

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, 2021

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)

84-1621425

(I.R.S. Employer
Identification Number)

320 Congress Street, 3rd Floor
Boston, Massachusetts

(Address of Principal Executive Offices)

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

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

☐

Non-accelerated filer

☒

Accelerated filer

☐

Smaller reporting company

☒

Emerging growth company

☐

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

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

The total number of shares of the registrant's common stock outstanding on April 20, 2021, was 88,095,659.

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;
- the severity, magnitude and duration of the COVID-19 pandemic, including impacts of the pandemic and of corporate and governmental responses to the pandemic on our clinical trials and personnel;
- our inability to predict the extent to which the COVID-19 pandemic and related impacts will continue to adversely impact our business operations, financial performance, results of operations, financial position and the achievement of our strategic objectives;
- 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.

GI DYNAMICS, INC.
QUARTERLY REPORT ON FORM 10-Q
FOR THE QUARTER ENDED MARCH 31, 2021

TABLE OF CONTENTS

	Page
<u>PART I – FINANCIAL INFORMATION</u>	1
Item 1. <u>Financial Statements (unaudited)</u>	1
<u>Consolidated Balance Sheets as of March 31, 2021 and December 31, 2020</u>	1
<u>Consolidated Statements of Operations for the Three Months Ended March 31, 2021 and 2020</u>	2
<u>Consolidated Statements of Changes in Stockholders' Deficit for the Three Months Ended March 31, 2021 and 2020</u>	3
<u>Consolidated Statements of Cash Flows for the Three Months Ended March 31, 2021 and 2020</u>	4
<u>Notes to Consolidated Financial Statements</u>	5
Item 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	15
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	23
Item 4. <u>Controls and Procedures</u>	23
<u>PART II – OTHER INFORMATION</u>	24
Item 1. <u>Legal Proceedings</u>	24
Item 1A. <u>Risk Factors</u>	24
Item 2. <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	24
Item 6. <u>Exhibits</u>	25
<u>Signatures</u>	26

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 direct 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 United States Eastern Daylight Time zone or Eastern Standard Time zones.

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.

Trademarks

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

PART I – FINANCIAL INFORMATION

Item 1. Financial Statements.

GI Dynamics, Inc. and Subsidiaries

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

	March 31, 2021	December 31, 2020
Assets		
Current assets:		
Cash	\$ 931	\$ 1,159
Restricted cash	30	30
Prepaid expenses and other current assets	2,628	3,029
Total current assets	3,589	4,218
Property and equipment, net	9	14
Operating lease right-of-use assets, net	206	244
Total assets	<u>\$ 3,804</u>	<u>\$ 4,476</u>
Liabilities and stockholders' deficit		
Current liabilities:		
Accounts payable	\$ 249	\$ 430
Accrued expenses	666	583
Short term debt	222	263
Operating lease liability	172	172
Total current liabilities	1,309	1,448
Long term debt to related party, net of debt discount	3,726	3,496
Operating lease liability, non-current	27	67
Total liabilities	<u>5,062</u>	<u>5,011</u>
Commitments (Note 9)		
Stockholders' deficit:		
Preferred stock, \$0.01 par value – 118,000,000 shares authorized at March 31, 2021 and December 31, 2020; 77,609,875 and 60,085,583 shares issued and outstanding at March 31, 2021 and December 31, 2020, respectively	776	601
Common stock, \$0.01 par value – 280,000,000 shares authorized at March 31, 2021 and December 31, 2020; 88,095,659 shares issued and outstanding at March 31, 2021 and December 31, 2020	881	881
Additional paid-in capital	295,082	293,611
Accumulated deficit	(297,997)	(295,628)
Total stockholders' deficit	<u>(1,258)</u>	<u>(535)</u>
Total liabilities and stockholders' deficit	<u>\$ 3,804</u>	<u>\$ 4,476</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)

	Three Months Ended March 31,	
	2021	2020
Operating expenses:		
Research and development	\$ 920	\$ 1,173
General and administrative	1,152	1,543
Total operating expenses	<u>2,072</u>	<u>2,716</u>
Loss from operations	(2,072)	(2,716)
Other income (expense):		
Interest expense	(292)	(284)
Foreign exchange loss	(5)	(10)
Gain on reversal of accrued product return liability	—	164
Other income	-	10
Other expense, net	<u>(297)</u>	<u>(120)</u>
Loss before income taxes	(2,369)	(2,836)
Provision for income taxes	<u>-</u>	<u>5</u>
Net loss	<u><u>\$ (2,369)</u></u>	<u><u>\$ (2,841)</u></u>
Basic and diluted net loss per common share	\$ (0.03)	\$ (0.08)
Weighted-average number of common shares used in basic and diluted net loss per common share	88,095,659	36,598,291

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 amounts)
(unaudited)

