GI Dynamics, Inc. – ASX Announcement

Form 10-Q Filed with SEC

LEXINGTON, Massachusetts, United States and SYDNEY, Australia – 10 November 2016 – GI Dynamics, Inc. (**ASX: GID**) (**GI Dynamics** or the **Company**), a medical device company developing innovative treatments for type 2 diabetes and obesity, today provides the attached Quarterly Report on Form 10-Q, as filed with the U.S. Securities and Exchange Commission on 9 November 2016.

Robert Simkevich
Corporate Corporate Controller

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 $\geq$ 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. 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 Boston, 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, 2016

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)**
355 Congress Street	
Boston, Massachusetts	**02210**
(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, 2016 there were 9,510,557 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.

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

You are urged to consider these factors carefully in evaluating the forward-looking statements and are cautioned not to place undue reliance on the forward-looking statements. You should read this Quarterly Report on Form 10-Q and the documents that we have filed as exhibits to our Annual Report on Form 10-K completely and with the understanding that our actual future results may be materially different from what we expect. These forward-looking statements speak only as of 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, 2016

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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 “$”, “US$” 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, 2016	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	$ 9,662	$ 19,590
Restricted cash	150	—
Accounts receivable, net	106	40
Inventory	417	1,025
Prepaid expenses and other current assets	525	726
Total current assets	10,860	21,381
Property and equipment, net	156	401
Total assets	$ 11,016	$ 21,782
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 529	$ 435
Accrued expenses	1,363	2,810
Short term loan payable	307	-
Other current liabilities	13	276
Total current liabilities	2,212	3,521
Other liabilities	15	3
Commitments (Note 10)		
Stockholders' equity:		
Preferred stock, $0.01 par value – 500,000 shares authorized; no shares issued and outstanding at September 30, 2016 and December 31, 2015	—	—
Common stock, $0.01 par value – 13,000,000 shares authorized; 9,510,557 shares issued and outstanding at September 30, 2016 and 9,505,557 shares issued and 9,505,389 shares outstanding at December 31, 2015	95	95
Class B common stock, $0.01 par value – 1,000,000 shares authorized; no shares issued and outstanding at September 30, 2016 and December 31, 2015	—	—
Additional paid-in capital	253,863	253,250
Accumulated deficit	(245,169)	(235,087)
Total stockholders' equity	8,789	18,258
Total liabilities and stockholders' equity	$ 11,016	$ 21,782

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

GI Dynamics, Inc. and Subsidiaries

Condensed Consolidated Statements of Operations and Comprehensive Loss

(In thousands, except share and per share amounts)

(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	**2015**	**2016**	**2015**
Revenue	$ 136	$ 175	$ 477	$ 1,101
Cost of revenue	138	918	1,128	3,816
Gross loss	(2)	(743)	(651)	(2,715)
Operating expenses:				
Research and development	962	3,865	2,993	14,142
Sales and marketing	479	1,270	1,753	4,412
General and administrative	1,321	2,027	4,687	6,758
Total operating expenses	2,762	7,162	9,433	25,312
Loss from operations	(2,764)	(7,905)	(10,084)	(28,027)
Other income (expense):				
Interest income	9	7	36	61
Interest expense	-	(1)	-	(1)
Foreign exchange gain (loss)	6	(180)	9	(645)
Remeasurement of warrant liability	3	16	(14)	6
Other income (expense), net	18	(158)	31	(579)
Loss before income tax expense	(2,746)	(8,063)	(10,053)	(28,606)
Income tax expense	8	26	29	66
Net loss	$ (2,754)	$ (8,089)	$ (10,082)	$ (28,672)
Basic and diluted net loss per common share	$ (0.29)	$ (0.85)	$ (1.06)	$ (3.02)
Weighted-average number of common shares used in basic and diluted net loss per common share	9,510,557	9,484,731	9,509,055	9,482,323
Comprehensive loss	$ (2,754)	$ (8,089)	$ (10,082)	$ (28,672)

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,	
	2016	**2015**
Operating activities		
Net loss	$ (10,082)	$ (28,672)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	171	409
Stock-based compensation expense	609	2,438
Remeasurement of warrant liability	14	(6)
Impairment loss on property and equipment	145	389
Change in inventory reserve	(187)	1,699
Loss on sale of property and equipment	4	—
Changes in operating assets and liabilities:		
Accounts receivable	(66)	415
Prepaid expenses and other current assets	201	201
Inventory	799	1,058
Accounts payable	94	18
Accrued expenses	(1,447)	(4,030)
Other current liabilities	(263)	(492)
Net cash used in operating activities	(10,008)	(26,573)
Investing activities		
Change in restricted cash	(150)	—
Purchases of property and equipment	(79)	(179)
Proceeds from sale of property and equipment	4	—
Net cash used in investing activities	(225)	(179)
Financing activities		
Proceeds from short term loan	307	-
Proceeds from exercise of stock options	-	2
Payments on capital lease	(2)	(2)
Net cash provided/(used) in financing activities	305	—
Net decrease in cash and cash equivalents	(9,928)	(26,752)
Cash and cash equivalents at beginning of period	19,590	51,191
Cash and cash equivalents at end of period	$ 9,662	$ 24,439
Supplemental cash flow disclosures		
Cash paid for interest	$ -	$ 1
Income taxes paid	$ 56	$ 115
Equipment acquired under capital lease	$ 2	$ 8

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

GI Dynamics, Inc. and Subsidiaries

Notes to Condensed Consolidated Financial Statements

(unaudited)

1. Nature of Business

GI Dynamics, Inc. (the "Company") was incorporated on March 24, 2003, as a Delaware corporation, with operations based in Boston, Massachusetts. The Company is dedicated to restoring health and improving quality of life through the design and application of device and disease management solutions for treatment of metabolic disease. The Company's vision is to make our first product, EndoBarrier, a valued treatment option for patients suffering from type 2 diabetes and obesity by restoring more manageable blood sugar levels and reducing body weight. The Company is the developer of EndoBarrier®, the first endoscopically-delivered device therapy approved for the treatment of obese type 2 diabetes with BMI $\geq$ 30 kg/m^2, or obese patients with BMI $\geq$ 30 kg/m^2 with $\geq$ 1 comorbidities, or obese patients with BMI >35 kg/m^2. EndoBarrier is the only proven, 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 its product, EndoBarrier, which is approved and commercially available in multiple countries outside the U.S.

In the U.S., the Company received approval from the Food and Drug Administration ("FDA"), to commence its pivotal trial of EndoBarrier (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 stopped 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 stop 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 stopping 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 stopping 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.

