



Boston, United States  
Sydney, Australia  
7 May 2020 AEST

## Form 10-Q Filed with the SEC

**BOSTON and SYDNEY – 7 May 2020** – GI Dynamics<sup>®</sup> Inc. (ASX:GID) (the “Company”), a medical device company that is developing EndoBarrier<sup>®</sup> for patients with 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 (“SEC”) on 6 May 2020. The Form 10-Q includes the Company’s unaudited financial results for the three months ended 31 March 2020 and other required disclosures. The financial statements included in Form 10-Q were prepared in accordance with the United States Generally Accepted Accounting Principles and are denominated in United States dollars unless otherwise indicated.

This announcement has been authorized for release by Charles Carter, chief financial officer and company secretary of GI Dynamics.

### About GI Dynamics

GI Dynamics<sup>®</sup>, Inc. (ASX:GID) is the developer of EndoBarrier<sup>®</sup>, the first endoscopically-delivered medical device for the treatment of type 2 diabetes and the reduction of obesity. EndoBarrier is not approved for sale and is limited by federal law to investigational use only. EndoBarrier is subject to an Investigational Device Exemption by the FDA in the United States and is entering concurrent pivotal trials in the United States and India.

#### Chief Financial Officer / Secretary

United States:  
Charles Carter  
+1 (781) 357-3263  
ccarter@gidynamics.com

Founded in 2003, GI Dynamics is headquartered in Boston, Massachusetts. For more information please visit the Company website at [www.gidynamics.com](http://www.gidynamics.com).

#### Investor Relations

United States:  
Janell Shields  
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### Forward-Looking Statements

This announcement may contain forward-looking statements. These statements are based on management’s current estimates and expectations of future events as of the date of the press release. Furthermore, the estimates are subject to several risks and



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uncertainties that could cause actual results to differ materially and adversely from those indicated in or implied by such forward-looking statements.

These risks and uncertainties include, but are not limited to, risks associated with the ability of the Company, its critical vendors, and key regulatory agencies to resume operational capabilities subsequent to the removal of COVID-19 pandemic restrictions; the Company's ability to continue to operate as a going concern; the Company's ability to raise sufficient additional funds to continue operations and to conduct the planned pivotal trial of EndoBarrier in the United States (STEP-1); the Company's ability to maintain compliance with its obligations under its existing convertible note and warrant agreements executed with Crystal Amber, including its obligations to make payment on the convertible note that is due on 15 May 2020 and its ability to restructure the terms of the convertible note with Crystal Amber that is due on 15 May 2020 if the Company is unable to raise sufficient funds to enable it to fully repay such convertible note when due; the Company's ability to execute STEP-1 under the FDA's Investigational Device Exemption; the Company's ability to enlist clinical trial sites and enroll patients in accordance with STEP-1; the risk that the FDA stops STEP-1 early as a result of the occurrence of certain safety events or does not approve an expansion of STEP-1; the Company's ability to enroll patients in accordance with I-STEP; the Company's ability to secure a CE Mark; the Company's obtaining and maintaining regulatory approvals required to market and sell the Company's products; 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; intellectual-property risk; risks related to excess inventory; risks related to assumptions regarding the size of the available market; the benefits of the Company's products; product pricing; timing of product launches; future financial results; and other factors, including those described in the Company's filings with the SEC.

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Given these uncertainties, one should not place undue reliance on these forward-looking statements. The Company does not assume any obligation to publicly update or revise



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any forward-looking statements, whether as a result of new information or future events or otherwise, unless it is 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 March 31, 2020

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)

320 Congress Street, 3<sup>rd</sup> Floor  
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)

Securities registered pursuant to Section 12(b) of the Exchange Act: None

Securities registered pursuant to Section 12(g) of the Exchange Act: Common Stock, \$0.01 par value per share

Title of each class	Trading symbol(s)	Name of each non-U.S. exchange on which registered
Common Stock, par value \$0.01	GID.ASX	Australia Securities Exchange

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 every Interactive Data File required to be submitted 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 such files): Yes  No

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

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

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.

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

The registrant's common stock is publicly traded on the Australian Securities Exchange (the "ASX") in the form of CHESS Depositary Interests ("CDIs") convertible at the option of the holders into shares of the registrant's common stock on a 1-for-50 basis. The total number of shares of the registrant's common stock outstanding on May 1, 2020, including shares of common stock underlying CDIs, was 36,598,291.

## NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements as defined in Section 27A of the United States Securities Act of 1933, as amended, and the Securities Exchange Act of 1934, as amended. These forward-looking statements concern Company business, operations, financial performance and condition as well as plans, objectives and expectations for Company business, operations and financial performance and condition. Any statements contained in this Quarterly Report on Form 10-Q that are not of historical facts may be deemed to be forward-looking statements. The forward-looking statements are contained principally in the section entitled “Management’s Discussion and Analysis of Financial Condition and Results of Operations.” Forward-looking statements include, but are not limited to, statements about the Company’s:

- expectations with respect to the Company’s intellectual property position;
- expectations with respect to clinical trials for EndoBarrier®;
- expectations with respect to regulatory submissions and receipt and maintenance of regulatory approvals;
- ability to commercialize products;
- ability to develop and commercialize new products;
- expectation with regard to product manufacture and inventory; and
- estimates regarding capital requirements and 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,” “vision,” or the negative thereof and similar expressions intended to identify forward-looking statements.

These forward-looking statements are based on current expectations, estimates, forecasts and projections about the Company’s business and the industry in which the Company operates and 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 the Company’s control. As a result, any or all forward-looking statements in this Quarterly Report on Form 10-Q may later become inaccurate. The Company may not actually achieve the plans, intentions or expectations disclosed in the forward-looking statements and actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements made. The Company has 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 the Company’s 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 made by the Company.

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 filed as exhibits to the Company’s Annual Report on Form 10-K completely and with the understanding that actual future results may be materially different from what is stated as expectation. These forward-looking statements speak only as of the date of this Quarterly Report on Form 10-Q. Unless required by law, the Company does 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 described in the reports the Company will file from time to time with the SEC after the date of this Quarterly Report on Form 10-Q.

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**GI DYNAMICS, INC.**  
**QUARTERLY REPORT ON FORM 10-Q**  
**FOR THE QUARTER ENDED MARCH 31, 2020**

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**References**

Unless the context requires otherwise, references in this Quarterly Report on Form 10-Q to “GI Dynamics” and “the Company” refer to GI Dynamics, Inc. and its directly and indirectly consolidated subsidiaries.

**Dates**

Unless indicated otherwise in this Quarterly Report on Form 10-Q, all dates are stated as the date representing business hours in the Eastern Daylight Time zone or Eastern Standard Time zones. Any dates stated in the Australian Eastern Daylight Time zone or the Australian Eastern Standard Time zone will be denoted as “AEDT” or “AEST,” respectively.

**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<sup>®</sup> 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

Consolidated Balance Sheets  
(In thousands, except share and per share amounts)  
(unaudited)

	<u>March 31,</u> <u>2020</u>	<u>December 31,</u> <u>2019</u>
<b>Assets</b>		
Current assets:		
Cash	\$ 3,854	\$ 2,499
Restricted cash	30	30
Prepaid expenses and other current assets	1,377	1,230
Total current assets	<u>5,261</u>	<u>3,759</u>
Property and equipment, net	34	42
Right-of-use assets, net of amortization	352	386
Total assets	<u>\$ 5,647</u>	<u>\$ 4,187</u>
<b>Liabilities and stockholders' deficit</b>		
Current liabilities:		
Accounts payable	\$ 521	\$ 636
Accrued expenses	886	1,353
Short term debt to related party	5,000	5,000
Derivative liabilities	—	10
Short term lease liabilities	170	169
Total current liabilities	<u>6,577</u>	<u>7,168</u>
Long term debt to related party, net of debt discount	1,950	—
Long term lease liabilities	182	217
Total liabilities	<u>8,709</u>	<u>7,385</u>
Commitments and contingencies		
Stockholders' deficit:		
Common stock, \$0.01 par value – 75,000,000 shares authorized; 36,598,291 shares issued and outstanding	366	366
Additional paid-in capital	283,905	280,928
Accumulated deficit	(287,333)	(284,492)
Total stockholders' deficit	<u>(3,062)</u>	<u>(3,198)</u>
Total liabilities and stockholders' deficit	<u>\$ 5,647</u>	<u>\$ 4,187</u>

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

**GI Dynamics, Inc. and Subsidiaries**  
**Consolidated Statements of Operations**  
(In thousands, except share and per share amounts)  
(unaudited)

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2020</b>	<b>2019</b>
Operating expenses:		
Research and development	\$ 1,173	\$ 810
Sales and marketing	—	16
General and administrative	1,543	1,344
Total operating expenses	<u>2,716</u>	<u>2,170</u>
Loss from operations	(2,716)	(2,170)
Other income (expense):		
Interest income	—	3
Interest expense	(284)	(177)
Foreign exchange loss	(10)	(9)
Gain on write-off of accounts payable	—	29
Gain on write-off of accrued product return liability	164	—
Re-measurement of derivative liabilities	—	(1)
Other income	10	—
Other expense, net	<u>(120)</u>	<u>(155)</u>
Loss before income taxes	(2,836)	(2,325)
Provision for income taxes	5	6
Net loss	<u>\$ (2,841)</u>	<u>\$ (2,331)</u>
Basic and diluted net loss per common share	\$ (0.08)	\$ (0.12)
Weighted-average number of common shares used in basic and diluted net loss per common share	36,598,291	19,277,545

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

GI Dynamics, Inc. and Subsidiaries

Consolidated Statements of Changes in Stockholders' Deficit  
(In thousands, except share)  
(unaudited)

THREE MONTHS ENDED MARCH 31, 2020	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Par Value			
Balance at January 1, 2020	36,598,291	\$ 366	\$ 280,928	\$ (284,492)	\$ (3,198)
Stock-based compensation expense	—	—	212	—	212
Relative fair value of warrants and beneficial conversion feature in connection with August 2019 Note	—	—	2,765	—	2,765
Net loss	—	—	—	(2,841)	(2,841)
Balance at March 31, 2020	<u>36,598,291</u>	<u>\$ 366</u>	<u>\$ 283,905</u>	<u>\$ (287,333)</u>	<u>\$ (3,062)</u>

