrease) in cash held	(9,333)	(9,333)
1.21 Cash at beginning of quarter/year to date	58,616	58,616
1.22 Exchange rate adjustments to item 1.20	203	203
1.23 Cash at end of quarter	49,486	49,486

+ See chapter 19 for defined terms.

Payments to directors of the entity and associates of the directors

Payments to related entities of the entity and associates of the related entities

		Current quarter (Q1) \$'000 USD
1.24	Aggregate amount of payments to the parties included in item 1.2	319
1.25	Aggregate amount of loans to the parties included in item 1.11	—
1.26	<p>Explanation necessary for an understanding of the transactions</p> <div style="border: 1px solid black; padding: 5px;"> <p>Payments represent wages paid to executive director for services provided during the first quarter of 2014 and bonus related to 2013 services (\$240) and directors' fees paid to non-executive directors (\$79) for services provided during the first quarter of 2014.</p> </div>	

Non-cash financing and investing activities

- 2.1 Details of financing and investing transactions which have had a material effect on consolidated assets and liabilities but did not involve cash flows

N/A
- 2.2 Details of outlays made by other entities to establish or increase their share in businesses in which the reporting entity has an interest

N/A

Financing facilities available

Add notes as necessary for an understanding of the position.

		Amount available \$'000 USD	Amount used \$'000 USD
3.1	Loan facilities	165	165
3.2	Credit standby arrangements	150	—

+ See chapter 19 for defined terms.

Appendix 4C
Quarterly report for entities
admitted on the basis of commitments

Reconciliation of cash


Reconciliation of cash at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts is as follows.	Current quarter (Q1) \$'000 USD	Previous quarter (Q4) \$'000 USD
4.1 Cash on hand and at bank	8,423	13,056
4.2 Deposits at call	41,063	45,560
4.3 Bank overdraft	—	—
4.4 Other (provide details)	—	—
Total: cash at end of quarter (item 1.23)	49,486	58,616

Acquisitions and disposals of business entities

	Acquisitions (Item 1.9(a))	Disposals (Item 1.10(a))
5.1 Name of entity	N/A	N/A
5.2 Place of incorporation or registration		
5.3 Consideration for acquisition or disposal		
5.4 Total net assets		
5.5 Nature of business		

Compliance statement

- 1 This statement has been prepared under accounting policies which comply with accounting standards as defined in the Corporations Act (except to the extent that information is not required because of note 2) or other standards acceptable to ASX.
- 2 This statement does give a true and fair view of the matters disclosed.

Sign here:  Date: 29 April 2014
 (Company secretary)

Print name: Robert Crane

+ See chapter 19 for defined terms.

Notes

1. The quarterly report provides a basis for informing the market how the entity's activities have been financed for the past quarter and the effect on its cash position. An entity wanting to disclose additional information is encouraged to do so, in a note or notes attached to this report.
2. The definitions in, and provisions of, *AASB 107: Statement of Cash Flows* apply to this report except for any additional disclosure requirements requested by AASB 107 that are not already itemised in this report.
3. **Accounting Standards.** ASX will accept, for example, the use of International Financial Reporting Standards for foreign entities. If the standards used do not address a topic, the Australian standard on that topic (if any) must be complied with.

+ See chapter 19 for defined terms.