



Form 10-Q Filed with SEC

Boston, United States
Sydney, Australia
11 November 2019 AEDT

BOSTON and SYDNEY – 11 November 2019 — GI Dynamics® Inc. (ASX:GID) (Company or GI Dynamics), a medical device company that is developing EndoBarrier® for patients with type 2 diabetes and obesity, today provides the attached Quarterly Report on Form 10-Q, as filed with the U.S. Securities and Exchange Commission on 08 November 2019. The Form 10-Q includes the Company's unaudited financial results for the three and nine months ended 30 September 2019 and other required disclosures. The financial statements included in Form 10-Q were prepared in accordance with United States Generally Accepted Accounting Principles and are denominated in United States dollars unless otherwise indicated.

About GI Dynamics

GI Dynamics®, Inc. (ASX:GID) is the developer of EndoBarrier®, the first endoscopically-delivered device therapy for the treatment of type 2 diabetes and obesity. EndoBarrier is not approved for sale and is limited by federal law to investigational use only. EndoBarrier is subject to an Investigational Device Exemption by the FDA in the United States and is entering concurrent pivotal trials in the United States and India. Founded in 2003, GI Dynamics is headquartered in Boston, Massachusetts. For more information please visit www.gidynamics.com.

Forward-Looking Statements

This announcement may contain forward-looking statements. These statements are based on GI Dynamics management's current estimates and expectations of future events as of the date of this announcement. Furthermore, the estimates are subject to several risks and uncertainties that could cause actual results to differ materially and adversely from those indicated in or implied by such forward-looking statements.

These risks and uncertainties include, but are not limited to, risks associated with our ability to continue to operate as a going concern; our ability to obtain stockholder approval of the conversion feature of the August 2019 Note and issuance of the August 2019 Warrant, our ability to raise sufficient additional funds to continue

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operations and to conduct the planned pivotal trial of EndoBarrier in the United States (STEP-1); our ability to execute STEP-1 under FDA's Investigational Device Exemption; our ability to enlist clinical trial sites and enroll patients in accordance with STEP-1; the risk that the FDA stops STEP-1 early as a result of the occurrence of certain safety events or does not approve an expansion of STEP-1; our ability to enroll patients in accordance with I-STEP; our ability to secure a CE Mark; our ability to maintain compliance with our obligations under our existing convertible note and warrant agreements executed with Crystal Amber, including our obligations to make payment on the Note that is due on 31 March 2020 and our ability to restructure the terms of the Note with Crystal Amber that is due on 31 March 2020 if we are unable to raise sufficient funds to enable us to fully repay such Note when due; obtaining and maintaining regulatory approvals required to market and sell our products; the possibility that future clinical trials will not be successful or confirm earlier results; the timing and costs of clinical trials; the timing of regulatory submissions; the timing, receipt and maintenance of regulatory approvals; the timing and amount of other expenses; the timing and extent of third-party reimbursement; intellectual-property risk; risks related to excess inventory; risks related to assumptions regarding the size of the available market; the benefits of our products; product pricing; timing of product launches; future financial results; and other factors, including those described in our filings with the U.S. Securities and Exchange Commission.

Given these uncertainties, one should not place undue reliance on these forward-looking statements. We do not assume any obligation to publicly update or revise any forward-looking statements, whether as a result of new information or future events or otherwise, unless we are required to do so by law.

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 2019

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
Boston, Massachusetts

(Address of Principal Executive Offices)

02210

(Zip Code)

(781) 357-3300

(Registrant's telephone number, including area code)

Securities registered or to be registered pursuant to Section 12(b) of the Act:

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

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days: Yes No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit such files): Yes No

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

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

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

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

As of November 5, 2019, there were 35,963,481 shares of common stock outstanding.

The registrant's common stock is publicly traded on the Australian Securities Exchange ("the ASX") in the form of CHES Depository Interests ("CDIs") convertible at the option of the holders into shares of the registrant's common stock on a 1-for-50 basis. The total number of shares of the registrant's common stock outstanding on November 5, 2019, including shares of common stock underlying CDIs, was 35,963,481.

NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

- expectations with respect to the Company’s intellectual property position;
- expectations with respect to clinical trials for EndoBarrier[®];
- expectations with respect to regulatory submissions and receipt and maintenance of regulatory approvals;
- ability to commercialize products;
- ability to develop and commercialize new products;
- expectation with regard to product manufacture and inventory; and
- estimates regarding capital requirements and need for additional financing.

In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “should,” “could,” “would,” “expects,” “plans,” “anticipates,” “believes,” “estimates,” “projects,” “predicts,” “aims,” “assumes,” “goal,” “intends,” “objective,” “potential,” “positioned,” “target,” “continue,” “seek,” “vision,” or the negative thereof and similar expressions intended to identify forward-looking statements.

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

You are urged to consider these factors carefully in evaluating the forward-looking statements and are cautioned not to place undue reliance on the forward-looking statements. You should read this Quarterly Report on Form 10-Q and the documents filed as exhibits to the Company’s Annual Report on Form 10-K completely and with the understanding that actual future results may be materially different from what is stated as expectation. These forward-looking statements speak only as of the date of this Quarterly Report on Form 10-Q. Unless required by law, the Company does not intend to publicly update or revise any forward-looking statements to reflect new information or future events or otherwise. You should, however, review the factors and risks described in the reports the Company will file from time to time with the SEC after the date of this Quarterly Report on Form 10-Q.

GI DYNAMICS, INC.
QUARTERLY REPORT ON FORM 10-Q
FOR THE QUARTER ENDED SEPTEMBER 30, 2019

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References

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Dates

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

Currency

Unless indicated otherwise in this Quarterly Report on Form 10-Q, all references to “\$,” “US\$” or “dollars” refer to United States dollars, the lawful currency of the United States of America. References to “A\$” refer to Australian dollars, the lawful currency of the Commonwealth of Australia. References to “€” or “euros” means euros, the single currency of Participating Member States of the European Union.

Trademarks

EndoBarrier[®] 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)

	September 30, 2019 <u>(unaudited)</u>	December 31, 2018 <u>(audited)</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 1,403	\$ 3,806
Restricted cash	30	30
Subscription receivable from related party	2,000	—
Prepaid expenses and other current assets	1,229	530
Total current assets	<u>4,662</u>	<u>4,366</u>
Property and equipment, net	50	63
Right-of-use assets, net of amortization	462	—
Total assets	<u>\$ 5,174</u>	<u>\$ 4,429</u>
Liabilities and stockholders' deficit		
Current liabilities:		
Accounts payable	\$ 890	\$ 1,050
Accrued expenses	1,047	1,645
Short term debt to related party, net of debt discount	4,770	4,960
Derivative liabilities	25	51
Short term lease liabilities	180	—
Total current liabilities	<u>6,912</u>	<u>7,706</u>
Long term debt to related party, net of debt discount	—	168
Long term lease liabilities	282	—
Total liabilities	<u>7,194</u>	<u>7,874</u>
Commitments and contingencies		
Stockholders' deficit:		
Preferred stock, \$0.01 par value – 500,000 shares authorized; no shares issued and outstanding at September 30, 2019 and December 31, 2018	—	—
Common stock, \$0.01 par value – 50,000,000 shares authorized; 31,239,068 and 19,277,545 shares issued and outstanding at September 30, 2019 and December 31, 2018, respectively	315	193
Common stock - subscribed but unissued, 3,149,606 shares	2,000	—
Additional paid-in capital	277,676	263,521
Accumulated deficit	(282,011)	(267,159)
Total stockholders' deficit	<u>(2,020)</u>	<u>(3,445)</u>
Total liabilities and stockholders' deficit	<u>\$ 5,174</u>	<u>\$ 4,429</u>

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Operating expenses:				
Research and development	\$ 1,391	\$ 494	\$ 3,011	\$ 1,121
Sales and marketing	—	167	22	683
General and administrative	1,260	1,338	3,997	3,378
Total operating expenses	<u>2,651</u>	<u>1,999</u>	<u>7,030</u>	<u>5,182</u>
Loss from operations	(2,651)	(1,999)	(7,030)	(5,182)
Other income (expense):				
Interest income	—	7	3	23
Interest expense	(109)	(201)	(6,198)	(489)
Foreign exchange gain (loss)	6	2	12	10
Gain on write-off of accounts payable	1	—	91	—
Re-measurement of derivative liabilities	(10)	10	(1,698)	13
Other income (expense), net	<u>(112)</u>	<u>(182)</u>	<u>(7,790)</u>	<u>(443)</u>
Loss before income taxes	(2,763)	(2,181)	(14,820)	(5,625)
(Benefit from) Provision for income taxes	—	2	32	(1)
Net loss	<u>\$ (2,763)</u>	<u>\$ (2,183)</u>	<u>\$ (14,852)</u>	<u>\$ (5,624)</u>
Basic and diluted net loss per common share	\$ (0.09)	\$ (0.17)	\$ (0.48)	\$ (0.46)
Weighted-average number of common shares used in basic and diluted net loss per common share	31,239,071	12,691,797	31,239,071	12,279,294

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

GI Dynamics, Inc. and Subsidiaries
Consolidated Statements of Stockholders' Deficit
(In thousands, except share)
(unaudited)