THREE MONTHS ENDED MARCH 31, 2019	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Par Value			
Balance at January 1, 2019	19,277,545	\$ 193	\$ 263,521	\$ (267,159)	\$ (3,445)
Stock-based compensation expense	—	—	59	—	59
Net loss	—	—	—	(2,331)	(2,331)
Balance at March 31, 2019	<u>19,277,545</u>	<u>\$ 193</u>	<u>\$ 263,580</u>	<u>\$ (269,490)</u>	<u>\$ (5,717)</u>

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

**GI Dynamics, Inc. and Subsidiaries**  
**Consolidated Statements of Cash Flows**  
(In thousands)  
(unaudited)

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2020</b>	<b>2019</b>
<b>Operating activities:</b>		
Net loss	\$ (2,841)	\$ (2,331)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	8	8
Re-measurement of derivative liabilities	—	1
Reclassification of warrant from derivative liabilities to other income	(10)	—
Non-cash interest expense	282	175
Stock-based compensation expense	212	59
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(147)	(26)
Accounts payable	(115)	(583)
Accrued expenses	(631)	(768)
Net cash used in operating activities	(3,242)	(3,465)
<b>Investing activities</b>		
Purchases of property and equipment	—	(5)
Net cash used in investing activities	—	(5)
<b>Financing activities</b>		
Debt issuance costs	—	(50)
Proceeds from short term and long term debt, related party	4,597	1,000
Net cash provided by financing activities	4,597	950
Net decrease in cash and restricted cash	1,355	(2,520)
Cash and restricted cash at beginning of period	2,529	3,836
Cash and restricted cash at end of period	\$ 3,884	\$ 1,316
<b>Supplemental disclosures of cash flow information and non-cash activities</b>		
Income taxes paid	\$ 5	\$ 6
Interest paid	—	394
Warrants issuance recorded to APIC and debt discount	2,330	—
Beneficial conversion feature discount associated with August 2019 Note	435	—

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

GI Dynamics, Inc. and Subsidiaries

Notes to Consolidated Financial Statements  
(unaudited)

1. Nature of Business

GI Dynamics<sup>®</sup> is a clinical stage medical device company focused on the development and commercialization of EndoBarrier, a medical device intended to treat patients with type 2 diabetes and to reduce obesity.

Diabetes mellitus type 2 (also known as type 2 diabetes) is a long-term progressive metabolic disorder characterized by high blood sugar, insulin resistance, and reduced insulin production. People with type 2 diabetes represent 90-95% of the worldwide diabetes population; only 5-10% of this population is diagnosed with type 1 diabetes (a form of diabetes mellitus wherein little to no insulin is produced).

Being overweight is a condition where the patient's BMI is greater than 25 (kg/m<sup>2</sup>); obesity is a condition where the patient's BMI is greater than 30. Obesity and its comorbidities contribute to the progression of type 2 diabetes. Many experts believe obesity contributes to higher levels of insulin resistance, which creates a feedback loop that increases the severity of type 2 diabetes.

When considering treatment for type 2 diabetes, it is optimal to address obesity concurrently with diabetes.

***EndoBarrier<sup>®</sup> is intended for the treatment of type 2 diabetes and to reduce obesity in a minimally invasive and reversible manner.***

The current treatment paradigm for type 2 diabetes is lifestyle therapy combined with pharmacological treatment, whereby treating clinicians prescribe a treatment regimen of one to four concurrent medications that could include insulin for patients with higher levels of blood sugar. Insulin carries a significant risk of increased mortality and may contribute to weight gain, which in turn may lead to higher levels of insulin resistance and increased levels of blood sugar. Fewer than 50% of patients treated pharmacologically for type 2 diabetes are adequately managed, meaning that medication does not lower blood sugar adequately and does not halt the progressive nature of diabetes of these patients.

***The current pharmacological treatment algorithms for type 2 diabetes fall short of ideal, creating a large and unfilled efficacy gap.***

The GI Dynamics vision is to make EndoBarrier the essential nonpharmacological and non-anatomy-altering treatment for patients with type 2 diabetes. The Company intends to achieve this vision by providing a safe and effective device, focusing on optimal patient care, supporting treating clinicians, adding to the extensive body of clinical evidence around EndoBarrier, gaining appropriate regulatory approvals, continuing to improve its products and systems, operating the Company in a lean fashion, and maximizing stockholder value.

EndoBarrier<sup>®</sup> is intended for the treatment of type 2 diabetes and to reduce obesity in a minimally invasive and reversible manner and is designed to mimic the mechanism of action of duodenal-jejunal exclusion created by gastric bypass surgery.

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.

## Going Concern Evaluation

As of March 31, 2020, the Company's primary source of liquidity is its cash and restricted cash balances. GI Dynamics is currently focused primarily on its clinical trials, which will support future regulatory submissions and potential commercialization activities. Until the Company is successful in gaining regulatory approvals, it is unable to sell the Company's product in any market at this time. Without revenues, GI Dynamics is reliant on funding obtained from investment in the Company to maintain business operations until the Company can generate positive cash flows from operations. The Company cannot predict the extent of future operating losses and accumulated deficit, and it may never generate sufficient revenues to achieve or sustain profitability.

GI Dynamics has incurred operating losses since inception and at March 31, 2020, had an accumulated deficit of approximately \$287 million and a working capital deficit of \$1.3 million. The Company expects to incur significant operating losses for the next several years. At March 31, 2020, the Company had approximately \$3.9 million in cash and restricted cash.

The Company will need to restructure the terms of the Senior Secured Convertible Promissory Note, issued on June 15, 2017 (as amended from time to time, the "2017 Note"), before May 15, 2020 or the 2017 Note will be in default and subject to a call notice at the discretion of Crystal Amber. If the 2017 Note terms are restructured or the note is not called, the Company must raise additional capital before May 31, 2020 in order to continue to pursue its current business objectives as planned and to continue to fund its operations. The Company and Crystal Amber Fund Limited ("Crystal Amber", a Related Party for ASX purposes) are currently in discussions regarding the 2017 Note maturity extension. 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 guarantee that the 2017 Note will be restructured or if in default, will not be called. If the Note is called, the Company has no guaranteed source of capital that will accommodate repayment of the 2017 Note. If the 2017 Note terms are restructured or the 2017 Note is in default, but not called, the Company anticipates that operating cash will be exhausted by May 31, 2020 and therefore additional financing will be required to be able to continue its operations after this date. There can be no assurance that any potential financing opportunities will be available on acceptable terms, if at all. If the Company is unable to raise sufficient capital on the Company's required timelines and on acceptable terms to stockholders and the Board of Directors, it could be forced to reduce or cease operations, including activities essential to support regulatory applications to commercialize EndoBarrier. If access to capital is not achieved before May 31, 2020, it will materially harm the Company's business, financial condition and results of operations to the extent that the Company may be required to cease operations altogether, file for bankruptcy, or undertake any combination of the foregoing.

In addition, if the Company does not meet its payment obligations to third parties as they become due, the Company may be subject to litigation claims and its credit worthiness would be adversely affected. Even if the Company is successful in defending 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 the Company's financial condition.

These factors raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that these consolidated financial statements are issued.

The accompanying consolidated financial statements have been prepared assuming GI Dynamics will continue as a going concern, which contemplates the realization of assets and liabilities and commitments in the normal course of business. The accompanying consolidated financial statements 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. Significant Accounting Policies and Basis of Presentation

The consolidated financial statements and related notes have been prepared pursuant to the rules and regulations of the Securities and Exchange Commission (the "SEC"). Accordingly, certain information and footnote disclosures normally included in complete financial statements prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP") have been omitted pursuant to such rules and regulations. These interim consolidated financial statements and related notes should be read in conjunction with the audited consolidated financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2019 filed with the SEC on March 27, 2020. The Company's balance sheet at December 31, 2019 has been derived from the audited financial statements at that date but does not include all the information and footnotes required by GAAP for complete financial statements.

In our opinion, the consolidated financial statements included herein contain all adjustments necessary to present fairly our financial position as of March 31, 2020 and the results of our operations and cash flows for the three months ended March 31, 2020 and 2019. Such adjustments are of a normal recurring nature. In addition, certain reclassifications of prior period balances have been made to conform to the current period presentation.

### Recently Adopted Accounting Pronouncements

In August 2018, the FASB issued ASU No. 2018-13, *Fair Value Measurement (Topic 820), Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement*, or ASU 2018-13, which provides guidance focused on the disclosure requirements for disclosing fair value estimates, assumptions, and methodology. Requirements removed include the requirement to disclose details around amount and reasoning for level 1 to level 2 transfers, timing policies for transfer between levels and the valuation processes for level 3 fair value measurements. Modified requirements include details regarding net asset redemption restrictions and timing related to uncertainty disclosures. Requirements added include disclosures of changes in unrealized gains and losses for recurring level 3 measurements held as of the reporting date and disclosures around the range and weighted average of significant inputs used to develop level 3 fair value measurements. These amendments are effective for all entities for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019. The amendments on changes in unrealized gains and losses, the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements and the narrative description of measurement uncertainty should be applied prospectively for only the most recent interim or annual period presented in the initial fiscal year of adoption. All other amendments should be applied retrospectively to all periods presented upon their effective date. Early adoption was permitted upon issuance of this update, however the Company has declined early adoption. The Company adopted this ASU on January 1, 2020 and concluded that it had no impact on its consolidated financial statements.

### 3. Net Loss per Common Share

Basic net loss per common share is computed by dividing net loss by the weighted-average number of common shares outstanding during the period. Potential common stock equivalents are determined using the treasury stock method. For diluted net loss per share purposes, stock options and other stock-based awards are excluded, 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. For diluted net loss per share purposes, derivatives to purchase shares of common stock or CDIs are treated identically because shares of common stock and CDIs are interchangeable at the sole election of the stockholder. For diluted net loss per share purposes, options and warrants conferring the right to purchase shares of common stock or CDIs are excluded from diluted net loss per share calculations as inclusion would have an anti-dilutive effect. During the three months ended March 31, 2020 and 2019, common stock equivalents were excluded from the calculation of diluted net loss per common share, as their effect was anti-dilutive due to the net loss incurred. Therefore, basic and diluted net loss per share was the same in all periods presented.