On May 10, 2016, the Company announced that it was reducing headcount by approximately 30% as part of its previously announced efforts to restructure its expenses in order to extend its cash runway.

On September 14, 2016, the Company announced that it received formal notification from the Australian Therapeutic Goods Administration ("TGA") of the cancellation of the EndoBarrier device's inclusion on the Australian Register of Therapeutic Goods ("ARTG") taking effect on October 12, 2016. As a result, with effect from October 12, 2016, the Company is not permitted to supply the EndoBarrier device in Australia, outside of approved trials. Inclusion on the ARTG, enabled EndoBarrier to be sold commercially in Australia subject to the requirements of the Therapeutic Goods Act 1989 (Cth).

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 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.

1. Nature of Business (continued)

The Company has incurred operating losses since inception and at September 30, 2016, had an accumulated deficit of approximately $245.2 million. Based on the Company's decision to stop the ENDO Trial, it continues to evaluate which markets are appropriate to continue pursuing reimbursement, market awareness and general market development efforts, and continues to restructure its business and costs, establish new priorities, continue limited research, and evaluate strategic options. As a result, the Company expects to incur significant operating losses for the next several years. At September 30, 2016, the Company had approximately $9.8 million in cash, cash equivalents and restricted cash. The Company does not expect its current cash balances will be sufficient to enable it to conduct an additional clinical trial for the purpose of seeking regulatory approval from the FDA. The Company continues to restructure its costs and will need to raise additional funds in order to implement its new business objectives and to continue to fund its operations in 2017. These factors raise substantial doubt about the Company's ability to continue as a going concern. The Company may seek to raise additional funds through any 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, which could have a material adverse effect on its business, financial condition and results of operations. In addition, the Company could be required to cease operations if it is unable to raise capital when needed.

The accompanying condensed consolidated financial statements have been prepared assuming the Company will continue as a going concern, which contemplates the realization of assets and liabilities and commitments in the normal course of business. The condensed consolidated financial statements as of September 30, 2016 and December 31, 2015 and for the three and nine months ended September 30, 2016, and 2015 do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from uncertainty related to the Company's ability to continue as a going concern.

2. Summary of Significant Accounting Policies and Basis of Presentation

The accompanying condensed consolidated financial statements and the related disclosures as of September 30, 2016, and for the three and nine months ended September 30, 2016 and 2015, 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"), filed with the SEC on March 30, 2016. The December 31, 2015 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, 2016, results of its operations for the three and nine months ended September 30, 2016 and 2015, and its cash flows for the nine months ended September 30, 2016 and 2015. The interim results for the three and nine months ended September 30, 2016 are not necessarily indicative of the results that may be expected for the year ending December 31, 2016.

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.

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

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, stock-based compensation, going concern considerations, and warrant valuations. The Company bases its estimates on historical experience and on various other assumptions that are believed to be reasonable, the results of which form the basis for making judgments about the carrying values of assets and liabilities. Actual results may differ from these estimates under different assumptions or conditions. Changes in estimates are reflected in reported results in the period in which they become known.

Guarantees

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

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

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

The Company leases office space under 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, 2016 and December 31, 2015, 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.

Restricted Cash

Restricted balances of cash, which are shown under current financial assets as restricted cash, relate to funds set aside to secure a letter of credit to the lessor in lieu of a rental deposit for the property at 25 Hartwell Avenue, Lexington MA. The current/non-current classification is based on the expected timing of the expiration of the lease.

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

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.

New Accounting Pronouncements

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

In May 2014, the FASB issued Accounting Standards Update ("ASU") No. 2014-09 ("ASU 2014-09"), *Revenue from Contracts with Customers*, 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, 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, and interim periods thereafter, with early application permitted. The Company does not expect that the adoption of ASU 2014-15 will have a material impact on its financial position, results of operations or cash flows, but may require further disclosure in its financial statements once adopted.

In July 2015, the FASB issued ASU No. 2015-11—Inventory: Simplifying the Measurement of Inventory. The update requires inventory not measured using either the last in, first out (LIFO) or the retail inventory method to be measured at the lower of cost and net realizable value. Net realizable value is the estimated selling price in the ordinary course of business, less reasonably predictable cost of completion, disposal and transportation. The update is effective for fiscal years beginning after December 15, 2016. Early adoption is permitted for financial statements that have not been previously issued. The Company is currently evaluating the impact of ASU 2015-11 on its consolidated financial condition and results of operations.

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)* ("ASU 2016-02"). ASU 2016-02 requires that lessees recognize in the statement of financial position for all leases (with the exception of short-term leases) a lease liability, which is a lessee's obligation to make lease payments arising from a lease, measured on a discounted basis, and a right-of-use asset, which is an asset representing the lessee's right to use the underlying asset for the lease term. ASU 2016-02 is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years, with early adoption permitted. Lessees must apply a modified retrospective transition approach for leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements. The modified retrospective approach would not require any transition accounting for leases that expired before the earliest comparative period presented. Lessees may not apply a full retrospective transition approach. The adoption of this guidance is not expected to have a significant impact on the Company's consolidated financial statements.

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

In March 2016, the FASB issued ASU No. 2016-09, *Compensation—Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting* ("ASU 2016-09"). ASU 2016-09 will simplify the income tax consequences, accounting for forfeitures and classification on the statements of consolidated cash flows. ASU 2016-09 is effective for annual periods beginning after December 15, 2016, and interim periods within those annual periods, with early adoption permitted. The Company is currently evaluating the potential impact that ASU 2016-09 may have on its consolidated financial statements.

In August, 2016, the FASB issued ASU No. 2016-15— Classification of Certain Cash Receipts and Cash Payments (a consensus of the Emerging Issues Task Force). The amendments in ASU 2016-15 address eight specific cash flow issues and apply to all entities that are required to present a statement of cash flows under FASB Accounting Standards Codification (FASB ASC) 230, Statement of Cash Flows. The amendments in ASU 2016-15 are effective for public business entities for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. Early adoption is permitted, including adoption during an interim period. The Company has not yet adopted this update and is currently evaluating the impact of ASU No. 2016-15 on its 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, 2016 and 2015, common stock equivalents were excluded from the calculation of diluted net loss per common share, as their effect was anti-dilutive due to the net loss incurred. Therefore, basic and diluted net loss per share was the same in all periods presented.

