GI Dynamics, Inc. – ASX Announcement

Form 10-Q Filed with SEC

LEXINGTON, Massachusetts, United States and SYDNEY, Australia – 18 May 2015 – 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 present the attached Quarterly Report on Form 10-Q, as filed with the U.S. Securities and Exchange Commission on 15 May 2015. The Form 10-Q includes the Company's unaudited financial results for the three months ended 31 March 2015 and other required disclosure. The financial statements included in the Form 10-Q were prepared in accordance with United States Generally Accepted Accounting Principles and are denominated in United States dollars unless otherwise indicated.

Robert Solomon
Vice President, 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/m^2, or obese patients with BMI ≥ 30 kg/m^2 with ≥ 1 comorbidities, or obese patients with BMI >35 kg/m^2. 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. 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 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 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, 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.

Investor Enquiries:	Media Enquiries:
United States Michael Dale, President & CEO +1 (781) 357-3310	United States/Europe: Bill Berry, Berry & Company Public Relations, LLC +1 (212) 253-8881
Australia David Allen or John Granger Hawkesbury Partners Pty Limited +61 2 9325 9046	

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended March 31, 2015

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission file number: 000-55195

GI DYNAMICS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**84-1621425**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification Number)**
25 Hartwell Avenue Lexington, Massachusetts	**02421**
(Address of Principal Executive Offices)	**(Zip Code)**

(781) 357-3300
(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days: Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files): Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ☐	Accelerated filer ☐
Non-accelerated filer ☒ (Do not check if a smaller reporting company)	Smaller reporting company ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act): ☐ Yes ☒ No

As of April 30, 2015 there were 9,484,671 shares of common stock outstanding.

NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements concerning our business, operations, financial performance and condition as well as our plans, objectives and expectations for our business, operations and financial performance and condition. Any statements contained in this Quarterly Report on Form 10-Q that are not of historical facts may be deemed to be forward-looking statements. The forward-looking statements are contained principally in the section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations." Forward-looking statements include, but are not limited to, statements about:

- our expectations with respect to regulatory submissions and approvals;
- our expectations with respect to our clinical trials, including enrollment in our clinical trials;
- our expectations with respect to our intellectual property position;
- our ability to commercialize our products;
- our ability to develop and commercialize new products;
- our expectation with regard to inventory; and
- our estimates regarding our capital requirements and our need for additional financing.

In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "could," "would," "expects," "plans," "anticipates," "believes," "estimates," "projects," "predicts," "potential," "aims," "assumes," "goal," "intends," "objective," "potential," "positioned," "target," "continue," "seek" and similar expressions intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

These forward-looking statements are based on current expectations, estimates, forecasts and projections about our business and the industry in which we operate and our management's beliefs and assumptions. These forward-looking statements are not guarantees of future performance or development and involve known and unknown risks, uncertainties and other factors that are in some cases beyond our control. As a result, any or all of our forward-looking statements in this Quarterly Report on Form 10-Q may later become inaccurate. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in this Quarterly Report on Form 10-Q, particularly in the "Risk Factors" section (which incorporates by reference to our Annual Report on Form 10-K filed with the Securities and Exchange Commission, or SEC), that could cause actual results or events to differ materially from the forward-looking statements that we make.

You are urged to consider these factors carefully in evaluating the forward-looking statements and are cautioned not to place undue reliance on the forward-looking statements. You should read this Quarterly Report on Form 10-Q and the documents that we have filed as exhibits to our Annual Report on Form 10-K completely and with the understanding that our actual future results may be materially different from what we expect. These forward-looking statements speak only as at the date of this Quarterly Report on Form 10-Q. Unless required by law, we do not intend to publicly update or revise any forward-looking statements to reflect new information or future events or otherwise. You should, however, review the factors and risks we describe in the reports we will file from time to time with the SEC after the date of this Quarterly Report on Form 10-Q.

GI DYNAMICS, INC.
QUARTERLY REPORT ON FORM 10-Q
FOR THE QUARTER ENDED MARCH 31, 2015

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References

Unless the context requires otherwise, references in this Quarterly Report on Form 10-Q to "GI Dynamics," "the Company," "we," "us" and "our" refer to GI Dynamics, Inc. and its consolidated direct and indirect subsidiaries.

Currency

Unless indicated otherwise in this Quarterly Report on Form 10-Q, all references to "$", "U.S.$" or "dollars" refer to United States dollars, the lawful currency of the United States of America. References to "A$" refer to Australian dollars, the lawful currency of the Commonwealth of Australia. References to "€" or "Euros" means Euros, the single currency of Participating Member States of the European Union.

Trademarks

EndoBarrier® and various company logos are the trademarks of the Company, in the United States and other countries. All other trademarks and trade names mentioned in this Quarterly Report on Form 10-Q are the property of their respective owners.

PART I – FINANCIAL INFORMATION

Item 1. ***Financial Statements***

GI Dynamics, Inc. and Subsidiaries

Condensed Consolidated Balance Sheets

(In thousands, except share and per share amounts)

(unaudited)

	March 31, 2015	December 31, 2014
Assets		
Current assets:		
Cash and cash equivalents	$ 40,016	$ 51,191
Accounts receivable, net	354	470
Inventory	4,962	5,488
Prepaid expenses and other current assets	1,457	1,165
Total current assets	46,789	58,314
Property and equipment, net	1,048	1,089
Other long-term assets	97	97
Total assets	$ 47,934	$ 59,500
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 740	$ 882
Accrued expenses	6,159	7,674
Deferred revenue	187	412
Other current liabilities	179	175
Total current liabilities	7,265	9,143
Deferred rent, net of current portion	127	166
Other liabilities	6	4
Warrants to purchase common stock	11	9
Commitments (Note 10)		
Stockholders' equity:		
Preferred stock, $0.01 par value – 500,000 shares authorized; no shares issued and outstanding at March 31, 2015 and December 31, 2014	—	—
Common stock, $0.01 par value – 13,000,000 shares authorized; 9,484,671 shares issued and 9,481,171 shares outstanding at March 31, 2015 and 9,483,671 shares issued and 9,480,171 shares outstanding at December 31, 2014	95	95
Class B common stock, $0.01 par value – 1,000,000 shares authorized; no shares issued and outstanding at March 31, 2015 and December 31, 2014	—	—
Additional paid-in capital	250,705	250,009
Accumulated deficit	(210,275)	(199,926)
Total stockholders' equity	40,525	50,178
Total liabilities and stockholders' equity	$ 47,934	$ 59,500

The accompanying notes are an integral part of these condensed consolidated financial statements.

GI Dynamics, Inc. and Subsidiaries

Condensed Consolidated Statements of Comprehensive Loss

(In thousands, except share and per share amounts)

(unaudited)

	Three Months Ended March 31,	
	2015	**2014**
Revenue	$ 616	$ 906
Cost of revenue	886	903
Gross (loss) profit	(270)	3
Operating expenses:		
Research and development	5,646	5,344
Sales and marketing	1,660	2,488
General and administrative	2,294	2,265
Total operating expenses	9,600	10,097
Loss from operations	(9,870)	(10,094)
Other income (expense):		
Interest income	30	52
Interest expense	—	(1)
Foreign exchange (loss) gain	(493)	203
Remeasurement of warrant liability	(2)	180
Other income (expense), net	(465)	434
Loss before income tax expense	(10,335)	(9,660)
Income tax expense	14	21
Net loss	$ (10,349)	$ (9,681)
Basic and diluted net loss per common share	$ (1.09)	$ (1.20)
Weighted-average number of common shares used in basic and diluted net loss per common share	9,481,027	8,096,485
Comprehensive loss	$ (10,349)	$ (9,681)

The accompanying notes are an integral part of these condensed consolidated financial statements.

GI Dynamics, Inc. and Subsidiaries

Condensed Consolidated Statements of Cash Flows

(In thousands)

(unaudited)

	Three Months Ended March 31,	
	2015	**2014**
Operating activities		
Net loss	$(10,349)	$ (9,681)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	174	159
Stock-based compensation expense	694	1,062
Remeasurement of warrant liability	2	(180)
Changes in operating assets and liabilities:		
Accounts receivable	116	(337)
Prepaid expenses and other current assets	(292)	(261)
Inventory	526	(210)
Accounts payable	(142)	(762)
Accrued expenses	(1,520)	518
Deferred revenue	(225)	65
Deferred rent	(36)	112
Net cash used in operating activities	(11,052)	(9,515)
Investing activities		
Purchases of property and equipment	(125)	(80)
Net cash used in investing activities	(125)	(80)
Financing activities		
Proceeds from exercise of stock options	2	484
Payments on long-term debt	—	(19)
Net cash provided by financing activities	2	465
Net decrease in cash and cash equivalents	(11,175)	(9,130)
Cash and cash equivalents at beginning of period	51,191	58,616
Cash and cash equivalents at end of period	$ 40,016	$49,486
Supplemental cash flow disclosures		
Cash paid for interest	$ —	$ 1
Income taxes paid	$ 47	$ 10
Equipment acquired under capital lease	$ 8	$ —

The accompanying notes are an integral part of these condensed consolidated financial statements.