The following potentially dilutive securities have been excluded from the computation of diluted weighted- average shares outstanding as of March 31, 2020 and 2019, as they would be anti-dilutive:

	Three Months Ended March 31,	
	2020	2019
Warrants to purchase common stock	4,625,425	3,552,672
Options to purchase common stock and other stock-based awards	3,376,154	1,545,719
<b>Total</b>	<b>8,001,579</b>	<b>5,098,391</b>

#### 4. Warrants to Purchase Common Stock or CDIs

The following series of warrants were outstanding and exercisable at March 31, 2020 and 2019 (warrants to purchase CDIs presented as shares at a 50 CDI per share ratio):

Warrant Series	Issue Date	Number of underlying shares	Exercise price per share	March 31,	
				2020	2019
Consultant warrant	May 4, 2016	28,532	\$ 0.64	28,532	28,532
2018 Warrant (1)	May 24, 2018	1,944,444	\$ 0.72	-	1,944,444
August 2019 Warrant (2)	January 13, 2020	4,596,893	\$ 1.00	4,596,893	-
Total Outstanding and Exercisable				4,625,425	1,972,976
Weighted average exercise price				\$ 1.00	\$ 0.72

(1) Exercise price was initially \$0.90 per share, but was adjusted to \$0.72 in November 2018

(2) Financing arranged August 2019, but funding did not occur until January 13, 2020

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") 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 is fully vested and expires on May 4, 2021. As of March 31, 2019, the Consultant Warrants had not been exercised.

On August 21, 2019, GI Dynamics and Crystal Amber entered into a securities purchase agreement for a total funding of up to approximately \$10 million (the "August 2019 SPA") comprised of the scheduled exercise of the 2018 Warrant, the March 2019 Warrant, and the May 2019 Warrant (totaling 8,248,549 shares of common stock purchased for approximately \$5.4 million) and the issue and sale of an Unsecured Convertible Note for up to approximately \$4.6 million (the "August 2019 Note"), which included an agreement to issue a warrant (the "August 2019 Warrant") to purchase up to 229,844,650 CDIs (representing 4,596,893 shares of common stock) for an exercise price of \$0.02 per CDI issued on exercise. On December 16, 2019, stockholders approved the issuance of the August 2019 Warrant, which was then issued on January 13, 2020.

## 5. Fair Value Measurements

The tables below present information about the Company's assets and liabilities that are measured at fair value on a recurring basis as of March 31, 2020 and December 31, 2019 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.

On March 31, 2020, the classification of the Consultant Warrant was reevaluated and the Company re-classified it as an equity instrument. On March 31, 2020, this reclassification resulted in a credit to Other Income.

Cash, restricted cash, prepaid expenses and other current assets, accounts payable, accrued expenses, short-term debt to related party and other current liabilities at March 31, 2020 and December 31, 2019 are carried at amounts that approximate fair value due to their short-term maturities and highly liquid nature of these instruments.

## 6. Concentrations of Credit Risk and Related Valuation Account

Financial instruments that subject GI Dynamics to credit risk primarily consist of cash and restricted cash. Cash balances are maintained with high quality financial institutions, and consequently, the Company believes that such funds are subject to minimal credit risk. The Company's short-term investments potentially subject the Company to concentrations of credit risk. GI Dynamics has adopted an investment policy that limits the amounts it may invest in any one type of investment and requires all held investments to hold at least an A rating from a recognized credit rating agency, thereby reducing credit risk concentration.

## 7. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	March 31, 2020	December 31, 2019
Payroll and related liabilities	\$ 188	\$ 531
Professional fees	176	335
Credit refunds	—	164
Interest payable	415	250
Other	107	73
Total	<u>\$ 886</u>	<u>\$ 1,353</u>

In 2017, following notification by the Medicines and Healthcare Products Regulatory Agency ("MHRA"), the Company notified its customers to return their inventory on hand. The Company calculated an estimate for returns, reversed its revenue and recorded an accrued expense estimate of \$202 thousand of product return related costs in addition to \$77 thousand of credit memos granted to customers. Through December 31, 2019, this reserve had various claims and adjustments of \$115 thousand. On March 31, 2020, the Company reversed the remaining accrual for \$164 thousand and recognized Other Income as the Company concluded that the likelihood that further claims will be made was remote, given the amount of time without such claims after product expiry.

In December 2018, the maturity of the 2017 Note was extended to March 31, 2019 in exchange for payment of \$394 thousand, which was the total accrued interest on the 2017 Note at December 31, 2018. Accrued interest at March 31, 2020 includes interest on the 2017 Note since January 1, 2019 and the August 2019 Note since January 13, 2020.

## 8. Notes Payable

### *2017 Convertible Note Financing*

On June 15, 2017, the Company entered into a Note Purchase Agreement (“2017 NPA”) by and between the Company and Crystal Amber, a Related Party. Pursuant to the 2017 NPA, the Company issued and sold to Crystal Amber, a Senior Secured Convertible Promissory Note in an aggregate original principal amount of \$5.0 million (the “2017 Note”).

The 2017 Note accrues interest at an annually compounded rate of 5% per annum, other than during the continuance of an event of default, when the 2017 Note accrues interest at a rate of 8% per annum. The entire outstanding principal balance and all unpaid accrued interest thereon was initially due on the original maturity date of December 31, 2018, and, as amended, is currently scheduled to mature on May 15, 2020.

The 2017 Note is secured by a first priority security interest in substantially all tangible and intangible assets of the Company, including intellectual property (the “Collateral”). In the event of an uncured default, Crystal Amber, is authorized to sell, transfer, assign or otherwise deal in or with the Collateral or the proceeds thereof or any related goods securing the Collateral, as fully and effectually as if Crystal Amber were the absolute owner thereof.

The ASX provided the Company with a waiver to allow all asset liens (the “Security”) to be granted to Crystal Amber, without the customary requirement of having to obtain stockholder approval for the grant of a security to a Related Party of the Company. As a result of the waiver, the Security contains a provision that provides that if an event of default occurs and Crystal Amber exercises its rights under the Security, neither Crystal Amber nor any of its associates can acquire any legal or beneficial interest in an asset of the Company or its subsidiaries in full or partial satisfaction of the Company’s obligations under the Security, or otherwise deal with the assets of the Company or its subsidiaries, without the Company first having complied with any applicable ASX Listing Rules, including ASX Listing Rule 10.1, other than as required by law or through a receiver, manager, or analogous person appointed by Crystal Amber exercising its power of sale under the Security and selling the assets to an unrelated third party on arm’s length commercial terms and conditions and distributing the cash proceeds to Crystal Amber or any of its associates in accordance with their legal entitlements.

The entire outstanding principal balance under the 2017 Note and all unpaid accrued interest thereon is convertible into CDIs (i) prior to the maturity date, at the option of Crystal Amber at a conversion price calculated based on the five-day volume weighted average price of the Company’s CDIs traded on the ASX (“Optional Conversion Price”), or (ii) automatically upon the occurrence of an equity financing in which the Company raises at least \$10 million (a “Qualified Financing”) at the price per CDI of the CDIs issued and sold in such financing.

In the event that the Company issues additional CDIs in a subsequent equity financing at a price per CDI that is less than the then-effective Optional Conversion Price, Crystal Amber has a 30-day option to convert at an adjusted conversion price reflecting, on a weighted average basis, the lower price per CDI. The number of CDIs that Crystal Amber may acquire upon conversion of the 2017 Note at this adjusted conversion price is limited to the number that maintains Crystal Amber’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 under the 2017 Note to pay all accrued and unpaid interest then due plus 110% of the remaining outstanding unconverted principal balance. If the change of control results in non-cash consideration, Crystal Amber may convert the entire outstanding principal balance under the 2017 Note and all unpaid accrued interest then due into CDIs at the abovementioned Optional Conversion Price. Other than as described above, the Company may not prepay the 2017 Note without the consent of Crystal Amber. The Company considers the change in control premium as a cash settleable feature, thereby requiring derivative liability classification. On applying a probability adjusted present value of the premium, the fair value was considered immaterial upon issuance and at all subsequent reporting period ends.

The 2017 NPA contains customary events of default including a failure to perform obligations under the 2017 NPA, 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 2017 Note may be accelerated. The 2017 NPA and related 2017 Note documents also contain additional representations and warranties, covenants and conditions, in each case customary for transactions of this type.

For the three months ended March 31, 2020 and 2019, the Company recognized interest expense of \$65 and \$62 thousand, respectively, related to the 2017 Note.

#### *August 2019 Securities Purchase Agreement*

On August 21, 2019, the Company entered into the August 2019 SPA by and between the Company and Crystal Amber. The August 2019 SPA detailed a timeline wherein Crystal Amber would exercise the 2018 Warrant, the March 2019 Warrant, and the May 2019 Warrant. Additionally, pursuant to the August 2019 SPA, the Company issued and sold to Crystal Amber a senior unsecured convertible promissory note in an aggregate principal amount of approximately \$4.6 million, or such lesser amount as may be set forth in a notice delivered by the Company to Crystal Amber (the "August 2019 Note"), to be funded on December 6, 2019, or such earlier or later date as may be requested by the Company (the "Funding Date"). In conjunction with the August 2019 Note, the Company agreed to issue to Crystal Amber a Warrant (the "August 2019 Warrant") to purchase CDIs, subject to the receipt of required stockholder approval approving the issuance of the August 2019 Warrant and the funding of the August 2019 Note (see Note 4).

