

Form 10Q Filed with SEC

Boston, Massachusetts, United States, and SYDNEY, Australia – 15 November 2017 AEDT.

GI Dynamics, Inc. (ASX: **GID**) (the **Company**), a medical technology company that has developed a pioneering device to improve outcomes for patients battling 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 15 November 2017. The Form 10-Q includes the Company's unaudited financial position as of September 30, 2017 and December 31, 2016 and results of operations for the three and nine-month periods ended 30 September 2017 and 2016 as well as other required disclosures. The financial statements included in the Form 10-Q were prepared in accordance with United States Generally Accepted Accounting Principles and are denominated in United States dollars unless otherwise indicated.

About GI Dynamics

GI Dynamics, Inc. (ASX: GID) is the developer of EndoBarrier[®], the first endoscopically delivered device approved for the treatment of type 2 diabetes and obesity. EndoBarrier is approved and commercially available in multiple countries outside the U.S. EndoBarrier is not approved for sale in the U.S. and is limited by federal law to investigational use only in the United States. 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. These forward-looking statements are based on GI Dynamics management's current estimates and expectations of future events as of the date of this announcement. Furthermore, the estimates are subject to several 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 obtaining and maintaining regulatory approvals required to market and sell our products; obtaining funding from third parties; the date at which we do not expect our current cash balances will be sufficient to continue to fund our operations; consequences of stopping the ENDO trial and the possibility that future clinical trials will not be successful or confirm earlier results; 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; the timing and extent of third-party reimbursement; risks associated with commercial product sales, including product performance, competition, market acceptance of products, intellectual-property risk; risks related to excess inventory; and risks related to assumptions regarding the size of the available market, the 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, one 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 because of new information or future events or otherwise, unless we are required to do so 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, 2017

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
(State or other jurisdiction of
incorporation or organization)

355 Congress Street
Boston, Massachusetts
(Address of Principal Executive Offices)

84-1621425
(I.R.S. Employer
Identification Number)

02210
(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

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒

As of November 1, 2017, there were 11,157,489 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 concerning the potential for EndoBarrier as an important treatment option for patients with type 2 diabetes and obesity. 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 receipt and maintenance of regulatory approvals;
- our expectations with respect to our clinical trials;
- our expectations with respect to our intellectual property position;
- our ability to commercialize our products;
- our ability to develop and commercialize new products;
- our expectation with regard to inventory; and
- our estimates regarding our capital requirements and our need for additional financing.

In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “should,” “could,” “would,” “expects,” “plans,” “anticipates,” “believes,” “estimates,” “projects,” “predicts,” “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, 2017

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References

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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)

	September 30, 2017 (unaudited)	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	\$ 5,510	\$ 8,293
Restricted cash	30	30
Accounts receivable, net	41	30
Inventory, net	—	213
Prepaid expenses and other current assets	430	483
Total current assets	6,011	9,049
Property and equipment, net	108	149
Total assets	<u>\$ 6,119</u>	<u>\$ 9,198</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 1,128	\$ 1,006
Accrued expenses	1,128	1,160
Deferred revenue	11	11
Other current liabilities	—	214
Total current liabilities	2,267	2,391
Long term debt-related party, net of debt issuance costs	4,910	—
Warrant liability	50	17
Total liabilities	7,227	2,408
Commitments (Note 12)		
Stockholders' equity (deficit):		
Preferred stock, \$0.01 par value – 500,000 shares authorized; no shares issued and outstanding at September 30, 2017 and December 31, 2016	—	—
Common stock, \$0.01 par value – 50,000,000 and 13,000,000 shares authorized at September 30, 2017 and December 31, 2016; 11,157,489 shares issued and outstanding at September 30, 2017 and 10,907,857 shares issued and outstanding at December 31, 2016	112	109
Class B common stock, \$0.01 par value – zero and 1,000,000 shares authorized at September 30, 2017 and December 31, 2016 and no shares issued and outstanding at September 30, 2017 and December 31, 2016	—	—
Additional paid-in capital	255,269	254,884
Accumulated deficit	(256,489)	(248,203)
Total stockholders' equity (deficit)	(1,108)	6,790
Total liabilities and stockholders' equity (deficit)	<u>\$ 6,119</u>	<u>\$ 9,198</u>

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,	
	2017	2016	2017	2016
Revenue	\$ 23	\$ 136	\$ 173	\$ 477
Cost of revenue	15	138	223	1,128
Gross margin (loss)	8	(2)	(50)	(651)
Operating expenses:				
Research and development	960	962	3,010	2,993
Sales and marketing	494	479	1,474	1,753
General and administrative	1,095	1,321	3,624	4,687
Total operating expenses	2,549	2,762	8,108	9,433
Loss from operations	(2,541)	(2,764)	(8,158)	(10,084)
Other income (expense):				
Interest income	13	9	25	36
Interest expense	(82)	—	(100)	—
Foreign exchange gain (loss)	—	6	(6)	9
Other Income	—	—	23	—
Re-measurement of warrant liability	7	3	(33)	(14)
Other income (expense), net	(62)	18	(91)	31
Loss before income tax expense	(2,603)	(2,746)	(8,249)	(10,053)
Income tax expense	6	8	9	29
Net loss	\$ (2,609)	\$ (2,754)	\$ (8,258)	\$ (10,082)
Basic and diluted net loss per common share	\$ (0.23)	\$ (0.29)	\$ (0.74)	\$ (1.06)
Weighted-average number of common shares used in basic and diluted net loss per common share	11,157,489	9,510,557	11,143,773	9,509,055

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,	
	2017	2016
Operating activities		
Net loss	\$(8,258)	\$(10,082)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	46	171
Amortization of debt issuance costs	25	—
Stock-based compensation expense	162	609
Remeasurement of warrant liability	33	14
Impairment loss on fixed assets	—	145
Change in inventory reserve	(76)	(187)
Gain on sale of property and equipment	—	4
Changes in operating assets and liabilities:		
Accounts receivable	(11)	(66)
Prepaid expenses and other current assets	53	201
Inventory	289	799
Accounts payable	122	94
Accrued expenses	(32)	(1,447)
Deferred rent	—	(263)
Net cash used in operating activities	(7,647)	(10,008)
Investing activities		
Change in restricted cash	—	(150)
Purchases of property and equipment	(5)	(79)
Proceeds from sale of property and equipment	—	4
Net cash used in investing activities	(5)	(225)
Financing activities		
Proceeds from issuance of common stock	198	307
Debt issuance costs	(115)	—
Proceeds from long term borrowing, related party	5,000	—
Payments on short term note payable	(214)	(2)
Net cash provided by financing activities	4,869	305
Net decrease in cash and cash equivalents	(2,783)	(9,928)
Cash and cash equivalents at beginning of period	8,293	19,590
Cash and cash equivalents at end of period	<u>\$ 5,510</u>	<u>\$ 9,662</u>
Supplemental cash flow disclosures		
Income taxes paid	\$ 31	\$ 56
Equipment acquired under capital lease	\$ —	\$ 2
Effect on accumulated deficit of adopting ASU No. 2016-09 in 2017	\$ 28	\$ —

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 near and long-term goal is to establish EndoBarrier as a vital 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 diabetic patients. EndoBarrier is the only proven, incision-free, non-anatomy altering solution designed to specifically mimic the duodenal-jejunal exclusion created by gastric bypass surgery, without the permanent safety issues associated with gastric bypass. Since incorporation, the Company has devoted substantially all of its efforts to product commercialization, research and development, business planning, recruiting management and technical staff, 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, the 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. In the second half of fiscal 2015, the Company announced its decision to stop the ENDO Trial.