GI Dynamics, Inc. and Subsidiaries

Notes to Condensed Consolidated Financial Statements

(unaudited)

1. Nature of Business

GI Dynamics, Inc. (the "Company") was incorporated on March 24, 2003, as a Delaware corporation, with operations based in Lexington, Massachusetts. The Company is dedicated to restoring health and improving quality of life, through the design and application of device and management solutions for treatment of metabolic disease. The Company's near-term goal is to establish EndoBarrier Therapy as a valued treatment option for patients suffering from type 2 diabetes and obesity by restoring more manageable blood sugar levels and reducing body weight. The Company is the developer of EndoBarrier, the first endoscopically-delivered device therapy approved for the treatment of obese type 2 diabetes with BMI $\geq$ 30 kg/m^2, or obese patients with BMI $\geq$ 30 kg/m^2 with $\geq$ 1 comorbidities, or obese patients with BMI >35 kg/m^2. EndoBarrier is the only incision-free, non-anatomy altering solution designed to specifically mimic the duodenal-jejunal exclusion created by gastric bypass surgery. Since incorporation, the Company has devoted substantially all of its efforts to research and development, business planning, clinical research, clinical study management, reimbursement development, product commercialization, acquiring operating assets, and raising capital. The Company currently operates in one reportable business segment which designs, manufactures and markets medical devices.

In 2011, the Company began commercial sales of EndoBarrier, which is currently sold in select markets in Europe, South America, the Asia Pacific region and the Middle East.

In the U.S., the Company received approval from the Food and Drug Administration ("FDA"), to commence its pivotal trial, the ENDO Trial, which the Company began in 2013. The multi-center, randomized, double-blinded study plans to enroll 500 patients with uncontrolled type 2 diabetes and obesity at 25 sites in the U.S. The primary endpoint is improvement in diabetes control as measured by HbA1c levels.

On March 5, 2015, the Company announced that the FDA recommended discontinuing placement of any additional devices in its pivotal trial of EndoBarrier Therapy in the U.S., although monitoring and data collection of patients currently enrolled in the ENDO Trial will continue. The decision to hold further enrollment resulted from four cases of hepatic abscess among the 325 subjects currently enrolled in the ENDO Trial. Hepatic abscess is a known event related to the use of EndoBarrier but has recently presented at a higher than anticipated rate in the ENDO Trial. The FDA had requested additional information to further assess the risk-benefit profile of EndoBarrier in the ENDO Trial. In May 2015, the Company provided the FDA with the information requested.

The Company is subject to a number of risks similar to other medical device companies, including, but not limited to, market acceptance of the Company's products, development by its competitors of new technological innovations, safety and efficacy of the products in clinical trials, the regulatory approval process governing medical devices and protection of proprietary technology. In addition, the Company will require additional funding to support its long-term operations. Any such financing may or may not be similar to transactions in which it has engaged in the past and there can be no assurance that any such financing opportunities will also be available on acceptable terms, if at all.

The Company has incurred operating losses since inception and at March 31, 2015, had an accumulated deficit of approximately $210.3million. The Company expects to incur significant operating losses for at least the next several years while it completes its ENDO Trial and seeks regulatory approval from the FDA. At March 31, 2015, the Company had approximately $40.0 million in cash and cash equivalents, which it believes is sufficient to fund its operations through March 2016. The Company does not expect its current cash balances will be sufficient to enable it to complete the full enrollment of the ENDO Trial. The Company will need to raise significant additional funding in order to complete the ENDO Trial and to continue to fund its operations beyond March 2016. The Company may seek to raise additional funds through a combination of collaborative arrangements, strategic alliances, and additional equity and debt financings or from other sources. There can be no assurance that any such financing opportunities will also be available on acceptable terms, if at all. If the Company is unable to raise capital when needed or on attractive terms, it could be forced to significantly delay, scale back or discontinue the ENDO Trial, other research and development activities and further commercialization of EndoBarrier.

In September 2011, the Company completed its initial public offering ("IPO") of common stock in the form of CHESS Depositary Interests ("CDIs") in Australia. As a result of the IPO and simultaneous private placement in the U.S., the Company raised a total of approximately $72.5 million in proceeds, net of expenses and repayment of $6.0 million of the Company's Convertible Term Promissory Notes. Additionally, in July and August 2013, the Company sold CDIs on the Australian Securities Exchange ("ASX") through a private placement and Share Purchase Plan ("SPP"), which raised a total of approximately $52.5 million, net of expenses. In May 2014, the Company raised an additional approximately $30.8 million, net of expenses, when it sold CDIs on the ASX through a private placement.

2. Summary of Significant Accounting Policies and Basis of Presentation

The accompanying condensed consolidated financial statements and the related disclosures as of March 31, 2015 and for the three months ended March 31, 2015 and 2014 are unaudited and have been prepared in accordance with accounting principles generally accepted in the U.S. ("GAAP") and the applicable rules and regulations of the Securities and Exchange Commission ("SEC") for interim financial information. Accordingly, they do not include all of the information and notes required by GAAP for complete financial statements. These interim condensed consolidated financial statements should be read in conjunction with the consolidated financial statements and notes thereto contained in the Company's Annual Report on Form 10-K ("Form 10-K"). The December 31, 2014 condensed consolidated balance sheet included herein was derived from the audited financial statements as of that date, but does not include all disclosures including notes required by GAAP for complete financial statements.

The unaudited interim condensed consolidated financial statements have been prepared on the same basis as the audited consolidated financial statements and, in the opinion of management, reflect all adjustments of a normal recurring nature considered necessary to present fairly the Company's financial position as of March 31, 2015, results of its operations for the three months ended March 31, 2015 and 2014, and its cash flows for the three months ended March 31, 2015 and 2014. The interim results for the three months ended March 31, 2015 are not necessarily indicative of the results that may be expected for the year ending December 31, 2015.

The Company's significant accounting policies are as described in Note 2, *Summary of Significant Accounting Policies and Basis of Presentation*, in the Company's Form 10-K.

Principles of Consolidation

The accompanying condensed consolidated financial statements include the accounts of GI Dynamics, Inc. and its wholly owned subsidiaries. All intercompany transactions and balances are eliminated in consolidation.

Use of Estimates

The preparation of consolidated financial statements in accordance with GAAP requires the Company's management to make estimates and judgments that may affect the reported amounts of assets, liabilities, revenues and expenses, and the related disclosure of contingent assets and liabilities. On an ongoing basis, the Company's management evaluates its estimates, including those related to revenue recognition, allowance for doubtful accounts, inventory valuation including reserves for excess and obsolete inventory, impairment of long-lived assets, income taxes including the valuation allowance for deferred tax assets, research and development, contingencies, and stock-based compensation. The Company bases its estimates on historical experience and on various other assumptions that are believed to be reasonable, the results of which form the basis for making judgments about the carrying values of assets and liabilities. Actual results may differ from these estimates under different assumptions or conditions. Changes in estimates are reflected in reported results in the period in which they become known.

Guarantees

The Company has identified the guarantees described below as disclosable, in accordance with ASC 460, *Guarantees*.

As permitted under Delaware law, the Company indemnifies its officers and directors for certain events or occurrences while the officer or director is, or was, serving at the Company's request in such capacity. The maximum potential amount of future payments the Company could be required to make is unlimited; however, the Company has directors' and officers' insurance coverage that should limit its exposure and enable it to recover a portion of any future amounts paid.

The Company is a party to a number of agreements entered into in the ordinary course of business that contain typical provisions that obligate the Company to indemnify the other parties to such agreements upon the occurrence of certain events. Such indemnification obligations are usually in effect from the date of execution of the applicable agreement for a period equal to the applicable statute of limitations. The aggregate maximum potential future liability of the Company under such indemnification provisions is uncertain.

The Company leases office space under several non-cancelable operating leases. The Company has standard indemnification arrangements under these leases that require it to indemnify its landlords against all costs, expenses, fines, suits, claims, demands, liabilities, and actions directly resulting from any breach, violation, or nonperformance of any covenant or condition of the respective lease. The aggregate maximum potential future liability of the Company under such indemnification provisions is uncertain.

2. Summary of Significant Accounting Policies and Basis of Presentation (continued)

As of March 31, 2015 and December 31, 2014, the Company had not experienced any material losses related to these indemnification obligations, and no material claims with respect thereto were outstanding. The Company does not expect significant claims related to these indemnification obligations and, consequently, concluded that the fair value of these obligations is negligible. As a result, no related reserves have been established.

Reverse Stock Split

In November 2014, the Company's stockholders approved a 1-for-10 reverse stock split of the Company's common stock that was effective April 9, 2015. All share and per share amounts in the condensed consolidated financial statements and notes thereto have been retroactively adjusted, where necessary, to reflect this reverse stock split. Because the par value of the Company's shares of common stock remain unchanged after the date of the split, the total stated par value and additional paid-in capital changed by offsetting amounts. The stated par value was reduced to one-tenth of the amount before the split and the additional paid-in capital was increased the same amount.

Subsequent Events

The Company evaluates events occurring after the date of its condensed consolidated balance sheet for potential recognition or disclosure in its condensed consolidated financial statements. There have been no subsequent events other than that disclosed in Note 11 that have occurred through the date the Company issued its condensed consolidated financial statements that require disclosure in or adjustment to its condensed consolidated financial statements.

New Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board ("FASB") or other standard setting bodies that are adopted by the Company as of the specified effective date. Unless otherwise discussed, the Company believes that the effect of recently issued standards that are not yet effective will not have a material effect on its consolidated financial position or results of operations upon adoption.

In May 2014, the FASB issued Accounting Standards Update ("ASU") No. 2014-09, *Revenue from Contracts with Customers* ("ASU 2014-09"), which stipulates that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. To achieve this core principle, an entity should apply the following steps: (1) identify the contract(s) with a customer; (2) identify the performance obligations in the contract; (3) determine the transaction price; (4) allocate the transaction price to the performance obligations in the contract; and (5) recognize revenue when (or as) the entity satisfies a performance obligation. ASU 2014-09 will be effective for the Company for reporting periods beginning after December 15, 2016. Early adoption is not permitted. Management is currently evaluating the impact of the pending adoption of ASU 2014-09 on the Company's consolidated financial statements.

In August 2014, the FASB issued ASU No. 2014-15, *Presentation of Financial Statements-Going Concern: Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern* ("ASU 2014-15"). This new standard gives a company's management the final responsibilities to decide whether there's substantial doubt about the company's ability to continue as a going concern and to provide related footnote disclosures. The standard provides guidance to management, with principles and definitions that are intended to reduce diversity in the timing and content of disclosures that companies commonly provide in their footnotes. Under the new standard, management must decide whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the company's ability to continue as a going concern within one year after the date that the financial statements are issued, or within one year after the date that the financial statements are available to be issued when applicable. This guidance is effective for annual reporting beginning after December 15, 2016, including interim periods within the year of adoption, with early application permitted. Accordingly, the standard is effective for the Company on January 1, 2017. The adoption of this guidance is not expected to have a material impact on the Company's consolidated financial statements.

2. Summary of Significant Accounting Policies and Basis of Presentation (continued)

In April 2015, the FASB issued ASU No. 2015-05, *Intangibles – Goodwill and Other – Internal-Use Software* ("ASU 2015-05"). This new standard provides guidance to customers about whether a cloud computing arrangement includes a software license. If a cloud computing arrangement includes a software license, then the customer should account for the software license element of the arrangement consistent with the acquisition of other software licenses. If a cloud computing arrangement does not include a software license, the customer should account for the arrangement as a service contract. ASU 2015-05 will be effective for the Company for reporting periods beginning after December 15, 2015. Early adoption is permitted and a company can elect to adopt ASU 2015-05 either (1) prospectively to all arrangements entered into or materially modified after the effective date or (2) retrospectively. Accordingly, the standard is effective for the Company on January 1, 2016. The adoption of this guidance is not expected to have a material impact on the Company's consolidated financial statements.

3. Net Loss per Common Share

Basic net loss per common share is computed by dividing net loss by the weighted-average number of common shares outstanding during the period. Potential common stock equivalents are determined using the treasury stock method. For diluted net loss per share purposes, the Company excludes stock options and other stock-based awards, including shares issued as a result of option exercises but which are subject to repurchase by the Company, whose effect would be anti-dilutive from the calculation. During the three months ended March 31, 2015 and 2014, common stock equivalents were excluded from the calculation of diluted net loss per common share, as their effect was anti-dilutive due to the net loss incurred. Therefore, basic and diluted net loss per share was the same in all periods presented.

The following potentially dilutive securities have been excluded from the computation of diluted weighted-average shares outstanding as of March 31, 2015 and 2014, as they would be anti-dilutive:

	Three Months Ended March 31,	
	2015	2014
Warrants to purchase common stock	50,000	50,000
Options to purchase common stock and other stock-based awards	1,318,996	1,019,972
Total	1,368,996	1,069,972

4. Common Stock Warrants

In connection with the Company's IPO in September 2011, the Company issued warrants in an aggregate amount of 50,000 shares of common stock at an exercise price of A$55.00 per share to the lead manager of the IPO and certain other investors. The warrants will expire on the fifth anniversary of their date of grant. The warrants may be converted on a cashless basis at the option of the holder. The Company has reserved 50,000 shares of common stock related to these warrants.

The Company accounts for the warrants under Accounting Standards Codification 815, *Derivatives and Hedging* ("ASC 815"). In accordance with the guidance included in ASC 815, because the Company's functional currency is the U.S. dollar and the exercise price of the warrants is in Australian dollars, the Company is exposed to currency exchange risk related to the warrants. As a result, the warrants are not considered indexed to the Company's own stock, and therefore, the warrants are classified as a liability and the fair value of the warrants must be remeasured at each reporting period. At the time the warrants were issued, the Company estimated the fair value of the warrants using the Black-Scholes option pricing model. The Company remeasures the fair value of the warrants at each reporting period using current assumptions and current foreign exchange rates, with changes in value recorded as other income or expense (Note 5).

5. Fair Value of Financial Instruments

The tables below present information about the Company's assets and liabilities that are measured at fair value on a recurring basis as of March 31, 2015 and December 31, 2014, and indicates the fair value hierarchy of the valuation techniques the Company used to determine such fair value. In general, fair values determined by Level 1 inputs utilize observable inputs such as quoted prices in active markets for identical assets or liabilities. Fair values determined by Level 2 inputs utilize data points that are either directly or indirectly observable, such as quoted prices, interest rates and yield curves. Fair values determined by Level 3 inputs utilize unobservable data points in which there is little or no market data, requiring the Company to develop its own assumptions for the asset or liability.

The following tables present the assets and liabilities the Company has measured at fair value on a recurring basis (in thousands):

Description	March 31, 2015	Fair Value Measurements at Reporting Date Using: Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets				
Money market funds (included in cash and cash equivalents)	$ 33,460	$ 33,460	$ —	$ —
Total assets	$ 33,460	$ 33,460	$ —	$ —
Liabilities				
Warrants to purchase common stock	$ 11	$ —	$ —	$ 11
Total liabilities	$ 11	$ —	$ —	$ 11

Description	December 31, 2014	Fair Value Measurements at Reporting Date Using: Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets				
Money market funds (included in cash and cash equivalents)	$ 38,454	$ 38,454	$ —	$ —
Total assets	$ 38,454	$ 38,454	$ —	$ —
Liabilities				
Warrants to purchase common stock	$ 9	$ —	$ —	$ 9
Total liabilities	$ 9	$ —	$ —	$ 9

5. Fair Value of Financial Instruments (continued)

The assumptions used in the Black-Scholes option pricing model to determine the fair value of the common stock warrants at March 31, 2015 and December 31, 2014 were as follows:

	March 31, 2015	December 31, 2014
Exercise price (A$55.00 at current exchange rate)	$ 41.99	$ 45.10
Fair value of common stock	$ 5.53	$ 9.80
Expected volatility	94.2%	62.2%
Expected term (in years)	1.4	1.7
Risk-free interest rate	0.4%	0.5%
Expected dividend yield	— %	— %

The following table rolls forward the fair value of the warrants, where fair value is determined by Level 3 inputs (in thousands):

Balance at December 31, 2014	$ 9
Increase in fair value of warrants upon remeasurement included in other income (expense)	2
Balance at March 31, 2015	$11

Cash equivalents, accounts receivable, prepaid expenses and other current assets, accounts payable, accrued expenses and other current liabilities at March 31, 2015 and December 31, 2014 are carried at amounts that approximate fair value due to their short-term maturities and highly liquid nature of these instruments.

6. Concentrations of Credit Risk, Accounts Receivable and Related Valuation Account

Financial instruments that subject the Company to credit risk primarily consist of cash and cash equivalents and accounts receivable. The Company maintains its cash and cash equivalent balances with high quality financial institutions, and consequently, the Company believes that such funds are subject to minimal credit risk. The Company's short-term investments potentially subject the Company to concentrations of credit risk. The Company has adopted an investment policy that limits the amounts the Company may invest in any one type of investment and requires all investments held by the Company to have a rating of not less than A, thereby reducing credit risk concentration.

Accounts receivable primarily consist of amounts due from customers, including distributors and health care providers in different countries. In light of the current economic state of many foreign countries, the Company continues to monitor the creditworthiness of its customers.

At March 31, 2015 and December 31, 2014, one distributor accounted for approximately 33% and 32%, respectively, of the Company's accounts receivable. At March 31, 2015, a second distributor accounted for approximately 11% of the Company's accounts receivable. No other customer accounted for greater than 10% of the Company's accounts receivable at March 31, 2015 and December 31, 2014.

The Company grants credit to customers in the normal course of business but generally does not require collateral or any other security to support its receivables. The Company makes judgments as to its ability to collect outstanding receivables and provides an allowance for receivables when collection becomes doubtful. Provisions are made based upon a specific review of all significant outstanding invoices and the overall quality and age of those invoices not individually reviewed. To date, the Company has not had any write-offs of bad debt; however, as of March 31, 2015, the Company had approximately $75,000 of accounts receivable where collection is deemed to be doubtful, and as such, the Company has established an allowance for doubtful accounts. At December 31, 2014, the Company had an allowance for doubtful accounts of approximately $41,000.

6. Concentrations of Credit Risk, Accounts Receivable and Related Valuation Account (continued)

In certain circumstances the Company allows customers to return defective or nonconforming products for credit or replacement products. Defective or nonconforming products typically consist of those products that resulted in an unsuccessful implant procedure. The Company records an estimate for product returns based upon historical trends. The associated reserve for product returns is recorded as a reduction of the Company's accounts receivable.