The August 2019 Note accrues interest at a rate equal to 10% per annum from the August 2019 Note Funding Date, compounded annually, other than during the continuance of an event of default, when the August 2019 Note accrues interest at a rate of 16% per annum. The entire outstanding principal balance and all unpaid accrued interest thereon is due on the fifth anniversary of the Funding Date. The entire outstanding principal balance under the August 2019 Note and all unpaid accrued interest thereon is immediately convertible into CDIs at the option of Crystal Amber at a conversion price equal to US\$0.02 per CDI. In the event that the Company issues additional CDIs to a stockholder other than Crystal Amber in a subsequent equity financing at a price per CDI that is less than the conversion price under the August 2019 Note, the conversion price shall be reduced to the lowest such price per CDI. In addition, upon a change of control of the Company resulting in cash proceeds, Crystal Amber may, at its option, demand that the Company prepay all accrued and unpaid interest plus 110% of the remaining outstanding unconverted principal balance. The Company may not prepay the August 2019 Note without the consent of Crystal Amber, a Related Party. If the stockholder approvals required to issue the August 2019 Warrant or to approve the conversion rights under the August 2019 Note are 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 Funding Date or the date that is six months following the date of the stockholder meeting at which the requisite approvals were not obtained. The Company considers the change in control premium and the stockholder approval premium to each represent a cash settleable feature, thereby requiring derivative liability classification. On applying a probability adjusted present value of the premiums, the fair value was considered immaterial upon issuance and through the end of this reporting period.

The August 2019 SPA contains customary events of default. If a default occurs and is not cured within the applicable cure period or is not waived, any outstanding obligations under the August 2019 Note may be accelerated. The August 2019 SPA and related August 2019 Note and August 2019 Warrant documents also contain additional representations and warranties, covenants and conditions, in each case customary for transactions of this type.

Prior to December 6, 2019, the Company notified Crystal Amber that it had elected to receive the full amount of approximately \$4.6 million under the August 2019 Note, but agreed to timing extensions.

On December 16, 2019, stockholder approval was obtained pursuant to ASX Listing Rule 10.11, for the August 2019 Note conversion feature and the issuance of the August 2019 Warrant, contingent on receipt of the August 2019 Note proceeds.

On January 13, 2020, the full amount of approximately \$4.6 million was received as proceeds from the August 2019 Note. On receipt of funds, the August 2019 Note was immediately convertible. On January 13, 2020, the Company issued to Crystal Amber an immediately exercisable August 2019 Warrant to purchase 229,844,650 CDIs (representing 4,596,893 shares of common stock) for an exercise price of \$0.02 per CDI (see Note 4).

On issuance, having already obtained the required stockholder approval to reserve the CDIs underlying the conversion feature and the August 2019 Warrant, the August 2019 Warrant was determined to be a freestanding instrument meeting the requirements for equity classification in accordance with ASC 480-10 *Distinguishing Liabilities from Equity*, ASC 815-40 *Contracts in an Entity's Own Equity* and ASC 470-20 *Debt with Conversion and Other Options*. Accordingly, proceeds from the August 2019 SPA were allocated to the August 2019 Note and Warrant based on their relative fair values. The relative fair value of the August 2019 Warrant of approximately \$2.3 million was recorded as a debt discount with the offset to additional paid-in capital. Additionally, the Company analyzed the conversion features of the August 2019 Note to determine whether a beneficial conversion feature (BCF) existed. The Company determined a BCF with a value of \$435 thousand existed and was recorded as a debt discount with the offset to additional paid-in capital. The total debt discount will be amortized to interest expense through the January 2025 maturity of the August 2019 Note.

For the three months ended March 31, 2020, the Company recorded \$98 thousand of accrued interest expense. For the three months ended March 31, 2020, the Company recognized interest expense of \$100 thousand from the amortization of the debt discount.

## **9. Commitments and Contingencies**

### **Lease Commitments**

In December 2018, the Company entered into a 6-month membership agreement with WeWork for 985 square feet of office space located in Boston, Massachusetts. The committed lease term expired in May 2019. The WeWork agreement contained no explicit or guaranteed extension provisions.

On April 22, 2019, the Company entered into a right-of-use lease for 3,520 square feet of office space in Boston, Massachusetts. The lease period contractually commenced June 1, 2019 and expires on May 31, 2022, but the space was available for occupancy on May 1, 2019 resulting in an effective period of May 2019 through May 2022, with no rent payment assessed in May 2019. The lease has defined escalating rent payments and contains no extension or expansion rights. On lease execution, the Company recorded the approximately \$463 thousand present value of the lease liability in short-term and long-term liabilities and recorded a related right-of-use asset. The right-of-use asset will be amortized to lease expense and the liability will be reduced by the rent payments over the term of the lease.

The Company's leases generally do not provide an implicit interest rate and therefore the Company uses 10% as an estimate of its incremental borrowing rate as the discount rate when measuring operating lease liabilities. The incremental borrowing rate represents an estimate of the interest rate the Company would incur at lease commencement to borrow an amount equal to the lease payments on a collateralized basis over the term of a lease in a similar economic environment. The Company had no leases currently classified as finance leases or previously classified as capital leases in either reporting period.

The Company's operating lease is reflected in the balance sheets. In the three months ended March 31, 2020, \$44 thousand of lease expense was incurred and an additional \$3 thousand of tax expense was accrued for property taxes associated with the leased facility. Other information related to leases was as follows (in 2019, leases were all short term and excluded from the adoption of ASU 2016-2):

	<b>Three Months Ended March 31,</b>	
	<b>2020</b>	<b>2019</b>
	<b>(in thousands)</b>	
Operating cash flows from operating leases in lease liability measurement	\$ 53	\$ —
Operating cash flows from short term leases	44	—
Remaining long-term lease term in years	2.2	—
Discount rate	10%	—

The maturity of the Company's operating lease liability as of March 31, 2020 is as follows:

	<b>March 31, 2020</b>
	<b>(in thousands)</b>
2020	134
2021	182
2022	76
Total future minimum lease payments	392
Less: imputed interest	40
Total liabilities	\$ 352

Rent expense on non-cancelable operating leases was approximately \$44 and \$56 thousand for the three months ended March 31, 2020 and 2019, respectively.

#### 10. Stockholders' Deficit

On December 19, 2019, GI Dynamics stockholders approved an increase of its authorized shares of common stock from 50 million to 75 million.

As of March 31, 2020, the authorized capital stock of the Company consists of 75.5 million shares, of which 75 million shares are designated as common stock and 500 thousand shares are designated as preferred stock.

#### 11. Share-Based Compensation

The Company has two stock-based compensation plans. The Board of Directors adopted the 2003 Omnibus Stock Plan (the "2003 Plan"), which provides for the grant of qualified incentive stock options and nonqualified stock options or other awards to the Company's employees, officers, directors, advisors, and outside consultants to purchase up to an aggregate of 922,086 shares of the Company's common stock.

In August 2011, the Board of Directors adopted the 2011 Employee, Director and Consultant Equity Incentive Plan (the "2011 Plan", together with the 2003 Plan, the "Plans") as the successor to the 2003 Plan. Under the 2011 Plan, the Company may grant incentive stock options, nonqualified stock options, restricted and unrestricted stock awards and other stock-based awards. As of March 31, 2020, an additional 554,866 shares of common stock were available for grant under the Company's 2011 Plan.

In addition, the 2011 Plan allows for an annual increase in the number of shares available for issue under the 2011 Plan commencing on the first day of each fiscal year during the period beginning in fiscal year 2012 and ending in fiscal year 2020. The annual increase in the number of shares shall be equal to the lowest of:

- 500 thousand shares;
- 4% of the number of common shares outstanding as of such date; and
- an amount determined by the Board of Directors or the Company's compensation committee. Accordingly, during the quarters ended March 31, 2020 and March 31, 2019, 500 thousand shares were added to the 2011 Plan.

## Stock-Based Compensation

Stock-based compensation is reflected in the consolidated statements of operations as follows for the three months ended March 31, 2020 and 2019 (in thousands):

	Three Months Ended March 31,	
	2020	2019
Research and development	\$ 13	\$ 16
General and administrative	199	43
	<u>\$ 212</u>	<u>\$ 59</u>

The stock options granted under the Plans generally vest over a four-year period and expire ten years from the date of grant.

The weighted-average assumptions used to estimate the fair value of employee stock options using the Black-Scholes option-pricing model were as follows for the three months ended March 31, 2020 and 2019:

	Three Months Ended March 31,	
	2020	2019
Expected volatility	164.9%	122.0%
Expected term (in years)	5.84	6.05
Risk-free interest rate	0.9%	2.3%
Expected dividend yield	0%	0%

## Stock Options

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

	Shares of Common Stock Attributable to Options	Weighted- Average Exercise Price	Weighted- Average Contractual Life <i>(in years)</i>	Aggregate Intrinsic Value <i>(in thousands)</i>
<b>Outstanding at December 31, 2019</b>	3,096,154	\$ 1.47	8.3	\$ —
Granted	90,000	\$ 0.25		\$ —
Cancelled	(60,000)	\$ 0.74		\$ —
<b>Outstanding at March 31, 2020</b>	<u>3,126,154</u>	<u>\$ 1.46</u>	<u>8.6</u>	<u>\$ —</u>
Vested or expected to vest at March 31, 2020	<u>3,126,154</u>			
Exercisable at March 31, 2020	<u>781,360</u>	<u>\$ 1.46</u>	<u>6.7</u>	

The majority of the Company's option grants vest 25% on the first anniversary of the grant date, and in a quarterly straight-line rate thereafter until fully vested on the fourth anniversary of the grant date. The weighted average grant date fair value for options granted in the three-month period ended March 31, 2020, was \$0.18. The unrecognized stock compensation expense at March 31, 2020 was \$2.0 million and was expected to be recognized over a weighted average period of 3.07 years from March 31, 2020.

The Company has recorded non-employee stock-based compensation expense of approximately \$50 thousand and \$4 thousand during the three-month period ended March 31, 2020 and 2019, respectively, which is included in total stock-based compensation expense. The unrecognized compensation expense associated with outstanding non-employee grants was \$119 and \$21 thousand at March 31, 2020 and 2019, respectively.

On February 28, 2020, the Company's Board of Directors approved, subject to stockholder approval per ASX Listing Rule 10.14, the grant of stock options ("NED Options") conferring the right to purchase up to 30,000 shares of the Company's common stock to Praveen Tyle, a non-executive director pursuant to the Company's 2011 Plan. The exercise price is \$0.20 per share of common stock and the NED Options will vest in full on February 28, 2021 if Dr. Tyle remains a director of the Company through that date. The NED Options will vest immediately on a change in control event. The NED Options are immediately exercisable, subject to repurchase rights if purchased prior to vesting. The NED Options will be cancelled immediately upon termination of service as a director, unless such termination is the result of a defined change in control event, in which case the NED Options will be cancelled 12 months after such termination. As of March 31, 2020, stockholders had not yet approved the NED Options.