The following potentially dilutive securities have been excluded from the computation of diluted weighted-average shares outstanding as of September 30, 2016 and 2015, as they would be anti-dilutive:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	**2015**	**2016**	**2015**
Warrants to purchase common stock	28,532	50,000	28,532	50,000
Options to purchase common stock and other stock-based awards	1,165,427	1,341,303	1,165,427	1,341,303
	1,193,959	1,391,303	1,193,959	1,391,303

4. Common Stock Warrants

In connection with the Company's initial public offering ("IPO") in September 2011, the Company issued warrants ("IPO 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 IPO Warrants expired on September 1, 2016.

On May 4, 2016, the Company entered into a consulting agreement pursuant to which the consulting firm will provide strategic advisory, finance, accounting, human resources and administrative functions, including chief financial officer services, to the Company. In connection with the consulting agreement, the Company granted the consulting firm a warrant ("Consultant Warrant," together with the IPO Warrants, the "Warrants") to purchase up to 28,532 shares of the Company's common stock at an exercise price per share equal to $0.64. The Consultant Warrant vests on a monthly basis over two years and has a term of five years. The Company has reserved 28,532 shares of common stock related to the Consultant Warrant. As of September 30, 2016, no Consultant Warrants had been exercised.

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 IPO Warrants was in Australian dollars, the Company was exposed to currency exchange risk related to the IPO Warrants. As a result, the IPO Warrants were not considered indexed to the Company's own stock, and therefore, the IPO Warrants were classified as a liability. The Consultant Warrant contains a cashless exercise provision which meets the net settlement criteria of ASC 815 and is therefore considered a derivative and is classified as a liability.

Because the IPO Warrants were, and the Consultant Warrant is, classified as a liability, 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 in the case of the IPO Warrants the 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, 2016 and December 31, 2015, and indicates the fair value hierarchy of the valuation techniques the Company used to determine such fair value. In general, fair values determined by Level 1 inputs utilize observable inputs such as quoted prices in active markets for identical assets or liabilities. Fair values determined by Level 2 inputs utilize data points that are either directly or indirectly observable, such as quoted prices, interest rates and yield curves. Fair values determined by Level 3 inputs utilize unobservable data points in which there is little or no market data, requiring the Company to develop its own assumptions for the asset or liability.

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

		Fair Value Measurements at Reporting Date Using		
Description	**September 30, 2016**	**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, cash equivalents and restricted cash)	$ 7,385	$ 7,385	$ –	$ –
Total assets	$ 7,385	$ 7,385	$ –	$ –
Liabilities				
Warrant to purchase common stock (included in other liabilities)	$ 14	$ –	$ –	$ 14
Total liabilities	$ 14	$ –	$ –	$ 14

		Fair Value Measurements at Reporting Date Using		
Description	**December 31, 2015**	**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)	$ 17,207	$ 17,207	$ –	$ –
Total assets	$ 17,207	$ 17,207	$ –	$ –
Liabilities				
Warrants to purchase common stock (included in other liabilities)	$ –	$ –	$ –	$ –
Total liabilities	$ –	$ –	$ –	$ –

5. Fair Value of Financial Instruments (continued)

The IPO Warrants expired on September 1, 2016 and at September 30, 2016 were no longer subject to fair value accounting. The assumptions used in the Black-Scholes option pricing model to determine the fair value of the IPO Warrants at December 31, 2015 were as follows:

	December 31, 2015
Exercise price (A$55.00 at the then current exchange rate)	$ 40.18
Fair value of common stock	$ 1.06
Expected volatility	165.6%
Expected term (in years)	0.7
Risk-free interest rate	0.5%
Expected dividend yield	–%

The assumptions used in the Black-Scholes option pricing model to determine the fair value of the Consultant Warrant at the time the Consultant Warrant was issued and at September 30, 2016 were as follows:

	At Issuance	September 30, 2016
Exercise price	$ 0.64	$ 0.64
Fair value of common stock	$ 0.64	$ 0.76
Expected volatility	74.1%	80.3%
Expected term (in years)	5.0	4.6
Risk-free interest rate	1.2%	0.9%
Expected dividend yield	–%	–%

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

Balance at December 31, 2015	$ —
Issuance of Consultant Warrant	11
Increase in fair value of Warrants upon remeasurement included in other income (expense)	3
Balance at September 30, 2016	$ 14

Cash equivalents, restricted cash, accounts receivable, prepaid expenses and other current assets, accounts payable, accrued expenses , short term loans payable and other current liabilities at September 30, 2016 and December 31, 2015 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 Accounts

Financial instruments that subject the Company to credit risk primarily consist of cash and cash equivalents, restricted cash and accounts receivable. The Company maintains its cash and cash equivalents and restricted cash balances with high quality financial institutions, and consequently, the Company believes that such funds are subject to minimal credit risk.

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, 2016, one distributor accounted for approximately 46.1% of the Company's accounts receivable and one customer accounted for approximately 34.6 % of the outstanding receivables. At December 31, 2015, one health care provider accounted for approximately 15% of the Company's accounts receivable, two health care providers accounted for approximately 11% each and a fourth health care provider accounted for approximately 10%. No other customer accounted for greater than 10% of the Company's accounts receivable at September 30, 2016 and December 31, 2015.

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. Amounts determined to be uncollectible are written off against this reserve. In the three and nine months ended September 30, 2016 the Company wrote off approximately $0 and $48,000 respectively, in accounts receivable against the bad debt reserve. In the three and nine months ended September 30, 2015, the Company did not write-off any uncollectible accounts receivable. As of September 30, 2016 and December 31, 2015, the Company believes its allowance for doubtful accounts of approximately $16,000 and $59,000, respectively, is adequate based on its review.

In certain circumstances the Company allows customers to return defective or nonconforming products for credit or replacement products. Defective or nonconforming products typically include 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. As of September 30, 2016 and December 31, 2015, the Company believes its allowance for sales returns of approximately $ 0 and $22,000, respectively, is adequate based on its review.

The following table shows the components of the Company's accounts receivable at September 30, 2016 and December 31, 2015 (in thousands):

	September 30, 2016	December 31, 2015
Accounts receivable	$ 122	$ 121
Less: allowance for doubtful accounts	(16)	(59)
Less: allowance for sales returns	—	(22)
Total	$ 106	$ 40

The following is a roll forward of the Company's allowance for doubtful accounts (in thousands):

	Nine Months Ended September 30,	
	2016	2015
Beginning balance	$ 59	$ 41
Net charges to expenses	5	54
Utilization of allowances	(48)	—
Ending balance	$ 16	$ 95

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 additional reserves for excess, expired or obsolete inventory in the future.