	Common Stock		Common Stock subscribed but unissued		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Par Value	Shares	Carrying Value			
THREE MONTHS ENDED SEPTEMBER 2019							
Balance at July 1, 2019	19,277,545	\$ 193	9,072,197	\$ 5,991	\$ 269,476	\$ (279,248)	\$ (3,588)
Issuance of common shares upon conversion of notes payable to related party	9,072,197	91	(9,072,197)	(5,991)	5,900	—	—
Exercise of related party warrants	2,889,326	31	—	—	1,969	—	2,000
Shares subscribed upon exercise of related party warrants	—	—	3,149,606	2,000	—	—	2,000
2017 Note modification	—	—	—	—	273	—	273
Stock-based compensation expense	—	—	—	—	58	—	58
Net loss	—	—	—	—	—	(2,763)	(2,763)
Balance at September 30, 2019	<u>31,239,068</u>	<u>\$ 315</u>	<u>3,149,606</u>	<u>\$ 2,000</u>	<u>\$ 277,676</u>	<u>\$ (282,011)</u>	<u>\$ (2,020)</u>
THREE MONTHS ENDED SEPTEMBER 2018							
Balance at July 1, 2018	12,333,101	\$ 124	—	\$ —	\$ 258,599	\$ (262,562)	\$ (3,839)
Issuance of shares upon private placement, net of issuance costs	2,999,999	30	—	—	324	—	354
Beneficial conversion feature discount associated with 2018 Note	—	—	—	—	1,007	—	1,007
Relative fair value of warrant issued with 2018 Note	—	—	—	—	743	—	743
Stock-based compensation expense	—	—	—	—	22	—	22
Net loss	—	—	—	—	—	(2,183)	(2,183)
Balance at September 30, 2018	<u>15,333,100</u>	<u>\$ 154</u>	<u>—</u>	<u>\$ —</u>	<u>\$ 260,695</u>	<u>\$ (264,745)</u>	<u>\$ (3,896)</u>
NINE MONTHS ENDED SEPTEMBER 2019							
Balance at January 1, 2019	19,277,545	\$ 193	—	\$ —	\$ 263,521	\$ (267,159)	\$ (3,445)
Reclassification of derivative liabilities to additional paid-in capital upon stockholder approval	—	—	—	—	5,784	—	5,784
Issuance of common shares upon conversion of notes payable to related party	9,072,197	91	—	—	5,900	—	5,991
Exercise of related party warrants	2,889,326	31	—	—	1,969	—	2,000
Shares subscribed upon exercise of related party warrants	—	—	3,149,606	2,000	—	—	2,000
2017 Note modification	—	—	—	—	328	—	328
Stock-based compensation expense	—	—	—	—	174	—	174
Net loss	—	—	—	—	—	(14,852)	(14,852)
Balance at September 30, 2019	<u>31,239,068</u>	<u>\$ 315</u>	<u>3,149,606</u>	<u>\$ 2,000</u>	<u>\$ 277,676</u>	<u>\$ (282,011)</u>	<u>\$ (2,020)</u>
NINE MONTHS ENDED SEPTEMBER 2018							
Balance at January 1, 2018	11,157,489	\$ 112	—	\$ —	\$ 255,294	\$ (259,121)	\$ (3,715)
Issuance of shares upon private placement, net of issuance costs	4,175,611	42	—	—	3,565	—	3,607
Beneficial conversion feature discount associated with 2018 Note	—	—	—	—	1,007	—	1,007
Relative fair value of warrant issued with 2018 Note	—	—	—	—	743	—	743
Stock-based compensation expense	—	—	—	—	86	—	86
Net loss	—	—	—	—	—	(5,624)	(5,624)
Balance at September 30, 2018	<u>15,333,100</u>	<u>\$ 154</u>	<u>—</u>	<u>\$ —</u>	<u>\$ 260,695</u>	<u>\$ (264,745)</u>	<u>\$ (3,896)</u>

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

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

	Nine Months Ended September 30,	
	2019	2018
Operating activities:		
Net loss	\$ (14,852)	\$ (5,624)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	24	11
Re-measurement of derivative liabilities	1,698	(13)
Loss on disposal of leasehold improvements	—	2
Non-cash interest expense	6,194	486
Stock-based compensation expense	174	86
Other	(22)	—
Changes in operating assets and liabilities:		
Accounts receivable	—	40
Prepaid expenses and other current assets	(699)	6
Accounts payable	(160)	(442)
Accrued expenses	(662)	246
Net cash used in operating activities	<u>(8,305)</u>	<u>(5,202)</u>
Investing activities		
Purchases of property and equipment	(11)	—
Net cash used in investing activities	<u>(11)</u>	<u>—</u>
Financing activities		
Proceeds from issuance of common stock, net of issuance costs	—	3,607
Debt issuance costs	(87)	(85)
Proceeds from exercise of related party warrants	2,000	—
Proceeds from short term and long term debt, related party	4,000	1,750
Net cash provided by financing activities	<u>5,913</u>	<u>5,272</u>
Net decrease in cash and cash equivalents	(2,403)	70
Cash, cash equivalents and restricted cash at beginning of period	3,836	3,064
Cash, cash equivalents and restricted cash at end of period	<u>\$ 1,433</u>	<u>\$ 3,134</u>
Supplemental cash flow disclosures		
Income taxes paid	32	25
Beneficial conversion feature discount associated with 2018 Note	—	1,007
Relative fair value of warrant issued with 2018 Note	—	743
Interest paid	394	—
Modification of 2017 Note	328	—
Exercise of related party warrants in exchange for subscription receivable from related party	2,000	—
Right-of-use asset obtained in exchange for lease liability	509	—
Conversion of notes payable to related party into common stock	5,991	—
Reclassification of warrant from derivative liabilities to additional paid-in capital	5,784	—
Fair value of warrants issued with Notes to Related Party	4,072	—

The accompanying notes are an integral part of these 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 for treatment of patients with type 2 diabetes and 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. According to the Centers for Disease Control and Prevention (“CDC”), people with type 2 diabetes represent 90% of the worldwide diabetes population, whereas 10% of this population is diagnosed with type 1 diabetes (a form of diabetes mellitus in which not enough insulin is produced).

Being overweight is a condition where the patient’s body mass index (“BMI”) is greater than 25 (kg/m²); obesity is a condition where the patient’s BMI is greater than 30, according to the CDC. 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, The Company believes it is optimal to address obesity concurrently with diabetes.

EndoBarrier[®] is intended for the treatment of type 2 diabetes and 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 treatment gap.

The Company’s vision is to make EndoBarrier[®] the essential nonpharmacological and non-anatomy-altering treatment for patients with type 2 diabetes and obesity. 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 the Company’s 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 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.

EndoBarrier[®] History

In 2011, the Company began commercial sales of its product, EndoBarrier[®], which was approved and became commercially available in multiple countries outside the U.S.

In 2013, the Company received approval from the U.S. Food and Drug Administration (“FDA”) to commence its initial pivotal trial of EndoBarrier[®] (the “ENDO Trial”). The Company announced its decision to stop the ENDO Trial in the second half of fiscal year 2015 and thereafter announced that it was reducing headcount by approximately 46% as part of its efforts to restructure its business and expenses and to ensure sufficient cash remained available for it to establish new priorities, continue limited market development and research, and to evaluate strategic options.

In the second and third quarters of fiscal year 2016, in order to evolve strategic options, the Company took additional actions that resulted in non-recurring charges totaling approximately \$1.1 million. In October 2016, the Company received final cancellation notification from the Therapeutic Goods Administration (“TGA”) for the listing of EndoBarrier[®] on the Australian Register of Therapeutic Goods (“ARTG”).

In May 2017, the Company received notification from its notified body, SGS United Kingdom Limited (“SGS”), that the CE Mark for EndoBarrier[®] had been suspended pending closure of non-conformances related to its quality management system required under International Organization for Standardization (“ISO”) regulations.

On November 10, 2017, the Company received notification that SGS was withdrawing the Certificate of Conformance for EndoBarrier[®], ending the CE Marking of EndoBarrier[®] in Europe and select Middle East countries.

In December 2017, the Company received notification from the Medicines and Healthcare Products Regulatory Agency (“MHRA”) that all EndoBarrier[®] delivery systems (liners) in inventory needed to be returned to the Company.

In August 2018, the Company received approval of an investigational device exemption (“IDE”) from the FDA to begin enrollment in a pivotal trial evaluating the safety and efficacy of EndoBarrier[®] in the United States pending Institutional Review Board (“IRB”) approval, which was received in February 2019.

As of September 30, 2019, five U.S. clinical sites have been initiated and pre-screening for enrollment is being conducted.

Financing History

From its inception in 2003 to its initial public offering (“IPO”) in 2011, the Company was financed by a series of preferred stock financings. In September 2011, the Company completed its IPO of common stock in the form of CDIs in Australia. As a result of the IPO and simultaneous private placement in the U.S., the Company raised a total of approximately \$72.5 million in proceeds, net of expenses and repayment of \$6 million of the Company’s convertible term promissory notes. In July and August 2013, the Company issued CDIs on the ASX through a Private Investment in Public Equity placement (“PIPE”) and share purchase plan (“SPP”), which raised a total of approximately \$52.5 million, net of expenses. In May 2014, the Company raised approximately \$30.8 million, net of expenses, when it issued CDIs on the ASX through a PIPE. In December 2016, the Company raised approximately \$1 million, net of expenses, when it issued CDIs on the ASX through a PIPE. In January 2017, the Company raised approximately \$0.2 million, net of expenses, when it issued CDIs on the ASX through an SPP.

In June 2017, the Company completed a convertible term promissory note (the “2017 Note”) secured financing with Crystal Amber Fund Limited, its largest stockholder and due to the size of its ownership position, a Related Party for ASX purposes (hereafter referred to as “Crystal Amber, a Related Party”). The 2017 Note was placed for a gross amount of \$5 million and accrues annually compounded interest at 5% per annum. The 2017 Note was originally due on December 31, 2018 and is subject to security arrangements in favor of Crystal Amber, a Related Party (See Note 10 of the Consolidated Financial Statements for a more complete description of the terms and conditions of the financing).

In January and March 2018, the Company raised approximately \$1.6 million, net of expenses, in an offering of its CDIs to sophisticated and professional investors, including certain existing investors in Australia, the United States and the United Kingdom.

In May 2018, the Company completed a convertible term promissory note (the “2018 Note”) and warrant (the “2018 Warrant”) financing with Crystal Amber, a Related Party, for a gross amount of \$1.8 million. The 2018 Note accrued annually compounded interest at 10% per annum until notice of its conversion into CDIs was provided by Crystal Amber, a Related Party, on June 30, 2019, as described further below. The 2018 Warrant was exercised by Crystal Amber, a Related Party and the CDIs were issued on August 25, 2019, as described further below. (See Note 10 of these Consolidated Financial Statements for a more complete description of the terms and conditions of the financing).