THREE MONTHS ENDED MARCH 31, 2021	Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Par Value	Shares	Par Value			
Balance at December 31, 2020	60,085,583	\$ 601	88,095,659	\$ 881	\$ 293,611	\$ (295,628)	\$ (535)
Sales of Series A Preferred Shares	17,524,292	175	—	—	1,378	—	1,553
Stock-based compensation expense	—	—	—	—	93	—	93
Net loss	—	—	—	—	-	(2,369)	(2,369)
Balance at March 31, 2021	<u>77,609,875</u>	<u>\$ 776</u>	<u>88,095,659</u>	<u>\$ 881</u>	<u>295,082</u>	<u>\$ (297,997)</u>	<u>\$ (1,258)</u>

THREE MONTHS ENDED MARCH 31, 2020	Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Par Value	Shares	Par Value			
Balance at December 31, 2019	—	\$ —	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>—</u>	<u>\$ —</u>	<u>36,598,291</u>	<u>\$ 366</u>	<u>\$ 283,905</u>	<u>\$ (287,333)</u>	<u>\$ (3,062)</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)

	Three Months Ended March 31,	
	2021	2020
Operating activities:		
Net loss	\$ (2,369)	\$ (2,841)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	43	42
Reclassification of warrant from derivative liabilities to other income	—	(10)
Non-cash interest expense	230	282
Stock-based compensation expense	93	212
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	401	(147)
Accounts payable	(181)	(115)
Accrued expenses	83	(631)
Operating lease liability	(40)	(34)
Net cash used in operating activities	<u>(1,740)</u>	<u>(3,242)</u>
Financing activities:		
Proceeds from sale of preferred stock	1,553	—
Proceeds from short-term and long-term debt, related party	-	4,597
Payments on short term debt	(41)	-
Net cash provided by financing activities	<u>1,512</u>	<u>4,597</u>
Net increase (decrease) in cash	(228)	1,355
Cash and restricted cash at beginning of period	1,189	2,529
Cash and restricted cash at end of period	<u>\$ 961</u>	<u>\$ 3,884</u>
Supplemental disclosures of cash flow information and non-cash activities		
Income taxes paid	\$ -	\$ 5
Interest paid	1	-
Fair value of warrants issued with notes to related party	-	2,330
Beneficial conversion feature in connection with August 2019 Note to related party	-	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® 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/m²); 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® 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® 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.

COVID-19 Pandemic and Impacts to Business Operations

In December 2019, a novel strain of coronavirus was reported to have surfaced in Wuhan, China and in March 2020, the World Health Organization declared the Coronavirus (“SARS-CoV-2”) outbreak a “pandemic.” The Company’s operations experienced significant restrictions and delays in 2020, including the following operational impacts:

- The pause of enrollment of the Step-1 trial due to categorization of the EndoBarrier implantation procedure as an elective procedure, with such procedures disallowed during Covid-19 restriction periods. As of March 31, 2021, all sites were able to enroll, pending backlog clearance.
- Regulatory submission timelines were significantly delayed due to Covid-19 impacts on submission preparation, review schedules and backlogs, and agency reply periods.
- The economic impact of the pandemic and resulting restrictions may have affected investor perception of available funds for investment, sector focus, and risk tolerance.
- Business effectiveness may have been limited by inability to conduct in-person and on-site meetings.

As of April 2021 significant uncertainty remains as SARS-CoV-2 variants have emerged, there has been an uneven global vaccine roll-out, and there is risk that future containment strategies will be limited by societal fatigue.

Going Concern Evaluation

As of March 31, 2021, the Company’s primary source of liquidity is its cash and restricted cash balances. GI Dynamics is currently focused on obtaining an EndoBarrier CE mark and enrolling the Company’s 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. 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.

The Company has incurred operating losses since inception and at March 31, 2021 had an accumulated deficit of approximately \$298 million. The Company expects to incur significant operating losses for the next several years. At March 31, 2021, the Company had approximately \$961 thousand in cash and restricted cash.

The Company will need to arrange additional financing before September 1, 2021 in order to continue to pursue its current business objectives as planned and to continue to fund its operations. The Company is looking to raise additional funds through any combination of additional equity and debt financings or from other sources, however, the Company has no guaranteed source of capital that will sustain operations past September 1, 2021. There can be no assurance that any such potential financing opportunities will be available on acceptable terms, if at all. If the Company is unable to raise sufficient capital on the Company’s required timelines and on acceptable terms to existing stockholders and the Board of Directors, it could be forced to cease operations, including activities essential to support regulatory applications to commercialize EndoBarrier. If access to capital is not achieved in the near term, it will materially harm the Company’s business, financial condition and results of operations to the extent that the Company may be required to cease operations altogether, file for bankruptcy, or undertake any combination of the foregoing. These factors raise substantial doubt about the Company’s ability to continue as a going concern within one year after the date that these interim Consolidated Financial Statements are issued.

