GI Dynamics, Inc. – ASX Announcement

Form 10-Q Filed with SEC

LEXINGTON, Massachusetts, United States and SYDNEY, Australia – 13 November 2015 – GI Dynamics, Inc. (**ASX: GID**) (**GI Dynamics** or the **Company**), a medical device company developing innovative treatments for type 2 diabetes and obesity, today provides the attached Quarterly Report on Form 10-Q, as filed with the U.S. Securities and Exchange Commission on 12 November 2015. The Form 10-Q includes the Company's unaudited financial results for the three and nine months ended 30 September 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. Founded in 2003, GI Dynamics is headquartered in Lexington, Massachusetts. For more information, please visit www.gidynamics.com.

Forward-Looking Statements

This announcement contains forward-looking statements concerning: our development and commercialization plans; our potential revenues and revenue growth, costs, excess inventory, profitability and financial performance; our ability to obtain reimbursement for our products; our clinical trials, and associated regulatory submissions and approvals; the number and location of commercial centres offering the EndoBarrier; and our intellectual property position. These forward-looking statements are based on the current estimates and expectations of future events by the management of GI Dynamics, Inc. as of the date of this announcement and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those indicated in or implied by such forward-looking statements. These risks and uncertainties include, but are not limited to: risks associated with the consequences of terminating the ENDO Trial and the possibility that future clinical trials will not be successful or confirm earlier results; risks associated with obtaining funding from third parties; risks relating to the timing and costs of clinical trials, the timing of regulatory submissions, the timing, receipt and maintenance of regulatory approvals, the timing and amount of other expenses, and the timing and extent of third-party reimbursement; risks associated with commercial product sales, including product performance; competition; risks related to market acceptance of products; intellectual property risks; risks related to excess inventory; risks related to assumptions regarding the size of the available market, benefits of our products, product pricing, timing of product launches, future financial results and other factors including those described in our filings with the U.S. Securities and Exchange Commission. Given these uncertainties, you should not place undue reliance on these forward-looking statements. We do not assume any obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, unless required by law.

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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 September 30, 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 November 1, 2015 there were 9,505,557 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 the consequences of terminating the ENDO Trial (as defined herein);
- 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," "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 and our Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2015, each 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 SEPTEMBER 30, 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)

	September 30, 2015	December 31, 2014
Assets		
Current assets:		
Cash and cash equivalents	$ 24,439	$ 51,191
Accounts receivable, net	55	470
Inventory	2,731	5,488
Prepaid expenses and other current assets	964	1,165
Total current assets	28,189	58,314
Property and equipment, net	478	1,089
Other long-term assets	97	97
Total assets	$ 28,764	$ 59,500
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 900	$ 882
Accrued expenses	3,658	7,674
Deferred revenue	31	412
Warrants to purchase common stock	3	—
Other current liabilities	117	175
Total current liabilities	4,709	9,143
Deferred rent, net of current portion	43	166
Other liabilities	4	4
Warrants to purchase common stock	—	9
Commitments (Note 10)		
Stockholders' equity:		
Preferred stock, $0.01 par value – 500,000 shares authorized; no shares issued and outstanding at September 30, 2015 and December 31, 2014	—	—
Common stock, $0.01 par value – 13,000,000 shares authorized; 9,505,557 shares issued and 9,504,723 shares outstanding at September 30, 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 September 30, 2015 and December 31, 2014	—	—
Additional paid-in capital	252,511	250,009
Accumulated deficit	(228,598)	(199,926)
Total stockholders' equity	24,008	50,178
Total liabilities and stockholders' equity	$ 28,764	$ 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 September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Revenue	$ 175	$ 609	$ 1,101	$ 2,355
Cost of revenue	918	393	3,816	1,846
Gross (loss) profit	(743)	216	(2,715)	509
Operating expenses:				
Research and development	3,865	6,833	14,142	19,693
Sales and marketing	1,270	2,412	4,412	7,974
General and administrative	2,027	2,670	6,758	7,276
Total operating expenses	7,162	11,915	25,312	34,943
Loss from operations	(7,905)	(11,699)	(28,027)	(34,434)
Other income (expense):				
Interest income	7	41	61	217
Interest expense	(1)	—	(1)	(1)
Foreign exchange loss	(180)	(522)	(645)	(95)
Remeasurement of warrant liability	16	69	6	264
Other income (expense), net	(158)	(412)	(579)	385
Loss before income tax expense	(8,063)	(12,111)	(28,606)	(34,049)
Income tax expense	26	19	66	62
Net loss	$ (8,089)	$ (12,130)	$ (28,672)	$ (34,111)
Basic and diluted net loss per common share	$ (0.85)	$ (1.28)	$ (3.02)	$ (3.86)
Weighted-average number of common shares used in basic and diluted net loss per common share	9,484,731	9,476,046	9,482,323	8,836,526
Comprehensive loss	$ (8,089)	$ (12,130)	$ (28,672)	$ (34,111)

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)