In 2015, the Company performed an analysis of its inventory on hand and due to current evidence that the utility of certain amounts of its inventory as it was expected to be used will be less than its cost recorded an approximately $3.2 million charge for excess, expired and obsolete inventory. Factors contributing to the inventory write-down included: the effect that the ENDO Trial enrollment hold and subsequent stopping of the 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, 2016 and December 31, 2015, the Company has reserves totaling approximately $4.8 million and $5.0 million, respectively, for excess, expired and obsolete inventory. The Company continues to review any evidence that may indicate that the utility of additional amounts of inventory, as it was expected to be used, will be less than cost.

Inventory, net, at September 30, 2016 and December 31, 2015 was as follows (in thousands):

	September 30, 2016	December 31, 2015
Finished goods	$ 417	$ 391
Work-in-process	—	605
Raw materials	—	29
Total	$ 417	$ 1,025

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, 2016 and December 31, 2015, approximately 4 % and 6%, 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, 2016	December 31, 2015
Laboratory equipment and manufacturing equipment	$ 596	$ 457
Computer equipment and software	1,174	1,118
Office furniture and equipment	248	229
Leasehold improvements	5	848
	2,023	2,652
Less accumulated depreciation and amortization	(1,867)	(2,251)
Total	$ 156	$ 401

The Company left its facility in Lexington, Massachusetts in July 2016. In anticipation of this move, in June 2016 the Company recognized a charge for impaired property and equipment related to the facility. In August 2015, the Company recognized a charge for impaired property and equipment as part of its restructuring. Property and equipment impairment charges were as follows for the three and nine months ended September 30, 2016 and 2015 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Cost of revenue	$ —	$ 265	$ 24	$ 265
Research and development	—	100	79	100
Sales and marketing	—	5	—	5
General and administrative	—	19	42	19
	$ —	$ 389	$ 145	$ 389

In January 2015, the Company entered into a capital lease for certain office equipment. As of September 30, 2016, the Company had approximately $8,000 of assets under capital leases with an accumulated amortization balance of approximately $4,000.

Depreciation and amortization expense of property and equipment, including equipment recorded under capital leases, and the charge for impaired property and equipment totaled approximately $16,000 and $0.5 million for the three months ended September 30, 2016 and 2015, respectively. Depreciation and amortization expense of property and equipment, including equipment recorded under capital leases, and the charge for impaired property and equipment, totaled approximately $0.3 million and $0.8 million for the nine months ended September 30, 2016 and 2015, respectively.

(unaudited)

9. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following (in thousands):

	September 30, 2016	December 31, 2015
Clinical trials	$ 300	$ 1,809
Payroll and related liabilities	389	501
Professional fees	445	454
Rent and deferred rent, current portion	167	168
Other	62	154
Total	$ 1,363	$ 3,086

Included in payroll and related liabilities at December 31, 2015, were approximately $0.1 million of separation related expenses which were paid in the nine months ended September 30, 2016.

10. Short Term Notes Payable

GI Dynamics, Inc. entered into a short term loan agreement with First Insurance Funding Corp to borrow $306,380 to be used to purchase insurance. The agreement calls for ten monthly payments of $30,638 which includes principal and interest. The annual interest rate on the borrowing is 1.95%. The first payment is due on 10/06/2016

11. 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 a secured letter of credit of approximately $0.2 million securing its obligations under the sublease agreement. In July 2016, the Company left this facility prior to the expiration of the lease.

In June 2016, the Company entered into a noncancelable agreement to lease approximately 4,200 square feet of office and laboratory space in Boston, Massachusetts. The lease commenced in June 2016 and expires in April 2018. Rent during the term is $11,900 per month.

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. In April 2016 this lease expired and the Company vacated this space.

Rent expense on noncancelable operating leases was approximately $0.3 million and $0.1 million for the three months ended September 30, 2016 and 2015, respectively. Rent expense on noncancelable operating leases was approximately $0.5 million and $0.4 million for the nine months ended September 30, 2016 and 2015, respectively. In September the Company expensed approximately $0.1 million for rent at the facility at 25 Hartwell Ave in Lexington, MA. The company moved out of the Lexington, MA facility at the end of July and moved to its new location at 355 Congress Street in Boston MA. As a result the Company expensed the remaining rent expense under the noncancelable lease through December 31, 2016.

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, 2016, are as follows (in thousands):

Year Ending December 31,	
2016	$ 186
2017	146
2018	48
Total	$ 380

12. Stockholders' Equity

The authorized capital stock of the Company 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 to meet the Listing Rules of the Australian Securities Exchange ("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.

13. Stock Plans

The Company has two stock-based compensation plans under which incentive stock options, nonqualified stock options, restricted and unrestricted stock awards, and other stock-based awards are available for grant to employees, directors and consultants of the Company. At September 30, 2016, there were 1,074,275 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, in the first quarter of fiscal 2016, 380,222 options available for future grant were added to the 2011 Plan.

13. Stock Plans (continued)

Stock-Based Compensation

Stock-based compensation is reflected in the condensed consolidated statements of operations and comprehensive loss as follows for the three and nine months ended September 30, 2016 and 2015 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Cost of revenue	$ -	$ 24	$ 34	$ 71
Research and development	6	61	49	410
Sales and marketing	35	97	130	353
General and administrative	59	643	395	1,604
	$ 100	$ 825	$ 609	$ 2,438

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").

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, 2016 and 2015:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Expected volatility	73.4%	-	71.0%	56.8%
Expected term (in years)	6.05	-	6.05	6.04
Risk-free interest rate	1.36%	- %	1.27%	1.6%
Expected dividend yield	- %	- %	-%	- %

The Company uses historical data to estimate forfeiture rates. The Company's estimated forfeiture rates were 15% and 10% at September 30, 2016 and 2015, respectively.

13. Stock Plans (continued)

Stock Options

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

	Shares of Common Stock Attributable to Options	Weighted-Average Exercise Price	Weighted-Average Contractual Life	Aggregate Intrinsic Value
			(in years)	*(in thousands)*
Outstanding at December 31, 2015	779,028	$ 23.92	7.64	$ —
Granted	575,106	$ 1.00		
Exercised	—	$ —		
Cancelled	592,208	$ 21.44		
Outstanding at September 30, 2016	761,926	$ 8.56	8.67	$ 10
Vested or expected to vest at September 30, 2016	671,868	$ 9.50	8.55	$ 8
Exercisable at September 30, 2016	161,539	$ 34.57	5.21	$ —

As of September 30, 2016, there was approximately $0.4 million of unrecognized stock-based compensation, net of estimated forfeitures, related to unvested stock option grants having service-based vesting under the Plans which is expected to be recognized over a weighted-average period of 3.7 years. The total unrecognized stock-based compensation cost will be adjusted for future changes in estimated forfeitures.