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.

As a result of the factors described above, the Company’s interim Consolidated Financial Statements include a going-concern disclosure. See “Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations — Liquidity and Capital Resources” for further information regarding the Company’s funding requirements.

The accompanying interim 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 interim Consolidated Financial Statements for the quarter ended March 31, 2021 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 within one year after the date that these interim Consolidated Financial Statements are issued.

2. Significant Accounting Policies and Basis of Presentation

The interim 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, 2020 filed with the SEC on March 12, 2021. The Company’s balance sheet at December 31, 2020 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, 2021 and the results of our operations and cash flows for the three months ended March 31, 2021 and 2020. 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.

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.

3. Net Loss per Common Share

Basic net loss per common share is computed by dividing net loss by the weighted-average number of shares of Common Stock 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 CHESS depository Interests (CDIs, the Company’s security that was traded on the Australian Securities Exchange) 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. For diluted net loss per share purposes, shares of preferred stock that are convertible into shares of common stock are excluded from diluted net loss per share calculations as inclusion would have an anti-dilutive effect. During the three months ended March 31, 2021 and 2020, 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 were equivalent in each period presented.

The following potentially dilutive securities have been excluded from the computation of diluted weighted- average shares outstanding as of March 31, 2021 and 2020, as they would be anti-dilutive:

	Three Months Ended March 31,	
	2021	2020
Shares of preferred stock convertible into shares of common stock	77,609,875	-
Warrants to purchase common stock	28,532	4,625,425
Options to purchase common stock and other stock-based awards	25,386,995	3,376,154
Total	103,025,402	8,001,579

4. Warrants to Purchase Common Stock or CDIs

The following series of warrants were outstanding and exercisable at March 31, 2021 and 2020 (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,	
				2021	2020
Consultant warrant	May 4, 2016	28,532	\$ 0.64	28,532	28,532
August 2019 Warrant (1)	January 13, 2020	4,596,893	\$ 1.00	-	4,596,893
Total Outstanding and Exercisable				28,532	4,625,425
Weighted Average Exercise Price				\$ 0.64	\$ 1.00

(1) 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 was fully vested and expired on May 4, 2021.

On August 21, 2019, GI Dynamics and Crystal Amber entered into a securities purchase agreement (“SPA”) 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 as detailed above and the 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. On December 16, 2019, stockholder approval for the warrant to be issued was obtained and it was issued on January 13, 2020 together with the funding of the August 2019 Note. The August 2019 Warrant was issued on January 13, 2020 and estimated fair value was determined to allocate relative fair values of the August 2019 Note and the August 2019 Warrant. The assumptions used to estimate the fair value of \$2.3 million included an expected volatility of approximately 141%, an expected term of 5 years, a risk-free interest rate of 1.65%, and no dividend yield.

On September 4, 2020, the Company and Crystal Amber executed financing documents (the “September 2020 Financing”) that included the sale of up to \$10 million of shares of Series A Preferred Stock, the cancellation of the August 2019 Warrants, and the restructuring of the August 2019 Note (described more fully in Note 8 of these interim consolidated financial statements).

5. Fair Value Measurements

Information about the Company’s assets and liabilities that are measured at fair value initially or on a recurring basis as of March 31, 2021 and December 31, 2020 is provided below and includes 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 derivative liability classification of the Consultant Warrant was re-evaluated, and the Company re-classified it as an equity instrument. On March 31, 2020, this reclassification resulted in an immaterial credit to Other Income.

Cash, restricted cash, prepaid expenses and other current assets, accounts payable, accrued expenses, short-term debt and other current liabilities at March 31, 2021 and December 31, 2020 are carried at amounts that approximate fair value due to their short-term maturities and the highly liquid nature of these instruments.

At March 31, 2021, there are no assets or liabilities that require remeasurement of fair value on a recurring basis.

6. Prepaid Expenses

Prepaid expenses and other current assets consisted of the following (in thousands):

	March 31, 2021	December 31, 2020
Prepaid insurance	\$ 1,337	\$ 1,426
Prepaid clinical trial expenses	467	489
Escrowed severance reserves	335	544
Prepaid corporate identity project	165	165
Other	324	405
Total	<u>\$ 2,628</u>	<u>\$ 3,029</u>

Effective as of December 31, 2020, the Company and Charles Carter, the Company's Chief Financial Officer, Treasurer and Secretary, mutually agreed to terminate Mr. Carter's employment with the Company and the Company engaged Mr. Carter for his continued services as a consultant in the capacity of Chief Financial Officer, Treasurer and Secretary. In connection with the transition of Mr. Carter's engagement with the Company, from an employee to a consultant, the Company paid Mr. Carter a retention bonus of \$209 thousand in exchange for a guaranteed minimum amount of service provision in the months of January, February, and March, 2021. Termination by the Company for cause, termination by Mr. Carter or default related to failure to meet the minimum provision of services would result in pro-rata repayment of the retention bonus. At March 31, 2021, the bonus was fully earned and no longer subject to repayment.

7. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	March 31, 2021	December 31, 2020
Payroll and related liabilities	\$ 154	\$ 203
Professional fees	152	177
Accrued interest	140	80
Other	220	123
Total	<u>\$ 666</u>	<u>\$ 583</u>

Accrued interest at March 31, 2021 is comprised of interest on the September 2020 Convertible Note and an immaterial amount for the Company's Paycheck Protection Program loan.

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 accrued interest at an annually compounded rate of 5% per annum. The 2017 Note was secured by a first priority security interest in substantially all tangible and intangible assets of the Company, including intellectual property.

The entire outstanding principal balance and all unpaid accrued interest thereon was due, as most recently amended, on July 31, 2020. The entire outstanding principal balance under the 2017 Note and all unpaid accrued interest thereon was 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 (“VWAP”) 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. On July 13, 2020, Crystal Amber provided the Company with a notice of optional conversion of the 2017 Note. On the conversion date, the principal of \$5 million and the accrued and unpaid interest of \$390 thousand totaling \$5,390,240 was converted into 2,574,873,400 CDIs, which was equivalent to 51,497,468 shares of Common Stock. The conversion price equaled the 5-day VWAP per CDI for the 5 trading days immediately preceding the date of notice, which equaled \$0.002093 per CDI or \$0.10467 per share of Common Stock.

On receipt of the notice of conversion, the Company did not have sufficient authorized shares to issue to CHESS Depository Nominees, Ltd. (“CDN”) to enable the required number of CDIs to be allotted to Crystal Amber. The available 38,401,704 shares were issued to CDN, allowing the allotment of 1,920,085,200 CDIs to Crystal Amber. The Company and Crystal Amber executed a Right to Shares and Waiver Agreement in which the Company agreed to issue the remaining 13,095,764 shares of Common Stock owed under the conversion when the Company filed an amended and restated certification of incorporation with the Delaware Secretary of State after the Company was delisted from the ASX and in connection with the consummation of the September 2020 Financing. On July 22, 2020, the Company was removed from the Official List of the ASX (“Delisted”) and the CDN trust was subsequently dissolved, causing all CDIs to automatically convert to shares of Common Stock. The remaining 13,095,764 shares of Common Stock owed under the conversion were issued as shares of Common Stock immediately after Shareholders approved the increase in the authorized shares of common stock to 280,000,000 shares at the Special Meeting of Shareholders held on September 3, 2020.

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

August 2019 Securities Purchase Agreement and Restructuring into the September 2020 Note.

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 the August 2019 Note in an aggregate principal amount of up to approximately \$4.6 million 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 the August 2019 Warrant (see Note 4 of the consolidated financial statements) conferring the right to purchase 229,844,650 CDIs (representing 4,596,893 shares of common stock), with warrant issuance subject to the funding of the August 2019 Note and the receipt of required stockholder approval to issue the August 2019 Warrant.

The August 2019 Note accrued 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 would accrue interest at a rate of 16% per annum. The entire outstanding principal balance and all unpaid accrued interest thereon would become 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 was immediately convertible into CDIs at the option of Crystal Amber at a conversion price equal to \$0.02 per CDI (representing \$1.00 per share of Common Stock). In the event that the Company issued additional CDIs to a stockholder other than Crystal Amber in a subsequent equity financing at a price per CDI that was less than the conversion price under the August 2019 Note, the conversion price was to 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 could, at its option, demand that the Company prepay all accrued and unpaid interest plus 110% of the remaining outstanding unconverted principal balance. The Company was unable to 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 were not obtained, the Company was 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 was six months following the date of the stockholder meeting at which the requisite approvals were not obtained. The Company considered 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 values of these features were considered immaterial upon issuance.

The August 2019 SPA contained 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 contained 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 of these interim consolidated financial statements).

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 was to be amortized to interest expense through the January 2025 maturity of the August 2019 Note.

On September 4, 2020, the Company executed a series of financing-related agreements ("the September 2020 Financing") which included the cancellation of the August 2019 Warrant, the restructuring of the August 2019 Note into the September 2020 Note, the conversion of the June and August 2020 Convertible Notes into shares of Series A Preferred, and the sale of \$8.75 million of Series A Preferred Stock to Crystal Amber under the Series A Preferred Stock Purchase Agreement (the "Series A SPA"). The Initial Close of the September 2020 Financing occurred on September 4, 2020, and included all components of the September 2020 Financing, except that \$5 million of the total Series A Preferred Stock sale was originally deferred to October 31, 2020 (the "Second Close" of the September 2020 Financing).

For the three months ended March 31, 2021, the Company recorded accrued interest expense of \$60 thousand and recognized interest expense of \$230 thousand from the amortization of the debt discount related to the September 2020 Note.