The following table shows the components of the Company's accounts receivable at March 31, 2015 and December 31, 2014 (in thousands):

	March 31, 2015	December 31, 2014
Accounts receivable	$ 472	$ 555
Less: allowance for doubtful accounts	(75)	(41)
Less: allowance for sales returns	(43)	(44)
Total	$ 354	$ 470

7. Inventory

The Company states inventory at the lower of first-in, first-out cost or market. The Company records a provision for excess, expired, and obsolete inventory based primarily on estimates of forecasted revenues. A significant change in the timing or level of demand for products as compared to forecasted amounts may result in recording additional provisions for excess, expired, and obsolete inventory in the future. When capitalizing inventory, the Company considers factors such as status of regulatory approval, alternative use of inventory, and anticipated commercial use of the product.

The determination of obsolete or excess inventory requires the Company to estimate the future demand for its products within appropriate time horizons. The estimated future demand is compared to inventory levels to determine the amount, if any, of obsolete and excess inventory. The demand forecast includes the Company's estimates of market growth and various internal estimates, and is based on assumptions that are consistent with the plans and estimates the Company is using to manage its underlying business and short-term manufacturing plans. Forecasting demand for EndoBarrier in a market in which there are few, if any, comparable approved devices and for which reimbursement from third-party payers is limited has been difficult. To the extent the Company's demand forecast is less than its inventory on-hand, the Company could be required to record reserves for excess inventory.

In 2014, the Company determined that its raw material sleeve inventory was in excess of its currently anticipated commercial demand for future sales and as a result recorded a $1.6 million charge to reduce the carrying value of the raw material sleeve inventory. Factors contributing to the write-down included: the effect of the shipment hold that began on October 6, 2014 and ended on December 1, 2014 had on the Company's inventory levels, the change in management and resulting changes to the Company's commercial strategy, the expected timing of third-party payer reimbursement in its commercial markets, the uncertainty around the timing and success of its ENDO Trial and the historical accuracy of its demand forecasts. The Company continues to review any evidence that may indicate that the utility of additional amounts of the raw material sleeve inventory, as it was expected to be used, will be less than cost.

Inventory at March 31, 2015 and December 31, 2014 was as follows (in thousands):

	March 31, 2015	December 31, 2014
Finished goods	$ 881	$ 733
Work-in-process	1,808	2,401
Raw materials	2,273	2,354
Total	$ 4,962	$ 5,488

The Company has entered into consignment arrangements in which the Company delivers product to the customer but retains title to the product until it is implanted or otherwise consumed. At March 31, 2015 and December 31, 2014, approximately 5% and 4%, respectively, of the finished goods inventory was at customer locations pursuant to these arrangements.

8. Property and Equipment

Property and equipment consisted of the following (in thousands):

	March 31, 2015	December 31, 2014
Laboratory equipment and manufacturing equipment	$ 545	$ 545
Computer equipment and software	1,125	1,125
Office furniture and equipment	229	221
Construction in process	173	48
Leasehold improvements	921	921
	2,993	2,860
Less accumulated depreciation and amortization	(1,945)	(1,771)
Total	$ 1,048	$ 1,089

In January 2015, the Company entered into a capital lease for certain office equipment. As of March 31, 2015, the Company had approximately $8,000 of assets under capital leases with a minimal accumulated amortization balance.

Depreciation and amortization expense of property and equipment, including equipment recorded under capital leases, was approximately $0.2 million for both the three months ended March 31, 2015 and 2014, respectively.

9. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	March 31, 2015	December 31, 2014
Clinical trials	$ 3,316	$ 3,906
Payroll and related liabilities	1,597	2,629
Professional fees	714	634
Deferred rent, current portion	154	151
Current portion of capital lease obligation	2	—
Other	376	354
Total	$ 6,159	$ 7,674

Included in payroll and related liabilities at March 31, 2015, is a total of approximately $0.8 million of separation expenses which will be paid out through March 2016.

10. Commitments and Contingencies

Lease Commitments

In June 2013, the Company entered into a noncancelable agreement to sublease 33,339 square feet of office, laboratory and manufacturing space in Lexington, Massachusetts. The sublease commenced in June 2013 and expires in December 2016, subject to earlier termination under certain conditions. Base rent during the initial rent period is approximately $0.6 million per year and increases annually by approximately $17,000. The space was delivered to the Company in June 2013 and rent payments commenced in May 2014. The rent expense, inclusive of the escalating rent payments and free rent period, is recognized on a straight-line basis over the term of the sublease agreement. In accordance with the terms of the sublease agreement, the Company maintains an unsecured letter of credit of approximately $0.2 million securing its obligations under the sublease agreement.

10. Commitments and Contingencies (continued)

In March 2012, the Company's subsidiary, GID Germany GmbH, entered into a noncancelable operating lease for office space in Dusseldorf, Germany. The lease was renewed in September 2013 and again in January 2015 and was extended through April 2016. The agreement was extended under substantially the same terms as the original agreement and is subject to earlier termination based on certain terms and conditions. The rent expense, inclusive of the free rent periods, is recognized on a straight-line basis over the term of the current lease agreement.

In July 2013, the Company's subsidiary, GI Dynamics Australia Pty Ltd, entered into a noncancelable operating lease for office space in Baulkham Hills, Australia. The initial term of the lease was for twelve months, which expired in July 2014. The Company exercised its option to renew the lease and extended the term through July 2015, subject to earlier termination under certain conditions.

Rent expense on noncancelable operating leases was approximately $0.1 million for each of the three month periods ended March 31, 2015 and 2014, respectively.

In March 2015, the Company entered into a capital lease for certain office equipment totaling approximately $8,000. The capital lease has a three year term and an interest rate of 14.1%.

Future minimum lease payments under all noncancelable lease arrangements at March 31, 2015, are as follows (in thousands):

Year Ending December 31,	
2015	$ 481
2016	626
2017	3
2018	1
Total	$1,111

11. Stockholders' Equity

On April 9, 2015, the Company amended its certificate of incorporation to reflect the one-for-ten reverse stock split approved by its shareholders. After giving effect to the reverse stock split, the authorized capital stock of the Company now consists of 14,500,000 shares, of which 13,000,000 shares are designated as common stock, 1,000,000 shares are designated as Class B common stock, and 500,000 shares are designated as preferred stock.

Common Stock

The Company authorized Class B common stock in order meet the Listing Rules of the ASX so far as they apply to escrowed securities. In the event that holders of common stock, who were subject to ASX-imposed escrow, breached the terms of their escrow agreement or the Listing Rules as they apply to escrowed securities, their common stock would have been automatically converted into Class B common stock until the earlier to occur of the expiration of the escrow period or the breach being rectified. The Class B common stock is identical to and ranks equally with the common stock except that Class B common stock has no voting rights and is not entitled to any dividends.

12. Stock Plans

The Company has two stock-based compensation plans under which stock options, restricted and unrestricted stock awards, restricted stock units, and other share-based awards are available for grant to employees, directors and consultants of the Company. At March 31, 2015, there were 668,516 shares available for future grant under both plans.

12. Stock Plans (continued)

The 2011 Employee, Director and Consultant Equity Incentive Plan (the "2011 Plan", together with the 2003 Omnibus Stock Plan, the "Plans") allows for an annual increase in the number of shares available for issue under the 2011 Plan commencing on the first day of each fiscal year during the period beginning in fiscal year 2012 and ending in fiscal year 2020. The annual increase in the number of shares shall be equal to the lowest of:

- 500,000 shares;
- 4% of the number of common shares outstanding as of such date; and
- an amount determined by the Board of Directors or the Company's compensation committee.

Accordingly, during the three months ended March 31, 2015, 379,346 shares were added to the 2011 Plan.

Stock-Based Compensation

Stock-based compensation is reflected in the condensed consolidated statements of comprehensive loss as follows for the three months ended March 31, 2015 and 2014 (in thousands):

	Three Months Ended March 31,	
	2015	2014
Cost of revenue	$ 22	$ 28
Research and development	186	307
Sales and marketing	145	413
General and administrative	341	314
	$ 694	$ 1,062

During the three months ended March 31, 2015, the Company modified the post-employment exercise period of stock awards previously granted to the Company's former chief financial officer in relation to his separation from the Company. The modification extended the exercise period to December 8, 2015. The modification resulted in an approximately $19,000 increase in stock-based compensation for the three months ended March 31, 2015. The Company accounted for the modification of these stock awards in accordance with the provisions of ASC 718, *Stock Compensation* ("ASC 718").

In calculating stock-based compensation costs, the Company estimated the fair value of stock options using the Black-Scholes option-pricing model. The Black-Scholes option-pricing model was developed for use in estimating the fair value of short-lived, exchange-traded options that have no vesting restrictions and are fully transferable. The Company estimates the number of awards that will be forfeited in calculating compensation costs. Such costs are then recognized over the requisite service period of the awards on a straight-line basis.

