



GI Dynamics, Inc. – ASX Announcement

Appendix 4C Quarterly Report Quarter Ended 31 December 2015

LEXINGTON, Massachusetts, United States and SYDNEY, Australia – 29 January 2016 – GI Dynamics, Inc. (**ASX: GID**) (**GI Dynamics** or the **Company**), a medical device company developing innovative treatments for type 2 diabetes and obesity, today announced its financial results for the quarter ended 31 December 2015 (**Quarter**), as well as a discussion of the full-year 2015 performance. The Appendix 4C, which has been prepared in U.S. dollars under U.S. GAAP, is attached and the results disclosed in the Appendix 4C are unaudited.

The Company plans to file its Appendix 4E Preliminary Final Report with the Australian Securities Exchange (**ASX**) on or before the due date of 29 February 2016 and file its Annual Report on Form 10-K, including audited financial statements, with the U.S. Securities and Exchange Commission and ASX on or before the due date of 31 March 2016.

“Our Q4 2015 financial results reflect the reorganization of our business begun in the third quarter to align our operating expenses with the current levels of commercial and research and development activity. Because of the actions taken to date, the fourth quarter’s operating expenses were \$2.4 million lower than that of the prior quarter. Equally important as controlling our operating expenses is completing the last of the post-explant patient follow-up visits, closing the remaining open clinical investigator sites, locking the ENDO Trial database and performing the data analysis necessary to share the ENDO Trial results with our stakeholders,” said Michael D. Dale, president and CEO of GI Dynamics. “We remain confident that the ENDO Trial results will demonstrate that EndoBarrier Therapy is a valued treatment option for patients suffering from type 2 diabetes and obesity by helping to restore more manageable blood sugar levels and a healthier body weight. Our observations from the ENDO Trial will form the basis of our future plans for building the company,” continued Mr. Dale.

“Before the end of the first quarter, we expect to be in a position to publicly disclose the topline results for the ENDO Trial. At that time, we will hold a conference call to discuss these results as well as our goals for the future. In general, these include enhancing the clinical algorithm for the use of EndoBarrier Therapy and incorporating best clinical practices from EndoBarrier users around the world, based on observations and outcomes from the ENDO Trial. We believe that the new clinical algorithm will provide a more positive benefit/risk profile for EndoBarrier Therapy, which in turn we hope will provide the company an opportunity to conduct a new investigational device exemption study in the U.S. for the purpose of assessing the value of EndoBarrier Therapy for treating type 2 diabetes and obesity,” said Mr. Dale.

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

Financial Review

The Company's key financial results for the Quarter and year ended 31 December 2015 include the following:

- Revenue decreased to US\$0.2 million for the Quarter compared to US\$0.5 million for the same period last year, a decrease of US\$0.3 million. Revenue decreased to US\$1.3 million for the year ended 31 December 2015 compared to US\$2.8 million for the previous year, a decrease of US\$1.5 million. The decrease in the Company's revenue in the Quarter compared to the same period last year and for 2015 compared to 2014 was a result of a decrease in sales across all markets for the Quarter and 2015. This decrease was a result of the termination of the ENDO Trial in the third quarter of 2015. Additionally, as part of the Company's reorganization efforts begun in the third quarter of 2015, it decided to focus sales activity on a limited number of countries while disengaging from others.
- Cost of revenue for the Quarter was US\$1.9 million compared to US\$2.2 million in the same period last year, a decrease of US\$0.3 million. Cost of revenue for the year ended 31 December 2015 was US\$5.7 million compared to US\$4.1 million for the previous year, an increase of US\$1.6 million. The primary reasons for the decrease in cost of revenue for the Quarter compared to the same period last year was a decrease in sales unit volume, lower personnel related expenses and lower expense related to an increase in inventory reserves, partially offset by increased manufacturing inefficiencies due to lower production volume. The increase in cost of revenue for 2015 compared to 2014 was primarily a result of an increase in the expense for additional inventory reserves needed to write-down the net realizable value of the Company's existing inventory due to lower anticipated commercial activity and increased expense resulting from manufacturing inefficiencies due to lower production volume, partially offset by a decrease in sales unit volume and personnel related expenses. As a result, gross loss decreased by US\$0.1 million for the Quarter and increased by US\$3.1 million for the year ended 31 December 2015.
- Operating expenses decreased to US\$4.8 million for the Quarter compared to US\$12.0 million for the same period last year, a decrease of US\$7.2 million. Operating expenses decreased to US\$30.1 million for the year ended 31 December 2015 compared to US\$46.9 million for the previous year, a decrease of US\$16.8 million.
 - Research and development expenses were US\$2.5 million for the Quarter compared to US\$7.0 million for the same period last year, a decrease of US\$4.5 million. Research and development expenses were US\$16.6 million for the year ended 31 December 2015 compared to US\$26.7 million for the previous year, a decrease of US\$10.1 million. The decrease in research and development expenses for the Quarter compared to the same quarter in the prior year and 2015 compared to 2014 was primarily a result of decreased expenses to support

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the ENDO Trial as a result of the ENDO Trial's enrollment hold and subsequent termination and decreased personnel related expenses.