For the three months ended March 31, 2020, the Company recorded accrued interest expense of \$98 thousand and recognized interest expense of \$100 thousand from the amortization of the debt discount related to the August 2019 Note.

Paycheck Protection Program (“PPP”) Loan

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. On April 4, 2020, GI Dynamics submitted an application to a lending institution for a loan of approximately \$200 thousand under the Paycheck Protection Program (“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. The loan was granted by the lending institution on May 8, 2020 and funds were received into the Company’s bank account on May 11, 2020. The Company believes expenditures of the loan proceeds are fully compliant with the terms for loan forgiveness. The Company anticipates the lending institution to accept the Company’s loan forgiveness application in the second quarter of 2021.

9. Commitments

Lease Commitments

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 commenced May 1, 2019 and expires on May 31, 2022. The lease had a one-month rent-free period, has 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 is amortizing to lease expense and the liability is 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’s operating lease is reflected in the balance sheets. Lease expense totaled \$44 thousand for each of the quarters ended March 31, 2021 and 2020. Other information related to leases was as follows:

	Three Months Ended	
	March 31,	
	2021	2020
	(in thousands)	
Operating cash flows from operating leases in lease liability measurement	\$ 49	\$ 53
Operating cash flows from short term leases	-	44
Remaining long-term lease term in years	1.2	2.2

The maturity of the Company’s operating lease liability as of March 31, 2021 is as follows for the years ended December 31:

	Amount
	(in thousands)
Remainder of 2021	\$ 137
2022	76
Total future minimum lease payments	213
Less: imputed interest	(14)
Total lease liabilities	<u>\$ 199</u>

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.

On September 3, 2020, GI Dynamics stockholders approved an increase of its authorized shares of common stock from 75 million to 280 million shares and approved the authorization of 118 million shares of Series A Convertible Preferred Stock.

At December 31, 2020, GI Dynamics had issued a total of 60,085,583 shares of Series A Preferred Stock and 88,095,659 shares of common stock were issued and outstanding.

Pursuant to the Series A Preferred Stock Share Purchase Agreement and multiple related amendments, the Second Close of the September 2020 Financing was restructured such that \$53 thousand was received in the February 24, 2021 sale of 600 thousand shares of Series A Preferred Stock to an existing investor; \$1.5 million was received in the March 4, 2021 for the sale of 16,924,292 shares of Series A Preferred Stock to Crystal Amber; \$1.0 million was received on April 14, 2021 for the sale of 11,282,861 shares of Series A Preferred Stock to Crystal Amber. The remaining approximately \$2.4 million committed under the September 2020 Securities Purchase Agreement will be closed on or before May 28, 2021. Independent investors may subscribe for up to the 27,607,153 remaining shares being offered and Crystal Amber will purchase any shares not subscribed by independent investors prior to May 28, 2021.

11. Share-Based Compensation

The Company has three stock-based compensation plans. The Board of Directors adopted the 2003 Omnibus Stock Plan (the "2003 Plan"), which provided 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. At March 31, 2021, one fully vested grant conferring the right to purchase 5,000 shares for \$8.20 per share remained outstanding and expired April 5, 2021.

In August 2011, the Board of Directors adopted the 2011 Employee, Director and Consultant Equity Incentive Plan (the "2011 Plan") 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 August 20, 2020, the date of the adoption of the 2020 Plan detailed below, 863,307 shares of common stock were available for grant under the Company's 2011 Plan. Existing, outstanding grants issued under the 2011 Plan will remain active unless they are exercised or cancelled due to forfeiture or expiry. The Board of Directors have disallowed the granting of any new awards using shares available under the 2011 Plan.

In August 2020, the Board of Directors adopted the 2020 Employee, Director and Consultant Equity Incentive Plan (the "2020 Plan") as the successor to the 2011 and 2003 Plans. On September 3, 2020, shareholders approved the adoption of the 2020 Plan. Under the 2020 Plan, the Company may grant incentive stock options, nonqualified stock options, restricted and unrestricted stock awards and other stock-based awards up to a total of 41,710,968 shares. The 2003 Plan, 2011 Plan and 2020 Plan are collectively referred to herein as the "Plans". As of March 31, 2020, 16,737,707 shares of common stock were available for grant under the Company's 2020 Plan.

On January 28, 2021, the Board of Directors granted 15 option awards to employees, board members, and a consultant, representing the right to purchase a total of 24,973,261 shares of common stock for a strike price of \$0.06, which is the fair value determined by the Board of Directors.