	Nine Months Ended September 30,	
	2015	**2014**
Operating activities		
Net loss	$(28,672)	$(34,111)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	409	485
Stock-based compensation expense	2,438	3,370
Remeasurement of warrant liability	(6)	(264)
Impairment of fixed assets	389	—
Change in inventory reserve	1,699	(139)
Changes in operating assets and liabilities:		
Accounts receivable	415	(210)
Prepaid expenses and other current assets	201	(385)
Inventory	1,058	(75)
Accounts payable	18	(126)
Accrued expenses	(4,030)	2,907
Deferred revenue	(381)	(63)
Deferred rent	(111)	91
Net cash used in operating activities	(26,573)	(28,520)
Investing activities		
Purchases of property and equipment	(179)	(234)
Net cash used in investing activities	(179)	(234)
Financing activities		
Proceeds from exercise of stock options	2	604
Net proceeds from issuance of common stock	—	30,782
Payments on capital lease	(2)	—
Payments on long-term debt	—	(58)
Net cash provided by financing activities	—	31,328
Net (decrease) increase in cash and cash equivalents	(26,752)	2,574
Cash and cash equivalents at beginning of period	51,191	58,616
Cash and cash equivalents at end of period	$ 24,439	$ 61,190
Supplemental cash flow disclosures		
Cash paid for interest	$ 1	$ 1
Income taxes paid	$ 115	$ 36
Equipment acquired under capital lease	$ 8	$ —

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

GI Dynamics, Inc.

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 ≥ 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. 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 of EndoBarrier Therapy (the "ENDO Trial"), which the Company began in 2013. The multi-center, randomized, double-blinded study planned to enroll 500 patients with uncontrolled type 2 diabetes and obesity at 25 sites in the U.S. The primary endpoint was 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 the ENDO Trial as a result of, at that date, four cases of hepatic abscess among the 325 subjects then enrolled in the ENDO Trial. Hepatic abscess, a bacterial infection of the liver, is a known event related to the use of EndoBarrier. As a result, the Company halted enrollment in the ENDO Trial, although monitoring and data collection of patients then enrolled in the ENDO Trial continued.

On July 30, 2015, the Company announced its decision to discontinue the ENDO Trial. The decision followed discussions with the FDA regarding resumption of ENDO Trial enrollment, which despite collaborative efforts by both parties were unable to yield a feasible path forward for the mitigation of a higher than anticipated incidence of hepatic abscess. The Company concluded that terminating the ENDO Trial was in the best interest of all stakeholders.

On August 21, 2015, the Company announced that it was reducing headcount by approximately 46% as part of its efforts to restructure its business and expenses in response to the termination of the ENDO Trial and to ensure sufficient cash remains available for it to establish new priorities, continue limited market development and research, and to evaluate strategic options.

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 be available on acceptable terms, if at all.

The Company has incurred operating losses since inception and at September 30, 2015, had an accumulated deficit of approximately $228.6 million. Based on the Company's decision to conclude the ENDO Trial, it has begun to evaluate which markets are appropriate to continue pursuing reimbursement, market awareness and general market development efforts, and started restructuring its business and costs, establishing new priorities, continuing limited research, and evaluating strategic options. As a result, the Company expects to incur significant operating losses for the next several years. At September 30, 2015, the Company had approximately $24.4 million in cash and cash equivalents, which it believes is sufficient to fund its operations through December 2016. The Company does not expect its current cash balances will be sufficient to enable it to complete development of an improved EndoBarrier for its current use and potential new indications. The Company will need to raise additional funding in order to continue to fund its operations beyond December 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 be available on acceptable terms, if at all. If the Company is unable to raise capital when needed, it could be forced to significantly delay or discontinue research and development activities and further commercialization of EndoBarrier.

1. Nature of Business (continued)

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 September 30, 2015 and for the three and nine months ended September 30, 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 September 30, 2015, results of its operations for the three and nine months ended September 30, 2015 and 2014, and its cash flows for the nine months ended September 30, 2015 and 2014. The interim results for the three and nine months ended September 30, 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.

Impairment of Long-Lived Assets

The Company regularly reviews the carrying amount of its long-lived assets to determine whether indicators of impairment may exist that warrant adjustments to carrying values or estimated useful lives. If indications of impairment exist, projected future undiscounted cash flows associated with the asset are compared to the carrying amount to determine whether the asset's value is recoverable. If the carrying value of the asset exceeds such projected undiscounted cash flows, the asset will be written down to its estimated fair value.

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

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.

As of September 30, 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 one-for-ten 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 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.

Reclassifications

Certain reclassifications related to the presentation of the change in inventory in the condensed consolidated statements of cash flows have been made to prior year amounts to conform with current year presentation.

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.

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

In May 2014, the FASB issued Accounting Standards Update ("ASU") No. 2014-09, *Revenue from Contracts with Customers* ("ASU 2014-09"), which supersedes the revenue recognition requirements in ASC Topic 605, *Revenue Recognition*, and most industry-specific guidance. The new standard requires that an entity 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. ASU 2014-09 also requires additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to obtain or fulfill a contract. In July 2015, the FASB approved a one year deferral of the effective date of this standard to annual reporting periods, and interim reporting periods within those years, beginning after December 15, 2017. Early adoption is permitted to the original effective date of December 15, 2016, including interim reporting periods within those years. The Company is currently evaluating the potential impact that ASU 2014-09 may have on its 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 is 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. This guidance is effective for annual reporting beginning after December 15, 2016, including interim periods within the year of adoption, with early application permitted. The Company is currently evaluating the potential impact that ASU 2014-15 may have on its 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 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.