- Sales and marketing expenses were US\$0.7 million for the Quarter compared to US\$2.0 million for the same period last year, a decrease of US\$1.3 million. Sales and marketing expenses were US\$5.1 million for the year ended 31 December 2015 compared to US\$10.0 million for the previous year, a decrease of US\$4.9 million. The decrease in sales and marketing expenses for the Quarter compared to the same quarter in the prior year and 2015 compared to 2014 was the result of lower personnel related expenses, including stock-based compensation expense, and lower spending on marketing related activities.
- General and administrative expenses were US\$1.6 million for the Quarter and US\$3.0 million for the same period last year, a decrease of US\$1.4 million. General and administrative expenses were US\$8.4 million for the year ended 31 December 2015 and US\$10.2 million for the previous year, a decrease of US\$1.8 million. The decrease in general and administrative expenses for the Quarter compared to the same quarter in the prior year and 2015 compared to 2014 was primarily due to decreases in personnel related expenses and professional and consulting expenses.
- Other income (expense) for the Quarter was a minimal gain compared to a loss of US\$0.3 million for the same period last year, an increase of US\$0.3 million. Other income (expense) for the year ended 31 December 2015 was a loss of US\$0.6 million compared to income of US\$0.1 million for the previous year, a decrease of US\$0.7 million. The increase in the Quarter compared to the same period last year was primarily associated with a decrease in foreign exchange loss of US\$0.4 million. The decrease for 2015 was primarily associated with a decrease in the gain on re-measurement of the warrant liability of US\$0.3 million, a decrease in interest income of US\$0.2 million and an increase in foreign exchange loss of US\$0.1 million due to the depreciation of the Australian dollar versus the U.S. dollar.
- As a result, the Company recorded a net loss of US\$6.5 million for the Quarter compared to US\$14.1 million for the same period last year, a decrease of US\$7.6 million. For the year ended 31 December 2015, the Company's net loss was US\$35.2 million compared to US\$48.2 million for the previous year, a decrease of US\$13.0 million.
- The Company had cash and cash equivalents of US\$19.6 million at 31 December 2015 compared to US\$51.2 million at 31 December 2014, a decrease of US\$31.6 million.

Robert Solomon
Vice President of Finance & Company Secretary

About GI Dynamics

GI Dynamics, Inc. (ASX: GID) is the developer of EndoBarrier[®], the first endoscopically-delivered device therapy approved for the treatment of obese type 2 diabetes with BMI ≥ 30 kg/m², or obese patients with BMI ≥ 30 kg/m² with ≥ 1 comorbidities, or obese patients with BMI >35 kg/m². The liner is indicated for a maximum implant duration of 12 months. 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. 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 and revenue growth, costs, excess inventory, 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 consequences of terminating the ENDO Trial and the possibility that future 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, the timing of regulatory submissions, the timing, receipt and maintenance of regulatory approvals, the timing and amount of other expenses, and the timing and extent of third-party reimbursement; risks associated with commercial product sales, including product performance; competition; risks related to market acceptance of products; intellectual property risks; risks related to excess inventory; risks related to assumptions regarding the size of the available market, 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, 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 December 2015

Consolidated statement of cash flows

Cash flows related to operating activities		Current quarter (Q4) \$'000 USD	Year to date (12 months) \$'000 USD
1.1	Receipts from customers	195	1,393
1.2	Payments for		
	(a) staff costs	(1,409)	(9,337)
	(b) advertising and marketing	(230)	(2,357)
	(c) research and development	(1,828)	(11,985)
	(d) leased assets	—	(2)
	(e) other working capital	(1,557)	(8,416)
1.3	Dividends received	—	—
1.4	Interest and other items of a similar nature received	7	68
1.5	Interest and other costs of finance paid	—	(1)
1.6	Income taxes paid	(25)	(140)
1.7	Other (provide details if material)	—	—
Net operating cash flows		(4,847)	(30,777)

+ See chapter 19 for defined terms.

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

	Current quarter (Q4) \$'000 USD	Year to date (12 months) \$'000 USD
1.8 Net operating cash flows (carried forward)	(4,847)	(30,777)
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	—	(179)
(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	—	(179)
1.14 Total operating and investing cash flows	(4,847)	(30,956)
Cash flows related to financing activities		
1.15 Proceeds from issues of shares, options, etc.	—	2
1.16 Proceeds from sale of forfeited shares	—	—
1.17 Proceeds from borrowings	—	—
1.18 Repayment of borrowings	—	—
1.19 Dividends paid	—	—
1.20 Other (share capital raising cost)	—	—
Net financing cash flows	—	2
Net increase (decrease) in cash held	(4,847)	(30,954)
1.21 Cash at beginning of quarter/year to date	24,439	51,191
1.22 Exchange rate adjustments to item 1.20	(2)	(647)
1.23 Cash at end of quarter	19,590	19,590

+ 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 (Q4) \$'000 USD
1.24	Aggregate amount of payments to the parties included in item 1.2	235
1.25	Aggregate amount of loans to the parties included in item 1.11	—
1.26	Explanation necessary for an understanding of the transactions Payments represent wages and relocation paid to an executive director for services provided during the fourth quarter of 2015 (\$143) and directors' fees paid to non-executive directors (\$92) for services provided during the fourth quarter of 2015.	

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

The Company entered into a capital lease (\$8) for office equipment in the first quarter of 2015.

- 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	—	—
3.2 Credit standby arrangements	150	—

+ See chapter 19 for defined terms.

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 (Q4) \$'000 USD	Previous quarter (Q3) \$'000 USD
4.1	Cash on hand and at bank	2,383	5,237
4.2	Deposits at call	17,207	19,202
4.3	Bank overdraft	—	—
4.4	Other (provide details)	—	—
Total: cash at end of quarter (item 1.23)		19,590	24,439

Acquisitions and disposals of business entities

	Acquisitions (Item 1.9(a))	Disposals (Item 1.10(a))
5.1	Name of entity	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: Robert Solomon
 (Company secretary)

Date: 29 January 2016

Print name: Robert Solomon

+ 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.

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