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 remained available for it to establish new priorities, continue limited market development and research, and to evaluate strategic options.

In the second and third quarters of fiscal 2016, the Company took additional actions to provide additional time to evaluate and develop its strategic options. These actions resulted in non-recurring charges totaling approximately \$1.1 million, including \$0.4 million related to restructuring charges in our second quarter, \$0.6 million related to employee departures in both our second and third quarters and \$0.1 million related to abandonment of our former headquarters in Lexington, MA.

In October 2016, the Company received final cancellation notification from the Therapeutic Goods Administration (“TGA”) for the listing of EndoBarrier on the Australian Register of Therapeutic Goods (“ARTG”). The TGA stated that the Company failed to provide adequate evidence of compliance with certain provisions of the TGA Essential Principles within the required number of working days in 2015.

In May 2017, the Company received notification from its notified body SGS United Kingdom Limited (“SGS”) that the CE Mark for its EndoBarrier® system has been suspended pending closure of non-conformances related to its quality management system required under International Organization for Standardization (“ISO”) regulations. GI Dynamics is working diligently to resolve all outstanding non-conformances and have the suspension of the CE mark removed. As disclosed in the Company’s Form 8-K filed on November 13, 2017, on November 10, 2017 (November 11, 2017 Australian Eastern Daylight Time), the Company received notification from SGS that it will withdraw the CE Certificate of Conformity for EndoBarrier effective November 12, 2017. Withdrawal of the CE Certificate of Conformity means that the Company will not be able to affix the CE Mark and sell EndoBarrier in European Union countries until another Certificate of Conformity is issued by SGS or another notified body or any appeal is successful. The company is evaluating its options including grounds for appeal of the decision, consulting with its advisors and has initiated communications with SGS to clarify certain procedural and substantive matters relating to the notice.

To date, the Company has focused its commercialization efforts within select European Union and Middle East countries and is re-engaging with the FDA with the intent of seeking agreement regarding a new investigational device exemption (IDE) pivotal trial to move towards potential to explore regulatory approval for EndoBarrier in the United States.

GI Dynamics, Inc. and Subsidiaries

Notes to Condensed Consolidated Financial Statements

(unaudited)

1. Nature of Business (continued)

From its inception in 2003 to its initial public offering (“IPO”) in 2011, the Company was financed by a series of preferred stock financings. In September 2011, the Company completed its IPO of common stock in the form of CHESS Depositary Interests (“CDIs”) in Australia and has completed a number of equity financings since that time.

On December 20, 2016, the Company completed a private placement sale of 69,865,000 CDIs (1,397,300 shares) for approximately \$1.0 million, net of expenses. In January 2017, the Company completed the sale of 249,632 shares (12,481,600 CDIs) to eligible investors under a Security Purchase Plan for approximately \$0.83 per share resulting in net proceeds after expenses of approximately \$0.2 million. To date, GI Dynamics has raised approximately \$238 million in net proceeds through issuance of debt and sales of its equity.

In June 2017, the Company completed a Convertible Term Promissory Note (the “Note”) financing for a gross amount of \$5.0 million that accrues interest at 5% per annum compounded annually. The Note is due by December 31, 2018 and contains provisions for conversion during the term of the Note (See Note 11 of the Condensed Consolidated Financial Statements for a more complete description of the terms and conditions).

Going Concern Evaluation

As of September 30, 2017, the Company’s primary source of liquidity is its cash and cash equivalents balances. The Company continues to evaluate which markets are appropriate to continue pursuing reimbursement, market awareness and general market development and selling efforts, and continue to restructure its business and costs, establish new priorities, and evaluate strategic options. As a result, if the Company remains in business, it expects to incur significant operating losses for the next several years.

The Company does not expect its current cash balances will be sufficient to continue to fund its operations after February 2018. In addition, as previously disclosed, in May 2017, it received notification from its notified body SGS United Kingdom Limited (SGS) that the CE Mark for EndoBarrier has been suspended pending closure of non-conformances related to its quality management system required under ISO 13485:2003 and 93/42/EEC. As disclosed in the Company’s Form 8-K filed on November 13, 2017, on November 10, 2017 (November 11, 2017 Australian Eastern Daylight Time), the Company received notification from SGS that it will withdraw the CE Certificate of Conformity for EndoBarrier effective November 12, 2017. Withdrawal of the CE Certificate of Conformity means that the Company will not be able to affix the CE Mark and sell EndoBarrier in European Union countries until another Certificate of Conformity is issued by SGS or another notified body or any appeal is successful. The company is evaluating its options including grounds for appeal of the decision, consulting with its advisors and has initiated communications with SGS to clarify certain procedural and substantive matters relating to the notice. If the Company decides to initiate an appeal process and the appeal is not resolved favorably by November 17, 2017, the Company expects that it will be required to make further significant reductions in its operations which could include an orderly wind down of the Company.

If an appeal of the withdrawal by SGS is successful, the Company will need to raise additional capital before February 2018 in order to continue to pursue its current business objectives as planned and to continue to fund its operations. The Company is looking to raise additional funds through any combination of additional equity and debt financings or from other sources. However, the Company has no guaranteed source of capital that will sustain operations after February 2018 and there can be no assurance that any such potential 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 cease operations, including discontinuing research and development activities and further commercialization of EndoBarrier. As such, if access to capital is not achieved in the near term, it will materially harm the Company’s business, financial condition and results of operations. These factors raise substantial doubt about the Company’s ability to continue as a going concern.

The Company has incurred operating losses since inception and at September 30, 2017 had an accumulated deficit of approximately \$256.5 million. GI Dynamics expects to incur significant operating losses for the next several years. At September 30, 2017, the Company had approximately \$5.5 million in cash, cash equivalents and restricted cash. The Company does not expect its current cash balances will be sufficient to fund its operations after February 2018.

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, 2017, and December 31, 2016 and the three and nine months ended September 30, 2017 and 2016 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, 2017, and for the three and nine months ended September 30, 2017 and 2016, 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, 2017. The December 31, 2016 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.

GI Dynamics, Inc. and Subsidiaries

Notes to Condensed Consolidated Financial Statements

(unaudited)

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

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, 2017, results of its operations for the three and nine months ended September 30, 2017 and 2016, and its cash flows for the nine months ended September 30, 2017 and 2016. The interim results for the nine months ended September 30, 2017 are not necessarily indicative of the results that may be expected for the year ending December 31, 2017.

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

Principles of Consolidation

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

Use of Estimates

The preparation of consolidated financial statements in accordance with GAAP requires the Company's management to make estimates and judgments that may affect the reported amounts of assets, liabilities, revenues and expenses, and the related disclosure of contingent assets and liabilities. On an ongoing basis, the Company's management evaluates its estimates, including those related to revenue recognition, allowance for doubtful accounts, inventory valuation including reserves for excess and obsolete inventory, impairment of long-lived assets, income taxes including the valuation allowance for deferred tax assets, research and development, contingencies, 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.

As of September 30, 2017, and December 31, 2016, 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 assets as restricted cash, relate to funds set aside to secure amounts outstanding on company supported credit card balances.

GI Dynamics, Inc. and Subsidiaries
Notes to Condensed Consolidated Financial Statements
(unaudited)

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

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 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.

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 elected to adopt ASU 2016-09 in the first quarter of 2017 retrospectively to January 1, 2017. As a result of adopting ASU No. 2016-09 during the three and nine months ended September 30, 2017, the Company adjusted its accumulated deficit related to the accounting policy election to recognize the impact of share-based award forfeitures only as they occur rather than by applying an estimated forfeiture rate as previously required. ASU No. 2016-09 requires that this change be applied using a modified-retrospective transition method by means of a cumulative-effect adjustment to accumulated deficit as of the beginning of the fiscal year in which the guidance is adopted. As a result of this adoption, the Company recorded a decrease to accumulated deficit of approximately \$28,000.