In July 2015, the FASB issued ASU No. 2015-11, *Simplifying the Measurement of Inventory* ("ASU 2015-11"). ASU 2015-11, which simplifies the measurement of inventories valued under most methods, including the Company's inventories valued under FIFO – the first-in, first-out cost method. Inventories valued under LIFO – the last-in, first-out method – are excluded. Under this new guidance, inventories valued under these methods would be valued at the lower of cost and net realizable value, with net realizable value defined as the estimated selling price less reasonable costs to sell the inventory. This guidance is effective for annual reporting beginning after December 15, 2016, including interim periods within the year of adoption, with early application permitted. The adoption of this guidance is not expected to have a significant 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 and nine months ended September 30, 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.

3. Net Loss per Common Share (continued)

The following potentially dilutive securities have been excluded from the computation of diluted weighted-average shares outstanding as of September 30, 2015 and 2014, as they would be anti-dilutive:

	Three and Nine Months Ended September 30,	
	2015	2014
Warrants to purchase common stock	50,000	50,000
Options to purchase common stock and other stock-based awards	1,341,303	1,541,923
	1,391,303	1,591,923

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 September 30, 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.

5. Fair Value of Financial Instruments (continued)

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

Description	September 30, 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)	$ 19,202	$ 19,202	$ —	$ —
Total assets	$ 19,202	$ 19,202	$ —	$ —
Liabilities				
Warrants to purchase common stock	$ 3	$ —	$ —	$ 3
Total liabilities	$ 3	$ —	$ —	$ 3

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

The assumptions used in the Black-Scholes option pricing model to determine the fair value of the common stock warrants at September 30, 2015 and December 31, 2014 were as follows:

	September 30, 2015	December 31, 2014
Exercise price (A$55.00 at current exchange rate)	$ 38.56	$ 45.10
Fair value of common stock	$ 1.23	$ 9.80
Expected volatility	172.3%	62.2%
Expected term (in years)	0.9	1.7
Risk-free interest rate	0.3%	0.5%
Expected dividend yield	— %	— %

5. Fair Value of Financial Instruments (continued)

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
Decrease in fair value of warrants upon remeasurement included in other income (expense)	(6)
Balance at September 30, 2015	$ 3

Cash equivalents, accounts receivable, prepaid expenses and other current assets, accounts payable, accrued expenses and other current liabilities at September 30, 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 September 30, 2015, one health care provider and one distributor accounted for approximately 15% and 12%, respectively, of the Company's accounts receivable. At December 31, 2014, one distributor accounted for approximately 32% of the Company's accounts receivable. No other customer accounted for greater than 10% of the Company's accounts receivable at September 30, 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 September 30, 2015, the Company had approximately $0.1 million 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.

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 September 30, 2015 and December 31, 2014 (in thousands):

	September 30, 2015	December 31, 2014
Accounts receivable	$ 171	$ 555
Less: allowance for doubtful accounts	(95)	(41)
Less: allowance for sales returns	(21)	(44)
Total	$ 55	$ 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 June of 2015, the Company performed an analysis of its inventory on hand and due to current evidence that the utility of certain amounts of the raw material sleeve inventory as it was expected to be used will be less than its cost, recorded an approximately $1.4 million charge for excess inventory. Factors contributing to the inventory write-down included: the effect that the ENDO Trial enrollment hold and related uncertainty around the timing and success of the Company's ENDO Trial had on commercial activity and the Company's inventory levels, the expected timing of third-party payer reimbursement in its commercial markets, its conclusion that certain inventory will not be used for sales inside or outside the U.S. and the historical accuracy of its demand forecasts. As of September 30, 2015, the Company has a reserve totaling approximately $3.0 million for raw material sleeve inventory. 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 September 30, 2015 and December 31, 2014 was as follows (in thousands):

	September 30, 2015	December 31, 2014
Finished goods	$ 266	$ 733
Work-in-process	1,414	2,401
Raw materials	1,051	2,354
Total	$ 2,731	$ 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 September 30, 2015 and December 31, 2014, approximately 9% 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):

	September 30, 2015	December 31, 2014
Laboratory equipment and manufacturing equipment	$ 415	$ 545
Computer equipment and software	1,118	1,125
Office furniture and equipment	229	221
Construction in process	42	48
Leasehold improvements	848	921
	2,652	2,860
Less accumulated depreciation and amortization	(2,174)	(1,771)
Total	$ 478	$ 1,089

As part of the Company's restructuring in August 2015, the Company recognized a charge for impaired fixed assets as follows for the three and nine months ended September 30, 2015 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Cost of revenue	$ 265	$ —	$ 265	$ —
Research and development	100	—	100	—
Sales and marketing	5	—	5	—
General and administrative	19	—	19	—
	$ 389	$ —	$ 389	$ —

In January 2015, the Company entered into a capital lease for certain office equipment. As of September 30, 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, and the charge for impaired assets totaled approximately $0.5 million for the three months ended September 30, 2015 and approximately $0.2 million for the three months ended September 30, 2014. Depreciation and amortization expense of property and equipment, including equipment recorded under capital leases, and the charge for impaired assets was approximately $0.8 million for the nine months ended September 30, 2015 and approximately $0.5 million for the nine months ended September 30, 2014.

9. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	September 30, 2015	December 31, 2014
Clinical trials	$ 1,622	$ 3,906
Payroll and related liabilities	891	2,629
Professional fees	730	634
Deferred rent, current portion	162	151
Current portion of capital lease obligation	2	—
Other	251	354
Total	$ 3,658	$ 7,674

9. Accrued Expenses (continued)

Included in payroll and related liabilities at September 30, 2015, is a total of approximately $0.2 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.

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. In July 2015 the Company vacated this office space.

Rent expense on noncancelable operating leases was approximately $0.1 million for each of the three-month periods ended September 30, 2015 and 2014, respectively. Rent expense on noncancelable operating leases was approximately $0.4 million for each of the nine-month periods ended September 30, 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 September 30, 2015, are as follows (in thousands):

Year Ending December 31,	
2015	$160
2016	626
2017	3
2018	1
Total	$790

Separation Arrangements

The Company expects to incur approximately $0.1 million of additional separation expenses in the three months ending December 31, 2015 under existing separation agreements.

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. No shares of common stock are currently subject to such an escrow.

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 September 30, 2015, there were 622,654 shares available for future grant under both plans.

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 nine months ended September 30, 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 and nine months ended September 30, 2015 and 2014 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Cost of revenue	$ 24	$ 33	$ 71	$ 93
Research and development	61	330	410	970
Sales and marketing	97	376	353	1,202
General and administrative	643	423	1,604	1,105
	$ 825	$ 1,162	$ 2,438	$ 3,370

During the nine months ended September 30, 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 nine months ended September 30, 2015. The Company accounted for the modification of these stock awards in accordance with the provisions of ASC 718, *Stock Compensation* ("ASC 718").

12. Stock Plans (continued)

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 and nine months ended September 30, 2015 and 2014:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Expected volatility	— %	61.0%	56.8%	61.6%
Expected term (in years)	—	6.05	6.04	6.05
Risk-free interest rate	— %	2.1%	1.6%	2.1%
Expected dividend yield	— %	— %	— %	— %

The Company uses historical data to estimate forfeiture rates. The Company's estimated forfeiture rates were 10% and 5% at September 30, 2015 and 2014, respectively.

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	246,604	$ 5.42		
Exercised	(1,000)	$ 1.50		
Cancelled	(368,757)	$ 28.14		
Outstanding at September 30, 2015	1,078,343	$ 20.99	5.86	$ —
Vested or expected to vest at September 30, 2015	1,031,154	$ 21.05	5.54	$ —
Exercisable at September 30, 2015	606,398	$ 22.08	3.73	$ —

As of September 30, 2015, there was approximately $4.6 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 2.5 years. The total unrecognized stock-based compensation cost will be adjusted for future changes in estimated forfeitures.

12. Stock Plans (continued)

There were no options granted during the three months ended September 30, 2015. The weighted-average grant date fair value of options granted during the three months ended September 30, 2014 was $12.38. The weighted-average grant date fair value of options granted during the nine months ended September 30, 2015 and 2014 was $2.91 and $15.46, respectively. There were no options exercised during the three months ended September 30, 2015. The options exercised during the three months ended September 30, 2014 had no intrinsic value. The total intrinsic value of options exercised during the nine months ended September 30, 2015 and 2014 was approximately $10,000 and $4.3 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 September 30, 2015 and 2014 was none and approximately $82,000. Cash received from option exercises during the nine months ended September 30, 2015 and 2014 was approximately $1,500 and $0.6 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 September 30, 2015 and December 31, 2014, there were 834 shares and 3,500 shares, respectively, 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 unvested shares is not substantive and as a result, the portion of cash paid for the exercise price of these shares is considered a deposit or prepayment of the exercise price and is recorded as a liability. The liability related to these shares was approximately $19,000 and $0.1 million, respectively, at September 30, 2015 and December 31, 2014. 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.

Restricted Stock Units

Each restricted stock unit ("RSU") represents a contingent right to receive one share of the Company's common stock. The RSUs outstanding as of September 30, 2015 vest on the first anniversary of the issuance date, vest on a pro-rata basis on each anniversary of the issuance date over four years or vest upon the achievement of certain product revenue, regulatory and reimbursement milestones. 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 nine months ended September 30, 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	143,506		
Vested/Exercised	(20,886)		
Cancelled	(66,234)		
Outstanding at September 30, 2015	262,126	4.55	$ 322

The aggregate intrinsic value at September 30, 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. No RSUs were granted during the three months ended September 30, 2015. The weighted average grant date fair value per share of RSUs granted during the nine months ended September 30, 2015 was $5.39. The weighted average grant date fair value per share of RSUs granted during the three and nine months ended September 30, 2014 was $21.50 and $22.64, respectively.

12. Stock Plans (continued)

At September 30, 2015, 193,468 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 certain product revenue, regulatory and reimbursement milestones. 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 September 30, 2015, the Company did not recognize any stock-based compensation for RSUs subject to performance-based vesting criteria. During the nine months ended September 30, 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 estimate was recognized through a cumulative adjustment in the first nine months of 2015, resulting in a reduction of stock-based compensation of approximately $0.3 million. In the three and nine months ended September 30, 2014, stock-based compensation expense associated with RSUs subject to performance-based vesting criteria was approximately $12,000 and $0.1 million, respectively, as certain milestones were deemed probable of achievement at that time. Stock-based compensation for RSUs that have service-based vesting was approximately $15,000 for the three and nine months ended September 30, 2014, and $0.1 million and $0.4 million for the three and nine months ended September 30, 2015, respectively.