In September 2018, the Company received commitments for a private placement of approximately \$5 million in an offering of its CDIs to sophisticated and professional investors, including certain existing investors in Australia, the United States and the United Kingdom. The first tranche of \$2.2 million closed and cash was received in September 2018. The issuance of the second and final tranche of \$2.8 million was contingent upon stockholder approval, which was obtained in October 2018. Cash proceeds from the second tranche were received in November 2018.

In December 2018, the maturity date of the 2017 Note was extended from December 31, 2018 to March 31, 2019 in exchange for payment of \$394 thousand, the total accrued interest on the 2017 Note at December 31, 2018.

In March 2019, the Company completed a convertible term promissory note (the “March 2019 Note”) and warrant (the “March 2019 Warrant”) financing with Crystal Amber, a Related Party, for a gross amount of \$1 million. The March 2019 Note accrued annually compounded interest at 10% per annum until notice of its conversion into CDIs was provided by Crystal Amber, a Related Party, on June 30, 2019, as described further below. Certain specific conversion terms related to the March 2019 Note and issuance of the March 2019 Warrant required stockholder approval, which was obtained by the Company at the Annual Meeting of Stockholders held on June 30, 2019. On June 30, 2019, after the relevant stockholder approval was obtained, the March 2019 Warrant was issued to Crystal Amber, a Related Party and on such date the March 2019 Warrant became immediately exercisable until its expiry on June 30, 2024 (see Note 10 of these Consolidated Financial Statements for a more complete description of the terms and conditions of the financing).

In March 2019, the maturity date of the 2017 Note was extended to May 1, 2019. In April 2019, the maturity date of the 2017 Note was extended to July 1, 2019. A further extension of the maturity date of the 2017 Note is described below.

In May 2019, the Company completed a convertible term promissory note (the “May 2019 Note”) and warrant (the “May 2019 Warrant”) financing with, Crystal Amber, a Related Party, for a gross amount of \$3 million. The May 2019 Note was funded in four tranches between May 10, 2019 and June 28, 2019, during which period 10% per annum interest was accrued on daily outstanding principal balances. Upon funding completion on June 28, 2019, accrued interest began to compound annually at 10% per annum until notice of its conversion into CDIs was provided by Crystal Amber, a Related Party, on June 30, 2019, as described further below. Certain specific conversion terms related to the May 2019 Note and issuance of the March 2019 Warrant required stockholder approval, which was obtained by the Company at the 2019 Annual Meeting of Stockholders held on June 30, 2019. On June 30, 2019, after the stockholder approval was obtained, the May 2019 Warrant was issued to Crystal Amber, a Related Party on such date the May 2019 Warrant became immediately exercisable until its expiry on June 30, 2024 (see Note 10 of these Consolidated Financial Statements for a more complete description of the terms and conditions of the financing).

In June 2019, the maturity date of the 2017 Note was extended to October 1, 2019.

On June 30, 2019, Crystal Amber, a Related Party, elected to convert the 2018 Note, the March 2019 Note and the May 2019 Note into CDIs. Under the terms of the respective notes, an aggregate of 453,609,963 CDIs (representing approximately 9,072,197 shares of common stock) were subscribed but unissued on conversion and concurrent cancellation of the 2018 Note, the March 2019 Note and the May 2019 Note. The CDIs were issued on July 3, 2019.

On August 21, 2019, the Company and Crystal Amber, a Related Party, 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 is comprised of scheduled existing warrant exercises between August 25, 2019 and November 15, 2019 of the 2018 Warrant, the March 2019 Warrant, and the May 2019 Warrant issued to Crystal Amber, a Related Party, as further detailed above. The remaining amount, up to \$4.6 million, is expected to be funded on or before December 6, 2019, at the request of the Company, pursuant to the terms of a convertible term promissory note (the "August 2019 Note") in substantially the same form as the March 2019 and May 2019 convertible term promissory note. The Company, at its sole discretion, may elect to request any of the \$4.6 million to be funded. In connection with the August 2019 Note, the Company agreed to issue Crystal Amber, a Related Party, a warrant (the "August 2019 Warrant") to purchase CDIs or common stock as set forth in the August 2019 Warrant, subject to the receipt of required stockholder approval approving the issuance of the August 2019 Warrant. Stockholder approval will also be required to enable certain specific conversion features under the August 2019 Note as well for the issue the related August 2019 Warrant (see Note 10 of these Consolidated Financial Statements for a more complete description of the terms and conditions of the financing).

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

On August 25, 2019, Crystal Amber, a Related Party, exercised the 2018 Warrant and a portion of the March 2019 Warrant in accordance with the terms of the August 2019 SPA. For an aggregate cash payment of \$2 million, 97,222,200 CDIs (representing approximately 1,944,444 shares of common stock) were issued at \$0.0144 per CDI under the 2018 Warrant and 47,244,119 CDIs (representing approximately 944,882 shares of common stock) were issued at \$0.0127 per CDI under the March 2019 Warrant.

On September 30, 2019, Crystal Amber, a Related Party, exercised the remaining portion of the March 2019 Warrant and a portion of the May 2019 Warrant further in accordance with the August 2019 SPA. For an aggregate cash payment of \$2 million, 31,740,704 CDIs (representing approximately 634,814 shares of common stock) were issued at \$0.0127 per CDI under the March 2019 Warrant and 125,739,610 CDIs (representing approximately 2,514,792 shares of common stock) were issued on October 4, 2019 at \$0.0127 per CDI under the May 2019 Warrant. As of September 30, 2019, this was recorded as a subscription receivable from related party and the cash was received on October 1, 2019.

On October 31, 2019, Crystal Amber, a Related Party, exercised another portion of the May 2019 Warrant in accordance with the August 2019 SPA. For an aggregate cash payment of \$1 million, 78,740,157 CDIs (representing approximately 1,574,803 shares of common stock) were issued on November 4, 2019 at \$0.0127 per CDI under the May 2019 Warrant. Cash was received on October 31, 2019.

Going Concern

As of September 30, 2019, the Company's primary source of liquidity is its cash and cash equivalents balances. The Company continues to evaluate which markets are appropriate to pursue regulatory approvals, pursue reimbursement, raise market awareness and conduct general market development efforts. The Company continues to restructure its business and costs, establish new priorities, and evaluate strategic options. As a result, if the Company remains in business, it expects to incur significant operating losses for the next several years. The Company has incurred operating losses since inception and at September 30, 2019 had an accumulated deficit of approximately \$282 million, a working capital deficit of approximately \$2.3 million, cash used in 2019 for operating activities of approximately \$8.3 million and cash, cash equivalents and restricted cash of approximately \$1.4 million. Cash provided by these activities will be used predominantly to prepare for and conduct the Company's U.S. clinical trial, which will result in increased expenses. The Company does not expect its current cash balances will be sufficient to operate beyond the end of February 2020. The Company will need to raise additional funds through any combination of collaborative arrangements, strategic alliances, and additional equity and debt financings or from other sources. Furthermore, if the Company raises insufficient funds or is required to make payment to Crystal Amber, a Related Party, under the 2017 Note on its maturity date of March 31, 2020, the Company will be required either to renegotiate the maturity date of the loan or to potentially cease operations. The Company expects to discuss a further extension of the maturity date of the 2017 Note with Crystal Amber, a Related Party, but there can be no assurance that any extension will occur.

The Company has no guaranteed source of capital that will sustain operations beyond February 2020. There can be no assurance that other potential financing opportunities will be available on acceptable terms, if at all. As such, if access to capital is not achieved to satisfy cash needs in the near term, the Company's business, financial condition and results of operations will be materially harmed or the Company may be required to cease operations. These factors raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that these financial statements are issued.

The accompanying interim consolidated financial statements have been prepared assuming the Company will continue as a going concern, which contemplates the realization of assets and liabilities and commitments in the normal course of business. The consolidated financial statements as of September 30, 2019 and December 31, 2018 and the three and nine months ended September 30, 2019 and 2018 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 the financial statements are issued.

2. Summary of Significant Accounting Policies and Basis of Presentation

The accompanying interim consolidated financial statements and related disclosures as of September 30, 2019, and for the three and nine months ended September 30, 2019 and 2018, are unaudited and have been prepared in accordance with generally accepted accounting principles in the U.S. ("GAAP") and the applicable rules and regulations of the Securities and Exchange Commission ("SEC") for interim financial information. Accordingly, they do not include all of the information and notes required by GAAP for complete financial statements. These interim consolidated financial statements should be read in conjunction with the consolidated financial statements and notes thereto contained in the Company's Annual Report on Form 10-K ("Form 10-K"), filed with the SEC on March 13, 2019. The December 31, 2018 consolidated balance sheet included herein was derived from the audited financial statements as of that date but does not include all disclosures including notes required by GAAP for complete financial statements.

Principles of Consolidation

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

Use of Estimates

The preparation of consolidated financial statements in accordance with GAAP requires the Company's management to make estimates and judgments that may affect the reported amounts of assets, liabilities, revenues and expenses, and the related disclosure of contingent assets and liabilities. On an ongoing basis, the Company's management evaluates its estimates, including those related to impairment of long-lived assets, income taxes including the valuation allowance for deferred tax assets, research and development expenses, contingencies, lease liabilities, valuation of derivatives and derivative liabilities, estimates used to assess its ability to continue as a going concern and stock-based compensation. The Company bases its estimates on historical experience and on various other assumptions that are believed to be reasonable, the results of which form the basis for making judgments about the carrying values of assets and liabilities. Actual results may differ from these estimates under different assumptions or conditions. Changes in estimates are reflected in reported results in the period in which they become known.

Cash and Cash Equivalents

The Company considers all highly liquid investment instruments with an original maturity when purchased of three months or less to be cash equivalents. Investments qualifying as cash equivalents primarily consist of money market funds and have a carrying amount that approximates fair value. The amount of cash equivalents included in cash and cash equivalents was approximately nil at September 30, 2019 and \$1.1 million at December 31, 2018.

As of September 30, 2019 and December 31, 2018, the Company has \$30 thousand in restricted cash used to secure a corporate credit card account.

Inventory

When the Company gains regulatory approval to resume commercial activity, inventory will be stated at the lower of first-in, first-out cost or net realizable value. When capitalizing inventory, the Company will consider factors such as status of regulatory approval, alternative use of inventory, and anticipated commercial use of the product. At September 30, 2019 and December 31, 2018, there was no inventory.