Determining the fair value of stock-based awards using the Black-Scholes option-pricing model requires the use of highly subjective assumptions, including the expected term of the award and expected stock price volatility. The weighted-average assumptions used to estimate the fair value of employee stock options using the Black-Scholes option-pricing model were as follows for the three months ended March 31, 2015 and 2014:

	Three Months Ended March 31,	
	2015	2014
Expected volatility	56.5%	62.9%
Expected term (in years)	6.05	6.05
Risk-free interest rate	1.5%	2.0%
Expected dividend yield	— %	— %

The Company uses historical data to estimate forfeiture rates. The Company's estimated forfeiture rates were 5% and 2% at March 31, 2015 and 2014, respectively.

12. Stock Plans (continued)

Stock Options

The following table summarizes share-based activity under the Company's stock option plans:

	Shares of Common Stock Attributable to Options	Weighted-Average Exercise Price	Weighted-Average Contractual Life	Aggregate Intrinsic Value
			(in years)	*(in thousands)*
Outstanding at December 31, 2014	1,201,496	$ 26.36	6.41	$ 1,406
Granted[(1)]	2,750	$ 8.54		
Exercised	(1,000)	$ 1.50		
Cancelled	(89,784)	$ 36.65		
Outstanding at March 31, 2015	1,113,462	$ 25.51	6.12	$ 261
Vested or expected to vest at March 31, 2015	1,084,378	$ 25.46	6.06	$ 261
Exercisable at March 31, 2015	531,631	$ 23.60	3.59	$ 261

(1) Does not include 6,000 options granted to non-executive directors which are subject to shareholder approval under ASX Listing Rules.

As of March 31, 2015, there was approximately $7.6 million of unrecognized stock-based compensation, net of estimated forfeitures, related to unvested stock option grants having service-based vesting under the Plans which is expected to be recognized over a weighted-average period of 3.0 years. The total unrecognized stock-based compensation cost will be adjusted for future changes in estimated forfeitures.

The weighted-average grant date fair value of options granted during the three months ended March 31, 2015 and 2014 was $4.57 and $21.73, respectively. The total intrinsic value of options exercised during the three months ended March 31, 2015 and 2014 was approximately $10,000 and $4.2 million, respectively. The intrinsic value represents the difference between the fair value of the Company's common stock on the date of exercise and the exercise price of the stock option. Cash received from option exercises during the three months ended March 31, 2015 and 2014 was approximately $1,500 and $0.5 million, respectively. No tax benefits were realized from options and other stock-based payment arrangements during these periods.

The stock-based compensation plans provide that grantees may have the right to exercise an option prior to vesting. Shares purchased upon the exercise of unvested options will be subject to the same vesting schedule as the underlying options, and are subject to repurchase at the original exercise price by the Company should the grantee discontinue providing services to the Company for any reason, prior to becoming fully vested in such shares. At March 31, 2015 and December 31, 2014, there were 3,500 shares of common stock issued pursuant to the exercise of unvested options that remain unvested and subject to repurchase by the Company. The exercise of these shares is not substantive and as a result, the cash paid of approximately $0.1 million for the exercise price is considered a deposit or prepayment of the exercise price and is recorded as a liability. Additionally, while the shares of common stock subject to repurchase are included in the legally issued shares, they are excluded from the calculation of outstanding shares.

12. Stock Plans (continued)

Restricted Stock Units

Each restricted stock unit ("RSU") represents a contingent right to receive one share of the Company's common stock. All RSUs outstanding as of March 31, 2015 vest on a pro-rata basis on each anniversary of the issuance date over four years or vest in equal parts upon the achievement of a product revenue milestone and a regulatory milestone. There is no consideration payable on the vesting of RSUs issued under the Plans. Upon vesting, the RSUs are exercised automatically and settled in shares of the Company's common stock.

The following table summarizes information related to the RSUs and activity during the three months ended March 31, 2015:

	Number of Units	Weighted-Average Contractual Life (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2014	205,740	5.43	$ 2,016
Granted[1]	—		
Vested/Exercised	—		
Cancelled	(3,706)		
Outstanding at March 31, 2015	202,034	5.05	$ 1,117

(1) Does not include 6,000 RSUs granted to non-executive directors which are subject to shareholder approval under ASX Listing Rules.

The aggregate intrinsic value at March 31, 2015 noted in the table above represents the closing price of the Company's common stock multiplied by the number of RSUs outstanding.

The fair value of each RSU award equals the closing price of the Company's common stock on the date of grant. The weighted average grant date fair value per share of RSUs granted in the three months ended March 31, 2014 was $37.79. No RSUs were granted in the three months ended March 31, 2015 that are not subject to shareholder approval under the ASX Listing Rules.

At March 31, 2015, 118,490 of the RSUs outstanding are subject to performance-based vesting criteria as described above. For these awards, the vesting will occur upon the achievement of a certain product revenue milestone and a certain regulatory milestone. When achievement of the milestone is deemed probable, the Company expenses the compensation of the respective stock award over the implicit service period. During the three months ended March 31, 2015 the Company determined that a milestone previously deemed probable was now not probable of being achieved prior to the expiration of the award. This change in estimated forfeitures was recognized through a cumulative adjustment in the three months ended March 31, 2015, resulting in a reduction of stock-based compensation of approximately $0.3 million. In the three months ended March 31, 2014, stock-based compensation expense associated with RSUs was approximately $34,000, all of which was related to performance-based awards having milestones deemed probable of achievement at that time.

As of March 31, 2015, there was approximately $1.6 million of unrecognized stock-based compensation expense, net of estimated forfeitures, related to non-vested RSU awards that have service-based vesting. This expense is expected to be recognized over a weighted average period of 3.5 years. At March 31, 2015, no RSUs that have performance-based vesting criteria are considered probable of achievement and there remains approximately $2.5 million of unrecognized stock-based compensation, including the amount of the cumulative adjustment above.

13. Segment Reporting

Operating segments are components of an enterprise for which separate financial information is available and is evaluated regularly by the Company's chief operating decision-maker in deciding how to allocate resources and in assessing performance. The Company has one reportable segment which designs, develops, manufactures and markets medical devices for non-surgical approaches to treating type 2 diabetes and obesity.

Geographic Reporting

All the Company's revenue is attributable to customers outside the U.S. The Company is dependent on favorable economic and regulatory environments for its products. Products are sold to customers located in Europe, the Middle East, the Asia Pacific region and South America and sales are attributed to a country or region based on the location of the customer to whom the products are sold.

At March 31, 2015, long-lived assets, comprised of property and equipment, of approximately $1.0 million are primarily held in the U.S. Total long-lived assets held outside of the U.S. represent less than 1% of total long-lived assets.

Product sales by geographic location for the three months ended March 31, 2015 and 2014 are listed in the table below (in thousands):

	Three Months Ended March 31,	
	2015	2014
Europe	$ 441	$ 522
Middle East	101	207
South America	30	87
Asia Pacific	44	90
Total Revenue	$ 616	$ 906

Major Customers

In the three months ended March 31, 2015, two distributors accounted for approximately 24% and 12%, respectively, of the Company's revenue. In the three months ended March 31, 2014, three distributors accounted for 12%, 11% and 10% of the Company's revenue, respectively, and one health care provider accounted for approximately 12% of the Company's revenue. No other customer accounted for greater than 10% of the Company's revenue during the three months ended March 31, 2015 and 2014.

Item 2. ***Management's Discussion and Analysis of Financial Condition and Results of Operations***

Forward-Looking Information

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our condensed consolidated financial statements and the notes to those financial statements appearing elsewhere in this Quarterly Report on Form 10-Q and the audited consolidated financial statements and notes thereto and management's discussion and analysis of financial condition and results of operations for the year ended December 31, 2014 included in our Annual Report on Form 10-K. This discussion contains forward-looking statements that involve significant risks and uncertainties. As a result of many factors, such as those set forth under "Risk Factors" in Item 1A. of our Annual Report on Form 10-K which are incorporated herein by reference, our actual results may differ materially from the results described in or implied by the forward-looking statements described in the following discussion and analysis.

Overview

We are a medical device company headquartered in Lexington, Massachusetts, that is dedicated to restoring health and improving quality of life through the design and application of device and management solutions for treatment of metabolic disease. Our near-term goal is to establish EndoBarrier Therapy as a valued treatment option for patients suffering from type 2 diabetes and obesity by restoring more manageable blood sugar levels and reducing body weight. We are the developer of EndoBarrier, the first endoscopically-delivered device therapy approved for the treatment of obese type 2 diabetes with BMI $\geq$ 30 kg/m^2, or obese patients with BMI $\geq$ 30 kg/m^2 with $\geq$ 1 comorbidities, or obese patients with BMI >35 kg/m^2. EndoBarrier is the only incision-free, non-anatomy altering solution designed to specifically mimic the duodenal-jejunal exclusion created by gastric bypass surgery. We have commercially launched EndoBarrier which is now being sold in select markets in Europe and South America, as well as the Asia Pacific region and the Middle East. In countries where reimbursement is required for broad-based use, we are endeavoring to secure such reimbursement. In other countries where patients are more accustomed to paying for all or a majority of health care expenses, we are growing such markets or pursuing regulatory approvals.

Currently, we are focused on the commercial rollout of EndoBarrier in selected countries in Europe, South America, the Asia Pacific region and the Middle East. We expect to continue to drive broad-based market awareness among patients and physicians in our commercial geographies, continue to support increasing adoption of EndoBarrier Therapy at existing medical centers, and train doctors in new medical centers. To achieve broad-based clinical acceptance and commercial uptake, reimbursement coverage by health care insurers will be required in many markets.