As of September 30, 2015, there was approximately $1.2 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 2.8 years. At September 30, 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 September 30, 2015, long-lived assets, comprised of property and equipment, of approximately $0.5 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 and nine months ended September 30, 2015 and 2014 are listed in the table below (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Europe	$ 127	$ 405	$ 810	$1,453
Middle East	20	14	139	242
South America	6	63	40	284
Asia Pacific	22	127	112	376
Total Revenue	$ 175	$ 609	$1,101	$2,355

13. Segment Reporting (continued)

Major Customers

In the three months ended September 30, 2015, two health care providers accounted for approximately 17% and 10%, respectively, of the Company's revenue, and two distributors accounted for approximately 13% and 11%, respectively, of the Company's revenue. In the three months ended September 30, 2014, one health care provider accounted for approximately 13% of the Company's revenue and one distributor accounted for approximately 10% of the Company's revenue. No other customer accounted for greater than 10% of the Company's revenue during the three months ended September 30, 2015 and 2014.

In the nine months ended September 30, 2015, one distributor accounted for approximately 17% of the Company's revenue. In the nine months ended September 30, 2014, one distributor accounted for approximately 11% of the Company's revenue. No other customer accounted for greater than 10% of the Company's revenue during the nine months ended September 30, 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 and our Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2015 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, which 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, South America, the Asia Pacific region and the Middle East.

As part of our reorganization efforts in the third quarter of 2015, we decided to focus sales activity on a limited number of countries while disengaging from others. As a result, we are focused on the commercialization of EndoBarrier in selected countries in Europe, the Asia Pacific region and the Middle East. 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 the product use per center.

In the U.S., we commenced enrollment of patients in our pivotal trial of EndoBarrier Therapy, the ENDO Trial, in 2013. The multi-center, randomized, double-blinded study planned to enroll 500 patients with uncontrolled type 2 diabetes and obesity at 25 sites in the U.S. The primary endpoint was improvement in diabetes control as measured by HbA1c levels. On March 5, 2015, at the recommendation of the Food and Drug Administration, or FDA, as a result of the higher than anticipated incidence of hepatic abscess, a bacterial infection of the liver, we halted enrollment in the ENDO Trial, although monitoring and data collection of patients then enrolled in the ENDO Trial continued.

On July 30, 2015, we announced our decision to discontinue the ENDO Trial. The decision followed discussions with the FDA regarding resumption of ENDO Trial enrollment, which despite collaborative efforts by both parties were unable to yield a feasible path forward for the mitigation of a higher than anticipated incidence of hepatic abscess. We concluded that terminating the ENDO Trial was in the best interest of all stakeholders. With seven cases of hepatic abscess in the ENDO Trial, the incidence rate was approximately 3.5%, which exceeded a previously established safety threshold of 2%. The incidence of hepatic abscess in markets outside the U.S. is approximately 0.73% based on experience with approximately 3,000 units shipped commercially since 2009. A preliminary review of available efficacy data suggests a likely outcome (>90% probability) would have been a statistically significant benefit of EndoBarrier Therapy that exceeded the predefined trial endpoint for efficacy as measured by reduction of HbA1c blood sugar levels.

On August 21, 2015, we announced that we were reducing headcount by approximately 46% as part of our efforts to restructure our business and expenses in response to the termination of the ENDO Trial and to ensure sufficient cash remains available for us to establish new priorities, continue limited market development and research, and to evaluate strategic options.

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 September 30, 2015, we had an accumulated deficit of approximately $228.6 million. We expect to incur net losses for the next several years while we close out our ENDO Trial, restructure our business and costs, establish new priorities, continue limited market development and research, and evaluate strategic options.

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 September 30, 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 September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Revenue	$ 175	$ 609	$ 1,101	$ 2,355
Cost of revenue	918	393	3,816	1,846
Gross (loss) profit	(743)	216	(2,715)	509
Operating expenses:				
Research and development	3,865	6,833	14,142	19,693
Sales and marketing	1,270	2,412	4,412	7,974
General and administrative	2,027	2,670	6,758	7,276
Total operating expenses	7,162	11,915	25,312	34,943
Loss from operations	(7,905)	(11,699)	(28,027)	(34,434)
Other income (expense):				
Interest income	7	41	61	217
Interest expense	(1)	—	(1)	(1)
Foreign exchange loss	(180)	(522)	(645)	(95)
Remeasurement of warrant liability	16	69	6	264
Other income (expense), net	(158)	(412)	(579)	385
Loss before income tax expense	(8,063)	(12,111)	(28,606)	(34,049)
Income tax expense	26	19	66	62
Net loss	$(8,089)	$(12,130)	$(28,672)	$(34,111)

Three and Nine Months Ended September 30, 2015 Compared to Three and Nine Months Ended September 30, 2014