On February 15, 2020, the Company granted a consultant an option to purchase up to 10 thousand shares of common stock at a price of \$0.40 per share. The option vests in equal monthly amounts over a 24-month period and expires in 10 years.

At March 31, 2020, the Company had unvested outstanding options to purchase 167,673 shares of common stock granted to non-employees.

#### Performance Stock Units

Each performance stock unit ("PSU") represents a contingent right to receive one share of the Company's common stock. There is no consideration payable on the vesting of PSUs issued under the Plans. Upon vesting, the PSUs are exercised automatically and settled in shares of the Company's common stock. During the three months ended March 31, 2020, the Company awarded no PSUs to employees and directors of the Company.

The following table summarizes information related to PSU activity for the three months ended March 31, 2020:

	<u>Number of Units</u>	<u>Weighted- Average Contractual Life</u> <i>(in years)</i>	<u>Aggregate Intrinsic Value</u> <i>(in thousands)</i>
<b>Outstanding at December 31, 2019</b>	250,000	6.23	\$ 149
Granted	—		
Exercised	—		
Cancelled	—		
<b>Outstanding at March 31, 2020</b>	<u>250,000</u>	<u>5.98</u>	<u>\$ 23</u>

The aggregate intrinsic value at March 31, 2020 noted in the table above represents the closing price of the Company's common stock multiplied by the number of PSUs outstanding. The fair value of each PSU award equals the closing price of the Company's common stock on the date of grant.

At March 31, 2020, 250,000 of the PSUs outstanding vest on the achievement of certain milestones. When achievement of the milestone is deemed probable, the Company will expense the compensation of the respective stock award over the implicit service period.

At March 31, 2020, the Company recognized no stock-based compensation related to performance-based vesting of PSUs.

As of March 31, 2020, there was approximately \$200 thousand of unrecognized stock-based compensation expense related to non-vested PSU awards that have performance-based vesting.

## **12. 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**

The Company has historically reported various geographic segments but does not do so currently as the right-of-use asset of approximately \$463 thousand and all long-lived assets, comprised of property and equipment of approximately \$34 thousand are all held in the U.S. at March 31, 2020. Additionally, the Company did not have revenue in any geography for the three months ended March 31, 2020 and 2019, respectively.

### **Major Customers**

The Company did not recognize any revenue for the three months ended March 31, 2020 and 2019, respectively.

## **13. Subsequent Events**

On March 27, 2020, the CARES Act was signed into law in the United States providing economic assistance for American workers and families, small businesses, and preserves jobs for American industries. GI Dynamics qualifies for the Payroll Protection Program ("PPP") administered by the United States Small Business Administration ("SBA") and existing lending institutions. On April 4, 2020, GI Dynamics submitted an application to a lending institution for a loan of approximately \$200 thousand under the PPP. In accordance with the provisions of the PPP, the loan accrues interest at a rate of 1% and all or a portion of the loan may be forgiven if it is used to pay for qualifying costs such as payroll, rent and utilities. Amounts that are not forgiven will be repaid 2 years from the date of the loan. Due to backlog, the application was not received by the SBA before funding for the CARES Act was exhausted. Additional CARES Act funds were allocated on April 23, 2020 and GI Dynamics was notified by our lending institution that the application was approved by the SBA on April 30, 2020.

The Company announced on May 3, 2020 that it reached an agreement with Crystal Amber to extend the maturity date of the 2017 Note from May 1, 2020 to May 15, 2020.

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

### Forward-Looking Information

*The following discussion and analysis of the Company's financial condition and results of operations should be read in conjunction with the 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, 2019 included in the Company's 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 the Company's Annual Report on Form 10-K, which are incorporated herein by reference, 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

GI Dynamics is a clinical stage medical device company located in Boston, Massachusetts. The Company has developed EndoBarrier, a medical device intended to treat patients with type 2 diabetes and to reduce obesity. GI Dynamics is taking the steps necessary to obtain the regulatory approvals required to market this product. In order to market EndoBarrier in the U.S., GI Dynamics must obtain approval from the FDA. In order to market EndoBarrier outside of the U.S., GI Dynamics is required to comply with various regulations imposed by the countries in which it seeks to sell the product.

In 2010, EndoBarrier received CE Marking for sale in the European Union and in 2011, EndoBarrier was listed on the Australian Register of Therapeutic Goods. As a result, during 2013 and 2014, the Company received approximately \$2.8 million and \$2.3 million, respectively, in revenue from the sale of EndoBarrier in Europe, South America and the Asia Pacific region. In the U.S. in 2013, the Company began enrollment of patients in the initial pivotal trial of EndoBarrier, which is referred to as the ENDO trial.

In the third quarter of 2015, the Company announced its decision to discontinue the ENDO trial because patients were experiencing a higher than previously observed level of hepatic (liver) abscesses. In the fourth quarter of 2016, GI Dynamics received formal notification from the TGA of the Australian government of the cancellation of EndoBarrier's inclusion on the ARTG. In the fourth quarter of 2017 the Company received formal notification of CE mark withdrawal from its notified body in Europe, preventing the sale of EndoBarrier in Europe and select Middle Eastern countries. The Company undertook comprehensive cost-cutting measures throughout 2015 and 2016, including significantly reducing the number of its employees.

Following the decision to discontinue the ENDO trial, GI Dynamics undertook significant investigational and scientific analyses with the goal of reducing the incidence rate and severity of hepatic abscess concurrent with the EndoBarrier treatment. This investigational work focused on understanding the root cause of hepatic abscess and how to reduce the rate of occurrence. This included: DNA analysis of normal EndoBarrier removals as well as hepatic abscess EndoBarrier removals, numerous meta-analyses and responder cohort analyses, investigation into the contributing factors represented by proton pump inhibitors (PPIs), leaky gut syndrome and microbiome analyses, among other research. This allowed the Company to modify the medications utilized with EndoBarrier, most notably discontinuation of chronic double-dose PPI usage during EndoBarrier implant.

As a result of the efforts described above, in August 2018, GI Dynamics received an IDE from the FDA to begin enrollment in a pivotal trial evaluating the safety and efficacy of EndoBarrier in the United States pending IRB approval, which was received on February 13, 2019. In this report, the Company refers to this pivotal trial as the GI Dynamics STEP-1 clinical trial. On January 27, 2020, the first patient was randomized into the STEP-1 Trial Protocol.

For financial reporting purposes, the Company have one reportable segment, which designs, manufactures and plans to market EndoBarrier.

To date, GI Dynamics has devoted substantially all of its efforts to research and development, business planning, clinical research, clinical study management, reimbursement development, product commercialization, acquiring operating assets and raising capital. GI Dynamics has incurred significant operating losses since its inception in 2003. As of March 31, 2020, the Company had an accumulated deficit of approximately \$287 million. The Company expects to incur net losses for the next several years while it continues to evaluate which markets are appropriate to continue pursuing reimbursement, market awareness and general market development efforts, and continues to restructure its business and costs, establish new priorities, continue limited research, and evaluate strategic options.

GI Dynamics has raised net proceeds of approximately \$278 million through sales of the Company's equity and placement of debt, of which \$9.3 million was raised through the Company's 2019 financings.

On August 21, 2019, the Company and Crystal Amber entered into a securities purchase agreement for a total funding of up to approximately \$10 million (the "August 2019 SPA"). The initial \$5.4 million was comprised of existing warrant exercises scheduled between August 25, 2019 and November 15, 2019. The remaining amount of the August 2019 funding was represented by a Convertible Term Promissory Note ("August 2019 Note") of up to approximately \$4.6 million and a related Warrant ("August 2019 Warrant"). Under the terms of the August 2019 SPA and August 2019 Note, the Company, at its sole discretion, could elect to request any of the \$4.6 million to be funded at any date on or before December 6, 2019. The conversion feature allows the conversion of the August 2019 Note's unpaid principal and interest at \$0.02 per CDI and the August 2019 Warrant, upon its issue, allowed the purchase for \$0.02 per CDI a number of CDIs represented by the August 2019 Note principal divided by \$0.02 per CDI.

On August 21, 2019, the maturity date of the 2017 Note was extended to March 31, 2020.

On March 31, 2020, the maturity date of the 2017 Note was extended to May 1, 2020.

On December 2, 2019, GI Dynamics provided notice to Crystal Amber that the Company elected to place the August 2019 Note at the full amount, on or before December 6, 2019. In December, the Company and Crystal Amber agreed to confer the right to tranche the funding of the August 2019 Note in amounts and per timing chosen solely by Crystal Amber, provided the August 2019 Note total was funded on or before January 15, 2020.

On December 16, 2019, GI Dynamics' stockholders approved the August 2019 Note conversion feature and the issuance of the August 2019 Warrant, pending funding of the August 2019 Note by Crystal Amber.

On January 13, 2020, GI Dynamics received approximately \$4.6 million in cash representing the full funding of the August 2019 Note. As stockholder approval had been obtained in December 2019, the August 2019 Note became convertible at Crystal Amber's sole discretion until maturity in January 2025. Additionally, the August 2019 Warrant was issued to Crystal Amber, providing for the purchase of up to 229,844,650 CDIs (representing 4,596,893 shares of common stock) at \$0.02 per CDI.

The Company's costs include employee salaries and benefits, compensation paid to consultants, materials and supplies for research, costs associated with development activities including materials, sub-contractors, travel and administration, legal expenses, sales and marketing costs, general and administrative expenses, and other costs associated with an early stage, publicly-traded medical technology company. As of March 31, 2020, GI Dynamics has 15 full-time employees. The number of employees required to support the Company's activities as it moves the EndoBarrier through the GI Dynamics STEP-1 clinical trial, as well as in the areas of research and development, sales and marketing, and general and administrative functions, may increase. GI Dynamics expects to continue to incur consulting expenses related to technology development that will increase as it enters into the recruitment phase of the STEP-1 and India clinical trials, and the Company expects to continue to incur expenses to protect its intellectual property.