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.

In November 2016, the FASB issued ASU No. 2016-18, *Statement of Cash Flows (Topic 230): Restricted Cash (a consensus of the FASB Emerging Issue Task Force)*, or ASU 2016-18. This new standard addresses the diversity that exists in the classification and presentation of changes in restricted cash on the statement of cash flows. The amendments in ASU 2016-18 require that a statement of cash flows explain the change during the period in the total of cash, cash equivalents, and amounts generally described as restricted cash or restricted cash equivalents.

GI Dynamics, Inc. and Subsidiaries

Notes to Condensed Consolidated Financial Statements

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

Therefore, amounts generally described as restricted cash and restricted cash equivalents should be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. This guidance is effective for fiscal years beginning after December 15, 2017, including interim periods within the year of adoption, with early adoption permitted. We do not expect that the adoption of ASU 2016-18 will have a material impact on our 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, 2017 and 2016, 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, 2017 and 2016, as they would be anti-dilutive:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Warrants to purchase common stock	28,532	28,532	28,532	28,532
Options to purchase common stock and other stock-based awards	1,504,938	1,165,427	1,504,938	1,165,427
Total	<u>1,533,470</u>	<u>1,193,959</u>	<u>1,533,470</u>	<u>1,193,959</u>

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 a consulting firm provides 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, 2017, the Consultant Warrants had not 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

GI Dynamics, Inc. and Subsidiaries

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4. Common Stock Warrants (continued)

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.

The Consultant Warrant is classified as a liability and as such the fair value of the Warrant must be remeasured at each reporting period. At the time the Warrant was issued, the Company estimated the fair value of the Warrant using the Black-Scholes option pricing model. The Company remeasures the fair value of the Warrant at each reporting period using current assumptions. Changes in value recorded are 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, 2017 and December 31, 2016, and indicates the fair value hierarchy of the valuation techniques the Company used to determine such fair value. In general, fair values determined by Level 1 inputs utilize observable inputs such as quoted prices in active markets for identical assets or liabilities. Fair values determined by Level 2 inputs utilize data points that are either directly or indirectly observable, such as quoted prices, interest rates and yield curves. Fair values determined by Level 3 inputs utilize unobservable data points in which there is little or no market data, requiring the Company to develop its own assumptions for the asset or liability.

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

Description	September 30, 2017	Fair Value Measurements at Reporting Date Using		
		Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets				
Money market funds (included in cash and cash equivalents)	\$ 5,510	\$ 5,510	\$ —	\$ —
Total assets	\$ 5,510	\$ 5,510	\$ —	\$ —
Liabilities				
Warrants to purchase common stock	\$ 50	\$ —	\$ —	\$ 50
Total liabilities	\$ 50	\$ —	\$ —	\$ 50

Description	December 31, 2016	Fair Value Measurements at Reporting Date Using		
		Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets				
Money market funds (included in cash and cash equivalents)	\$ 6,344	\$ 6,344	\$ —	\$ —
Total assets	\$ 6,344	\$ 6,344	\$ —	\$ —
Liabilities				
Warrants to purchase common stock	\$ 17	\$ —	\$ —	\$ 17
Total liabilities	\$ 17	\$ —	\$ —	\$ 17

GI Dynamics, Inc. and Subsidiaries

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5. Fair Value of Financial Instruments (continued)

The assumptions used in the Black-Scholes option pricing model to determine the fair value of the Consultant Warrant as of September 30, 2017, and December 31, 2016 were as follows:

	September 30, 2017	December 31, 2016
Exercise price	\$ 0.64	\$ 0.64
Fair value of common stock	\$ 1.96	\$ 0.59
Expected volatility	135.96%	90.5%
Expected term (in years)	3.59	4.34
Risk-free interest rate	1.71%	1.78%
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, 2016	\$ 17
Issuance of Consultant Warrant	—
Increase in fair value of Warrants upon remeasurement included in other income (expense)	33
Balance at September 30, 2017	<u>\$ 50</u>

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, 2017 and December 31, 2016 are carried at amounts that approximate fair value due to their short-term maturities and highly liquid nature of these instruments. The carrying value of the Company's Senior Secured Convertible Promissory Note approximates fair value based on certain industry studies obtained by the Company.

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

Financial instruments that subject the Company to credit risk primarily consists of cash and cash equivalents, restricted cash and accounts receivable. The Company maintains its cash, 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.

In May 2017, the Company entered into a sales arrangement with certain distributors totaling \$517,000 of EndoBarrier inventory. Due to certain extended right of return periods and payment terms, the Company determined that the revenue and related product costs associated with this transaction should be deferred for accounting purposes. No revenue or cost of sales have been recorded for the three and nine months ended September 30, 2017 related to this transaction. Additionally, no payments have been received from distributors in connection with the transaction. As a result, the Company has recorded an adjustment to accounts receivable of \$559,000 for the unpaid portion of deferred revenue which includes an adjustment of approximately \$42,000 for revaluation of receivables denominated in foreign currency at September 30, 2017. As of September 30, 2017, the Company has also reported deferred product costs, which represents the value of the inventory transferred to distributors in connection with this sale transaction of approximately \$27,000 in other current assets. The Company expects to recognize revenue and the related costs for this transaction after payment has been received and the right of return periods are elapsed or once an estimate for returns can be established, as appropriate.

GI Dynamics, Inc. and Subsidiaries

Notes to Condensed Consolidated Financial Statements

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

At September 30, 2017, one distributor accounted for approximately 29.6% and a second distributor accounted for approximately 13.3% of the Company's accounts receivable. One healthcare provider accounted for approximately 14.9 % and a second healthcare provider accounted for approximately 14.0 % and a third healthcare provider accounted for approximately 13.7% of the Company's accounts receivables. At December 31, 2016 one health care provider accounted for approximately 43% of the Company's accounts receivable and another health care provider accounted for approximately 22% of the Company's accounts receivable. No other customer accounted for greater than 10% of the Company's accounts receivable at September 30, 2017 and December 31, 2016.

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. During the three and nine months ended September 30, 2017 the company wrote off approximately \$0 and \$22,000 in accounts receivable, respectively, against the allowance for doubtful accounts. During the three and nine months ended September 30, 2016 the Company wrote off approximately \$0 and \$48,000 respectively, in accounts receivable against the allowance for doubtful accounts.

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.

The following table shows the components of the Company's accounts receivable at September 30, 2017 and December 31, 2016 (in thousands):

	September 30, 2017	December 31, 2016
Accounts receivable	\$ 85	\$ 68
Less: allowance for doubtful accounts	(42)	(16)
Less: allowance for sales returns	(2)	(22)
Total	<u>\$ 41</u>	<u>\$ 30</u>

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

	Nine Months Ended September 30,	
	2017	2016
Beginning balance	\$ 16	\$ 59
Net charges to expenses	48	5
Utilization of allowances	(22)	(48)
Ending balance	<u>\$ 42</u>	<u>\$ 16</u>

GI Dynamics, Inc. and Subsidiaries

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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 is challenging. 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.

The Company has reserves totaling approximately \$4.5 million and \$5.0 million for excess, expired and obsolete inventory as of September 30, 2017 and December 31, 2016, respectively. 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, 2017 and December 31, 2016 was as follows (in thousands):

	<u>September 30, 2017</u>	<u>December 31, 2016</u>
Finished goods	\$ —	\$ 213
Work-in-process	—	—
Raw materials	—	—
Total	<u>\$ —</u>	<u>\$ 213</u>

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 December 31, 2016, approximately 5% of the finished goods inventory was at customer locations pursuant to these arrangements.