In certain geographies where reimbursement is necessary for clinical acceptance and commercial uptake, such as in Europe, we are already receiving partial reimbursement in certain markets at a local or national level, but we have not yet achieved full or national reimbursement in any market.

In self-pay markets where we have regulatory approval, we are currently focusing on expanding both the product use per center and the number of centers. We are also seeking regulatory approval in other countries that we believe will have a large self-pay population, such as Brazil, Colombia, Singapore and others.

In the U.S., we have received approval from the Food and Drug Administration, or FDA, to commence our pivotal trial, the ENDO Trial, which we began in 2013. The multi-center, randomized, double-blinded study plans to enroll 500 patients with uncontrolled type 2 diabetes and obesity at 25 sites in the U.S. The primary endpoint is improvement in diabetes control as measured by HbA1c levels.

On March 5, 2015, we announced that the FDA recommended discontinuing placement of any additional devices in our pivotal trial of EndoBarrier Therapy in the U.S., although monitoring and data collection of patients currently enrolled in the ENDO Trial will continue. The decision to hold further enrollment resulted from four cases of hepatic abscess among the 325 subjects currently enrolled in the ENDO Trial. Hepatic abscess is a known event related to the use of EndoBarrier but has recently presented at a higher than anticipated rate in the ENDO Trial. The FDA had requested additional information to further assess the risk-benefit profile of EndoBarrier in the ENDO Trial. In May 2015, we provided the FDA with the information requested.

For financial reporting purposes, we have one reportable segment which designs, manufactures and markets medical devices for the treatment of type 2 diabetes and obesity.

To date, we have devoted substantially all of our efforts to research and development, business planning, clinical research, clinical study management, reimbursement development, product commercialization, acquiring operating assets, and raising capital. We have incurred significant operating losses since our inception in 2003. As of March 31, 2015, we had an accumulated deficit of approximately $210.3 million. We expect to incur net losses for the foreseeable future as we continue our clinical trials, continue research and development into product improvements and next generation products, enhance our infrastructure and expand commercial markets.

We have raised net proceeds of approximately $231.5 million through sales of our equity. We generated $75.7 million in proceeds, net of expenses, through the sale of convertible preferred stock to a number of U.S. venture capital firms, two global medical device manufacturers and individuals. In September 2011, we raised approximately $72.5 million, net of expenses and repayment of $6.0 million of Convertible Term Promissory Notes, in our initial public offering, or IPO, in Australia and simultaneous private placement of CHESS Depositary Interests, or CDIs, to accredited investors in the U.S. In July and August 2013, we raised approximately $52.5 million, net of expenses, in an offering of our CDIs to sophisticated, professional and accredited investors in Australia, the U.S. and certain other jurisdictions. In May 2014, we raised approximately $30.8 million, net of expenses, in an offering of our CDIs to sophisticated, professional and accredited investors in Australia, Hong Kong, the United Kingdom and certain other jurisdictions. In connection with the IPO, all of our existing shares of preferred stock were converted into common stock.

In June 2011, we issued Convertible Term Promissory Notes to several of our shareholders totaling $6.0 million, which were repaid concurrent with the closing of our IPO with the associated gross proceeds.

Our corporate headquarters and manufacturing facility are located in Lexington, Massachusetts.

Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition and results of operations is based upon our condensed consolidated financial statements prepared in accordance with generally accepted accounting principles in the U.S. The preparation of these financial statements requires us to make certain estimates and assumptions that may affect the reported amounts of assets and liabilities and the reported amounts of revenues and expenses during the reported periods and related disclosures. These estimates and assumptions, including those related to revenue recognition, inventory valuation, impairment of long-lived assets, income taxes including the valuation allowance for deferred tax assets, research and development expenses and stock-based compensation are monitored and analyzed by us for changes in facts and circumstances, and material changes in these estimates could occur in the future. We base our estimates on our historical experience and various other assumptions that are believed to be reasonable under the circumstances. Actual results may differ from our estimates under different assumptions or conditions.

During the three months ended March 31, 2015, there were no material changes to our critical accounting policies as reported in our Annual Report on Form 10-K.

Results of Operations

The following is a description of significant components of our operations, including significant trends and uncertainties that we believe are important to an understanding of our business and results of operations.

	Three Months Ended March 31,	
	2015	2014
	(in thousands)	
Revenue	$ 616	$ 906
Cost of revenue	886	903
Gross (loss) profit	(270)	3
Operating expenses:		
Research and development	5,646	5,344
Sales and marketing	1,660	2,488
General and administrative	2,294	2,265
Total operating expenses	9,600	10,097
Loss from operations	(9,870)	(10,094)
Other income (expense):		
Interest income	30	52
Interest expense	—	(1)
Foreign exchange (loss) gain	(493)	203
Remeasurement of warrant liability	(2)	180
Other income (expense), net	(465)	434
Loss before income tax expense	(10,335)	(9,660)
Income tax expense	14	21
Net loss	$ (10,349)	$ (9,681)

Three Months Ended March 31, 2015 Compared to Three Months Ended March 31, 2014

	Three Months Ended March 31,		Change	
	2015	2014	$	%
	(dollars in thousands)			
Revenue	$ 616	$ 906	$(290)	(32.0)%
Cost of revenue	886	903	(17)	(1.9)%
Gross (loss) profit	$ (270)	$ 3	$(273)	(9,100.0)%

Revenue. The decrease in revenue of approximately $0.3 million for the three months ended March 31, 2015 compared to the three months ended March 31, 2014 was primarily due to decreased revenue across all markets. Revenue decreased approximately 15%, 51%, 51% and 66% in Europe, the Asia Pacific region, the Middle East and South America, respectively, primarily as a result of lower unit volume.

Though it is uncertain to what extent the FDA's recommendation that we discontinue placement of any additional devices in the ENDO Trial affected revenue in the three months ended March 31, 2015 as compared to other market factors, we believe that the ENDO Trial enrollment hold has and will likely continue to adversely affect sales. In general, we believe the recommendation by the FDA to halt further enrollment in the ENDO Trial, following the Notified Body request to stop shipment of CE Mark product in late 2014, have together adversely affected our commercial operations.

Cost of Revenue. The decrease in cost of revenue was approximately $17,000 for the three months ended March 31, 2015 compared to the three months ended March 31, 2014. The decrease in the cost of revenue was primarily related to lower unit volume partially offset by higher expenses related to decreased utilization of our manufacturing capacity due to lower production volume.

Gross profit decreased by approximately $0.3 million for the three months ended March 31, 2015 compared to the three months ended March 31, 2014 for the reasons discussed above. We expect that our gross margin will vary, and may vary significantly, quarter to quarter and year to year due to our current stage of commercial development. Specifically, factors such as changes in volume of inventory production, utilization of our manufacturing capacity, changes in our manufacturing spending, and overall economies of scale may vary as revenues change.

Operating Expenses

	Three Months Ended March 31,		Change	
	2015	2014	$	%
	(dollars in thousands)			
Research and development expense	$5,646	$ 5,344	$ 302	5.7%
Sales and marketing expense	1,660	2,488	(828)	(33.3)%
General and administrative expense	2,294	2,265	29	1.3%
Total operating expenses	$9,600	$10,097	$(497)	(4.9)%

Research and Development Expense. The increase in research and development expense of approximately $0.3 million for the three months ended March 31, 2015 compared to the three months ended March 31, 2014 was primarily due to an increase of approximately $0.6 million in clinical trial and other clinical study related expenses, primarily third-party expenses related to the ENDO Trial, and an increase of approximately $0.2 million in consulting expenses; partially offset by an approximately $0.3 million decrease in compensation and employee related expenses, primarily from lower stock-based compensation expense and a decrease in headcount.

In March 2015, we announced that the FDA recommended discontinuing placement of any additional devices in the ENDO Trial, although monitoring and data collection of patients currently enrolled will continue. The enrollment hold's impact on the costs of the ENDO Trial is uncertain at this time. It is possible that in the short-term we may realize savings in patient recruiting expenses; however, the long-term costs associated with the risk mitigation strategies we implement are unknown at this time.

Sales and Marketing Expense. The decrease in sales and marketing expense of approximately $0.8 million for the three months ended March 31, 2015 compared to the three months ended March 31, 2014 was primarily the result of a decrease of approximately $0.5 million in compensation and employee related expenses, including an approximate $0.3 million reduction in stock-based compensation expense, associated with a lower number of sales and marketing employees, as well as a decrease of approximately $0.3 million marketing activities to support our commercialization efforts.

General and Administrative Expense. The increase in general and administrative expense of approximately $29,000 for the three months ended March 31, 2015 compared to the three months ended March 31, 2014 was primarily a result of an increase in the allowance for doubtful accounts.

Other Income (Expense), Net

	Three Months Ended March 31,		Change	
	2015	2014	$	%
	(dollars in thousands)			
Other income (expense):				
Interest income	$ 30	$ 52	$ (22)	(42.3)%
Interest expense	—	(1)	1	100.0%
Foreign exchange (loss) gain	(493)	203	(696)	(342.9)%
Remeasurement of warrant liability	(2)	180	(182)	(101.1)%
Total other income (expense), net	$ (465)	$ 434	$(899)	(207.1)%

Interest Income. The decrease in interest income of approximately $22,000 for the three months ended March 31, 2015 compared to the three months ended March 31, 2014 was due to both decreases in interest rates and average cash and cash equivalents balances.