On March 11, 2020, the World Health Organization declared the outbreak of a coronavirus (COVID-19) a pandemic. As a result, economic uncertainties have arisen which, as of March 31, 2020, have negatively impacted GI Dynamics short term-operations, for example in delays in timing of regulatory audits and other key operational activities due to widespread sequestration and in facing enrollment pauses in our clinical trials due to the clinic-level restriction of elective procedures, for which EndoBarrier implantation qualifies. When operational activities are delayed, expenditures on certain items may decrease, such as travel. There is no certainty which reduced expenditures will result in higher than usual expenditures as activities resume and which will return to the expected rate. If the restrictions are limited in duration, the Company anticipates an ability to overcome delays and return to original timing estimates, but there can be no guarantee the duration and operational impact will be limited to the degree required. Additionally, market-level impacts may affect the timing or the negotiation of terms in the Company's financing efforts. These and other financial impacts that could occur may appear as positive or negative impacts to the Company's future financial statements.

The amount that GI Dynamics spends for any specific purpose may vary significantly from quarter to quarter or year to year, and could depend on a number of factors including, but not limited to, the pace of progress of the GI Dynamics STEP-1 and India clinical trials, commercialization and development efforts and actual needs with respect to development and research.

Research, development, and commercial acceptance of new medical technologies are, by their nature, unpredictable. Although the Company will undertake development and commercialization efforts with reasonable diligence, there can be no assurance that the net proceeds from the Company's securities offerings will be sufficient to enable the Company to develop the Company's technology to the extent needed to create future sales to sustain operations. If the net proceeds from these offerings are insufficient for this purpose, GI Dynamics will consider other options to continue its path to commercialization, including, but not limited to, additional financing through follow-on equity offerings, debt financing, co-development agreements, sale or licensing of developed intellectual or other property, or other alternatives.

GI Dynamics cannot assure that its technology will be accepted, that it will ever earn revenues sufficient to support its operations, or that it will ever be profitable. Furthermore, the Company has no committed source of financing and cannot assure that it will be able to raise money as and when it needs it to continue operations. If the Company cannot raise funds as and when it needs them, it may be required to scale back development plans by reducing expenditures for employees, consultants, business development and marketing efforts or to otherwise severely curtail, or even to cease, business operations.

The Company's corporate headquarters are located in Boston, Massachusetts. The Company leases 3,520 square feet of office space with a lease expiration in May 2022. This space is adequate for current operations.

#### **Critical Accounting Policies and Estimates**

The Company's discussion and analysis of its financial condition and results of operations is based upon the Company's consolidated financial statements prepared in accordance with generally accepted accounting principles in the United States. GI Dynamics believes that its application of the following accounting policies, each of which require significant judgments and estimates on the part of management, are the most critical to aid in fully understanding and evaluating the Company's reported financial results. The Company's significant accounting policies are more fully described in Note 2, "Summary of Significant Accounting Policies and Basis of Presentation", to the Company's consolidated financial statements appearing elsewhere in the Company's Annual Report on Form 10-K for the year ended December 31, 2019. There have been no material changes to these policies since December 31, 2019.

## Results of Operations

The following is a description of significant components of Company operations, including significant trends and uncertainties that are believed to be important to an understanding of the Company's business and results of operations.

	Three Months Ended March 31,	
	2020	2019
	(in thousands)	
Operating expenses:		
Research and development	\$ 1,173	\$ 810
Sales and marketing	—	16
General and administrative	1,543	1,344
Total operating expenses	<u>2,716</u>	<u>2,170</u>
Loss from operations	(2,716)	(2,170)
Other income (expense):		
Interest income	—	3
Interest expense	(284)	(177)
Foreign exchange gain (loss)	(10)	(9)
Gain on write-off of accounts payable	—	29
Gain on write-off of accrued product return liability	164	—
Re-measurement of derivative liabilities	—	(1)
Other income	10	—
Other expense, net	<u>(120)</u>	<u>(155)</u>
Loss before income tax expense	(2,836)	(2,325)
Provision for income taxes	5	6
Net loss	<u>\$ (2,841)</u>	<u>\$ (2,331)</u>
Basic and diluted net loss per common share	(0.08)	\$ (0.12)
Weighted-average number of common shares used in basic and diluted net loss per common share	36,598,291	19,277,545

### Three months ended March 31, 2020 compared to three months ended March 31, 2019

*Revenue.* The Company did not record any revenues or associated cost of revenue during the three months ended March 31, 2020 and 2019, respectively.

### Operating expenses

	Three Months Ended March 31,		Change	
	2020	2019	\$	%
	(in thousands)			
Research and development	\$ 1,173	\$ 810	\$ 363	44.8%
Sales and marketing	—	16	(16)	(100.0)%
General and administrative	1,543	1,344	199	14.8%
Total operating expenses	<u>\$ 2,716</u>	<u>\$ 2,170</u>	<u>\$ 546</u>	25.2%

*Research and Development Expense.* The increase in research and development expense for the three months ended March 31, 2020 compared to the three months ended March 31, 2019 was primarily due to an increase in spending on internal and external resources as the Company initiated the STEP-1 trial in the United States, submitted the protocol for the I-Step trial (under joint venture with Apollo Sugar) in India to the regulatory agency and preparing to file for CE Mark designation under the Medical Device Directive standard revision.

*Sales and Marketing Expense.* The decrease in sales and marketing expense for the three months ended March 31, 2020 compared to the three months ended March 31, 2019 was primarily due to a reclassification of existing overseas employee efforts from sales and marketing support to research and development.

*General and Administrative Expense.* The increase in general and administrative expense for the three months ended March 31, 2020 compared to the three months ended March 31, 2019 was primarily due to increased headcount and employee-related expenses as well as corporate insurance expenses due to a higher directors' and officers' premium.

The Company continues to look for ways to realize a more efficient cost structure in order to extend the Company's cash runway. Cost reductions may not be achievable in all instances as the Company executes clinical development in support of commercial regulatory approvals. Additionally, on March 11, 2020, the World Health Organization declared the outbreak of a coronavirus (COVID-19) a pandemic. As a result, economic uncertainties have arisen which, as of March 31, 2020, have negatively impacted GI Dynamics short term-operations, for example in delays in timing of regulatory audits and other key operational activities due to widespread sequestration and in facing enrollment pauses in our clinical trials due to the clinic-level restriction of elective procedures, for which EndoBarrier implantation qualifies. When operational activities are delayed, expenditures on certain items may decrease, such as travel. There is no certainty which reduced expenditures will result in higher than usual expenditures as activities resume and which will return to the expected rate. If the restrictions are limited in duration, the Company anticipates an ability to overcome delays and return to original timing estimates, but there can be no guarantee the duration and operational impact will be limited to the degree required. Additionally, market-level impacts may affect the timing or the negotiation of terms in the Company's financing efforts. These and other financial impacts that could occur may appear as positive or negative impacts to the Company's future financial statements.

#### Other income (expense)

	Three Months Ended		Change	
	March 31,		\$	%
	2020	2019		
	( in thousands)			
Other income (expense):				
Interest income	\$ —	\$ 3	\$ (3)	(100.0)%
Interest expense	(284)	(177)	(107)	60.5%
Foreign exchange gain (loss)	(10)	(9)	(1)	11.1%
Gain on write-off of accounts payable	—	29	(29)	100.0%
Gain on write-off of accrued product return liability	164	—	164	(—)%
Re-measurement of derivative liabilities	—	(1)	1	(100.0)%
Other income	10	—	10	(—)%
Total other expense, net	<u>\$ (120)</u>	<u>\$ (155)</u>	<u>\$ 35</u>	<u>(22.6)%</u>

*Other income (expense).* The change to other expense, net, for the three months ended March 31, 2020 compared to the three months ended March 31, 2019 is primarily due to the changes in gain on write off of accounts payable, increases in non-cash interest, reclass of derivative liabilities to equity and the elimination of the right of product return reserves of \$164 thousand, which is included in other income.

#### Liquidity and Capital Resources

As of March 31, 2020, the Company's primary source of liquidity is its cash and restricted cash balances. GI Dynamics is currently focused primarily on its clinical trials, which will support future regulatory submissions and potential commercialization activities. Until the Company is successful in gaining regulatory approvals, it is unable to sell the Company's product in any market at this time. Without revenues, GI Dynamics is reliant on funding obtained from investment in the Company to maintain business operations until the Company can generate positive cash flows from operations. The Company cannot predict the extent of future operating losses and accumulated deficit, and it may never generate sufficient revenues to achieve or sustain profitability.

GI Dynamics has incurred operating losses since inception and at March 31, 2020, had an accumulated deficit of approximately \$287 million and a working capital deficit of \$1.3 million. The Company expects to incur significant operating losses for the next several years. At March 31, 2020, the Company had approximately \$3.9 million in cash and restricted cash.

The Company will need to restructure the terms of the Senior Secured Convertible Promissory Note, issued on June 15, 2017 (as amended from time to time, the “2017 Note”), before May 15, 2020 or the 2017 Note will be in default and subject to a call notice at the discretion of Crystal Amber. If the 2017 Note terms are restructured or the note is not called, the Company must raise additional capital before May 31, 2020 in order to continue to pursue its current business objectives as planned and to continue to fund its operations. The Company and Crystal Amber Fund Limited (“Crystal Amber”, a Related Party for ASX purposes) are currently in discussions regarding the 2017 Note maturity extension. 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 guarantee that the 2017 Note will be restructured or if in default, will not be called. If the 2017 Note is called, the company has no guaranteed source of capital that will accommodate repayment of the 2017 Note. If the 2017 Note terms are restructured or the 2017 Note is in default, but not called, the Company anticipates that operating cash will be exhausted by May 31, 2020 and therefore additional financing will be required to be able to continue its operations after this date. There can be no assurance that any potential financing opportunities will be available on acceptable terms, if at all. If the Company is unable to raise sufficient capital on the Company’s required timelines and on acceptable terms to stockholders and the Board of Directors, it could be forced to reduce or cease operations, including activities essential to support regulatory applications to commercialize EndoBarrier. If access to capital is not achieved before May 31, 2020, it will materially harm the Company’s business, financial condition and results of operations to the extent that the Company may be required to cease operations altogether, file for bankruptcy, or undertake any combination of the foregoing.