GI Dynamics, Inc. and Subsidiaries

Notes to Condensed Consolidated Financial Statements

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8. Property and Equipment

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

	September 30, 2017	December 31, 2016
Laboratory equipment and manufacturing equipment	\$ 591	\$ 591
Computer equipment and software	1,179	1,174
Office furniture and equipment	183	183
Leasehold improvements	21	21
	<u>1,974</u>	<u>1,969</u>
Less accumulated depreciation and amortization	(1,866)	(1,820)
Total	<u>\$ 108</u>	<u>\$ 149</u>

Depreciation and amortization expense of property and equipment, including equipment recorded under capital leases, and the charge for impaired property and equipment totaled approximately \$11,000 and \$16,000 for the three months ended September 30, 2017 and 2016, respectively and \$46,000 and \$0.3 million for the nine months ended September 30, 2017 and 2016, respectively.

The Company recognized a charge for the impaired property and equipment related to abandonment of its former facility in Lexington, MA, for the nine months ended September 30, 2017 and September 30, 2016 (in thousands).

	Nine Months Ended September 30,	
	2017	2016
Cost of revenue	\$ —	\$ 24
Research and development	—	79
General and administrative	—	42
Total	<u>\$ —</u>	<u>\$ 145</u>

The Company did not recognize a charge for impaired property and equipment for the three months ended September 30, 2017 and September 30, 2016.

9. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	September 30, 2017	December 31, 2016
Payroll and related liabilities	\$ 386	\$ 430
Professional fees	498	617
Interest payable	73	—
Other	171	113
Total	<u>\$ 1,128</u>	<u>\$ 1,160</u>

GI Dynamics, Inc. and Subsidiaries
Notes to Condensed Consolidated Financial Statements
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10. Short Term Notes Payable

In September 2016, 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%. There was no outstanding balance at September 30, 2017 and \$214,466 was outstanding at December 31, 2016, and amounts are included in other current liabilities in the accompanying balance sheet.

11. Long-Term Debt

On June 15, 2017, the Company entered into a Note Purchase Agreement by and between the Company, as borrower, and Crystal Amber Fund Limited, as purchaser (the "Purchaser"). Pursuant to the Note Purchase Agreement, the Company issued and sold to the Purchaser a Senior Secured Convertible Promissory Note in an aggregate original principal amount of \$5.0 million (the "Note"). The Purchaser is a related party and is the Company's largest shareholder.

The Note accrues interest at a rate equal to 5% per annum, compounded annually, other than during the continuance of an event of default, when the Note accrues interest at a rate of 8% per annum. The entire outstanding principal balance and all unpaid accrued interest thereon is due on the maturity date, December 31, 2018. The Note is secured by a first priority security interest in substantially all personal property assets of the Company, including intellectual property.

Subject to the receipt of any required shareholder approval (as described in the Listing Rules of the Australian Securities Exchange (the "ASX")), the entire outstanding principal balance under the Note and all unpaid accrued interest thereon is convertible into CHESS Depositary Interests ("CDIs"), each representing 1/50th of a share of the Company's common stock, (i) at the option of the Purchaser at a conversion price calculated based on the five-day volume weighted average closing price of the Company's CDIs on the ASX, or (ii) automatically upon the occurrence of an equity financing in which the Company raises at least \$10.0 million (a "Qualified Financing") at the price per CDI of the CDIs issued and sold in such financing. If shareholder approval is required to approve the issuance of any CDIs upon such a conversion and such approval is not obtained, the Company is obligated to prepay all accrued and unpaid interest plus 110% of the remaining outstanding unconverted principal balance on the earlier of the maturity date or the date that is six months following the date of the stockholder meeting at which the requisite approval was not obtained.

In the event that the Borrower issues additional CDIs in a subsequent equity financing at a price per CDI that is less than the then-effective optional conversion price (based on the five-day volume weighted average price on the ASX), the Purchaser has a 30-day option to convert (subject to any applicable shareholder approval) at an adjusted conversion price reflecting, on a weighted average basis, the lower price per CDI. The number of CDIs that the Purchaser may acquire upon conversion of the Note at this adjusted conversion price is limited to the number that maintains the Purchaser's fully-diluted ownership percentage of the Company at the same level as existed immediately preceding the applicable subsequent equity financing.

In addition, upon a change of control of the Company (other than a change of control resulting from a Qualified Financing) in which the Company's stockholders receive cash consideration, the Company is obligated to prepay all accrued and unpaid interest plus 110% of the remaining outstanding unconverted principal balance. Other than as described above, the Company may not prepay the Note without the consent of the Purchaser.

The Note Purchase Agreement contains customary events of default including a failure to perform obligations under the Note Purchase Agreement, bankruptcy, a decision by the board of directors of the Company to wind up the Company, or if the Company otherwise ceases to carry on its ongoing business operations. If a default occurs and is not cured within the applicable cure period or is not waived, any outstanding obligations under the Note may be accelerated. The Note Purchase Agreement and related Note documents also contain additional representations and warranties, covenants and conditions, in each case customary for transactions of this type.

The company has recorded the \$5.0 million note net of its debt issuance costs and will amortize this cost over life of the note. For the three and nine months ended September 30, 2017, the Company recognized interest expense of \$63,000 and \$73,000 and amortization of the issuance costs of \$18,500 and \$24,700 related to the Senior Secured Convertible Promissory Note.

GI Dynamics, Inc. and Subsidiaries

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12. 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 expired in December 2016. The rent expense, inclusive of the escalating rent payments and free rent period, was recognized on a straight-line basis over the term of the sublease agreement. In accordance with the terms of the sublease agreement, the Company maintained 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.

Rent expense on noncancelable operating leases was approximately \$36,000 and \$0.3 million for the three months ended September 30, 2017 and 2016, respectively and \$107,000 and \$0.5 million for the nine months ended September 30, 2017 and 2016, respectively. Future minimum lease payments under all noncancelable lease arrangements at September 30, 2017, are as follows (in thousands):

Year Ending December 31,	
2017	\$36
2018	48
Total	<u>\$84</u>

13. Stockholders' Equity (Deficit)

On May 22, 2017, the Stockholders of the Company approved an increase of its authorized shares of Common Stock from 13,000,000 to 50,000,000 and to eliminate Class B shares of Common Stock of the Company. As of September 30, 2017, the authorized capital stock of the Company consists of 50,500,000 shares, of which 50,000,000 shares are designated as Common Stock and 500,000 shares are designated as Preferred Stock.

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14. 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, 2017, there were 1,269,721 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:

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

Accordingly, in the first quarter of fiscal 2017, 436,314 options available for future grant were added to the 2011 Plan.

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, 2017 and 2016 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Cost of revenue	\$ —	\$ —	\$ —	\$ 34
Research and development	11	6	24	49
Sales and marketing	38	35	67	130
General and administrative	32	59	71	396
	<u>\$ 81</u>	<u>\$ 100</u>	<u>\$ 162</u>	<u>\$ 609</u>

The stock options granted under the Plans generally vest over a four-year period and expire ten years from the date of grant. From time to time, the Company grants stock options to purchase common stock subject to performance-based milestones. The vesting of these stock options will occur upon the achievement of certain milestones. When achievement of the milestone is deemed probable, the Company expenses the compensation of the respective stock option over the implicit service period.

In calculating stock-based compensation costs, the Company estimates 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. Such costs are then recognized over the requisite service period of the awards on a straight-line basis.