Property and Equipment

Property and equipment are recorded at cost and are depreciated when placed in service using the straight-line method based on their estimated useful lives.

Included in property and equipment are certain costs of software obtained for internal use. Costs incurred during the preliminary project stage are expensed as incurred, while costs incurred during the application development stage are capitalized and amortized over the estimated useful life of the software. The Company also capitalizes costs related to specific upgrades and enhancements when it is probable the expenditures will result in additional functionality. Maintenance and training costs related to software obtained for internal use are expensed as incurred.

Leasehold improvements, if obtained, will be amortized over the shorter of the estimated useful life of the asset or the remaining lease term. Costs for capital assets not yet placed into service are capitalized as construction in progress and will be subsequently depreciated in accordance with the above guidelines once placed into service. Maintenance and repair costs are expensed as incurred.

Lease Liabilities and Related Assets

The Company adopted Accounting Standards Codification ("ASC"), Topic 842, *Leases* ("ASC 842") on January 1, 2019, but had no long-term leases to which it would apply. In May 2019, the Company entered into the first right-of-use Lease requiring the adoption of ASC 842.

At the inception of an arrangement, the Company determines whether the arrangement is or contains a lease based on the unique facts and circumstances present. The Company has elected not to recognize on the balance sheet leases with terms of one year or less. Leases with a non-cancellable term greater than one year are recognized on the balance sheet as lease assets, short-term lease liabilities and long-term lease liabilities. Using criteria defined in ASC 842, the Company determines whether the lease is a Financing Lease or an Operating Lease.

Lease liabilities and their corresponding right-of-use assets are recorded based on the present value of lease payments over the expected remaining lease term. Options to renew an Operating lease are not included in the Company's initial lease term assessment unless there is reasonable certainty that the Company will renew. However, certain adjustments to the right-of-use operating asset may be required for items such as incentives received. The interest rate implicit in lease contracts is typically not readily determinable. As a result, the Company utilizes an estimated incremental borrowing rate, which is the rate it is expected to incur to borrow an amount equal to the lease payments on a collateralized basis (or on an unsecured basis if existing debt covenants prevent further securitization) over a similar term in a similar economic environment.

In accordance with the guidance in ASC 842, components of a lease are split into lease components and non-lease components. A policy election is available pursuant to which an entity may elect to not separate lease and non-lease components. For new and amended leases beginning in 2019 and after, the Company has not made the election to combine lease and non-lease components.

Research and Development Costs

Research and development costs are expensed when incurred. Research and development costs include costs of all basic research activities as well as other research, engineering, and technical effort required to develop a new product or service or make significant improvement to an existing product or manufacturing process. Research and development costs also include regulatory and clinical trial expenses incurred prior to regulatory approval.

Patent Costs

The Company expenses as incurred all costs, including legal expenses, associated with obtaining patents until the patented technology becomes feasible. All costs incurred after the patented technology is feasible will be capitalized as an intangible asset. As of September 30, 2019 and December 31, 2018, no such costs had been capitalized. The Company expensed patent costs within general and administrative expenses of \$59 and \$63 thousand for the three months ended September 30, 2019 and 2018, respectively, and \$153 and \$143 thousand for the nine months ended September 30, 2019 and 2018, respectively.

Stock-Based Compensation

The Company accounts for stock-based compensation in accordance with the Financial Accounting Standards Board (“FASB”), ASC 718, *Stock Compensation* (“ASC 718”), which requires that stock-based compensation be measured and recognized as an expense in the financial statements and that such expense be measured at the grant date fair value.

For awards that vest based on service conditions, the Company uses the straight-line method to allocate compensation expense to reporting periods. The grant date fair value of options granted is calculated using the Black-Scholes option pricing model, which requires the use of subjective assumptions including volatility, expected term and the fair value of the underlying common stock, among others.

The assumptions used in determining the fair value of stock-based awards represent management’s best estimates, but these estimates involve inherent uncertainties and the application of management judgment. As a result, if factors change, and different assumptions are used, stock-based compensation could be materially different in the future. The risk-free interest rate used for each grant is based on a zero-coupon U.S. Treasury instrument with a remaining term similar to the expected term of the stock-based award. The Company uses the simplified method for estimating the expected term, which is based on the average of the vesting tranches and the contractual life of each grant. Expected stock volatility is based on the Company’s to-date historical price volatility. The Company has not paid and does not anticipate paying cash dividends on the Company’s shares of common stock; therefore, the expected dividend yield is assumed to be zero. In 2017, the Company elected to use an actual occurrence method of recording award forfeitures rather than the prior standard of estimating forfeitures as of the grant date.

The Company periodically issues performance-based awards. For these awards, vesting will occur upon the achievement of certain milestones. When achievement of the milestone is deemed probable, the Company expenses the compensation of the stock award over the implicit service period.

Stock awards to non-employees are accounted for in accordance with Accounting Standards Update (“ASU”) 2018-07 which amends ASC 718 with Improvements to Nonemployee Share-Based Payment Accounting. Under the main provision of ASU 2018-07, the fair value of the award is determined as of the grant date of the award (the date terms and conditions are agreed to between the Company and the Non-Employee vendor). The fair value at grant date estimate includes a probability component reflecting likelihood of achievement of any performance requirements. For the three and nine months ended September 30, 2019, the Company had no granted Nonemployee Share-Based Payments that had not been fully vested and earned.

Impairment of Long-Lived Assets

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

Loss Contingencies

In accordance with ASC 450, *Contingencies*, the Company accrues anticipated costs of settlement, damages, and losses for loss contingencies based on historical experience or to the extent specific losses are probable and estimable. Otherwise, the Company expenses these costs as incurred. If the estimate of a probable loss is a range, and no amount within the range is more likely, the Company accrues the minimum amount of the range.

Income Taxes

The Company provides for income taxes under the liability method. The Company records deferred tax assets and liabilities for the expected future tax consequences of temporary differences between the Company's financial reporting and the tax bases of assets and liabilities measured using the enacted tax rates expected to be in effect in the years in which the differences are expected to reverse. Deferred tax assets are reduced by a valuation allowance to reflect the uncertainty associated with their ultimate realization.

The Company accounts for uncertain tax positions recognized in the consolidated financial statements by applying a more-likely-than-not threshold for financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return.

Guarantees

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

As permitted under Delaware law, the Company indemnifies its officers and directors for certain events or occurrences while the officer or director is, or was, serving at the Company's request in such capacity. The maximum potential amount of future payments the Company could be required to make is unlimited; however, the Company has directors' and officers' insurance coverage that would limit its exposure and enable it to recover a portion of any future amounts paid. The Company has never filed a claim under directors' and officers' insurance.

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

For the three and nine months ended September 30, 2019 and 2018, the Company had not experienced any material losses related to these indemnification obligations, and no material claims with respect thereto were outstanding. The Company does not expect significant claims related to these indemnification obligations and, consequently, concluded that the fair value of these obligations is negligible. As a result, no related reserves have been established.

Issuance Costs Related to Equity and Debt

The Company allocates issuance costs between the individual freestanding instruments identified on the same basis as proceeds were allocated. Issuance costs associated with the issuance of stock or equity contracts (i.e., equity-classified warrants and convertible preferred stock) are recorded as a charge against the gross proceeds of the offering. Any issuance costs associated with the issuance of liability-classified warrants are expensed as incurred. Issuance costs associated with the issuance of debt (i.e., convertible debt) is recorded as a direct reduction of the carrying amount of the debt liability but limited to the notional value of the debt. The Company accounts for debt as liabilities measured at amortized cost and amortizes the resulting debt discount to interest expense using the effective interest method over the expected term of the notes pursuant to ASC 835, *Interest* ("ASC 835"). To the extent that the reduction from issuance costs of the carrying amount of the debt liability would reduce the carrying amount below zero, such excess is recorded as interest expense.

Embedded Conversion Features

The Company evaluates embedded conversion features within convertible debt under ASC 815, *Derivatives and Hedging* to determine whether the embedded conversion feature(s) should be bifurcated from the host instrument and accounted for as a derivative at fair value with changes in fair value recorded in earnings. If the conversion feature does not require derivative treatment under ASC 815, the instrument is evaluated under ASC 470-20 "Debt with Conversion and Other Options." Under ASC 470-20, an entity must separately account for the liability and equity components of the convertible debt instruments that may be settled entirely or partially in cash upon conversion in a manner that reflects the issuer's economic interest cost. The effect of ASC 470-20 on the accounting for the Company convertible debt instruments is that the equity component is required to be included in the additional paid-in capital section of stockholders' equity on the consolidated balance sheets and the value of the equity component is treated as original issue discount for purposes of accounting for the debt component of the notes. Therefore, the Company is required to record as non-cash interest expense the amortization of the discounted carrying value of the convertible debt to the face amount over the term of the convertible debt. The Company reports higher interest expense in the Company's financial results because ASC 470-20 requires interest to include both the current period's amortization of the debt discount and the instrument's coupon interest.

For conventional convertible debt where the rate of conversion is below market value, the Company values and records a beneficial conversion feature ("BCF") and related debt discount on issuance. When the Company records a BCF, the relative fair value of the BCF is recorded as a debt discount against the face amount of the respective debt instrument (offset to additional paid in capital) and amortized to interest expense over the life of the debt.

Reclassification

On the consolidated statement of cash flows, the Company reclassified amortization of debt issuance costs non-cash interest expense of \$141 thousand and accretion of debt discount of \$96 thousand into non-cash interest expense for the nine months ended September 30, 2018 in order to conform with current year presentation.

Subsequent Events

The Company evaluates events occurring after the date of its consolidated balance sheet for potential recognition or disclosure in its consolidated financial statements.

On October 31, 2019, Crystal Amber, a Related Party, exercised another portion of the May 2019 Warrant as scheduled in the August 2019 SPA. For an aggregate cash payment of \$1 million, 78,740,157 CDIs (representing approximately 1,574,803 shares of common stock) were issued on November 4, 2019 at \$0.0127 per CDI under the May 2019 Warrant. This was recorded as a subscription receivable from related party and the cash was received on October 1, 2019 (see Note 4 of these Consolidated Financial Statements for a more complete description of the terms and conditions of the May 2019 Warrant).