Interest Expense. The decrease in interest expense of approximately $1,000 during the three months ended March 31, 2015 compared to the three months ended March 31, 2014 was due to the repayment of our debt in August 2014.

Foreign Exchange Gain (Loss). The decrease in foreign exchange gain of approximately $0.7 million for the three months ended March 31, 2015 compared to the three months ended March 31, 2014 was primarily the result of the depreciation of the Australian dollar versus the U.S. dollar during the three months ended March 31, 2015.

Remeasurement of Warrant Liability. The change in the remeasurement of warrant liability of approximately $0.2 million for the three months ended March 31, 2015 compared to the three months ended March 31, 2014 was the result of a small increase in the fair value of the warrants issued in connection with our IPO at March 31, 2015 compared to a decrease in the fair value of the warrants at March 31, 2014.

Liquidity and Capital Resources

We have incurred losses since our inception in March 2003 and, as of March 31, 2015, we had an accumulated deficit of approximately $210.3 million. We have financed our operations from a combination of sales of equity securities and issuances of convertible term notes. In June 2011, we generated approximately $6.0 million in net proceeds from the issuance of our Convertible Term Promissory Notes. In September 2011, we generated approximately $72.5 million in proceeds, net of expenses and repayment of $6.0 million of Convertible Term Promissory Notes, from our IPO in Australia and simultaneous private placement in the U.S. In July and August 2013, we generated approximately $52.5 million in proceeds, net of expenses, from a private placement and share purchase plan of our CDIs. In May 2014, we generated approximately $30.8 million in proceeds, net of expenses, from a private placement of our CDIs. As of March 31, 2015, we had approximately $40.0 million of cash and cash equivalents.

During the three months ended March 31, 2015, our cash and cash equivalents balance decreased by approximately $11.2 million as a result of funds used to support our operations and to purchase property and equipment. We made payments related to, among other things, research and development, sales and marketing, and general and administrative expenses as we continued to invest in our commercialization of EndoBarrier and fund our ENDO Trial.

The following table sets forth the major sources and uses of cash for each of the periods set forth below:

	Three Months Ended March 31,	
	2015	2014
	(in thousands)	
Net cash (used in) provided by:		
Operating activities	$(11,052)	$(9,515)
Investing activities	(125)	(80)
Financing activities	2	465
Net decrease in cash and cash equivalents	$(11,175)	$(9,130)

Cash Flows From Operating Activities

Net cash used in operating activities totaled approximately $11.0 million for the three months ended March 31, 2015. The primary uses of cash were:

- to fund our net loss of approximately $10.3 million;
- a net negative adjustment to cash flow from changes in working capital of approximately $1.6 million resulting primarily from decreases in accrued expenses, accounts payable and deferred rent and an increase in prepaids and other current assets, partially offset by decreases in accounts receivable and inventory; and
- a net positive adjustment to cash flow from non-cash items of approximately $0.9 million, primarily from stock-based compensation.

Due to the nature and timing of the cash flows related to our ENDO Trial, we do not believe that the enrollment hold had a significant effect on our cash flows from operations for the three month's ended March 31, 2015. It is possible that in the short-term the enrollment hold may have a favorable impact on cash flows from operating activities as we spend less on patient recruiting; however, the long-term impact on cash flows from operations will be dependent upon when enrollment may resume, if at all, and what risk mitigation strategies are implemented.

Net cash used in operating activities totaled approximately $9.5 million for the three months ended March 31, 2014. The primary uses of cash were:

- to fund our net loss of approximately $9.7 million;
- a net negative adjustment to cash flow from changes in working capital of approximately $0.9 million resulting primarily from increases in accounts receivable, prepaid and other current assets and inventory and a decrease in accounts payable, partially offset by increases in accrued expenses and deferred rent; and
- a net positive adjustment to cash flow from non-cash items of approximately $1.1 million, primarily from stock-based compensation expense.

Cash Flows From Investing Activities

Cash used in investing activities for the three months ended March 31, 2015 and 2014 totaled approximately $0.1 million in each period and resulted from the purchase of property and equipment.

Cash Flows From Financing Activities

Cash provided by financing activities for the three months ended March 31, 2015 was approximately $2,000 and resulted from proceeds received upon the exercise of stock options.

Cash provided by financing activities for the three months ended March 31, 2014 totaled approximately $0.5 million and resulted primarily from the proceeds from the issuance of shares upon the exercise of stock options.

Funding Requirements

As of March 31, 2015, our primary source of liquidity was our cash and cash equivalents on hand of approximately $40.0 million. We expect to incur significant operating losses for at least the next several years while we complete our ENDO Trial and seek regulatory approval from the FDA, the timing and success of which is uncertain. We believe our current cash balances, together

with the net product revenues, will be sufficient to meet our anticipated cash requirements to fund our ENDO Trial, continue the commercialization of EndoBarrier, invest in our manufacturing and supply chain infrastructure, and to fund our currently contemplated research and development efforts through March 2016. However, we do not expect our current cash balances will be sufficient to enable us to complete the full enrollment of the ENDO Trial. We will need to raise significant additional funding in order to complete the ENDO Trial and to continue to fund our operations beyond that point in time.

Our forecast of the period of time through which our financial resources will be adequate to support our operations are forward-looking statements and involve risks and uncertainties, and actual results could vary materially and negatively as a result of a number of factors, including the factors discussed in the "Risk Factors" in Item 1A. of our Annual Report on Form 10-K which are incorporated herein by reference. We have based these estimates on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect.

Due to the numerous risks and uncertainties associated with the development and commercialization of EndoBarrier, we are unable to estimate precisely the amounts of capital outlays and operating expenditures necessary to complete the development of, and to obtain regulatory approval for, EndoBarrier (other than in select markets in Europe, South America, the Middle East and the Asia Pacific region) for the U.S. and other markets for which we believe EndoBarrier is suited. Our funding requirements will depend on many factors, including, but not limited to, the following:

- the rate of progress and cost of our commercialization activities;
- the expenses we incur in marketing and selling EndoBarrier;
- the timing and decisions of payer organizations related to reimbursement;
- the revenue generated by sales of EndoBarrier;
- the product performance from a safety and efficacy standpoint in addressing diabetes and obesity;
- the success of our investment in our manufacturing and supply chain infrastructure;
- the time and costs involved in obtaining regulatory approvals for EndoBarrier in new markets;
- the success of our research and development efforts, including the ENDO Trial;
- the ability to ship CE marked products;
- the emergence of competing or complementary developments; and
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights.

We may seek to raise additional funds through a combination of collaborative arrangements, strategic alliances, and additional equity and debt financings or from other sources. We will continue to manage our capital structure and to consider all financing opportunities, whenever they may occur, that could strengthen our long-term liquidity profile. Any such capital transactions may or may not be similar to transactions in which we have engaged in the past and the ownership interests of our existing stockholders may be materially diluted. There can be no assurance that any such financing opportunities will also be available on acceptable terms, if at all. If we are unable to raise capital when needed or on attractive terms, we could be forced to significantly delay, scale back or discontinue the ENDO Trial, other research and development activities and further commercialization of EndoBarrier.

Off–Balance Sheet Arrangements

We do not have any relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities, that would have been established for the purpose of facilitating off-balance sheet arrangements (as that term is defined in Item 303(a)(4)(ii) of Regulation S-K) or other contractually narrow or limited purposes. As such, we are not exposed to any financing, liquidity, market or credit risk that could arise if we had engaged in those types of relationships. We enter into guarantees in the ordinary course of business related to the guarantee of our own performance and the performance of our subsidiaries.

Contractual Obligations and Commitments

The disclosure of our contractual obligations and commitments is set forth under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations—Contractual Commitments and Obligations" in our Annual Report on Form 10-K.

In March 2015, we entered into a capital lease for certain office equipment totaling approximately $8,000. The capital lease has a three year term and an interest rate of 14.1%. Other than this, there have been no material changes from the contractual commitments and obligations previously disclosed in our Annual Report on Form 10-K.

Recent Accounting Pronouncements

For a discussion of recent accounting pronouncements please refer to Note 2, "Summary of Significant Accounting Policies and Basis of Presentation," to our condensed consolidated financial statements included in this Quarterly Report on Form 10-Q.

In May 2014, the Financial Accounting Standards Board issued Accounting Standards Update No. 2014-09, *Revenue from Contracts with Customers* (ASU 2014-09), which stipulates that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. To achieve this core principle, an entity should apply the following steps: (1) identify the contract(s) with a customer; (2) identify the performance obligations in the contract; (3) determine the transaction price; (4) allocate the transaction price to the performance obligations in the contract; and (5) recognize revenue when (or as) the entity satisfies a performance obligation. ASU 2014-09 will be effective for us for reporting periods beginning after December 15, 2016, with early adoption not permitted. Management is currently evaluating the impact of the pending adoption of ASU 2014-09 on our consolidated financial statements.