GI Dynamics, Inc. and Subsidiaries

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14. Stock Plans (continued)

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, 2017 and 2016:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Expected volatility	88.2%	73.4%	87.8%	71.0%
Expected term (in years)	6.05	6.05	6.05	6.05
Risk-free interest rate	2.05%	1.36%	2.05%	1.27%
Expected dividend yield	— %	— %	— %	— %

Stock Options

The following table summarizes share-based activity under the Company's stock option plans for the nine months ended September 30, 2017:

	Shares of Common Stock Attributable to Options	Weighted- Average Exercise Price	Weighted- Average Contractual Life (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2016	748,571	\$ 8.67	8.38	\$ —
Granted	408,635	\$ 1.07		
Exercised	—			
Cancelled	(55,769)	\$ 33.81		
Outstanding at September 30, 2017	<u>1,101,437</u>	<u>\$ 4.58</u>	<u>8.37</u>	<u>\$ 913</u>
Vested or expected to vest at September 30, 2017	<u>1,101,437</u>	<u>\$ 4.58</u>	<u>8.37</u>	<u>\$ 913</u>
Exercisable at September 30, 2017	<u>342,447</u>	<u>\$ 11.98</u>	<u>6.97</u>	<u>\$ 218</u>

As of September 30, 2017, there was approximately \$0.5 million of unrecognized stock-based compensation related to unvested stock option grants having service-based vesting under the Plans which is expected to be recognized over a weighted-average period of 2.8 years. The intrinsic value in the table above represents the difference between the fair value of the Company's common stock on the measurement date and the exercise price of the stock option.

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.

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14. 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, 2017 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,

	Number of Units	Weighted- Average Contractual Life <i>(in years)</i>	Aggregate Intrinsic Value <i>(in thousands)</i>
Outstanding at December 31, 2016	403,501	9.11	\$ 365
Granted	—		
Vested	—		
Cancelled	—		
Outstanding at September 30, 2017	<u>403,501</u>	<u>8.37</u>	<u>\$ 791</u>

The aggregate intrinsic value at September 30, 2017 and December 31, 2016 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

At September 30, 2017, all of the RSUs outstanding are subject to performance-based vesting criteria as described in the applicable award agreement. For these awards, 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.

At September 30, 2017 and 2016, no RSUs that have performance-based vesting criteria are considered probable of achievement. For the three and nine months ended September 30, 2017 and 2016, the Company did not recognize any stock-based compensation for RSUs subject to performance-based vesting criteria.

As of September 30, 2017, there remains approximately \$0.3 million of unrecognized stock-based compensation.

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(unaudited)

15. 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 and the Asia Pacific region 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, 2017, long-lived assets, comprised of property and equipment, of approximately \$0.1 million are all held in the U.S.

Product sales by geographic location for the three and nine months ended September 30, 2017 and 2016 are listed in the table below (in thousands).

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Europe	\$ 23	\$ 26	\$ 155	\$ 232
Middle East	—	72	18	159
Asia Pacific	—	38	—	86
Total Revenue	<u>\$ 23</u>	<u>\$ 136</u>	<u>\$ 173</u>	<u>\$ 477</u>

Germany comprised a significant component of revenue in Europe for the three and nine months ended September 30, 2017.

Germany and the United Kingdom comprised a significant component of revenue in Europe for the three and nine months ended September 30, 2016.

Major Customers

For the three months ended September 30, 2017 we recognized as revenue a reversal of prior year rebate accruals of approximately \$27,000 originally granted to health care providers which was deemed to no longer be required, in addition we deferred a previously recognized sale.

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. No other customer accounted for greater than 10% of the Company's revenue during the three months ended September 30, 2017 and 2016.

For the nine months ended September 30, 2017 one health care provider accounted for 20.7% of the company's revenue. A second health care provider accounted for 15.3% of the company's revenue.

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 %. No other customer accounted for greater than 10% of the Company's revenue during the nine months ended September 30, 2017 and 2016.

16. Subsequent Event

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. As disclosed in the Company's Form 8-K filed on November 13, 2017, on

November 10, 2017 (November 11, 2017 Australian Eastern Daylight Time), the Company received notification from SGS United Kingdom Limited (SGS) that it will withdraw the CE Certificate of Conformity for EndoBarrier effective November 12, 2017. Withdrawal of the CE Certificate of Conformity means that the Company will not be able to affix the CE Mark and sell EndoBarrier in European Union countries until another Certificate of Conformity is issued by SGS or another notified body or any appeal is successful. The Company is evaluating its options including grounds for appeal of the decision, consulting with its advisors and has initiated communications with SGS to clarify certain procedural and substantive matters relating to the notice.

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, 2016 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" 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 product, EndoBarrier®, a vital treatment option for patients with type 2 diabetes and obesity by restoring healthier blood sugar levels and reducing body weight. EndoBarrier is the first endoscopically-delivered device approved for the treatment of obese type 2 diabetes. EndoBarrier is the only proven, incision-free, non-anatomy altering solution designed to specifically mimic the clinical benefit of 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.

In the U.S., we commenced enrollment of patients in our pivotal trial of EndoBarrier, the ENDO Trial, in 2013. In the third quarter of 2015, we announced our decision to stop the ENDO Trial. 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 remained available for us to establish new priorities, continue market development and research, and to evaluate strategic options.

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, currently 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.

On May 10, 2016, we announced that we were further 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 TGA of the cancellation of the inclusion of EndoBarrier on the ARTG, taking effect on October 12, 2016. As a result, with effect from October 12, 2016, we are not permitted to supply the EndoBarrier in Australia, outside of approved trials.

In May 2017, we received notification from our notified body SGS United Kingdom Limited (SGS) that the CE Mark for our EndoBarrier system has been suspended pending closure of non-conformances related to its quality management system required under ISO regulations. We are working diligently to resolve all outstanding non-conformances. As disclosed in our Form 8-K filed on November 13, 2017, on November 10, 2017 (November 11, 2017 Australian Eastern Daylight Time), we received notification from SGS that it will withdraw the CE Certificate of Conformity for EndoBarrier effective November 12, 2017. Withdrawal of the CE Certificate of Conformity means that we will not be able to affix the CE Mark and sell EndoBarrier in European Union countries until another Certificate of Conformity is issued by SGS or another notified body or any appeal is successful. We are evaluating our options including grounds for appeal of the decision, consulting with our advisors and have initiated communications with SGS to clarify certain procedural and substantive matters relating to the notice.

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

To date, we have devoted substantially all 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, 2017, we had an accumulated deficit of approximately \$256.5 million. We expect to incur net losses for the next several years while 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.

To date, we have raised net proceeds of approximately \$238 million through the issuance of convertible debt and sales of our equity. On June 15, 2017, we executed a Senior Secured Convertible Promissory Note ("Note") to a single note holder and our largest shareholder who is a related party for net proceeds of approximately \$5.0 million.