Stock-Based Compensation

Stock-based compensation is reflected in the consolidated statements of operations as follows for the three months ended March 31, 2021 and 2020 (in thousands):

	Three Months Ended March 31,	
	2021	2020
Research and development	\$ 45	\$ 13
General and administrative	48	199
	<u>\$ 93</u>	<u>\$ 212</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, 2021 and 2020:

	Three Months Ended March 31,	
	2021	2020
Expected volatility	111.4%	164.9%
Expected term (in years)	6.25	5.84
Risk-free interest rate	0.7%	0.9%
Expected dividend yield	0%	0%

Stock Options

The following table summarizes share-based activity under the 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>
Outstanding at December 31, 2020	463,104	\$ 2.04	7.6	\$ —
Granted	24,973,261	\$ 0.06		
Cancelled	49,370	\$ 1.33		
Outstanding at March 31, 2021	<u>25,386,995</u>	<u>\$ 0.09</u>	<u>9.8</u>	<u>\$ —</u>
Exercisable at March 31, 2021	<u>245,965</u>	<u>\$ 3.76</u>	<u>6.6</u>	<u>\$ —</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 months ended March 31, 2021 and 2020, was \$0.05 and \$0.18, respectively. The unrecognized stock compensation Expense at March 31, 2021 was approximately \$1.4 million and was expected to be recognized over a weighted average period of 1.86 years from March 31, 2021.

12. Subsequent Events

As noted in Note 10 - Stockholders' Deficit, \$1.0 million was received on April 14, 2021 for the sale of 11,282,861 shares of Series A Preferred Stock to Crystal Amber.

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, 2021, the Company had an accumulated deficit of approximately \$298 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 \$285.5 million through sales of the Company's equity and placement of debt, of which \$1.5 million related to the Second Close of the September 2020 financing was received in the three months ended March 31, 2021.

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 and 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, 2021, 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, 2021, 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, 2020. There have been no material changes to these policies since December 31, 2020.

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,	
	2021	2020
	(in thousands)	
Operating expenses:		
Research and development	\$ 920	\$ 1,173
General and administrative	1,152	1,543
Total operating expenses	2,072	2,716
Loss from operations	(2,072)	(2,716)
Other income (expense):		
Interest expense	(292)	(284)
Foreign exchange loss	(5)	(10)
Gain on reversal of accrued product return liability	—	164
Other income	—	10
Other expense, net	(297)	(120)
Loss before income tax expense	(2,369)	(2,836)
Provision for income taxes	—	5
Net loss	\$ (2,369)	\$ (2,841)
Basic and diluted net loss per common share	(0.03)	\$ (0.08)
Weighted-average number of common shares used in basic and diluted net loss per common share	88,095,659	36,598,291

Three months ended March 31, 2021 compared to three months ended March 31, 2020

Revenue. The Company did not record any revenues or associated cost of revenue during the three months ended March 31, 2021 and 2020, respectively.

Operating expenses

	Three Months Ended March 31,		Change	
	2021	2020	\$	%
	(in thousands)			
Operating expenses:				
Research and development	\$ 920	\$ 1,173	\$ (253)	(21.5)%
General and administrative	1,152	1,543	(391)	(25.3)%
Total operating expenses	\$ 2,072	\$ 2,716	\$ (644)	(23.7)%

Research and Development Expense. The decrease in research and development expense for the three months ended March 31, 2021 compared to the three months ended March 31, 2020 was primarily due to the COVID-19 related enrollment pause of the STEP-1 clinical trial in 2021 while patients were enrolled in the same period in 2020.

General and Administrative Expense. The decrease in general and administrative expense for the three months ended March 31, 2021 compared to the three months ended March 31, 2020 was primarily due to decreased expenses related to the Company's status as a delisted company and a reduction in salaries and headcount.

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 COVID-19 pandemic. As a result, economic uncertainties have arisen which, as of March 31, 2021, have negatively impacted GI Dynamics 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. There can be no guarantee that the duration and operational impact of COVID-19 will be limited to the degree required to allow original timelines to be met. 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 March 31,		Change	
	2021	2020	\$	%
	(in thousands)			
Other income (expense):				
Interest expense	\$ (292)	\$ (284)	\$ 8	(3)%
Foreign exchange loss	(5)	(10)	5	(5)%
Gain on reversal of accrued product return liability	-	164	(164)	(100)%
Other income	-	10	(10)	(100)%
Other income (expense), net	\$ (297)	\$ (120)	\$ 177	(148)%

Other income (expense), net. The change to other expense, net, for the three months ended March 31, 2021 compared to the three months ended March 31, 2020 is primarily due to the gain on reversal of product return liability in 2020 and no such transaction in 2021.

Liquidity and Capital Resources

As of March 31, 2021, the Company's primary source of liquidity is its cash and restricted cash balances. GI Dynamics is currently focused primarily on obtaining CE mark approval to allow commercialization in select markets and on conducting its clinical trials which will support future regulatory submissions and potential commercialization activities. Until the Company is successful in gaining regulatory approvals, including CE mark, 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, 2021, had an accumulated deficit of approximately \$298 million. The Company expects to incur significant operating losses for the next several years. At March 31, 2021, the Company had approximately \$960 thousand in cash and restricted cash.