The weighted-average grant date fair value of options granted during the three months ended September 30, 2016 was $1.35. 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 nine months ended September 30, 2016 and 2015 was $1.0 and $2.91, respectively. No options were exercised during the three months ended September 30, 2016 and 2015. The total intrinsic value of options exercised during the nine months ended September 30, 2016 and 2015, was none and approximately $10,000, 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 nine months ended September 30, 2015 was approximately $1,500. 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, 2016 and December 31, 2015, there were no shares and 168 shares of common stock, respectively, 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 cash paid for the exercise price is considered a deposit or prepayment of the exercise price and is recorded as a liability. The liability related to these shares was approximately $4,000 at December 31, 2015. 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.

13. Stock Plans (continued)

Restricted Stock Units

Each restricted stock unit ("RSU") represents a contingent right to receive one share of the Company's common stock. The RSUs outstanding at September 30, 2016 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 unvested RSUs and activity during the nine months ended September 30, 2016:

	Number of Units	Weighted-Average Contractual Life	Aggregate Intrinsic Value
		(in years)	*(in thousands)*
Outstanding at December 31, 2015	262,126	4.30	$ 278
Granted	392,659		
Vested	(5,000)		
Cancelled	(246,284)		
Outstanding at September 30, 2016	403,501	9.36	$ 308

The aggregate intrinsic value at September 30, 2016 and December 31, 2015 noted in the table above represents the closing price of the Company's common stock multiplied by the number of RSUs outstanding.

The fair value of each RSU award equals the closing price of the Company's common stock on the date of grant. The weighted-average grant date fair value per share of RSUs granted in the three and nine months ended September 30, 2016 was None and $0.75, respectively. 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.

At September 30, 2016, all 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 and nine months ended September 30, 2016, the Company did not recognize any stock-based compensation for RSUs subject to performance-based vesting criteria. 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 nine months ended September 30, 2015, resulting in a reduction of stock-based compensation of approximately $0.3 million, all of which was previously recognized in the year ended December 31, 2014.

During the nine months ended September 30, 2016, the forfeitures of RSUs having service-based vesting resulted in a reduction of stock-based compensation of approximately $0.1 million, all of which was previously recognized. During the three and nine months ended September 30, 2015, the Company recognized stock-based compensation related to RSUs having service-based vesting of approximately $0.1 million and $0.4 million, respectively.

At September 30, 2016, no RSUs that have performance-based vesting criteria are considered probable of achievement and there remains approximately $0.3 million, net of estimated forfeitures, of unrecognized stock-based compensation.

14. 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, 2016, long-lived assets, comprised of property and equipment, of approximately $0.2 million are all held in the U.S.

Product sales by geographic location for the three and nine months ended September 30, 2016 and 2015 are listed in the table below (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Europe	$ 26	$ 127	$ 232	$ 810
Middle East	72	20	159	139
South America	-	6	-	40
Asia Pacific	38	22	86	112
Total Revenue	$ 136	$ 175	$ 477	$ 1,101

For the three months ended September 30, 2016, one health care provider accounted for approximately 18% of the Company's revenue, and one distributor accounted for approximately 34% of the company's revenue. For 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. No other customer accounted for greater than 10% of the Company's revenue during the three months ended September 30, 2016 and 2015.

For the nine months ended September 30, 2016, one health care provider accounted for approximately 12 % of the Company's revenue and one distributor accounted for approximately 29 %. For the nine months ended September 30, 2015, one distributor accounted for approximately 17% 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, 2016 and 2015.

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 related 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, 2015 included in our Annual Report on Form 10-K. This discussion and analysis contains forward-looking statements that involve significant risks, uncertainties and assumptions. As a result of many factors, such as those set forth under "Risk Factors" in Item 1A. of our Annual Report on Form 10-K which are incorporated herein by reference, our actual results may differ materially from the results described in or implied by the forward-looking statements described in the following discussion and analysis.

Overview

We are a medical device company headquartered in Boston, Massachusetts, which is dedicated to restoring health and improving quality of life through the design and application of device and disease management solutions for treatment of metabolic disease. Our vision is to make our first product, EndoBarrier, a valued treatment option for patients with type 2 diabetes and obesity by restoring healthier blood sugar levels and reducing body weight. 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 proven, 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 approved and commercially available in multiple countries outside the U.S.

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

In the U.S., we commenced enrollment of patients in our pivotal trial of EndoBarrier, 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 stopped 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 stop 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 stopping the ENDO Trial was in the best interest of all stakeholders. With seven cases of hepatic abscess in the ENDO Trial, the incidence rate exceeded a previously established safety threshold of 2%. To date, fewer than 50 cases of hepatic abscess have occurred in over 3,500 commercial shipments worldwide and our clinical trials, with seven of these occurring in patients who participated in the ENDO Trial. This represents a cumulative hepatic abscess rate of < 1.1%**.**

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 stopping 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.

On May 10, 2016, we announced that we were reducing headcount by approximately 30% as part of our previously announced efforts to restructure our expenses in order to extend our cash runway.

On September 14, 2016, we announced that we received formal notification from the Australian Therapeutic Goods Administration, or TGA, of the cancellation of the EndoBarrier device's inclusion on the Australian Register of Therapeutic Goods, or ARTG, taking effect on October 12, 2016. As a result, with effect from October 12, 2016, we are not permitted to supply the EndoBarrier device in Australia, outside of approved trials. Inclusion on the ARTG, enabled EndoBarrier to be sold commercially in Australia subject to the requirements of the Therapeutic Goods Act 1989 (Cth).

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, 2016, we had an accumulated deficit of approximately $ 245.2 million. We expect to incur net losses for the next several years while we 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 approximately $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 is located in Boston, 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, 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 expenses, contingencies and stock-based compensation, going concern considerations, and warrant valuations 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, 2016, 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 (in thousands).