New Accounting Pronouncements

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)*, or ASU 2016-02. ASU 2016-02 requires that most operating leases be recorded on the balance sheet unless the practical expedient is elected for short-term operating leases. The lessee will record a lease liability, which is a lessee's obligation to make lease payments arising from a lease, measured on a discounted basis, and a right-of-use asset, which is an asset representing the lessee's right to use the underlying asset for the lease term. ASU 2016-02 is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years, with early adoption permitted. Lessees must apply a modified retrospective transition approach for leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements. The modified retrospective approach would not require any transition accounting for leases that expired before the earliest comparative period presented. Lessees may not apply a full retrospective transition approach. The Company elected to apply the practical expedient as it relates to short-term leases. The Company adopted ASU 2016-02 on January 1, 2019. There was no impact to retained earnings upon adoption as there were no long-term leases in effect at adoption (see Note 11 of these Consolidated Financial Statements for a more complete description of the lease accounting and impacts of adoption).

In June 2018, the FASB issued ASU No. 2018-07, *Compensation – Stock Compensation (Topic 718: Improvements to nonemployee share-based payment accounting)*, or ASU 2018-07, which provides measurement provisions and clarifications for the accounting for Non-employee Share-Based Payments ("NESBP"). As a result, most of the guidance within ASC 718 associated with employee share-based payments, including most of its requirements related to classification and measurement, applies to NESBP. ASU 2018-07 is effective for public business entities for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years, with early adoption permitted but not in advance of adoption of Topic 606, *Revenue Recognition*. Upon transition, the entity is required to measure these nonemployee awards at fair value as of the adoption date. The entity must not remeasure assets that are completed. The Company adopted ASC 2018-07 as of January 1, 2019 and there was no impact to retained earnings or equity as no uncompleted NESBPs were outstanding when adopted. For the three and nine months ended September 30, 2019, the Company had no unvested or unearned NESBPs outstanding.

In July 2018, the FASB issued ASU No. 2018-09, *Codification Improvements*, or ASU 2018-09, which affects a wide variety of topics, including the following: Amendments to Subtopic 220-10, *Income Statement—Reporting Comprehensive Income—Overall* relates to income taxes not payable in cash; Amendments to Subtopic 470-50, *Debt—Modifications and Extinguishments* relates to debt extinguishment and requires that the net carrying amount of extinguished fair value elected debt equals its fair value at reacquisition and related gains or losses in other comprehensive income must be included in net income upon extinguishment of the debt; Amendments to Subtopic 480-10, *Distinguishing Liabilities from Equity—Overall* relates to combinations of freestanding financial instruments with non-controlling interests; Amendments to Subtopic 718-740, *Compensation—Stock Compensation—Income Taxes* relate to recognition timing clarification for excess tax benefits or deficiencies for compensation expense; Amendments to Subtopic 805-740, *Business Combinations—Income Taxes* relate to allocating tax provisions to an acquired entity; Amendments to Subtopic 815-10, *Derivatives and Hedging—Overall* relate to accounting for offsetting derivatives; Amendments to Subtopic 820-10, *Fair Value Measurement—Overall* relate to the wording with respect to how transfer restrictions effect the fair value of an asset and adds explicit wording to allow entities to measure fair value on a net basis for those portfolios in which financial assets and financial liabilities and nonfinancial instruments are managed and valued together. Amendments to Subtopic 940-405, *Financial Services—Brokers and Dealers—Liabilities* relate to guidance about offsetting on the balance sheet; and Amendments to Subtopic 962-325, *Plan Accounting—Defined Contribution Pension Plans—Investments—Other* relate to plan evaluation of whether a readily determinable fair value exists to determine whether those investments may qualify for the practical expedient to measure at net asset value in accordance with Topic 820. The transition and selection of an effective date is based on the facts and circumstances of each amendment, but many of the amendments have transition guidance with effective dates for annual periods beginning after December 15, 2018, for public business entities. The Company is currently evaluating the relevance of each components and potential impact of ASU 2018-09 components to its consolidated financial statements.

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

3. Net Loss per Common Share

Basic net loss per common share is computed by dividing net loss by the weighted-average number of common shares outstanding during the period. Potential common stock equivalents are determined using the treasury stock method. For diluted net loss per share purposes, the Company excludes stock options and other stock-based awards, including shares issued as a result of option exercises but which are subject to repurchase by the Company, whose effect would be anti-dilutive from the calculation. During the three and nine months ended September 30, 2019 and 2018, common stock equivalents were excluded from the calculation of diluted net loss per common share, as their effect was anti-dilutive due to the net loss incurred. Therefore, basic and diluted net loss per share was the same in all periods presented.

The following potentially dilutive securities have been excluded from the computation of diluted weighted-average shares outstanding as of September 30, 2019 and 2018, as they would be anti-dilutive:

	As of September 30,	
	2019	2018
Warrants to purchase common stock	2,238,149	1,972,976
Options to purchase common stock and other stock-based awards	3,266,154	1,545,719
Total	5,504,303	3,518,695

4. Warrants to Purchase Common Stock and CDIs

On May 4, 2016, the Company entered into a consulting agreement pursuant to which a consulting firm provided strategic advisory, finance, accounting, human resources and administrative functions, including chief financial officer services, to the Company. In connection with the consulting agreement, the Company granted the consulting firm a warrant (“Consultant Warrant”) to purchase up to 28,532 shares of the Company’s common stock at an exercise price per share equal to \$0.64. The Consultant Warrant is fully vested and expires on May 4, 2021. The Company has reserved 28,532 shares of common stock related to the Consultant Warrant. As of September 30, 2019, the Consultant Warrant had not been exercised.

On May 30, 2018, the Company entered into a note (the “2018 Note”) and warrant (the “2018 Warrant”) Purchase agreement that included a warrant to purchase 97,222,200 CDIs (representing approximately 1,944,444 shares of common stock). The exercise price of the 2018 Warrant was initially \$0.018 per CDI and was subsequently reset to \$0.0144 when the Company issued securities at the lower price in September 2018. The 2018 Warrant was exercised for \$1.4 million on August 25, 2019.

On March 15, 2019, the Company entered into a note (the “March 2019 Note”) and warrant (the “March 2019 Warrant”) Purchase agreement that included a form of warrant to purchase 78,984,823 CDIs (representing approximately 1,579,696 shares of common stock). The March 2019 Warrant was subsequently approved by stockholders and issued on June 30, 2019 with an exercise price of \$0.0127 per CDI. On August 25, 2019, a portion of the March 2019 Warrant totaling 47,244,119 CDIs (representing approximately 944,882 shares of common stock) was exercised for \$600 thousand. The remaining portion of the March 2019 Warrant, totaling 31,740,704 CDIs (representing approximately 634,814 shares of common stock) was exercised for approximately \$400 thousand on September 30, 2019. The exercise was recorded as common shares subscribed, but unissued and subscription receivable as notice of exercise had been received, but cash had not posted to the Company accounts and CDIs had not been issued at September 30, 2019. The cash was received on October 1, 2019 and the CDIs were issued on October 4, 2019.

On May 8, 2019, the Company entered into a note (the “May 2019 Note”) and warrant (the “May 2019 Warrant”) purchase agreement that included a form of warrant to purchase up to 236,220,472 CDIs (representing 4,724,409 shares of common stock). The May 2019 Warrant to purchase the maximum number of CDIs of 236,220,472, was both approved by stockholders and issued on June 30, 2019. The May 2019 Warrant’s exercise price was \$0.0127 per CDI. A portion of the May 2019 Warrant totaling 125,739,610 CDIs (representing approximately 2,514,792 shares of common stock) was exercised for approximately \$1.6 million on September 30, 2019. The exercise was recorded as common shares subscribed, but unissued and subscription receivable as notice of exercise had been received, but cash had not posted to the Company accounts and CDIs had not been issued at September 30, 2019. The cash was received on October 1, 2019 and the CDIs were issued on October 4, 2019.

Another portion of the May 2019 Warrant totaling 78,740,157 CDIs (equivalent to 1,574,803 shares of common stock) was exercised for approximately \$1 million on October 31, 2019.

5. Fair Value of Assets and Liabilities

The tables below present information about the Company's assets and liabilities that are measured at fair value on a recurring basis as of September 30, 2019 and December 31, 2018 and indicates the fair value hierarchy of the valuation techniques the Company used to determine such fair value. In general, fair values determined by Level 1 inputs utilize observable inputs such as quoted prices in active markets for identical assets or liabilities. Fair values determined by Level 2 inputs utilize data points that are either directly or indirectly observable, such as quoted prices, interest rates and yield curves. Fair values determined by Level 3 inputs utilize unobservable data points in which there is little or no market data, requiring the Company to develop its own assumptions for the asset or liability.

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

Description	September 30, 2019	Fair Value Measurements at Reporting Date Using		
		Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets				
Money market funds (included in cash and cash equivalents)	\$ —	\$ —	\$ —	\$ —
Total assets	\$ —	\$ —	\$ —	\$ —
Liabilities				
Derivative liability	\$ 25	\$ —	\$ —	\$ 25
Total liabilities	\$ 25	\$ —	\$ —	\$ 25

Description	December 31, 2018	Fair Value Measurements at Reporting Date Using		
		Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets				
Money market funds (included in cash and cash equivalents)	\$ 1,097	\$ 1,097	\$ —	\$ —
Total assets	\$ 1,097	\$ 1,097	\$ —	\$ —
Liabilities				
Derivative liability	\$ 51	\$ —	\$ —	\$ 51
Total liabilities	\$ 51	\$ —	\$ —	\$ 51

The assumptions used in the Black-Scholes option pricing model to determine the fair value of the derivative liabilities as of September 30, 2019, and December 31, 2018 were as follows:

	September 30, 2019	December 31, 2018
Exercise price (A\$55.00 at the then current exchange rate)	\$ 0.64	\$ 0.64
Fair value of common stock	\$ 1.25	\$ 0.57
Expected volatility	118%	134%
Expected term (in years)	1.6	2.35
Risk-free interest rate	1.7%	2.5%
Expected dividend yield	0%	0%

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

Balance at December 31, 2018	\$ 51
Increase in fair value of warrants upon re-measurement	1,726
Amortization of conversion rights	(40)
Fair value of warrants issued with notes to related party	4,072
Reclassification of warrants to additional paid-in capital	(5,784)
Balance at September 30, 2019	\$ 25

Cash, cash equivalents, restricted cash, subscription receivable from related party, prepaid expenses and other current assets, right-of-use assets, accounts payable, accrued expenses, short-term lease liabilities and short-term debt to Crystal Amber, a Related Party, at September 30, 2019 and December 31, 2018 are carried at amounts that approximate fair value due to their short-term maturities and highly liquid nature of these instruments. The carrying value of the Company's long-term debt to Crystal Amber, a Related Party at December 31, 2018, and long-term lease liabilities at September 30, 2019 approximates fair value based on commonly applied estimation methodologies, published market data and industry studies obtained by the Company.