	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2015	2014	$	%	2015	2014	$	%
	(dollars in thousands)				(dollars in thousands)			
Revenue	$ 175	$ 609	$(434)	(71.3)%	$ 1,101	$2,355	$(1,254)	(53.2)%
Cost of revenue	918	393	525	133.6%	3,816	1,846	1,970	106.7%
Gross (loss) profit	$ (743)	$ 216	$(959)	(444.0)%	$(2,715)	$ 509	$(3,224)	(633.4)%

Revenue. The decrease in revenue of approximately $0.4 million for the three months ended September 30, 2015 compared to the three months ended September 30, 2014 was primarily due to decreased revenue across all markets except the Middle East. Revenue decreased approximately 69%, 83% and 90% in Europe, Asia Pacific region and South America, respectively, primarily as a result of lower unit volume. Revenues increased 45% in the Middle East for the three month period ending September 30, 2015.

The decrease in revenue of approximately $1.3 million for the nine months ended September 30, 2015 compared to the nine months ended September 30, 2014 was primarily due to decreased revenue across all markets. Revenue decreased approximately 43%, 44%, 70%, and 86% in the Middle East, Europe, Asia Pacific region and South America, respectively, primarily as a result of lower unit volume.

We believe that the regulatory-related questions arising out of the termination of the ENDO Trial were the primary reasons for the decrease in revenue in the three months ended September 30, 2015 compared to the three months ended September 30, 2014. Additionally, as part of our reorganization efforts in the three months ended September 30, 2015, we decided to focus sales activity on a limited number of markets while disengaging from others. We believe that the regulatory-related questions arising out of our decision to terminate the ENDO Trial will likely continue to adversely affect sales. In general, we believe the Notified Body request to stop shipment of CE Mark product in late 2014, followed by the ENDO Trial enrollment hold and subsequent termination of the ENDO Trial, have together adversely affected our commercial operations and will continue to adversely affect our commercial operations until we complete the evaluation of our strategic options and make clear our plans for the future, finalize the results of the ENDO Trial and develop market specific priorities.

Cost of Revenue. Cost of revenue increased by approximately $0.5 million for the three months ended September 30, 2015 compared to the three months ended September 30, 2014. The increase in cost of revenue was primarily a result of a $0.3 million charge for impaired fixed assets and increased expenses resulting from decreased manufacturing efficiency due to lower production volume compared to the same period last year. Cost of revenue increased approximately $2.0 million for the nine months ended September 30, 2015 compared to the nine months ended September 30, 2014. The nine month increase in cost of revenue was primarily related to an increase in inventory reserves of approximately $1.7 million and a $0.3 million charge for impaired fixed assets. The increase in inventory reserves was primarily related to a charge of approximately $1.4 million for raw material sleeve inventory in excess of our currently anticipated commercial requirements for future sales of EndoBarrier due to current evidence that the utility of certain amounts of the raw material sleeve inventory, as it was expected to be used, will be less than cost. Factors contributing to the inventory write-down in the nine months ended September 30, 2015 included: the effect that the ENDO Trial enrollment hold and subsequent termination of the ENDO Trial had on commercial activity and our inventory levels, the expected timing of third-party payer reimbursement in our commercial markets, our conclusion that certain inventory will not be used for sales inside or outside the U.S. and the historical accuracy of our demand forecasts. The sleeves were purchased in 2013 prior to the termination of our supply agreement with Gore. Excluding the increase in inventory reserves and charge for impaired fixed assets, cost of revenue was flat in the nine months ended September 30, 2015 compared to the same period last year.

Gross (loss) profit decreased by approximately $1.0 million and $3.2 million for the three and nine months ended September 30, 2015 compared to the three and nine months ended September 30, 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 the effect on commercial operations of our decision to terminate the ENDO Trial, 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 September 30,		Change		Nine Months Ended September 30,		Change	
	2015	2014	$	%	2015	2014	$	%
	(dollars in thousands)				(dollars in thousands)			
Research and development expense	$ 3,865	$ 6,833	$(2,968)	(43.4)%	$14,142	$19,693	$(5,551)	(28.2)%
Sales and marketing expense	1,270	2,412	(1,142)	(47.3)%	4,412	7,974	(3,562)	(44.7)%
General and administrative expense	2,027	2,670	(643)	(24.1)%	6,758	7,276	(518)	(7.1)%
Total operating expenses	$ 7,162	$ 11,915	$(4,753)	(39.9)%	$25,312	$34,943	$(9,631)	(27.6)%

Research and Development Expense. The decrease in research and development expense of approximately $3.0 million for the three months ended September 30, 2015 compared to the three months ended September 30, 2014 was primarily due to a decrease of approximately $2.3 million in clinical trial and other clinical study related expenses, primarily third-party expenses related to the ENDO Trial, and decreases of approximately $0.8 million in compensation and employee related expenses, including approximately $0.3 million in lower stock-based compensation expense, due to decreases in headcount.

The decrease in research and development expense of approximately $5.6 million for the nine months ended September 30, 2015 compared to the nine months ended September 30, 2014 was primarily due to a decrease of approximately $3.6 million in clinical trial and other clinical study related expenses, primarily third-party expenses related to the ENDO Trial, and a decrease of approximately $1.8 million in compensation and employee related expenses, including approximately $0.6 million in lower stock-based compensation expense, due to decreases in headcount.