The Company completed an initial public offering on the Australian Securities Exchange (“ASX”) on September 2, 2011. The Company’s Chess Depository Interests (“CDIs”), which represented 1/50th of a share of the Company’s Common Stock were publicly traded until July 22, 2020, when the Company completed all requirements and was removed from the Official List of the ASX (the “Delisting”). On Delisting, all CDIs were automatically converted to shares of Common Stock with any resulting fractional shares being redeemed by the Company for cash payment. Although the Company is not listed on any public exchange, the Company remains subject to all SEC reporting requirements due to the number of holders of shares of Common Stock.

On September 4, 2020, the Company and Crystal Amber Fund Limited (“Crystal Amber”) executed financing documents (the “September 2020 Financing”) that included the sale of up to \$10 million of shares of Series A Preferred Stock and the conversion of the June 2020 and August 2020 Convertible Notes into shares of Series A Preferred Stock, the cancellation of the August 2019 Warrant (described more fully in Note 4 and Note 8 of the consolidated financial statements), the extinguishment of the August 2019 Convertible Note, and the issuance of the September 2020 Convertible Note. The Initial Close occurred on September 4, 2020 and resulted in cash proceeds of \$3.75 million for the sale of approximately 42.3 million shares of Series A Preferred Stock. The Initial Close also included the conversion of \$1.26 million of Note principal and interest due under the June 2020 and August 2020 Note into 17.7 million shares of Series A Preferred Stock. The Initial Close also included the cancellation of the August 2019 Warrant, the extinguishment of the August 2019 Convertible Note, and the issuance of the September 2020 Convertible Note. Pursuant to the Series A Preferred Stock Share Purchase Agreement and multiple related amendments, the Second Close of the September 2020 Financing was restructured such that \$53 thousand was received in the February 24, 2021 sale of 600 thousand shares of Series A Preferred Stock to an existing investor; \$1.5 million was received in the March 4, 2021 for the sale of 16,924,292 shares of Series A Preferred Stock to Crystal Amber; \$1.0 million was received on April 14, 2021 for the sale of 11,282,861 shares of Series A Preferred Stock to Crystal Amber. The remaining approximately \$2.4 million committed under the September 2020 Securities Purchase Agreement will be closed on or before May 28, 2021. Independent investors may subscribe for up to the 27,607,153 remaining shares being offered and Crystal Amber will purchase any shares not subscribed by independent investors prior to May 28, 2021.

The Company expects that the cash received in the September 2020 Financing will be sufficient to fund the Company’s operations through the later of obtaining of CE mark approval or September 1, 2021, after which additional financing will be required to continue the Company’s operations. Further additional financing will be required to fund operations until the Company achieves sustainably positive cash flow. 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 that may include activities essential to support regulatory applications to commercialize EndoBarrier, file for bankruptcy, or undertake a combination of the foregoing.

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, 2021 the Company’s cash and restricted cash balance decreased by approximately \$0.2 million primarily due to receipt of proceeds from the sale of Series A Preferred Stock, 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:

	Three Months Ended March 31,	
	2021	2020
	(in thousands)	
Net cash (used in) provided by:		
Operating activities	\$ (1,740)	\$ (3,242)
Financing activities	1,512	4,597
Net increase (decrease) in cash and restricted cash	\$ (228)	\$ 1,355

Cash Flows Used in Operating Activities

The primary uses of cash for operating activities for the three months ended March 31, 2021 were:

- to fund the Company's net loss of approximately \$2.4 million;
- a net positive adjustment to cash flow from changes in working capital of approximately \$0.2 million resulting primarily from decreases in prepaid expenses, increase in accrued expenses and offset by decreases in accounts payable and;
- a net positive adjustment to cash flow from non-cash items of approximately \$0.3 million, primarily from non-cash interest expense.

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 and;
- a net positive adjustment to cash flow from non-cash items of approximately \$0.5 million, primarily from non-cash interest expense and stock-based compensation expense; and
- a net negative adjustment to cash flow from changes in working capital of approximately \$0.9 million resulting primarily from an increase in prepaid expenses and decreases in accounts payable and accrued expenses as funding uncertainty led to delayed disbursements.

Cash Flows Used in Investing Activities

No cash was used in investing activities for the three months ended March 31, 2021 or 2020.

Cash Flows Provided by Financing Activities

Cash provided by financing activities for the three months ended March 31, 2021 totaled approximately \$1.6 million and resulted from proceeds received from the sale of Series A Preferred Stock.

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 issuance of the August 2019 Note.