In addition, if the Company does not meet its payment obligations to third parties as they become due, the Company may be subject to litigation claims and its credit worthiness would be adversely affected. Even if the Company is successful in defending 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 the Company’s financial condition.

These factors raise substantial doubt about the Company’s ability to continue as a going concern within one year after the date that these consolidated financial statements are issued.

During the three months ended March 31, 2020 the Company’s cash and restricted cash balance increased by approximately \$1.4 million primarily due to receipt of the relevant funding amount under the convertible note issued to Crystal Amber and funded on January 13, 2020 less cash payments related to, among other things, research and development and general and administrative expenses as GI Dynamics continued to focus on clinical and regulatory strategies that exceeded its various financings.

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

	<b>Three Months Ended March 31,</b>	
	<b>2020</b>	<b>2019</b>
	<b>(in thousands)</b>	
Net cash (used in) provided by:		
Operating activities	\$ (3,242)	\$ (3,465)
Investing activities	—	(5)
Financing activities	4,597	950
Net increase (decrease) in cash and restricted cash	<u>\$ 1,355</u>	<u>\$ (2,520)</u>

#### **Cash Flows Used in Operating Activities**

The primary uses of cash for operating activities for the three months ended March 31, 2020 were:

- to fund the Company’s net loss of approximately \$2.8 million;

- a net negative adjustment to cash flow from changes in working capital of approximately \$893 thousand resulting primarily from an increase in prepaid expenses offset by decreases in accounts payable and accrued expenses and;
- a net positive adjustment to cash flow from non-cash items of approximately \$492 thousand, primarily from non-cash interest expense, a reclassification of warrant from derivative liabilities to other income and stock-based compensation.

The primary uses of cash for operating activities for the three months ended March 31, 2019 were:

- to fund the Company's net loss of approximately \$2.4 million and;
- a net negative adjustment to cash flow from changes in working capital of approximately \$1.2 million resulting primarily from decreases in accounts payable and accrued expenses.

#### **Cash Flows Used in Investing Activities**

No cash was used in investing activities for three months ended March 31, 2020. Cash used in investing activities for the three months ended March 31, 2019 was approximately \$5 thousand related to capital expenditures.

#### **Cash Flows Provided by Financing Activities**

Cash provided by financing activities for the three months ended March 31, 2020 totaled approximately \$4.6 million and resulted from proceeds received from the August 2019 Note.

Cash provided by financing activities for the three months ended March 31, 2019 totaled approximately \$950 thousand and primarily resulted from proceeds received in March 2019 from the March 2019 Note payable to a related party.

#### *Funding Requirements*

As of March 31, 2020, the Company's primary source of liquidity is its cash and restricted cash balances. GI Dynamics is currently focused primarily on its clinical trials, which will support future regulatory submissions and potential commercialization activities. Until the Company is successful in gaining regulatory approvals, it is unable to sell the Company's product in any market at this time. Without revenues, GI Dynamics is reliant on funding obtained from investment in the Company to maintain business operations until the Company can generate positive cash flows from operations. The Company cannot predict the extent of future operating losses and accumulated deficit, and it may never generate sufficient revenues to achieve or sustain profitability.

GI Dynamics has incurred operating losses since inception and at March 31, 2020, had an accumulated deficit of approximately \$287 million and working capital of \$915 thousand. The Company expects to incur significant operating losses for the next several years. At March 31, 2020, the Company had approximately \$3.9 million in cash and restricted cash.

Due to the numerous risks and uncertainties associated with securing regulatory approval for EndoBarrier<sup>®</sup>, at this time the Company is unable to estimate precisely the amounts of capital outlays and operating expenditures necessary to complete the task of obtaining regulatory approval for EndoBarrier<sup>®</sup>. Funding requirements will depend on many factors, including, but not limited to, the following:

- the timing and conditions related to COVID-19 restrictions on clinical development and corporate activities;
- the timing, cost, and resulting success of research and development efforts;
- the rate of progress and cost of commercialization activities after regulatory approval;

- the expenses the Company may incur in marketing and selling EndoBarrier subject to future regulatory approvals;
- the timing and decisions of payer organizations related to reimbursement;
- the revenue generated by sales of EndoBarrier;
- the safety and efficacy of the Company's product in treating diabetes and reducing obesity;
- the success of the Company's investment in its manufacturing and supply chain infrastructure;
- the time and costs involved in obtaining regulatory approvals for EndoBarrier in new markets;
- the costs associated with any additional clinical trial(s) required in the U.S. and other countries on a case by case basis;
- 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.

GI Dynamics will continue to manage its capital structure and to consider all financing opportunities, whenever they may occur, that could strengthen its long-term liquidity profile. Any such capital transactions may or may not be similar to transactions in which the Company has engaged in the past and the ownership interests of existing stockholders may be materially diluted.

#### **Off-Balance Sheet Arrangements**

The Company does 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, the Company is not exposed to any financing, liquidity, market or credit risk that could arise if the Company had engaged in those types of relationships. Guarantees are provided in the ordinary course of business related to the guarantee of the performance of the Company and its subsidiaries.

#### **Contractual Obligations and Commitments**

The disclosure of 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 the Company Annual Report on Form 10-K for the year ended December 31, 2019.

There have been no material changes from the contractual commitments and obligations previously disclosed in the Company's 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 the consolidated financial statements included in this Quarterly Report on Form 10-Q.

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

The Company conducts business in foreign countries and cash flows are thereby exposed to market risk from changes in currency exchange and interest rates.

#### *Interest Rate Sensitivity*

The Company's cash of approximately \$3.9 million at March 31, 2020, which will be used for working capital purposes. The Company does not enter into investments for trading or speculative purposes. The goals of the Company's investment policy are preservation of capital, fulfillment of liquidity needs and fiduciary control of cash and investments. The Company also seeks to maximize income from investments without assuming significant risk. The Company's 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 the Company's cash and restricted cash, GI Dynamics does not believe that it has any material exposure to changes in their fair values as a result of changes in interest rates.

#### *Foreign Currency Risk*

GI Dynamics conducts business in foreign countries. For U.S. reporting purposes, all assets and liabilities of non-U.S. entities are remeasured at the period-end exchange rate and income and expenses at the average exchange rates in effect during the periods. The net effect of these remeasurement adjustments is shown in the accompanying consolidated financial statements as a component of net loss. Continued fluctuation of these exchange rates could result in financial results that are not comparable from quarter to quarter. The Company does not currently utilize foreign currency contracts to mitigate the gains and losses generated by the remeasurement of non-functional currency assets and liabilities and do not currently hold material cash reserves in currencies in which certain expenditures are denominated.

#### *Effects of Inflation*

The Company does not believe that inflation and prices fluctuations over the three months ended March 31, 2020 and 2019 had a significant impact on the results of operations.

### **Item 4. Controls and Procedures.**

#### **Evaluation of Disclosure Controls and Procedures**

In accordance with Exchange Act Rules 13a-15 and 15d-15(f), GI Dynamics carried out an evaluation, under the supervision and with the participation of management, including the Chief Executive Officer and Chief Financial Officer (the "Certifying Officers"), of the effectiveness of the Company's disclosure controls and procedures as of the end of the period covered by this report. Based on that evaluation, the Company's Certifying Officers concluded that the Company's disclosure controls and procedures were effective as of March 31, 2020 in enabling GI Dynamics to record, process, summarize and report information required to be included in its periodic SEC filings within the required time period.

#### **Changes in Internal Control Over Financial Reporting**

As required by Rule 13a-15(d) of the Exchange Act, the Certifying Officers conducted an evaluation of the internal control over financial reporting to determine whether any changes occurred during the first fiscal quarter of 2020 that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting. The evaluation performed by the Certifying Officers resulted in a conclusion that no such changes occurred.

#### **Inherent Limitations on Controls and Procedures**

Company management, including the principal executive officer and principal financial and accounting officer, does not expect that the Company's disclosure controls and procedures or internal control over financial reporting will prevent all error and all fraud. Internal control over financial reporting cannot provide absolute assurance of achieving financial reporting objectives because of its inherent limitations. It is a process that involves human diligence and compliance and is subject to lapses in judgment or breakdowns resulting from human failures. Internal control over financial reporting also can be circumvented by collusion or improper management override. While process safeguards can reduce risks, because of inherent limitations, there is a risk that material misstatements may not be prevented or detected on a timely basis. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

## PART II – OTHER INFORMATION

### Item 1. Legal Proceedings

GI Dynamics is currently not involved in any litigation that it believes could have a materially adverse effect on its financial condition or results of operations. There is no action, suit, proceeding, inquiry or investigation before or by any court, public board, government agency, self-regulatory organization or body pending or, to the knowledge of the executive officers of the Company or any of its subsidiaries, threatened against or affecting the Company, its common stock, any of its subsidiaries or of the Company's or its subsidiaries' officers or directors in their capacities as such, in which an adverse decision could have a material adverse effect. From time to time, the Company may become involved legal proceedings, lawsuits, claims and regulations in the ordinary course of its business.

### 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 the Company's Annual Report on Form 10-K for the year ended December 31, 2019, filed with the SEC on March 27, 2020, which could materially affect the Company business, financial condition or future results. The risks described in the Company's Annual Report on Form 10-K are not the only risks faced by the Company. Additional risks that we do not presently know or that we currently believe are immaterial could also materially and adversely affect any of the Company business, financial condition or future results. The trading price of the Company's CDIs may decline due to these risks.

### Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

Other than as previously disclosed on the Company's Current Reports on Form 8-K filed with the SEC, the Company did not issue any unregistered equity securities during the three months ended March 31, 2020.