6. Concentrations of Credit Risk and Related Valuation Accounts

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

When the Company had regulatory approval to sell EndoBarrier[®] in select markets, the Company granted unsecured credit to customers in the normal course of business. The Company made judgments as to its ability to collect outstanding receivables and provided an allowance for receivables when collection became doubtful. Provisions were made based upon a specific review of all significant outstanding invoices and the overall quality and age of those invoices not individually reviewed. Amounts determined to be uncollectible are written off against the total reserve. After regulatory approval for EndoBarrier[®] was suspended, the Company deemed certain remaining accounts receivable uncollectible and recorded write-offs of uncollectible accounts receivable of \$42 thousand in the nine months ended September 30, 2018. As of September 30, 2019 and December 31, 2018, the Company had no accounts receivable and no reserves for uncollectible accounts receivable.

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

	Nine Months Ended September 30,	
	2019	2018
Beginning balance	\$ —	\$ 42
Net charges to expenses	—	—
Utilization of allowances	—	(42)
Ending balance	<u>\$ —</u>	<u>\$ —</u>

7. Inventory

The Company assessed the probability and timing of regulatory approval and appropriate inventory life span and deemed the inventory on hand as of December 31, 2017 to be obsolete and subsequently wrote off all inventory and reserves in 2018. There is no inventory or reserves against inventory on the balance sheet at September 30, 2019 and December 31, 2018.

8. Property and Equipment

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

	September 30, 2019	December 31, 2018
Laboratory and manufacturing equipment	\$ 591	\$ 591
Computer equipment and software	1,193	1,182
Office furniture and equipment	183	183
	<u>1,967</u>	<u>1,956</u>
Less accumulated depreciation and amortization	(1,917)	(1,893)
Total	<u>\$ 50</u>	<u>\$ 63</u>

Depreciation and amortization expense of property and equipment totaled approximately \$7 thousand and nil for the three months ended September 30, 2019 and 2018 and \$24 and \$11 thousand for the nine months ended September 30, 2019 and 2018, respectively.

At September 30, 2019 and December 31, 2018, the Company had no property and equipment assets financed in any capital lease arrangement.

9. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	September 30, 2019	December 31, 2018
Payroll and related liabilities	\$ 392	\$ 386
Professional fees	247	573
Credit refunds	164	186
Interest	187	494
Other	57	6
Total	<u>\$ 1,047</u>	<u>\$ 1,645</u>

10. Notes Payable

2017 Convertible Note Financing

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

The 2017 Note accrues interest at an annually compounded rate of 5% per annum, other than during the continuance of an event of default, when the 2017 Note accrues interest at a rate of 8% per annum. The entire outstanding principal balance and all unpaid accrued interest thereon was initially due on the original maturity date of December 31, 2018, but the maturity date was extended multiple times as described below.

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

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

The 2017 Note was issued without stockholder approval of certain specific conversion features and as a consequence, Crystal Amber, a Related Party, had no right to exercise any note conversion rights until stockholders approved the 2017 Note conversion terms on May 24, 2018. Subsequently, the entire outstanding principal balance under the 2017 Note and all unpaid accrued interest thereon is convertible into CDIs (i) prior to the maturity date, at the option of Crystal Amber, a Related Party, at a conversion price calculated based on the five-day volume weighted average price of the Company's CDIs traded on the ASX ("Optional Conversion Price"), or (ii) automatically upon the occurrence of an equity financing in which the Company raises at least \$10 million (a "Qualified Financing") at the price per CDI of the CDIs issued and sold in such financing.

In the event that the Company issues additional CDIs in a subsequent equity financing at a price per CDI that is less than the then-effective Optional Conversion Price, Crystal Amber, a Related Party, has a 30-day option to convert at an adjusted conversion price reflecting, on a weighted average basis, the lower price per CDI. The number of CDIs that Crystal Amber, a Related Party, may acquire upon conversion of the 2017 Note at this adjusted conversion price is limited to the number that maintains Crystal Amber's, a Related Party, fully-diluted ownership percentage of the Company at the same level as existed immediately preceding the applicable subsequent equity financing.

In addition, upon a change of control of the Company (other than a change of control resulting from a Qualified Financing) in which the Company's stockholders receive cash consideration, the Company is obligated under the 2017 Note to pay all accrued and unpaid interest then due plus 110% of the remaining outstanding unconverted principal balance. If the change of control results in non-cash consideration, Crystal Amber, a Related Party, may convert the entire outstanding principal balance under the 2017 Note and all unpaid accrued interest then due into CDIs at the abovementioned Optional Conversion Price. Other than as described above, the Company may not prepay the 2017 Note without the consent of Crystal Amber, a Related Party.

The 2017 Note Purchase Agreement contains customary events of default including a failure to perform obligations under the 2017 Note Purchase Agreement, bankruptcy, a decision by the board of directors of the Company to wind up the Company, or if the Company otherwise ceases to carry on its ongoing business operations. If a default occurs and is not cured within the applicable cure period or is not waived, any outstanding obligations under the 2017 Note may be accelerated. The 2017 Note Purchase Agreement and related 2017 Note documents also contain additional representations and warranties, covenants and conditions, in each case customary for transactions of this type.

The Company recorded the \$5 million 2017 Note, net of debt issuance costs of \$115 thousand and amortized the debt issuance costs over the life of the 2017 Note.

In December 2018, the maturity date of the 2017 Note was extended to March 31, 2019 in exchange for payment of \$394 thousand, which was the total interest accrued on the 2017 Note at December 31, 2018. Payment of this amount was made in January 2019. The modification extended the conversion rights and resulted in an additional \$40 thousand of debt discount liability being recorded along with issuance costs of \$53 thousand.

In March 2019, the maturity date of the 2017 Note was extended to May 1, 2019. The modification extended the beneficial conversion rights and resulted in an additional debt discount liability, which was not recorded since it was determined to be immaterial to the consolidated financial statements. In April 2019, the maturity date of the 2017 Note was further extended to July 1, 2019, which resulted in \$24 thousand of debt discount liability being recorded. In June 2019, the maturity date of the 2017 Note was further extended to October 1, 2019, which resulted in an additional \$31 thousand of the debt discount liability being recorded. On August 21, 2019 the maturity date of the 2017 Note was further extended to March 31, 2020, which resulted in an additional \$273 thousand of the debt discount liability being recorded.

For the three and nine months ended September 30, 2019, the Company accrued interest expense of \$63 and \$187 thousand and amortization of the debt discount to interest expense of \$75 and \$194 thousand, respectively, related to the 2017 Note. For the three and nine months ended September 30, 2018, the Company recognized interest expense of \$67 and \$191 thousand and amortization of debt issuance costs of \$19 and \$56 thousand, respectively, related to the 2017 Note.

2018 Convertible Note and Warrant Financing

On May 30, 2018, the Company entered into a Note Purchase Agreement by and between the Company and Crystal Amber, a Related Party. Pursuant to the Note Purchase Agreement, the Company issued and sold to Crystal Amber a Senior Unsecured Convertible Promissory Note in an aggregate original principal amount of \$1.8 million (the "2018 Note") with a maturity date of May 30, 2023. Interest accrued at an annually compounded rate of 10% per annum.

Subsequent to stockholder pre-approval of the conversion features on May 24, 2018, the entire outstanding principal balance under the 2018 Note and all unpaid accrued interest thereon was immediately convertible into CDIs, at the option of Crystal Amber, a Related Party, at an initial conversion price of \$0.018 per CDI. Subsequently, the Company issued additional CDIs in a subsequent equity financing in September 2018 at a price per CDI of \$0.0144, resulting in an adjustment of the conversion price to \$0.0144 per CDI. Notice to convert the 2018 Note was provided by Crystal Amber, a Related Party on June 30, 2019 to 134,852,549 CDIs (representing 2,697,050 shares of common stock). The principal of \$1.8 million converted to 121,527,777 CDIs (representing 2,430,555 shares of common stock) and the accrued interest of \$192 thousand converted to 13,324,772 CDIs (representing 266,495 shares of common stock). Upon the conversion of the 2018 Note, the Company also recorded \$1.4 million of unamortized interest expense related to the unamortized debt discount. As of June 30, 2019, the conversion of the CDIs had been executed, but not yet settled with the CDIs issued and available. The CDIs were then issued on July 3, 2019 and have a one-year restriction on trading on the ASX.

In connection with the issuance of the 2018 Note and subsequent to pre-approval by stockholders on May 24, 2018, the Company also issued to Crystal Amber, a Related Party, a warrant (the "2018 Warrant") to purchase 97,222,200 CDIs (representing 1,944,444 shares of common stock) at an initial exercise price of \$0.018 per CDI. As per the 2018 Note conversion price, the warrant exercise price was subsequently adjusted to \$0.0144 per CDI. The 2018 Warrant was exercised in full on August 25, 2019 for \$1.4 million.