Funding Requirements

As of March 31, 2021, the Company's primary source of liquidity is its cash and restricted cash balances. GI Dynamics is currently focused primarily on gaining CE mark and executing its clinical trials, which will support future regulatory submissions and potential commercialization activities. Until the Company is successful in gaining CE mark and various 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, 2021, had an accumulated deficit of approximately \$298 million. The Company expects to incur significant operating losses for the next several years. At March 31, 2021, the Company had approximately \$960 thousand in cash and restricted cash.

Due to the numerous risks and uncertainties associated with securing regulatory approval for EndoBarrier[®], 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[®]. 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, 2020.

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

There have been no material changes from the Recent Accounting Pronouncements previously disclosed in the Company's Annual Report on Form 10-K.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Other than the negative impact the COVID-19 pandemic has had and will continue to have on our business and results of operations as discussed elsewhere in this Quarterly Report on Form 10-Q, there have been no material changes in our primary risk exposures or management of market risks from those disclosed in our Annual Report on Form 10-K for the year ended December 31, 2020.

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, 2021 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 2021 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 and as set forth below, 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, 2020, filed with the SEC on March 12, 2021, 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.

Crystal Amber beneficially owns a large portion of our capital stock and retains voting control of the Company, and accordingly, has control over stockholder matters, our business and management.

As of March 31, 2021, Crystal Amber beneficially owns approximately 79.0 million shares of common stock, or approximately 90% of our issued and outstanding shares of common stock. Crystal Amber also holds approximately 76.3 million shares of our Series A Preferred Stock, which is approximately 99% of our issued and outstanding shares of Series A Preferred Stock. Crystal Amber's beneficial ownership of approximately 79 million shares of common stock and 79 million shares of Series A Preferred Stock provides Crystal Amber with 95% of the voting control of the Company.

Additionally, the shares of Series A Preferred Stock contain protective provisions, which precludes the Company from taking certain actions without the approval of Crystal Amber (or that of the holders of a majority of the shares of Series A Preferred Stock). More specifically, so long as any shares of Series A Preferred Stock are outstanding, the Company is not permitted to take certain actions without first obtaining the approval (by vote or written consent, as provided by law) of the holders of at least a majority of the then outstanding shares of Series A Preferred Stock, voting as a separate class, including for example and without limitation, amending the Company's certificate of incorporation, changing or modifying the rights of the Series A Preferred Stock, including increasing or decreasing the number of authorized shares of Series A Preferred Stock, increasing or decreasing the size of the board of directors or remove the directors appointed by the holders of our Series A Preferred Stock and declaring or paying any dividend or other distribution.

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, 2021.

Item 6. Exhibits.

Exhibit No:	Description
3.1	<u>Restated Certificate, incorporated by reference to Exhibit 3.1 of GI Dynamics, Inc.'s Current Report on Form 8-K filed with the SEC on September 10, 2020.</u>
3.2	<u>Restated Bylaws, incorporated by reference to Exhibit 3.2 of GI Dynamics, Inc.'s Current Report on Form 8-K filed with the SEC on September 10, 2020.</u>
10.1	<u>Fourth Amendment to Series A Preferred Stock Purchase Agreement, effective as of January 29, 2021, between GI Dynamics and Crystal Amber Fund Limited. Incorporated by reference to Exhibit 10.1 of GI Dynamics, Inc.'s Current Report on Form 8-K filed with the SEC on February 2, 2021</u>
10.2	<u>Fifth Amendment and Waiver to Series A Preferred Stock Purchase Agreement, effective as of February 24, 2021, between GI Dynamics and Crystal Amber Fund Limited. Incorporated by reference to Exhibit 10.1 of GI Dynamics, Inc.'s Current Report on Form 8-K filed with the SEC on March 9, 2021</u>
10.3	<u>Sixth Amendment and Waiver to Series A Preferred Stock Purchase Agreement, effective as of March 25, 2021, between GI Dynamics and Crystal Amber Fund Limited. Incorporated by reference to Exhibit 10.1 of GI Dynamics, Inc.'s Current Report on Form 8-K filed with the SEC on April 1, 2021</u>
31.1*	<u>Certification of principal executive officer pursuant to Rules 13a-14 or 15d-14 of the Exchange Act.</u>
31.2*	<u>Certification of principal financial officer pursuant to Rules 13a-14 or 15d-14 of the Exchange Act.</u>
32.1‡	<u>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.</u>
32.2‡	<u>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.</u>
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Database
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document

* Filed herewith.

‡ Furnished herewith.

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 7, 2021

By: /s/ JOSEPH VIRGILIO
Joseph Virgilio
Chief Executive Officer
(principal executive officer)

Date: May 7, 2021

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

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

I, Joseph Virgilio, 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 7, 2021

/s/ JOSEPH VIRGILIO

Joseph Virgilio
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 7, 2021

/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, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Joseph Virgilio, 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/ JOSEPH VIRGILIO

Joseph Virgilio
Chief Executive Officer
(principal executive officer)

May 7, 2021

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, 2021 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 7, 2021

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.