In July 2015, we announced our decision to discontinue the ENDO Trial. In October 2015, we completed all device removals from ENDO Trial subjects. As we continue closing out the ENDO Trial, including required post-explant patient follow-up, clinical investigator site closures and final data monitoring and analysis, we expect to incur lower expenses related to the ENDO Trial.

Sales and Marketing Expense. The decrease in sales and marketing expense of approximately $1.1 million for the three months ended September 30, 2015 compared to the three months ended September 30, 2014 was primarily the result of a decrease of approximately $0.8 million in compensation and employee related expenses, including approximately $0.3 million in lower stock-based compensation expense, due to decreases in headcount, as well as a decrease of approximately $0.3 million in marketing activities to support our commercialization efforts.

The decrease in sales and marketing expense of approximately $3.6 million for the nine months ended September 30, 2015 compared to the nine months ended September 30, 2014 was primarily the result of a decrease of approximately $2.3 million in compensation and employee related expenses, including an approximately $0.8 million in lower stock-based compensation expense, due to decreases in headcount, as well as a decrease of approximately $1.1 million in marketing activities to support our commercialization efforts.

General and Administrative Expense. The decrease in general and administrative expense of approximately $0.6 million for the three months ended September 30, 2015 compared to the three months ended September 30, 2014 was primarily a result of decreased compensation and employee related expenses of approximately $0.5 million as a result of our CEO transition in 2014 and an approximately $0.1 million decrease in consulting, professional services and expenses related to being a public company.

The decrease in general and administrative expense of approximately $0.5 million for the nine months ended September 30, 2015 compared to the nine months ended September 30, 2014 was primarily a result of decreased compensation and employee related expenses of approximately $0.4 million as a result of our CEO transition in 2014 and an approximately $0.1 million decrease in consulting and professional services and expenses related to being a public company.

Other Income (Expense), Net

	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2015	2014	$	%	2015	2014	$	%
	(dollars in thousands)				(dollars in thousands)			
Other income (expense):								
Interest income	$ 7	$ 41	$ (34)	(82.9)%	$ 61	$ 217	$(156)	(71.9)%
Interest expense	(1)	—	(1)	100.0%	(1)	(1)	—	0.0%
Foreign exchange loss	(180)	(522)	342	65.5%	(645)	(95)	(550)	(578.9)%
Remeasurement of warrant liability	16	69	(53)	(76.8)%	6	264	(258)	(97.7)%
Total other income (expense), net	$ (158)	$ (412)	$254	61.7%	$ (579)	$ 385	$(964)	(250.4)%

Interest Income. The decrease in interest income of approximately $34,000 and $0.2 million, respectively, for the three and nine months ended September 30, 2015 compared to the three and nine months ended September 30, 2014 was due to decreases in both interest rates and average cash and cash equivalents balances.

Interest Expense. The decrease in interest expense of approximately $1,000 for the three months ended September 30, 2015 compared to the three months ended September 30, 2014 was due to the repayment of our debt in August 2014.

Foreign Exchange Loss. The decrease in foreign exchange loss of approximately $0.3 million for the three months ended September 30, 2015 compared to the three months ended September 30, 2014 was primarily the result of lower cash and cash equivalent balances held in Australian dollars during the three months ended September 30, 2015 compared to the same period last year. The increase in the foreign exchange loss of approximately $0.6 million for the nine months ended September 30, 2015 compared to the nine months ended September 30, 2014 was primarily the result of the depreciation of the Australian dollar versus the U.S. dollar during the three and nine months ended September 30, 2015.

Remeasurement of Warrant Liability. The change in the remeasurement of warrant liability of approximately $53,000 and $0.3 million for the three and nine months ended September 30, 2015 compared to the three and nine months ended September 30, 2014, respectively, was the result of a smaller decrease in the fair value of the warrants issued in connection with our IPO for the three and nine months ended September 30, 2015 compared to the decrease in the fair value of the warrants for the three and nine months ended September 30, 2014.

Liquidity and Capital Resources

We have incurred losses since our inception in March 2003 and, as of September 30, 2015, we had an accumulated deficit of approximately $228.6 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 September 30, 2015, we had approximately $24.4 million of cash and cash equivalents.

During the nine months ended September 30, 2015, our cash and cash equivalents balance decreased by approximately $26.8 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:

	Nine Months Ended September 30,	
	2015	2014
	(in thousands)	
Net cash (used in) provided by:		
Operating activities	$ (26,573)	$ (28,520)
Investing activities	(179)	(234)
Financing activities	—	31,328
Net (decrease) increase in cash and cash equivalents	$ (26,752)	$ 2,574

Cash Flows From Operating Activities

Net cash used in operating activities totaled approximately $26.6 million for the nine months ended September 30, 2015. The primary uses of cash were:

- to fund our net loss of approximately $28.7 million;
- a net negative adjustment to cash flow from changes in working capital of approximately $2.8 million resulting primarily from decreases in accrued expenses, deferred revenue and deferred rent, partially offset by decreases in inventory, accounts receivable and prepaid and other current assets; and
- a net positive adjustment to cash flow from non-cash items of approximately $4.9 million, primarily from stock-based compensation and increases in inventory reserves resulting from a charge of approximately $1.7 million for inventory in excess of our commercial requirements.