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Revenue	$ 136	$ 175	$ 477	$ 1,101
Cost of revenue	138	918	1,128	3,816
Gross loss	(2)	(743)	(651)	(2,715)
Operating expenses:				
Research and development	962	3,865	2,993	14,142
Sales and marketing	479	1,270	1,753	4,412
General and administrative	1,321	2,027	4,687	6,758
Total operating expenses	2,762	7,162	9,433	25,312
Loss from operations	(2,764)	(7,905)	(10,084)	(28,027)
Other income (expense):				
Interest income	9	7	36	61
Interest expense	—	(1)	—	(1)
Foreign exchange gain (loss)	6	(180)	9	(645)
Remeasurement of warrant liability	3	16	(14)	6
Other income (expense), net	18	(158)	31	(579)
Loss before income tax expense	(2,746)	(8,063)	(10,053)	(28,606)
Income tax expense	8	26	29	66
Net loss	$ (2,754)	$ (8,089)	$ (10,082)	$ (28,672)

Three and Nine Months Ended September 30, 2016 Compared to Three and Nine Months Ended September 30, 2015

	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2016	2015	$	%	2016	2015	$	%
	(dollars in thousands)				(dollars in thousands)			
Revenue	$ 136	$ 175	$ (39)	(22)%	$ 477	$ 1,101	$ (624)	(56)%
Cost of revenue	138	918	(780)	(85)%	1,128	3,816	(2,688)	(70)%
Gross loss	$ (2)	$ (743)	$ 741	100%	$ (651)	$(2,715)	$ 2,064	76%

Revenue. The decrease in revenue of approximately $39,000 for the three months ended September 30, 2016 compared to the three months ended September 30, 2015 was primarily due to decreased unit volume across the Europe and South America markets with increases in unit volume from the Middle East and Asia Pacific markets. Revenue decreased approximately 75%, and 100% in Europe and South America markets, respectively, and increased in Asia Pacific and the Middle East markets by 72% and 260%, respectively.

The decrease in revenue of approximately $0.6 million for the nine months ended September 30, 2016 compared to the nine months ended September 30, 2015 was primarily due to decreased unit volume in the Europe, South America and Asia Pacific markets with an increase in the Middle East market. Revenue decreased approximately 71%, 100% and 23% in Europe, South America and Asia Pacific, respectively. Revenue increased in the Middle East market by approximately 14%.

We believe the following factors adversely affected our commercial activities for the three and nine months ended September 30, 2016:

- the stopping of the ENDO Trial;
- the regulatory-related questions arising out of our decision to stop the ENDO Trial; and
- our decision, as part of our reorganization efforts, to reduce the number of sales related employees and focus sales activity on a limited number of markets while disengaging from others.

In the near-term, we intend to focus commercialization efforts on strategic centers while continuing to support efforts in collecting additional clinical evidence via the numerous ongoing investigator-initiated studies around the world, many of which are randomized controlled trials. We will also continue to work to secure reimbursement in our target markets. We believe that the collection of additional data via patient registries is important to help support the attainment of reimbursement, but will likely adversely affect our commercial operations as it may limit commercial expansion.

Cost of Revenue. Cost of revenue decreased by approximately $0.8 million for the three months ended September 30, 2016 compared to the three months ended September 30, 2015. Cost of revenue decreased by approximately $2.7 million for the nine months ended September 30, 2016 compared to the nine months ended September 30, 2015. The decrease in cost of revenue for the three months ended September 30, 2016 compared to the same period in the prior year resulted from a decrease of approximately $0.2 million in excess, expired and obsolete inventory expense as well as a decrease of $0.1 million in standard cost variance, $0.3 million for asset impairment expense, $0.1 million in manufacturing wages and $0.1 million in other manufacturing costs. The decrease in cost of revenue for the nine months ended September 30, 2016 compared to the same period in the prior year resulted from an approximately $0.4 million decrease in product cost, approximately $0.2 million decrease in personnel related expenses, $0.2 share based compensation, $0.3 million in asset impairment expense and a decrease of approximately $1.6 million in excess, expired and obsolete inventory expense.

Gross loss decreased by approximately $0.7 million and $2.1 million for the three and nine months ended September 30, 2016, respectively, compared to the three and nine months ended September 30, 2015 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 and future plans. Specifically, factors such as our intention to focus on strategic centers and securing reimbursement in our target markets, our planned transition of production to a third-party manufacturer, changes in volume of inventory production, and overall economies of scale may result in variability in our gross margin.

Operating Expenses

	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2016	2015	$	%	2016	2015	$	%
	(dollars in thousands)				(dollars in thousands)			
Research and development expense	$ 962	$ 3,865	$(2,903)	(75)%	$ 2,993	$14,142	$ (11,149)	(79)%
Sales and marketing expense	479	1,270	(791)	(62)%	1,753	4,412	(2,659)	(60)%
General and administrative expense	1,321	2,027	(706)	(35)%	4,687	6,758	(2,071)	(31)%
Total operating expenses	$ 2,762	$ 7,162	$(4,400)	(61)%	$ 9,433	$25,312	$(15,879)	(63)%

Research and Development Expense. The decrease in research and development expense of approximately $2.9 million for the three months ended September 30, 2016 compared to the three months ended September 30, 2015 was primarily due to a decrease of approximately $1.3 million in clinical trial and other clinical study related expenses, a decrease of approximately $0.9 million in compensation and employee related expenses, as well as reductions in animal study expenses of approximately $0.3 million, internal use implant of $0.1 million, consulting expenses of approximately $0.1 million, proctoring expense of $0.1 million and travel, lodging and meals expense of approximately $0.1 million .

The decrease in research and development expense of approximately $11.1 million for the nine months ended September 30, 2016 compared to the nine months ended September 30, 2015 was primarily due to a decrease of approximately $6.6 million in clinical trial and other clinical study related expenses, primarily made up of third-party expenses related to the ENDO Trial, and a decrease of approximately $2.9 million in compensation and employee related expenses, including approximately $0.4 million in lower stock-based compensation expense, due to decreases in headcount. The decrease in clinical trial and other clinical study related expenses included a correction of an error which decreased research and development expense approximately $0.4 million in the three months ended March 31, 2016. Additional expense reduction included decreases in product development expenses of approximately $0.3 million, consulting expenses of approximately $0.3 million, travel, lodging, and meals expense of approximately $0.3 million, animal study expense of approximately $0.6 million, asset impairment expense of $0.1 million, internal use implant expense of approximately $0.1 million and proctoring and training expenses of approximately 0.2 million.

Though we expect to implement a more efficient cost structure in order to extend our cash runway, it may be partially offset by the costs associated with rebuilding the research and development management team and improving our regulatory relationships.