In August 2014, the FASB issued ASU No. 2014-15, *Presentation of Financial Statements-Going Concern: Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern,* or ASU 2014-15. This new standard gives a company's management the final responsibilities to decide whether there's substantial doubt about the company's ability to continue as a going concern and to provide related footnote disclosures. The standard provides guidance to management, with principles and definitions that are intended to reduce diversity in the timing and content of disclosures that companies commonly provide in their footnotes. Under the new standard, management must decide whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the company's ability to continue as a going concern within one year after the date that the financial statements are issued, or within one year after the date that the financial statements are available to be issued when applicable. This guidance is effective for annual reporting beginning after December 15, 2016, including interim periods within the year of adoption, with early application permitted. Accordingly, the standard is effective for us on January 1, 2017. The adoption of this guidance is not expected to have a material impact on our consolidated financial statements.

In April 2015, the FASB issued ASU No. 2015-05, *Intangibles – Goodwill and Other – Internal-Use Software* ("ASU 2015-05"). This new standard provides guidance to customers about whether a cloud computing arrangement includes a software license. If a cloud computing arrangement includes a software license, then the customer should account for the software license element of the arrangement consistent with the acquisition of other software licenses. If a cloud computing arrangement does not include a software license, the customer should account for the arrangement as a service contract. ASU 2015-05 will be effective for the Company for reporting periods beginning after December 15, 2015. Early adoption is permitted and a company can elect to adopt ASU 2015-05 either (1) prospectively to all arrangements entered into or materially modified after the effective date or (2) retrospectively. Accordingly, the standard is effective for us on January 1, 2016. The adoption of this guidance is not expected to have a material impact on our consolidated financial statements.

Item 3. ***Quantitative and Qualitative Disclosures About Market Risk***

We develop, manufacture and sell EndoBarrier globally and our earnings and cash flows are exposed to market risk from changes in currency exchange rates and interest rates.

Interest Rate Sensitivity

Our cash and cash equivalents of approximately $40.0 million at March 31, 2015 consisted of cash and money market funds, all of which will be used for working capital purposes. We do not enter into investments for trading or speculative purposes. The goals of our investment policy are preservation of capital, fulfillment of liquidity needs and fiduciary control of cash and investments. We also seek to maximize income from our investments without assuming significant risk. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of interest rates in the U.S. and Australia. Because of the short-term nature of our cash and cash equivalents, we do not believe that we have any material exposure to changes in their fair values as a result of changes in interest rates. The continuation of historically low interest rates in the U.S. will limit our earnings on investments held in U.S. dollars.

Our capital lease bears interest at a fixed rate and therefore has minimal exposure to changes in interest rates.

Foreign Currency Risk

We conduct business in foreign countries. For U.S. reporting purposes, we translate all assets and liabilities of our non-U.S. entities at the period-end exchange rate and revenue and expenses at the average exchange rates in effect during the periods. The net effect of these translation adjustments is shown in the accompanying condensed consolidated financial statements as a component of net loss.

We generate a significant portion of our revenue and collect receivables in foreign currencies. Fluctuations in the exchange rate of the U.S. dollar against major foreign currencies, including the Euro, British Pound and Australian dollar, can result in foreign currency exchange gains and losses that may significantly impact our financial results. These foreign currency transaction and translation gains and losses are presented as a separate line item in our condensed consolidated statements of comprehensive loss. Continued fluctuation of these exchange rates could result in financial results that are not comparable from quarter to quarter. We do not currently utilize foreign currency contracts to mitigate the gains and losses generated by the re-measurement of non-functional currency assets and liabilities but do hold cash reserves in currencies in which those reserves are anticipated to be expended.

All of the proceeds from our 2011, 2013 and 2014 offerings were denominated in Australian dollars, and as of March 31, 2015 we held the equivalent of approximately US$5.3 million denominated in Australian dollars. Accordingly, we have had and will continue to have exposure to foreign currency exchange rate fluctuations. A change of 10% or more in foreign currency exchange rates of the Australian dollar or the Euro would have a material impact on our financial position and results of operations if our revenue continues to be denominated in currencies other than the U.S. dollar or if we retain a substantial portion of our cash and cash equivalents in Australian dollars. For example during the three-month period ended March 31, 2015, the Australian dollar depreciated from US$0.82020 to US$0.7634 resulting in an unrealized foreign exchange loss of approximately $0.5 million.

Effects of Inflation

We do not believe that inflation and changing prices over the three months ended March 31, 2015 and 2014 had a significant impact on our results of operations.

Item 4. *Controls and Procedures*

Evaluation of Disclosure Controls and Procedures

As required by Rule 13a-15(b) of the Securities Exchange Act of 1934, or the Exchange Act, our management, including our principal executive officer and our principal financial officer, conducted an evaluation as of the end of the period covered by this Quarterly Report on Form 10-Q of the effectiveness of the design and operation of our disclosure controls and procedures. Based on that evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures are effective at the reasonable assurance level in ensuring that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports we file under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

Changes in Internal Control

As required by Rule 13a-15(d) of the Exchange Act, our management, including our principal executive officer and our principal financial officer, conducted an evaluation of the internal control over financial reporting to determine whether any changes occurred during the quarter ended March 31, 2015 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. Based on that evaluation, our principal executive officer and principal financial officer concluded no such changes during the quarter ended March 31, 2015 materially affected, or were reasonably likely to materially affect, our internal control over financial reporting.

PART II – OTHER INFORMATION

Item 1A. *Risk Factors*

In addition to the other information contained elsewhere in this Quarterly Report on Form 10-Q, you should carefully consider the factors discussed in "Item 1A. Risk Factors" in our Annual Report on Form 10-K, which could materially affect our business, financial condition or future results. The risks described in our Annual Report on Form 10-K are not the only risks we face. Additional risks that we do not presently know or that we currently believe are immaterial could also materially and adversely affect any of our business, financial condition or future results. The trading price of our CDIs may decline due to these risks.

Item 2. *Unregistered Sales of Equity Securities*

None.

Item 6. *Exhibits*

See the Exhibit Index following the signature page to this Quarterly Report on Form 10-Q, which is incorporated by reference herein.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

GI Dynamics, Inc.

Date: May 15, 2015

By: /s/ MICHAEL D. DALE
Michael D. Dale
President, Chief Executive Officer and Director
(principal executive officer)

Date: May 15, 2015

By: /s/ ROBERT M. SOLOMON
Robert M. Solomon
Vice President, Finance, Secretary and Treasurer
(principal financial officer and accounting officer)

EXHIBIT INDEX

Exhibit No:	Description
3.1.1	Certificate of Incorporation of GI Dynamics, Inc. incorporated by reference to Exhibit 3.1 of GI Dynamics, Inc.'s registration statement on Form 10, filed with the SEC on April 30, 2014
3.1.2	Certificate of Amendment to the Restated Certificate of Incorporation of GI Dynamics, Inc. incorporated by reference to Exhibit 3.1 of GI Dynamics, Inc.'s Current Report on Form 8-K, filed with the SEC on April 9, 2015
3.2	Bylaws of GI Dynamics, Inc. incorporated by reference to Exhibit 3.2 of GI Dynamics, Inc.'s registration statement on Form 10, filed with the SEC on April 30, 2014
31.1*	Certification of Chief Executive Officer pursuant to Rules 13a-14 or 15d-14 of the Exchange Act
31.2*	Certification of Chief Financial Officer pursuant to Rules 13a-14 or 15d-14 of the Exchange Act
32.1‡	Certification of Chief Executive Officer pursuant to Rules 13a-14(b) or 15d-14(b) of the Exchange Act and 18 U.S.C. Section 1350
32.2‡	Certification of Chief Financial Officer pursuant to Rules 13a-14(b) or 15d-14(b) of the Exchange Act and 18 U.S.C. Section 1350
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Database
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document

* Filed herewith.
‡ Furnished herewith.

EXHIBIT 31.1

CERTIFICATION PURSUANT
TO RULES 13a-14(a) OR 15d-14(a) UNDER
THE SECURITIES EXCHANGE ACT OF 1934

I, Michael D. Dale, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of GI Dynamics, Inc. (the "registrant");
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
    a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
    c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
    a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
    b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 15, 2015

/s/ MICHAEL D. DALE
Michael D. Dale
Chief Executive Officer
(principal executive officer)

EXHIBIT 31.2

CERTIFICATION PURSUANT
TO RULES 13a-14(a) OR 15d-14(a) UNDER
THE SECURITIES EXCHANGE ACT OF 1934

I, Robert M. Solomon, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of GI Dynamics, Inc. (the "registrant");
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f))for the registrant and have:
    a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
    c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
    a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
    b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 15, 2015

/s/ ROBERT M. SOLOMON
Robert M. Solomon
Vice President, Finance
(principal accounting and financial officer)

EXHIBIT 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of GI Dynamics, Inc. (the "Company") on Form 10-Q for the period ended March 31, 2015 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Michael D. Dale, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to my knowledge that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ MICHAEL D. DALE
Michael D. Dale
Chief Executive Officer
(principal executive officer)
May 15, 2015

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

EXHIBIT 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of GI Dynamics, Inc. (the "Company") on Form 10-Q for the period ended March 31, 2015 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Robert M. Solomon, Vice President, Finance of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to my knowledge that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ ROBERT M. SOLOMON
Robert M. Solomon
Vice President, Finance
(principal accounting and financial officer)
May 15, 2015

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.