### Item 6. Exhibits.

Exhibit No:	Description
10.1†	<a href="#">Board Member Agreement by and between GI Dynamics, Inc. and Praveen Tyle, incorporated by reference to Exhibit 10.2 of GI Dynamics, Inc.'s Current Report on Form 8-K filed with the SEC on March 3, 2020.</a>
10.2†	<a href="#">Form of Indemnification Agreement, incorporated by reference to Exhibit 10.4 of GI Dynamics, Inc.'s Quarterly Report on Form 10-Q, filed with the SEC on November 10, 2014.</a>
10.3*	<a href="#">Sixth Amendment to Note Purchase Agreement, dated June 15, 2017, between GI Dynamics, Inc. and Crystal Amber Fund Limited, as purchaser, dated March 31, 2020.</a>
10.4*	<a href="#">Sixth Amendment to Senior Secured Convertible Promissory Note, dated June 15, 2017, by and between GI Dynamics, Inc. and Crystal Amber Fund Limited, dated March 31, 2020.</a>
31.1*	<a href="#">Certification of principal executive officer pursuant to Rules 13a-14 or 15d-14 of the Exchange Act.</a>
31.2*	<a href="#">Certification of principal financial officer pursuant to Rules 13a-14 or 15d-14 of the Exchange Act.</a>
32.1‡	<a href="#">Certification of principal executive officer pursuant to Rules 13a-14(b) or 15d-14(b) of the Exchange Act and 18 U.S.C. Section 1350.</a>
32.2‡	<a href="#">Certification of principal financial officer pursuant to Rules 13a-14(b) or 15d-14(b) of the Exchange Act and 18 U.S.C. Section 1350.</a>
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Database
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document

\* Filed herewith.

‡ Furnished herewith.

† 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: May 6, 2020

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

Date: May 6, 2020

By: /s/ CHARLES R. CARTER  
Charles R. Carter  
Chief Financial Officer, Secretary  
*(principal financial and accounting officer)*

## GI DYNAMICS, INC.

## SIXTH AMENDMENT TO NOTE PURCHASE AGREEMENT

THIS SIXTH AMENDMENT (the "**Amendment**"), dated effective as of March 31, 2020, is made to that certain **NOTE PURCHASE AGREEMENT**, dated June 15, 2017, by and between **GI DYNAMICS, INC.**, a Delaware corporation (the "**Company**"), and **CRYSTAL AMBER FUND LIMITED** (the "**Purchaser**"), as amended on December 31, 2018, March 29, 2019, April 30, 2019, June 30, 2019 and August 21, 2019 (as so amended, the "**Agreement**"). Capitalized terms used herein and not otherwise defined shall have the meaning given to them in the Agreement.

WHEREAS, pursuant to Section 7.6 of the Agreement, any term of the Agreement may be amended, waived or modified only with the written consent of the Company and the Purchaser; and

WHEREAS, the Company and the Purchaser desire to amend certain provisions of the Agreement to provide for an amended form of senior secured convertible promissory note, which the Company issued to the Purchaser pursuant to the Agreement and subsequently amended (as amended, the "**Existing Note**"), such further amendment to the Existing Note in substantially the form attached hereto as Exhibit A.

NOW, THEREFORE, the undersigned Purchaser and the Company, in consideration of the mutual premises and covenants made herein and of the mutual benefits to be derived herefrom, hereby amend the Agreement as follows:

1. Amendments to the Agreement.
  - a. The Existing Note shall be amended in substantially the form set forth in Exhibit A.
  - b. The Company and the Purchaser hereby acknowledge and confirm by execution of this Amendment and as of the date hereof that (i) no event constituting an Event of Default under Section 5 of the Agreement has occurred and (ii) the Purchaser shall not be entitled to any remedy under such Section 5 with respect to any event that has occurred as of the date hereof.
2. Except as expressly modified by this Amendment, the Agreement shall remain unmodified and in full force and effect.
3. This Amendment may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute the same instrument. Facsimile or PDF transmission of execution copies or signature pages for this Amendment shall be legal, valid and binding execution and delivery for all purposes.
4. This Amendment shall be governed by, and construed and enforced in accordance with, the substantive laws of the State of New York, without regard to its principles of conflicts of laws.

*(Signatures Pages Immediately Follow)*

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IN WITNESS WHEREOF, the undersigned party has executed this Amendment as of the date first above written.

**COMPANY:**

GI DYNAMICS, INC.

By: /s/ Scott Schorer  
Name: Scott Schorer  
Title: Chief Executive Officer

IN WITNESS WHEREOF, the undersigned party has executed this amendment as of the date first written above.

**PURCHASER:**

CRYSTAL AMBER FUND LIMITED

By: Crystal Amber Asset Management (Guernsey) Limited, as  
Investment Manager

By: /s/ Laurence McNairn  
Name: Laurence McNairn  
Title: Director

**EXHIBIT A**

**SIXTH AMENDMENT TO  
SENIOR SECURED CONVERTIBLE PROMISSORY NOTE**

**SIXTH AMENDMENT TO SENIOR SECURED CONVERTIBLE PROMISSORY NOTE**

This Sixth Amendment to Senior Secured Promissory Note by and among **GI DYNAMICS, INC.**, a Delaware corporation (the “*Payor*”), and **CRYSTAL AMBER FUND LIMITED** (the “*Holder*”) is effective as of March [ ], 2020. Capitalized terms used but not defined herein have the definitions ascribed thereto in that certain Senior Secured Convertible Promissory Note issued on June 15, 2017 by the Payor to the Holder, as amended on December 31, 2018, March 29, 2019, April 30, 2019, June 30, 2019 and August 21, 2019 (as so amended, the “*Existing Note*”).

WHEREAS, the Payor and the Holder desire to further amend the terms of the Existing Note as set forth herein; and

WHEREAS, Section 10(f) of the Existing Note provides that any term of the Existing Note may be amended or waived only with the written consent of the Payor and the Holder.

NOW, THEREFORE, in consideration of the foregoing premises and for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Payor and the Holder, intending to be legally bound, agree as follows:

1. Maturity Date Extension. Sections 1(b), 2(a), 2(b) and 2(c) of the Existing Note are hereby amended with immediate effect to change the dates referred to in each such section (including, for the avoidance of doubt, the Maturity Date) from “March 31, 2020” to May 1, 2020”.

2. No Other Changes. Except as specifically amended in this amendment, all other terms of the Existing Note shall remain unchanged and in full force and effect.

3. Counterparts. This amendment may be executed in any number of counterparts, each of which shall be deemed an original but all of which taken together shall constitute one and the same instrument. Facsimile or PDF transmission of execution copies or signature pages for this amendment shall be legal, valid and binding execution and delivery for all purposes.

4. Governing Law. This amendment shall be governed by, and construed and enforced in accordance with, the substantive laws of the State of New York, without regard to its principles of conflicts of laws.

*[Signature Pages Immediately Follow]*

IN WITNESS WHEREOF, the undersigned party has executed this amendment as of the date first written above.

**PAYOR:**

GI DYNAMICS, INC.

By: EXHIBIT ONLY-DO NOT SIGN  
Name: Scott Schorer  
Title: Chief Executive Officer

IN WITNESS WHEREOF, the undersigned party has executed this amendment as of the date first written above.

**HOLDER:**

CRYSTAL AMBER FUND LIMITED

By: Crystal Amber Asset Management (Guernsey) Limited, as Investment Manager

By: EXHIBIT ONLY-DO NOT SIGN  
Name: Laurence McNairn  
Title: Director

## SIXTH AMENDMENT TO SENIOR SECURED CONVERTIBLE PROMISSORY NOTE

This Sixth Amendment to Senior Secured Promissory Note by and among **GI DYNAMICS, INC.**, a Delaware corporation (the "**Payor**"), and **CRYSTAL AMBER FUND LIMITED** (the "**Holder**") is effective as of March 31, 2020. Capitalized terms used but not defined herein have the definitions ascribed thereto in that certain Senior Secured Convertible Promissory Note issued on June 15, 2017 by the Payor to the Holder, as amended on December 31, 2018, March 29, 2019, April 30, 2019, June 30, 2019 and August 21, 2019 (as so amended, the "**Existing Note**").

WHEREAS, the Payor and the Holder desire to further amend the terms of the Existing Note as set forth herein; and

WHEREAS, Section 10(f) of the Existing Note provides that any term of the Existing Note may be amended or waived only with the written consent of the Payor and the Holder.

NOW, THEREFORE, in consideration of the foregoing premises and for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Payor and the Holder, intending to be legally bound, agree as follows:

1. Maturity Date Extension. Sections 1(b), 2(a), 2(b) and 2(c) of the Existing Note are hereby amended with immediate effect to change the dates referred to in each such section (including, for the avoidance of doubt, the Maturity Date) from "March 31, 2020" to May 1, 2020".

2. No Other Changes. Except as specifically amended in this amendment, all other terms of the Existing Note shall remain unchanged and in full force and effect.

3. Counterparts. This amendment may be executed in any number of counterparts, each of which shall be deemed an original but all of which taken together shall constitute one and the same instrument. Facsimile or PDF transmission of execution copies or signature pages for this amendment shall be legal, valid and binding execution and delivery for all purposes.

4. Governing Law. This amendment shall be governed by, and construed and enforced in accordance with, the substantive laws of the State of New York, without regard to its principles of conflicts of laws.

*[Signature Pages Immediately Follow]*

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IN WITNESS WHEREOF, the undersigned party has executed this amendment as of the date first written above.

**PAYOR:**

GI DYNAMICS, INC.

By: /s/ Scott Schorer  
Name: Scott Schorer  
Title: Chief Executive Officer

IN WITNESS WHEREOF, the undersigned party has executed this amendment as of the date first written above.

**HOLDER:**

CRYSTAL AMBER FUND LIMITED

By: Crystal Amber Asset Management (Guernsey) Limited, as Investment Manager

By: /s/ Laurence McNairn  
Name: Laurence McNairn  
Title: Director

*(Signature Page to Sixth Amendment to Senior Secured Convertible Promissory Note)*

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**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: May 6, 2020

/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, Charles R. Carter, certify that:

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

Date: May 6, 2020

/s/ CHARLES R. CARTER

Charles R. Carter

Chief Financial Officer, Secretary

*(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 March 31, 2020 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)*

May 6, 2020

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 March 31, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Charles R. Carter, 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/ CHARLES R. CARTER

Charles R. Carter

*Chief Financial Officer, Secretary*

*(principal accounting and financial officer)*

May 6, 2020

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.