Our corporate headquarters are 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, 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 and nine months ended September 30, 2017, 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,	
	2017	2016	2017	2016
Revenue	\$ 23	\$ 136	\$ 173	\$ 477
Cost of revenue	15	138	223	1,128
Gross margin (loss)	8	(2)	(50)	(651)
Operating expenses:				
Research and development	960	962	3,010	2,993
Sales and marketing	494	479	1,474	1,753
General and administrative	1,095	1,321	3,624	4,687
Total operating expenses	2,549	2,762	8,108	9,433
Loss from operations	(2,541)	(2,764)	(8,158)	(10,084)
Other income (expense):				
Interest income	13	9	25	36
Interest expense	(82)	—	(100)	—
Foreign exchange gain (loss)	—	6	(6)	9
Other Income	—	—	23	—
Re-measurement of warrant liability	7	3	(33)	(14)
Other income (expense), net	(62)	18	(91)	31
Loss before income tax expense	(2,603)	(2,746)	(8,249)	(10,053)
Income tax expense	6	8	9	29
Net loss	\$ (2,609)	\$ (2,754)	\$ (8,258)	\$ (10,082)
Basic and diluted net loss per common share	\$ (0.23)	\$ (0.29)	\$ (0.74)	\$ (1.06)
Weighted-average number of common shares used in basic and diluted net loss per common share	11,157,489	9,510,557	11,143,773	9,509,055

Three and Nine Months Ended September 30, 2017 compared to Three and Nine Months Ended September 30, 2016

	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2017	2016	\$	%	2017	2016	\$	%
	(dollars in thousands)				(dollars in thousands)			
Revenue	\$ 23	\$ 136	\$(113)	(83%)	\$ 173	\$ 477	\$(304)	(64%)
Cost of revenue	15	138	(123)	(89%)	223	1,128	(905)	(80%)
Gross loss	\$ 8	\$ (2)	\$ 10	(500%)	\$ (50)	\$ (651)	\$ 601	(92%)

Revenue

The decrease in revenue for the three months ended September 30, 2017 compared to the three months ended September 30, 2016 was primarily due to the suspension of CE Mark in May 2017. For the three months ended September 30, 2017, we recognized as revenue a prior year rebate accrual for approximately \$27,000, which was deemed to no longer be required, in addition we deferred a previously recognized sale.

The decrease in revenue for the nine months ended September 30, 2017 compared to the nine months ended September 30, 2016 was primarily due to decreased unit volume sales across Europe, the Middle East and Asia Pacific due to the suspension of the CE Mark in May 2017. Revenue decreased approximately 33.8% in Europe, 88.6 % in the Middle East and 100% in Asia Pacific. In May 2017, the Company entered into a sales arrangement with certain distributors totaling \$517,000. Due to certain extended right of return periods and payment terms, the Company determined that the revenue and related product costs associated with this transaction should be deferred for accounting purposes. No revenue or cost of sales have been recorded for the three and nine months ended September 30, 2017 related to this transaction. Additionally, no payments have been received from distributors in connection with the transaction. As a result, the Company has recorded an adjustment to accounts receivable of \$559,000 for the unpaid portion of deferred revenue which includes an adjustment of approximately \$42,000 for revaluation of receivables denominated in foreign currency at September 30, 2017. The Company expects to recognize revenue after payment has been received and the right of return periods are elapsed or once an estimate for returns can be established, as appropriate.

We decided in the second quarter of 2016 that, for the near term, we would concentrate sales and marketing efforts on select treatment centers in limited geographies. In addition, due to the cancellation of EndoBarrier inclusion on the ARTG in October 2016 we are no longer permitted to supply EndoBarrier in Australia. In May 2017, the CE Mark was suspended due to the notified body observations regarding the Company's Quality Management System (QMS). The suspension does not constitute a recall and does not call into question the safety and efficacy of EndoBarrier. Although EndoBarrier cannot be sold to GI Dynamics customers during the suspension period, EndoBarrier inventory intended to be sufficient during the suspension period was sold to GI Dynamics customers prior to the suspension with the approval of GI Dynamics' notified body. All EndoBarrier inventory currently residing with GI Dynamics customers may be used to conduct EndoBarrier procedures and the suspension has no relationship to the safety and efficacy of the device. Any investigator led trials in process were allowed to continue to enroll patients and use EndoBarrier.

We believe the following factors continue to adversely affect our commercial activities:

- stopping the ENDO Trial in 2015 and the regulatory-related questions arising out of that decision;
- 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; and
- Suspension of our CE Mark in the second quarter of fiscal 2017.

In the near-term, we intend to continue 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

The decrease in cost of revenue for the three and nine months ended September 30, 2017 compared to the same period in the prior year is due in part to the reduction in sales for the comparative periods and to us no longer maintaining a manufacturing organization to produce the EndoBarrier.

In May 2017, the Company entered into a distributor agreement and transferred its inventory to a distributor. As of September 30, 2017, the Company has also reported deferred products costs of \$27,000 which represented the value of the inventory transferred to distributors under these agreements, in other current assets. The Company will recognize cost of revenue once the Company determines that it has met the revenue recognition criteria for this transaction.

During the nine months ended September 30, 2016, we incurred approximately \$0.6 million of manufacturing production related costs and only produced one quarter of the capacity, resulting in expensing unabsorbed manufacturing costs in that nine-month period of approximately \$0.4 million.

Operating expenses

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2017	2016	Change		2017	2016	Change	
	(dollars in thousands)		\$	%	(dollars in thousands)		\$	%
Research and development	\$ 960	\$ 962	\$ (2)	(0.2%)	\$ 3,010	\$ 2,993	\$ 17	0.6%
Sales and marketing	494	479	15	3.1%	1,474	1,753	(279)	(15.9%)
General and administrative	1,095	1,321	(226)	(17.1%)	3,624	4,687	(1,063)	(22.7%)
Total operating expenses	<u>\$ 2,549</u>	<u>\$ 2,762</u>	<u>\$ (213)</u>	<u>(7.7%)</u>	<u>\$ 8,108</u>	<u>\$ 9,433</u>	<u>\$ (1,325)</u>	<u>(14.0%)</u>

Research and Development Expense. The decrease in research and development expense for the three months ended September 30, 2017 compared to the three months ended September 30, 2016 was primarily due to lower compensation and employee related costs caused by lower headcount and lower facility related costs. These were offset by higher professional service related costs in connection with rectifying quality and regulatory deficiencies. Further, expenses for the three months ended September 30, 2016 reflected adjustments to our accrued clinical study costs as we were winding up our U.S. study during that period.

The increase in research and development expense for the nine months ended September 30, 2017 compared to the nine months ended September 30, 2016 was primarily due to higher professional services costs related to quality and regulatory related costs and to the transfer of our manufacturing to a third-party manufacturer. These were offset by lower compensation and employee related expenses, primarily due to lower headcount and lower facility and information technology support costs. Further, expenses for the nine months ended September 30, 2016 reflected adjustments to our accrued clinical trial and related costs as we were winding up our U.S. study during that period.

Sales and Marketing Expense. The increase in sales and marketing expense for the three months ended September 30, 2017 compared to three months ended September 30, 2016 is primarily due to additional marketing consulting effort. The decrease in sales and marketing expense for the nine months ended September 30, 2017 compared to September 30, 2016 was primarily the result of a decrease in headcount resulting in lower compensation and employee related expenses, lower marketing and sales support expenses and lower facility related support expenses. This was offset by higher professional service costs in connection with our ongoing efforts to qualify EndoBarrier for reimbursement in Europe.

General and Administrative Expense. The decrease in general and administrative expense for the three and nine months ended September 30, 2017 compared to the three and nine months ended September 30, 2016 was primarily a result of decreased compensation and employee related expenses, including non-cash stock compensation expense and to a lesser extent lower costs related to being a public company, lower corporate insurance expenses and lower facility and information related support costs, offset by higher professional service costs.

We continue to look for ways to realize a more efficient cost structure in order to extend our cash runway. We may not be able to achieve cost reductions in all instances as we look to build and support our organization for the potential of the future. We expect operating expenses for our fourth quarter of 2017 to approximate those of each of our three prior quarters in 2017.