Due to the nature and timing of the cash flows related to our ENDO Trial, we believe that the ENDO Trial had a significant effect on our cash flows from operations for the nine months ended September 30, 2015 as our clinical trial accrual decreased by approximately $2.3 million. It is likely that our decision to conclude the ENDO Trial will have a significant effect on our cash flows from operations for the remainder of 2015 as we close out the ENDO Trial and reduce the existing clinical trial accruals.

Net cash used in operating activities totaled approximately $28.5 million for the nine months ended September 30, 2014. The primary uses of cash were:

- to fund our net loss of approximately $34.1 million;
- a net positive adjustment to cash flow from changes in working capital of approximately $2.0 million resulting primarily from increases in accrued expenses; and
- a net positive adjustment to cash flow from non-cash items of approximately $3.6 million, primarily from stock-based compensation expense.

Cash Flows From Investing Activities

Cash used in investing activities for the nine months ended September 30, 2015 and 2014 totaled approximately $0.2 million in each period and resulted from the purchase of property and equipment.

Cash Flows From Financing Activities

Cash from financing activities for the nine months ended September 30, 2015 consisted of proceeds from the exercise of stock options offset by an equal amount of payments on capital leases.

Cash provided by financing activities for the nine months ended September 30, 2014 totaled approximately $31.3 million and resulted primarily from the approximately $30.8 million in net proceeds from the issuance of CDI's in the private equity placement in May 2014, and approximately $0.6 million in proceeds from the issuance of shares upon the exercise of stock options.

Funding Requirements

As of September 30, 2015, our primary source of liquidity was our cash and cash equivalents on hand of approximately $24.4 million. Based on our decision to conclude the ENDO Trial, we have begun to evaluate which markets are appropriate to continue pursuing reimbursement, market awareness and general market development efforts, and started restructuring our business and costs, establishing new priorities, continuing limited research, and evaluating strategic options. As a result, we expect to incur significant operating losses for the next several years. We believe our current cash balances will be sufficient to meet our anticipated cash requirements to fund operations through December 2016. However, we do not expect our current cash balances will be sufficient to enable us to complete development of an improved EndoBarrier for its current use and potential new indications. We will need to raise additional funding in order to complete development of an improved EndoBarrier for its current use and potential new indications 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 and our Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2015 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;
- the costs associated with terminating the ENDO Trial;
- the costs associated with any additional clinical trial(s) required in the U.S.;
- 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 be available on acceptable terms, if at all. If we are unable to raise capital when needed, we could be forced to significantly delay or discontinue 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%. In August 2015 we entered into separation agreements with former employees as part of our restructuring. We expect to pay approximately $0.2 million under these agreements through December 31, 2015. Other than these, 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*, or ASU 2014-09, which supersedes the revenue recognition requirements in ASC Topic 605, *Revenue Recognition*, and most industry-specific guidance. The new standard requires that an entity 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. ASU 2014-09 also requires additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to obtain or fulfill a contract. In July 2015, the FASB approved a one year deferral of the effective date of this standard to annual reporting periods, and interim reporting periods within those years, beginning after December 15, 2017. Early adoption is permitted to the original effective date of December 15, 2016, including interim reporting periods within those years. We are currently evaluating the potential impact that ASU 2014-09 may have 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 is 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. We are currently evaluating the potential impact that ASU 2014-15 may have on our consolidated financial statements.

In April 2015, the FASB issued ASU No. 2015-05, *Intangibles – Goodwill and Other – Internal-Use Software*, or 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.

In July 2015, the FASB issued ASU No. 2015-11, *Simplifying the Measurement of Inventory*, or ASU 2015-11. ASU 2015-11, which simplifies the measurement of inventories valued under most methods, including our inventories valued under FIFO – the first-in, first-out cost method. Inventories valued under LIFO – the last-in, first-out method – are excluded. Under this new guidance, inventories valued under these methods would be valued at the lower of cost and net realizable value, with net realizable value defined as the estimated selling price less reasonable costs to sell the inventory. This guidance is effective for annual reporting beginning after December 15, 2016, including interim periods within the year of adoption, with early application permitted. The adoption of this guidance is not expected to have a significant 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 $24.4 million at September 30, 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 the majority of the proceeds were converted to U.S. dollars by September 30, 2015. As of September 30, 2015, we held the equivalent of approximately US$0.2 million denominated in Australian dollars and approximately US$0.7 million denominated in Euros. 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 or Euros. For example during the nine-month period ended September 30, 2015, the Australian dollar depreciated from US$0.8202 to US$0.7010 resulting in a foreign exchange loss of approximately $0.6 million.

Effects of Inflation

We do not believe that inflation and changing prices over the three months ended September 30, 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 September 30, 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 September 30, 2015 materially affected, or were reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Controls and Procedures

Our management, including our principal executive officer and principal financial officer, does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent all error and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. Thus, misstatements due to error or fraud may occur and not be detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of controls.

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 and our Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2015, which could materially affect our business, financial condition or future results. The risks described in our Annual Report on Form 10-K and our Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2015 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: November 12, 2015

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

Date: November 12, 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(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: November 12, 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: November 12, 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 September 30, 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)
November 12, 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 September 30, 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)
November 12, 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.