The Company has evaluated the guidance 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* to determine the appropriate classification of the 2018 Note and 2018 Warrant. On issuance, the 2018 Warrant was determined to be a freestanding instrument meeting the requirements for equity classification. Accordingly, the fair value estimated for the 2018 Warrant, totaling approximately \$743 thousand, has been recorded as a discount to the debt with the offset to additional paid-in capital. The 2018 Note was also evaluated for a BCF subsequent to the allocation of proceeds among the 2018 Note and 2018 Warrant. Based upon the effective conversion price of the 2018 Note after considering the stock price at the date of issuance and the allocation of estimated fair value to the 2018 Warrant, it was determined that the 2018 Note contained a BCF. The value of the BCF was computed to be approximately \$1.2 million but has been capped at approximately \$1 million so as to not exceed the total proceeds from the 2018 Note after deducting the value allocated to the 2018 Note and 2018 Warrant. The effective interest rate on the note after the discounts is 26.4%.

The Company recorded the 2018 Note at issuance, net of the total debt discount of \$1.8 million and amortized the debt discount over the life of the 2018 Note. For the three and nine months ended September 30, 2019, the Company accrued interest expense of nil and \$91 thousand and debt discount amortization of nil and \$146 thousand, respectively. For the three and nine months ended September 30, 2018, the Company recognized interest expense of \$44 and \$58 thousand, debt discount amortization of \$70 and \$95 thousand and interest expense derived from issuance costs of nil and \$85 thousand, respectively.

March 2019 Convertible Note and Warrant Financing

On March 15, 2019, the Company entered into a Note Purchase Agreement by and between the Company and Crystal Amber, a Related Party. Pursuant to the Note Purchase Agreement, the Company issued and sold to Crystal Amber, a Related Party, a Senior Unsecured Convertible Promissory Note in an aggregate original principal amount of \$1 million (the "March 2019 Note"). The March 2019 Note accrued interest at a rate equal to 10% per annum, compounded annually. The March 2019 Note was to mature on March 15, 2024. Issuance costs related to the March 2019 Note were \$50 thousand.

After the Company obtained stockholder approval to enable Crystal Amber's, a Related Party, conversion right under the March 2019 Note on June 30, 2019, the entire outstanding principal balance under the March 2019 Note and all unpaid accrued interest thereon was convertible into CDIs, at the option of Crystal Amber, a Related Party, at a conversion price of \$0.012 per CDI. On June 30, 2019, Crystal Amber, a Related Party, elected to convert the March 2019 Note into 81,070,003 CDIs (representing 1,621,400 shares of common stock) with the principal of \$1 million converting to 78,740,157 CDIs (representing 1,574,803 shares of common stock) and the accrued interest of approximately \$30 thousand converting to 2,329,846 CDIs (representing 46,596 shares of common stock). As of June 30, 2019, notice of the conversion had been provided by Crystal Amber, a Related Party, no CDIs were issued on this date. The CDIs were then issued on July 3, 2019 and have a one-year restriction on trading on the ASX.

In conjunction with the issuance of the March 2019 Note, the Company issued a warrant (the "March 2019 Warrant") to Crystal Amber, a Related Party, to purchase 78,984,823 CDIs (representing 1,579,696 shares of common stock) at an initial exercise price of \$0.0127 per CDI. The issue of the March 2019 Warrant required the approval of stockholders and was recorded as a derivative liability as it was not exercisable until its issue was approved on June 30, 2019. On August 25, 2019, a portion of the March 2019 Warrant totaling 47,244,119 CDIs (equivalent to approximately 944,882 shares of common stock) was exercised for \$600 thousand. The remaining portion of the March 2019 Warrant, totaling 31,740,704 CDIs (equivalent to 634,814 shares of common stock) was exercised for approximately \$400 thousand on September 30, 2019.

The Company evaluated the guidance 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* to determine the appropriate classification of the March 2019 Note and March 2019 Warrant. On the date of the issuance of the March 2019 Note issuance the March 2019 Warrant was determined to be a freestanding instrument meeting the requirements for liability classification due to not having stockholder approval. Accordingly, the fair value estimated for the March 2019 Warrant, totaling approximately \$871 thousand, was recorded as a discount to the debt with the offset to derivative liabilities. No BCFs in respect of the March 2019 Note were present without stockholder approval.

Upon approval of the conversion features of the March 2019 Note and issuance of the warrants on June 30, 2019, the Company remeasured the warrant liability and recorded a \$576 thousand other expense to the consolidated statement of operations and then reclassified \$1.4 million of fair value of warrants from derivative liability to equity as the warrant became immediately exercisable. The Company then evaluated the March 2019 Note for a BCF. Based upon the effective conversion price of the March 2019 Note after considering the stock price at the date of stockholder approval and the allocation of estimated fair value to the March 2019 Warrant, it was determined that the March 2019 Note contained a BCF. The value of the BCF was computed to be approximately \$741 thousand but was capped at approximately \$265 thousand so as to not exceed the total proceeds from the March 2019 Note after deducting the value allocated to the March 2019 Note and 2019 Warrant. The relative fair value of the warrant upon stockholder approval was approximately \$735 thousand. The total debt discount on the March 2019 Note upon stockholder approval of its conversion feature was \$1 million. The effective interest rate on the Note after the discounts was 29.4%.

On the June 30, 2019 conversion of the March 2019 Note, an unamortized debt discount of \$1 million was recorded as interest expense. The March 2019 Note principal of \$1 million and accrued interest of \$30 thousand were transferred to common stock subscribed but unissued.

For the three and nine months ended September 30, 2019, the Company recognized accrued interest expense of nil and \$30 thousand and debt discount amortized to interest expense of nil and \$109 thousand, respectively.

May 2019 Convertible Note and Warrant Financing

On May 8, 2019, the Company entered into a Note Purchase Agreement by and between the Company and Crystal Amber, a Related Party. Pursuant to the Note Purchase Agreement, the Company issued and sold to Crystal Amber, a Related Party, a Senior Unsecured Convertible Promissory Note in an aggregate original principal amount of \$3 million (the "May 2019 Note"). The May 2019 Note was funded in four tranches, starting on May 8, 2019 and the full \$3 million funding was completed on June 28, 2019. The note accrued interest at 10% per annum, computed on the daily funded balance until completion of funding on June 28, 2019, when interest began to compound annually. The May 2019 Note was to mature on May 8, 2024. Issuance costs related to the May 2019 Note were \$37 thousand.

After the Company obtained stockholder approval to enable Crystal Amber's, a Related Party, conversion right under the May 2019 Note on June 30, 2019, the entire outstanding principal balance under the May 2019 Note and all unpaid accrued interest thereon was convertible into CDIs, at the option of Crystal Amber, a Related Party, at a conversion price of \$0.0127 per CDI. On June 30, 2019, Crystal Amber, a Related Party, elected to convert the May 2019 Note into 237,687,411 CDIs (representing 4,753,748 shares of common stock). The principal of \$3 million converted to 236,220,472 CDIs (representing 4,724,409 shares of common stock) and the accrued interest of approximately \$19 thousand converted to 1,466,939 CDIs (representing 29,338 shares of common stock). As of June 30, 2019, notice of the conversion had been provided by Crystal Amber, a Related Party, but no CDIs were issued on this date. The CDIs were issued on July 3, 2019 and have a one-year restriction on trading on the ASX.

In conjunction with the issuance of the May 2019 Note, the Company issued a warrant (the “May 2019 Warrant”) to Crystal Amber, a Related Party, to purchase 236,220,472 CDIs (representing 4,724,409 shares of common stock) at an initial exercise price of \$0.0127 per CDI. The issue of the May 2019 Warrant required the approval of stockholders and was recorded in derivative liability as it was not exercisable until its issue was approved on June 30, 2019. A portion of the May 2019 Warrant totaling 125,739,610 CDIs (equivalent to 2,514,792 shares of common stock) was exercised by Crystal Amber, a Related Party, for approximately \$1.6 million on September 30, 2019. Another portion of the May 2019 Warrant totaling 78,740,157 CDIs (equivalent to 1,574,803 shares of common stock) was exercised by Crystal Amber, a Related Party, for approximately \$1 million on October 31, 2019.

The Company evaluated the guidance 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* to determine the appropriate classification of the May 2019 Note and May 2019 Warrant. On the date of the issuance of the May 2019 Note issuance the May 2019 Warrant was determined to be a freestanding instrument meeting the requirements for liability classification due to not having stockholder approval. Accordingly, the fair value estimated for the May 2019 Warrant, totaling approximately \$3.2 million, was limited to the value relative to the debt of \$1.7 million, which was recorded as a discount to the debt with the offset to derivative liabilities. No BCFs in respect of the May 2019 Note were present without stockholder approval.

Upon approval of the conversion features of the May 2019 Note and issuance of the May 2019 Warrant on June 30, 2019, the Company revalued the warrant liability and recorded a \$1.1 million other expense to the consolidated statements of operations and then reclassified approximately \$4.3 million of fair value of warrants from derivative liability to equity as the May 2019 Warrant became immediately exercisable. The Company then evaluated the May 2019 Note for a BCF. Based upon the effective conversion price of the May 2019 Note after considering the stock price at the date of stockholder approval and the allocation of estimated fair value to the May 2019 Warrant, it was determined that the May 2019 Note contained a BCF. The value of the BCF was computed to be approximately \$2 million but was not recorded as doing so would exceed the total proceeds from the May 2019 Note after deducting the value allocated to the May 2019 Note and May 2019 Warrant. The relative fair value of the May 2019 Warrant upon stockholder approval was approximately \$2.1 million. The total debt discount on the May 2019 Note upon stockholder approval was \$3 million. The effective interest rate on the May 2019 Note after the discounts is 29.4%.

On the June 30, 2019 conversion of the May 2019 Note, unamortized debt discount of \$3 million was recorded as interest expense. The May 2019 Note principal of \$3 million and accrued interest of \$19 thousand were transferred to common stock subscribed but unissued.

For the three and nine months ended September 30, 2019, the Company recognized accrued interest expense of nil and \$19 thousand and debt discount amortized to interest expense of nil and \$152 thousand, respectively.