	Three Months Ended September 30,				Nine Months Ended September 30,			
			Change				Change	
	2017	2016	\$	%	2017	2016	\$	%
	(dollars in thousands)				(dollars in thousands)			
Interest income	\$ 13	\$ 9	\$ 4	44.4%	\$ 25	\$ 36	\$ (11)	(30.6%)
Interest expense	(82)	—	(82)	(100.0%)	(100)	—	(100)	(100.0%)
Foreign exchange gain (loss)	—	6	(6)	100.0%	(6)	9	(15)	(166.7%)
Other Income	—	—	—	0.0%	23	—	23	100.0%
Re-measurement of warrant liability	7	3	4	133.3%	(33)	(14)	(19)	135.7%
Other income (expense), net	<u>\$ (62)</u>	<u>\$ 18</u>	<u>\$ (80)</u>	<u>(444.4%)</u>	<u>\$ (91)</u>	<u>\$ 31</u>	<u>\$ (122)</u>	<u>(393.5%)</u>

Other income (expense). The change to other expense, net in the three and nine months ended September 30, 2017 from other income, net in the three and nine months ended September 30, 2016, is primarily due to the interest expense related to our Senior Secured Convertible Promissory Note issued in the second quarter of fiscal 2017. Other income in the nine months ended September 30, 2017 is due to a reimbursement from our prior landlord in connection with moving our headquarters to Boston in fiscal 2016.

The change in the re-measurement of warrant liability was due to a decrease in the fair value of our Consultant Warrant during the three month period ended September 30, 2017 compared to three months ended September 30, 2016 and increase in fair value during the nine month period ended September 30, 2017 compared to September 30, 2016.

Liquidity and Capital Resources

We have incurred losses since our inception in March 2003 and, as of September 30, 2017, we had an accumulated deficit of approximately \$256.5 million. We have financed our operations primarily from a combination of sales of equity securities and issuances of convertible term notes. As of September 30, 2017, we had approximately \$5.5 million of cash and cash equivalents.

On June 15, 2017, we entered into a Note Purchase Agreement by and between the Company, as borrower, and Crystal Amber Fund Limited, as purchaser (the “Purchaser”). Pursuant to the Note Purchase Agreement, we issued and sold to the Purchaser a Senior Secured Convertible Promissory Note in an aggregate original principal amount of \$5.0 million (the “Note”). The Purchaser is a related party and our largest shareholder.

The Note accrues interest at a rate equal to 5% per annum, compounded annually, other than during the continuance of an event of default, when the Note accrues interest at a rate of 8% per annum. The entire outstanding principal balance and all unpaid accrued interest thereon is due on the maturity date, December 31, 2018. The Note is secured by a first priority security interest in substantially all of our personal property assets, including intellectual property and is convertible into the Company’s CDIs on the terms set forth therein.

During the nine months ended September 30, 2017, our cash and cash equivalents balance decreased by approximately \$2.8 million as a result of funds utilized to support our operations, offset by proceeds from the issuance of convertible debt in the second quarter of fiscal 2017.

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,	
	<u>2017</u>	<u>2016</u>
	(dollars in thousands)	
Net Cash (used in) provided by:		
Operating activities	\$(7,647)	\$(10,008)
Investing activities	(5)	(225)
Financing activities	4,869	305
Net decrease in cash and cash equivalents	<u><u>\$(2,783)</u></u>	<u><u>\$ (9,928)</u></u>

Cash Flows From Operating Activities

The primary uses of cash used in operating activities for the nine months ended September 30, 2017 were:

- to fund our net loss of approximately \$8.3 million and;
- a net positive adjustment to cash flow from changes in working capital of approximately \$0.4 million resulting primarily from decreases in prepaid and other current assets, changes in inventory balances and accrued expenses; and
- a net positive adjustment to non-cash operating expenses of approximately \$0.2 million, the most significant being stock compensation expense and re-measurement of warrant liability offset with changes in depreciation and amortization of debt offering costs.

The primary uses of cash used in operating activities for the nine months ended September 30, 2016 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 which is partially offset by a decrease in inventory, and prepaid expense; and
- a net positive adjustment to cash flow for non-cash operating expenses 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 of 2016, we expensed \$0.7 million in restructuring and other employee departure costs.

Cash Flows From Investing Activities

Cash used in investing activities for the nine months ended September 30, 2017 totaled approximately \$5,000 and resulted from the purchase of equipment.

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 Flows From Financing Activities

Cash provided by financing activities for the nine months ended September 30, 2017 is due to the net proceeds from the approximately \$5 million Senior Secured Convertible Promissory Note we completed in June 2017 and to a lesser extent issuance of common stock in January 2017 offset by payments on our short-term note payable.

Cash provided by financing activities for the nine months ended September 30, 2016 totaled approximately \$0.3 million and primarily resulted from short term financing for insurance policies offset by capital lease payments of \$2,000.

Funding Requirements

As of September, 30, 2017, our primary source of liquidity is our cash and cash equivalents balances. 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 and evaluate strategic options. As a result, if we remain in business, we expect to incur significant operating losses for the next several years.

We do not expect our current cash balances will be sufficient to continue to fund our operations after February 2018. In addition, as previously disclosed, in May 2017, we received notification from our notified body SGS United Kingdom Limited (SGS) that the CE Mark for EndoBarrier has been suspended pending closure of non-conformances related to our quality management system required under ISO 13485:2003 and 93/42/EEC. As disclosed in our Form 8-K filed on November 13, 2017, on November 10, 2017 (November 11, 2017 Australian Eastern Daylight Time), we received notification from SGS that it will withdraw the CE Certificate of Conformity for EndoBarrier effective November 12, 2017. Withdrawal of the CE Certificate of Conformity means that we will not be able to affix the CE Mark and sell EndoBarrier in European Union countries until another Certificate of Conformity is issued by SGS or another notified body or any appeal is successful. We are evaluating our options including grounds for appeal of the decision, consulting with our advisors and have initiated communications with SGS to clarify certain procedural and substantive matters relating to the notice. If we decide to initiate an appeal process and the appeal is not resolved favorably by November 17, 2017, we expect that we will be required to make further significant reductions in our operations which could include an orderly wind down of the Company.

If an appeal of the withdrawal is successful, we will need to raise additional capital before February 2018 in order to continue to pursue our current business objectives as planned and to continue to fund our operations. We are looking to raise additional funds through any combination of additional equity and debt financings or from other sources. However, we have no guaranteed source of capital that will sustain operations after February 2018 and there can be no assurance that any such potential 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 cease operations, including discontinuing research and development activities and further commercialization of EndoBarrier. As such, if access to capital is not achieved in the near term, it will materially harm our business, financial condition and results of operations. These factors raise substantial doubt about our ability to continue as a going concern.

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 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 and maintaining regulatory approvals for EndoBarrier in new and existing markets;
- the success of our research and development efforts;
- 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. In addition, as mentioned above, we could be required to cease operations if we are unable to raise capital prior to February, 2018.

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.

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.

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 \$5.5 million at September 30, 2017, 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.

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 offerings were denominated in Australian dollars and as of September 30, 2017, we held the equivalent of approximately US \$50,000 denominated in Australian dollars and approximately US \$112,000 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 and nine months ended September 30, 2017 and 2016 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, 2017 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, 2017 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. In May 2017, we received notification from our notified body SGS United Kingdom Limited (SGS) that the CE Certificate of Conformity for EndoBarrier has been suspended pending closure of nonconformances related to its quality management system required under ISO 13485:2003 and 93/42/EEC. On November 10, 2017, we received notification that SGS will withdraw the CE Certificate of Conformity for EndoBarrier effective November 12, 2017. In addition, our revenue in the nine month period ended September 30, 2017 decreased by 64 % from our revenue in the corresponding period in 2016 and we continue to fund operations out of available cash. The following risk factors have been modified from those contained in our 2016 Annual Report on Form 10-K to reflect the risks related to such suspension and withdrawal of the CE Certificate of Conformity and revenue decrease.