Sales and Marketing Expense. The decrease in sales and marketing expense of approximately $0.7 million for the three months ended September 30, 2016 compared to the three months ended September 30, 2015 was primarily the result of a decrease of approximately $0.3 million in compensation and employee related expenses, including approximately $0.1 million in lower stock-based compensation expense, due to decreases in headcount, as well as a decrease of approximately $0.1 million in marketing related activities, a decrease of approximately $0.2 million in free unit EndoBarrier cost and a decrease in travel, lodging and meals expense of approximately $0.1 million.

The decrease in sales and marketing expense of approximately $2.7 million for the nine months ended September 30, 2016 compared to the nine months ended September 30, 2015 was primarily the result of a decrease of approximately $1.1 million in compensation and employee related expenses, including approximately $0.2 million in lower stock-based compensation expense, due to decreases in headcount, as well as a decrease of approximately $0.4 million in marketing related activities, a decrease in consulting costs of $0.3 million, a decrease of approximately $0.3 million of travel, lodging and meals expense, a decrease in proctoring expense of $0.1 million, free unit EndoBarrier expense of $0.2 million, patient outreach expense of $0.1 million and training costs of approximately $0.1 million.

General and Administrative Expense. The decrease in general and administrative expense of approximately $0.7 million for the three months ended September 30, 2016 compared to the three months ended September 30, 2015 was primarily a result of decreased compensation and employee related expenses of approximately $0.7 million as a result of headcount reductions which was attributable to stock-based compensation.

The decrease in general and administrative expense of approximately $2.1 million for the nine months ended September 30, 2016 compared to the nine months ended September 30, 2015 was primarily a result of decreased compensation and employee related expenses of approximately $1.5 million as a result of headcount reductions, including approximately $1.2 million in lower stock-based compensation expense, as well as approximately $0.6 million decrease in consulting, 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	
	2016	2015	$	%	2016	2015	$	%
	(dollars in thousands)				(dollars in thousands)			
Other income (expense):								
Interest income	$ 9	$ 7	$ 2	29%	$ 36	$ 61	$ (25)	(41)%
Interest expense	-	(1)	1	(100)%	-	(1)	1	(100)%
Foreign exchange gain (loss)	6	(180)	186	103%	9	(645)	654	101%
Remeasurement of warrant liability	3	16	(13)	(81)%	(14)	6	(20)	333%
Total other income (expense), net	$ 18	$ (158)	$ 176	111%	$ 31	$ (579)	$ 610	105%

Interest Income. The increase in interest income of approximately $2,000 and decrease of approximately $25,000 for three and nine months ended September 30, 2016, respectively, compared to the three and nine months ended September 30, 2015 was primarily due to decreases in average cash and cash equivalents balances for the 9 month period**.**

Interest Expense. The decrease in interest expense of approximately $1,000 for each of the three and nine month periods ended September 30, 2016, compared to the three and nine months ended September 30, 2015 was primarily due to lower outstanding balances on our capital lease.

Foreign Exchange Gain (Loss). The change from a loss of approximately $0.2 million to a gain of approximately $6,000 for the three months ended September 30, 2016 compared to the three months ended September 30, 2015 was a result of a strengthening U.S. dollar and lower average foreign currency balances. The change from a loss of approximately $0.6 million for the nine months ended September 30, 2015 to a gain of approximately $9,000 for the nine months ended September 30, 2016 for foreign exchange was the result of a strengthening U.S. dollar and large average foreign currency balances in the nine months ended September 30, 2015 compared to significantly lower average foreign currency balances in the nine months ended September 30, 2016.

Remeasurement of Warrant Liability. The change in the remeasurement of warrant liability was due to a decrease in the fair value of the warrants issued in connection with our IPO which had no fair value at the end of the third quarter 2015. The consultant warrant had a gain of approximately $3,000 in the third quarter 2016 after recognizing the initial expense and reameasurment in June 2016 of approximately $14,000.

Liquidity and Capital Resources

We have incurred losses since our inception in March 2003 and, as of September 30, 2016, we had an accumulated deficit of approximately $245.2 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, 2016, we had approximately $9.8 million of cash, cash equivalents and restricted cash.

During the nine months ended September 30, 2016, our cash and cash equivalents balance decreased by approximately $9.9 million as a result of funds utilized to support our operations and to cash collateralize our standby letter of credit. We made payments related to, among other things, research and development, sales and marketing, and general and administrative expenses as we continued to commercialize EndoBarrier and close out 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,	
	2016	2015
	(in thousands)	
Net cash (used in) provided by:		
Operating activities	$ (10,008)	$ (26,573)
Investing activities	(225)	(179)
Financing activities	305	—
Net decrease in cash and cash equivalents	$ (9,928)	$ (26,752)

Cash Flows From Operating Activities

Net cash used in operating activities totaled approximately $10.0 million for the nine months ended September 30, 2016. The primary uses of cash were:

- to fund our net loss of approximately $10.1 million;
- a net negative adjustment to cash flow from changes in working capital of approximately $0.7 million resulting primarily from decreases in accrued expenses and other current liabilities, partially offset by a decrease in inventory; and prepaid expenses; and
- a net positive adjustment to cash flow from non-cash items of approximately $0.8 million, primarily from stock-based compensation of approximately $0.6 million and depreciation , amortization and impairment of property and equipment of approximately $0.3 million.

During the second quarter 2016 we expensed $0.7 million in restructuring and other employee departure costs. As we restructure our costs by reducing expenses, we expect our cash used in operating activities to decrease over the remaining months of our fiscal year ending December 31, 2016.

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 of $2.4 million and increases in inventory reserves resulting from a charge of approximately $1.7 million for inventory in excess of our commercial requirements.

Cash Flows From Investing Activities

Cash used in investing activities for the nine months ended September 30, 2016 totaled approximately $0.2 million and primarily resulted from the change in restricted cash due to collateralizing our standby letter of credit.

Cash used in investing activities for the nine months ended September 30, 2015 totaled approximately $0.2 million resulted from the purchase of property and equipment and cash used for a standby letter of credit.

Cash Flows From Financing Activities

Cash of approximately $0.3 million was provided in financing activities for the nine months ended September 30, 2016 from a short term financing for insurance policies off set by capital lease payments of $2,000 for capital lease payments.

Cash provided by financing activities for the nine months ended September 30, 2015 consisted of proceeds received upon the exercise of stock options offset by payments on our capital lease.