In order to commercialize our products in the U.S. and certain other countries, we will need to obtain regulatory and other approvals. If we are unable to achieve, maintain or are delayed in achieving such approvals, this could have a significant effect on the time it takes to commercialize our technology in the U.S. and certain other countries.

At present, EndoBarrier is our only product that has been approved for marketing and sale. However, in October 2016, we received final cancellation notification from the Australian Therapeutic Goods Administration, or TGA, for the listing of EndoBarrier on the Australian Register of Therapeutic Goods, or ARTG. As a result, we are not permitted to supply the EndoBarrier in Australia for use outside of approved trials. In addition, in May 2017, we received notification from our notified body SGS United Kingdom Limited (SGS) that the CE Mark for EndoBarrier has been suspended pending closure of nonconformances related to its quality management system required under ISO 13485:2003 and 93/42/EEC, and on November 10, 2017, we received notification that SGS would withdraw the CE Certificate of Conformity effective November 12, 2017. Withdrawal of the CE Certificate of Conformity means that we will not be able to affix the CE Mark and sell EndoBarrier in European Union countries until another CE Certificate of Conformity is issued by SGS or another notified body or any appeal is successful.

We do not expect our current cash balances will be sufficient to continue to fund our operations after February 2018. We currently do not have sufficient funds to pursue regulatory approvals for our product in any country, and, as a result, we may not have sufficient funds to continue to pursue regulatory approvals for our product in any country. Even if we were to pursue regulatory approvals, there is no guarantee that we will be reapproved for inclusion on the ARTG, successfully appeal the withdrawal of our CE Certificate of Conformity, obtain another CE Certificate of Conformity, or obtain additional approvals from other regulatory bodies, including the FDA in the U.S., to commercialize EndoBarrier or any of our other products. In the U.S., we stopped our pivotal trial of EndoBarrier. Accordingly, we will not be able to obtain FDA approval to commercialize EndoBarrier in the U.S. without a new clinical trial which may be lengthy and expensive. The regulatory authorities in other countries may also require additional clinical trials. Necessary regulatory approvals could also be delayed, which could significantly impact our ability to commercialize our technology in the U.S. and other countries.

In addition, the company has evidenced a historical issue with compliance, leading to quality system issues that led to a 2014 shipping hold for European Union as well as the suspension of our CE Certificate of Conformity in May 2017, the withdrawal of our CE Certificate of Conformity in November 2017, multiple observations by the TGA in Australia regarding the Company’s failure to comply with Essential Principles of the TGA and compliance issues which led to the TGA’s cancellation of the EndoBarrier’s listing on the ARTG. Given the history of non-compliance on a quality system basis, a substantial risk exists of future compliance issues, until such time as the Company has had adequate time and resources to address the historical issues.

Regulatory requirements affecting the development, manufacture and sale of medical devices are evolving and subject to future change. We cannot predict what impact, if any, those changes might have on our business. Failure to comply with regulatory requirements could have a material adverse effect on our business, financial condition and results of operations. Later discovery of previously unknown problems with a product or manufacturer could result in fines, delays or suspensions of regulatory approvals. The failure to receive product approval on a timely basis, or the withdrawal of product approval by regulatory agencies, such as the TGA’s cancellation of the EndoBarrier’s listing on the ARTG and the withdrawal of our CE Certificate of Conformity, could have a material adverse effect on our business, financial condition or results of operations. For example, withdrawal of the CE Certificate of Conformity means that we will not be able to affix the CE Mark and sell EndoBarrier in European Union countries until another CE Certificate of Conformity is issued by SGS or another notified body or any appeal is successful.

We require substantial additional funding and may be unable to raise capital when needed, which could force us to delay, reduce, or eliminate planned activities or result in our inability to operate as a going concern.

As we have limited commercialization of our products, we are generating a small amount of revenue and are not cash flow positive or profitable. Our net revenue from product sales was approximately \$173,000 and \$477,000 for the nine months ended September 30, 2017 and September 30, 2016, respectively, and as of September 30, 2017, we had cash and cash equivalents of approximately \$5.5 million. Our existing capital is insufficient to meet our requirements (including the costs of commercializing our products, conducting clinical trials, obtaining regulatory approvals and partnering with third-party manufacturers) and cover any losses, and we do not expect our current cash balances will be sufficient to continue to fund our operations after February 2018. As such, we will need to raise additional funds through financings or borrowings before February 2018. Failure to raise additional funds could delay, reduce, or halt our commercialization and clinical trial efforts and would impact our ability to continue as a going concern.

In particular, as previously disclosed, on November 10, 2017 (November 11, 2017 Australian Eastern Daylight Time), we received notification from our notified body SGS United Kingdom Limited (SGS) that SGS will withdraw the CE Certificate of Conformity for EndoBarrier effective November 12, 2017. Withdrawal of the CE Certificate of Conformity means that we will not be able to affix the CE Mark and sell EndoBarrier in European Union countries until another Certificate of Conformity is issued by SGS or another notified body or any appeal is successful. We are evaluating our options including grounds for appeal of the decision, consulting with our advisors and have initiated communications with SGS to clarify certain procedural and substantive matters relating to the notice. If we decide to initiate an appeal process and the appeal is not resolved favorably by November 17, 2017, we expect that we will be required to make further significant reductions in our operations which could include an orderly wind down of the Company.

If an appeal of the withdrawal by SGS is successful, we will need to raise additional capital before February 2018 in order to continue to pursue our current business objectives as planned and to continue to fund our operations. We are looking to raise additional funds through any combination of additional equity and debt financings or from other sources. However, we have no committed sources of capital funding and there is no assurance that additional funding will be available to us in the future or be secured on acceptable terms. These factors raise substantial doubt about our ability to continue as a going concern. If adequate funding is not available before February 2018, we may no longer be a going concern and may be forced to curtail operations, including our commercial activities and research and development programs, or cease operations altogether, file for bankruptcy, or undertake any combination of the foregoing. In such event, our stockholders may lose their entire investment in our company.

In addition, if we do not meet our payment obligations to third parties as they become due, we may be subject to litigation claims and our credit worthiness would be adversely affected. Even if we are successful in defending against these claims, litigation could result in substantial costs and would be a distraction to management, and may have other unfavorable results that could further adversely impact our financial condition.

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.

EXHIBIT INDEX

<u>Exhibit No:</u>	<u>Description</u>
31.1*	<u>Certification of Chief Executive Officer pursuant to Rules 13a-14 or 15d-14 of the Exchange Act</u>
31.2*	<u>Certification of Chief Financial Officer pursuant to Rules 13a-14 or 15d-14 of the Exchange Act</u>
32.1‡	<u>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</u>
32.2‡	<u>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</u>
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
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*	Filed herewith.
‡	Furnished herewith.
†	Management contract or compensatory plan or arrangement.

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 14, 2017

By: /s/ SCOTT W. SCHORER

Scott W. Schorer
President and Chief Executive Officer
(principal executive officer)

Date: November 14, 2017

By: /s/ JAMES MURPHY

James Murphy
Chief Financial Officer
(principal financial officer and accounting officer)

**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 14, 2017

/s/ SCOTT W. SCHORER

Scott W. Schorer
Chief Executive Officer
(principal executive officer)

**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 14, 2017

/s/ JAMES MURPHY

James Murphy
Chief Financial Officer
(principal accounting and financial officer)

**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, 2017 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 14, 2017

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.

**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, 2017 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 14, 2017

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.