Funding Requirements

As of September 30, 2016, our primary source of liquidity was our cash, cash equivalents and restricted cash of approximately $9.8 million. Based on our decision to stop the ENDO Trial, we continue to evaluate which markets are appropriate to continue pursuing reimbursement, market awareness and general market development efforts, and continue to restructure our business and costs, establish new priorities, continue limited research, and evaluate strategic options. As a result, we expect to incur significant operating losses for the next several years. We do not expect our current cash balances will be sufficient to enable us to conduct an additional clinical trial for the purpose of seeking regulatory approval from the FDA and complete development of an improved EndoBarrier for its current use and potential new indications. We are restructuring our costs and will need to raise additional funds in order to implement our new business objectives and to continue to fund our operations in 2017. These factors raise substantial doubt about our ability to continue as a going concern. We may seek to raise additional funds through any 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 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, which could have a material adverse effect on our business, financial condition and results of operations. In addition, we could be required to cease operations if we are unable to raise capital when needed

Our forecast of the period of time through which our financial resources will be adequate to support our operations are forward-looking statements and involve risks and uncertainties, and actual results could vary materially and negatively as a result of a number of factors, including the factors discussed in the "Risk Factors" in Item 1A. of our Annual Report on Form 10-K which is 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, at this time 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 and the Middle East) 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 stopping 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 Obligations and Commitments" in our Annual Report on Form 10-K.

In June 2016, we entered into a noncancelable lease agreement for office and laboratory space in Boston, Massachusetts. The lease expires in April 2018 and rent during the term is $11,900 per month.

In June 2016, we entered into a purchase agreement to purchase certain furniture and fixtures for our new office space totaling approximately $48,000 based on shipping terms of FOB destination. The furniture and fixtures were delivered in July 2016. The invoices were paid September 6, 2016.

In September 2016 we entered a short term finance agreement to borrow $0.3 million to purchase insurance. Other than these obligations, 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 FASB issued Accounting Standards Update ("ASU") No. 2014-09 ("ASU 2014-09"), *Revenue from Contracts with Customers*, 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* ("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, and interim periods thereafter, with early application permitted. We do not expect that the adoption of ASU 2014-15 will have a material impact on our financial position, results of operations or cash flows, but may require further disclosure in our financial statements once adopted.

In July 2015, the FASB issued ASU No. 2015-11—Inventory: Simplifying the Measurement of Inventory. The update requires inventory not measured using either the last in, first out (LIFO) or the retail inventory method to be measured at the lower of cost and net realizable value. Net realizable value is the estimated selling price in the ordinary course of business, less reasonably predictable cost of completion, disposal and transportation. The update is effective for fiscal years beginning after December 15, 2016. Early adoption is permitted for financial statements that have not been previously issued. The Company is currently evaluating the impact of ASU 2015-11 on its consolidated financial condition and results of operations.

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)* ("ASU 2016-02"). ASU 2016-02 requires that lessees recognize in the statement of financial position for all leases (with the exception of short-term leases) a lease liability, which is a lessee's obligation to make lease payments arising from a lease, measured on a discounted basis, and a right-of-use asset, which is an asset representing the lessee's right to use the underlying asset for the lease term. ASU 2016-02 is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years, with early adoption permitted. Lessees must apply a modified retrospective transition approach for leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements. The modified retrospective approach would not require any transition accounting for leases that expired before the earliest comparative period presented. Lessees may not apply a full retrospective transition approach. The adoption of this guidance is not expected to have a significant impact on our consolidated financial statements.

In March 2016, the FASB issued ASU No. 2016-09, *Compensation—Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting* ("ASU 2016-09"). ASU 2016-09 will simplify the income tax consequences, accounting for forfeitures and classification on the statements of consolidated cash flows. ASU 2016-09 is effective for annual periods beginning after December 15, 2016, and interim periods within those annual periods, with early adoption permitted. We are currently evaluating the potential impact that ASU 2016-09 may have on our consolidated financial statements.

In August, 2016, the FASB issued ASU No. 2016-15— Classification of Certain Cash Receipts and Cash Payments (a consensus of the Emerging Issues Task Force). The amendments in ASU 2016-15 address eight specific cash flow issues and apply to all entities that are required to present a statement of cash flows under FASB Accounting Standards Codification (FASB ASC) 230, Statement of Cash Flows. The amendments in ASU 2016-15 are effective for public business entities for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. Early adoption is permitted, including adoption during an interim period. The Company has not yet adopted this update and is currently evaluating the impact of ASU No. 2016-15 on its 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, cash equivalents and restricted cash of approximately $9.8 million at September 30, 2016, 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, cash equivalents and restricted cash, 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 operations and comprehensive loss. Continued fluctuation of these exchange rates could result in financial results that are not comparable from quarter to quarter. We do not currently utilize foreign currency contracts to mitigate the gains and losses generated by the re-measurement of non-functional currency assets and liabilities but do hold cash reserves in currencies in which those reserves are anticipated to be expended.

All of the proceeds from our 2011, 2013 and 2014 offerings were denominated in Australian dollars and as of September 30, 2016, we held the equivalent of approximately US $44,000 denominated in Australian dollars and approximately US$2.4 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 not have a material impact on our financial position and results of operations.

Effects of Inflation

We do not believe that inflation and changing prices over the three months ended September 30, 2016 and 2015 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, 2016 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, 2016 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, which could materially affect our business, financial condition or future results. The risks described in our Annual Report on Form 10-K are not the only risks we face. Additional risks that we do not presently know or that we currently believe are immaterial could also materially and adversely affect any of our business, financial condition or future results. The trading price of our CDIs may decline due to these risks.

Item 2. *Unregistered Sales of Equity Securities*

None.

Item 6. *Exhibits*

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

SIGNATURES

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

GI Dynamics, Inc.

Date: November 9, 2016

By: /s/ SCOTT W. SCHORER
Scott W. Schorer
President and Chief Executive Officer
(principal executive officer)

Date: November 9, 2016

By: /s/ JAMES MURPHY
James Murphy
Chief Financial Officer
(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, Scott W. Schorer, 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 9, 2016

/s/ SCOTT W. SCHORER
Scott W. Schorer
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, James Murphy, 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 9, 2016

/s/ JAMES MURPHY
James Murphy
Chief Financial Officer
(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, 2016 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Scott W. Schorer, 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/ SCOTT W. SCHORER

Scott W. Schorer
Chief Executive Officer
(principal executive officer)
November 9, 2016

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, 2016 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, James Murphy, Chief Financial 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/ JAMES MURPHY

James Murphy
Chief Financial Officer
(principal accounting and financial officer)
November 9, 2016

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.