August 2019 Securities Purchase Agreement

On August 21, 2019, the Company entered into the August 2019 SPA by and between the Company and Crystal Amber, a Related Party. The August 2019 SPA detailed a timeline wherein Crystal Amber, a Related Party, would exercise existing warrants (for a detailed description of the exercises and the terms of the warrants, see Note 4. Warrants to Purchase Common Stock and CDIs). Additionally, pursuant to the August 2019 SPA, the Company issued and sold to Crystal Amber, a Related Party, a senior unsecured convertible promissory note in an aggregate principal amount of \$4,596,893, or such lesser amount as may be set forth in a notice delivered by the Company to Crystal Amber, a Related Party, (the “August 2019 Note”), to be funded on December 6, 2019, or such earlier or later date as may be requested by the Company (the “Funding Date”). In conjunction with the August 2019 Note, the Company agreed to issue to Crystal Amber, a Related Party, a warrant (the “August 2019 Warrant”) to purchase CDIs (with each CDI representing 1/50th of a share of Common Stock) or Common Stock as set forth in the August 2019 Warrant, subject to the receipt of required stockholder approval approving the issuance of the August 2019 Warrant and the funding of the August 2019 Note.

The August 2019 Note accrues interest at a rate equal to 10% per annum from the Funding Date, compounded annually, other than during the continuance of an event of default, when the August 2019 Note accrues interest at a rate of 16% per annum. The entire outstanding principal balance and all unpaid accrued interest thereon is due on the fifth anniversary of the Funding Date. Subject to the receipt of required stockholder approval (for the purposes of, among others, Rule 10.11 of the ASX Listing Rules), the entire outstanding principal balance under the August 2019 Note and all unpaid accrued interest thereon is convertible into CDIs at the option of Crystal Amber, a Related Party, at a conversion price equal to US\$0.02 per CDI. In the event that the Company issues additional CDIs to a stockholder other than Crystal Amber, a Related Party, in a subsequent equity financing at a price per CDI that is less than the conversion price under the August 2019 Note, the conversion price shall be reduced to the lowest such price per CDI. In addition, upon a change of control of the Company, Crystal Amber, a Related Party, may, at its option, demand that the Company prepay all accrued and unpaid interest plus 110% of the remaining outstanding unconverted principal balance. The Company may not prepay the August 2019 Note without the consent of Crystal Amber, a Related Party. If the stockholder approvals required to issue the August 2019 Warrant or to approve the conversion rights under the August 2019 Note are not obtained, the Company is obligated to prepay all accrued and unpaid interest plus 110% of the remaining outstanding unconverted principal balance on the earlier of the Funding Date or the date that is six months following the date of the stockholder meeting at which the requisite approvals were not obtained.

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

As of the issuance date of these financial statements, notice had not been given by the Company to Crystal Amber, a Related Party, representing a request to fund the August 2019 Note. No liabilities exist until the Company issues notice requesting funding. Until such time as notice is delivered and the Note is funded, there are no accounting considerations related to the August 2019 Note and August 2019 Warrant.

11. Leases

On January 1, 2019, the Company adopted Topic 842 using the modified retrospective approach. There was no impact to retained earnings upon adoption of Topic 842 as there were no active long-term leases in place at the adoption date. Leases with an initial term of 12 months or less are not recorded on the balance sheet, unless the arrangement includes an option to purchase the underlying asset, or an option to renew the arrangement, that the Company is reasonably certain to exercise (short-term leases).

In June 2016, the Company entered into a non-cancelable agreement to lease approximately 4,200 square feet of office space in Boston, Massachusetts. The lease commenced in June 2016 and expired in April 2018. Rent during the term was \$12 thousand per month.

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

On April 22, 2019, the Company entered into a right-of-use lease for 3,520 square feet of office space in Boston, Massachusetts. The lease period contractually commenced June 1, 2019 and expires on May 31, 2022, but the space was available for occupancy on May 1, resulting in an effective period of May 2019 through May 2022, with no rent payment assessed in May 2019. The lease has defined escalating rent payments and contains no extension or expansion rights. On lease execution, the Company recorded the approximately \$509 thousand present value of the lease liability in short-term and long-term liabilities and recorded a related right-of-use asset. The right-of-use asset will be amortized to lease expense and the liability will be reduced by the rent payments over the term of the lease. For the three and nine months ended September 30, 2019, the Company recorded amortization of the right-of-use asset of \$35 and \$46 thousand, respectively. Additional property tax allocations and separately metered utilities are expensed in the period incurred.

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

The total operating lease cost for short-term leases not included as lease liabilities and right-of-use assets on the balance sheet was nil and \$92 thousand for the three and nine months ended September 30, 2019, respectively. The total operating lease cost, including taxes and utilities, for long-term leases included as lease liabilities and right-of-use assets on the balance sheet was \$47 and \$63 thousand for the three and nine months ended September 30, 2019.

The following table presents supplemental balance sheet information related to the Company's operating lease:

	As of September 30, 2019
	Operating Leases
	(in thousands)
Right-of-use assets	\$ 462
Liabilities	
Short-term operating lease liabilities	\$ 180
Long-term operating lease liabilities	282
Total liabilities	\$ 462

Other information related to leases was as follows:

	Three months ended September 30, 2019	Nine months ended September 30, 2019
	(in thousands)	
Operating cash flows from operating leases in lease liability measurement	\$ 47	\$ 63
Operating cash flows from short term leases	92	92
Remaining long-term lease term in years	2.7	2.7
Discount rate	10%	10%

The maturity of the Company's finance and operating lease liabilities as of September 30, 2019 are as follows:

	Operating Leases (in thousands)
Year ending December 31,	
Remainder of 2019	\$ 47
2020	191
2021	195
2022	98
Total future minimum lease payments	531
Less: imputed interest	69
Total Liabilities	\$ 462

12. Stockholders' Equity (Deficit)

On May 22, 2017, the stockholders of the Company approved an increase of its authorized shares of common stock from 13,000,000 to 50,000,000 and to eliminate Class B shares of common stock of the Company. As of September 30, 2019, the authorized capital stock of the Company consists of 50,500,000 shares, of which 50,000,000 shares are designated as common stock and 500,000 shares are designated as Preferred Stock.

In 2018, the Company received commitments for two private placements to sophisticated and professional investors in Australia, the United States and the United Kingdom, consisting of U.S. and non-U.S. persons (as defined in Regulation S ("Regulation S") of the Securities Act of 1933, as amended (the "Securities Act")) to raise up to approximately \$6.6 million (the "2018 Placements"). The first placement ("First Quarter 2018 Placement") consisted of a total of 406,002,869 fully paid CDIs of the Company (representing 8,120,057 shares of common stock) at an issue price of A\$0.035 per CDI. The issue of CDIs under the First Quarter 2018 Placement occurred in two tranches. The first tranche closed on January 22, 2018 (US Eastern time), pursuant to which the Company issued 28,467,063 CDIs (representing 569,341 shares of common stock) resulting in gross proceeds of approximately \$781 thousand and related issuance costs of \$63 thousand. The closing of the second tranche of the First Quarter 2018 Placement resulted in gross proceeds of \$824 thousand and related issuance costs of \$39 thousand by the issue of 30,313,556 CDIs (representing 606,271 shares of common stock) following stockholder approval, which was granted on February 27, 2018. The two participants in the First Quarter 2018 Placement second tranche were Crystal Amber, a Related Party, who purchased 27,391,756 CDIs and a Director, also a Related Party, of the Company purchased 2,921,800 CDIs.

The second placement ("Autumn 2018 Placement") consisted of a total of 347,222,250 fully paid CDIs of the Company (representing 6,944,445 shares of common stock) at an issue price of A\$0.020 per CDI. The investors in the Autumn 2018 Placement included certain existing investors. The issue of these CDIs occurred in two tranches. The first tranche closed on September 20, 2018 (US Eastern time), pursuant to which the Company issued 150,000,000 CDIs (representing 3,000,000 shares of common stock) resulting in gross proceeds of approximately \$2.2 million with related issuance costs of \$56 thousand. The closing of the second tranche resulted in gross proceeds of \$2.8 million for the issue of 197,222,250 CDIs (representing 3,944,445 shares of common stock) following stockholder approval at the adjourned Special Meeting of Stockholders on October 29, 2018. There were three participants in the second tranche; Crystal Amber, a Related Party, purchased 168,194,450 CDIs. Existing investors in the United States and Australia also purchased 23,819,450 and 5,208,350 CDIs, respectively. All second tranche CDIs were issued to investors in November 2018.

On June 30, 2019, Crystal Amber, a Related Party, converted the 2018 Note to 134,852,549 CDIs (representing 2,697,050 shares of common stock). The principal of \$1.8 million converted to 121,527,778 CDIs (representing 2,430,555 shares of common stock) and the accrued interest of \$192 thousand converted to 13,324,772 CDIs (representing 266,495 shares of common stock).

On June 30, 2019, Crystal Amber, a Related Party, converted the March 2019 Note to 81,070,003 CDIs (representing 1,621,400 shares of common stock). The principal of \$1 million converted to 78,740,157 CDIs (representing 1,574,803 shares of common stock) and the accrued interest of approximately \$30 thousand converted to 2,329,846 CDIs (representing 46,596 shares of common stock).

On June 30, 2019, Crystal Amber, a Related Party, converted the May 2019 Note to 237,687,411 CDIs (representing 4,753,747 shares of common stock). The principal of \$3 million converted to 236,220,472 CDIs (representing 4,724,409 shares of common stock) and the accrued interest of approximately \$19 thousand converted to 1,466,939 CDIs (representing 29,338 shares of common stock).

On August 25, 2019, Crystal Amber, a Related Party, exercised the 2018 Warrant totaling 97,222,200 CDIs (representing 1,944,444 shares of common stock) and a portion of the March 2019 Warrant totaling 47,244,119 CDIs (equivalent to approximately 944,882 shares of common stock) for an aggregate cash payment of \$2 million.

On September 30, 2019, Crystal Amber, a Related Party, exercised the remaining March 2019 Warrant totaling 31,740,704 CDIs (equivalent to 634,814 shares of common stock) and a portion of the May 2019 Warrant totaling 125,739,610 CDIs (equivalent to 2,514,792 shares of common stock) for an aggregate cash payment of \$2 million. As of September 30, 2019, this was recorded as common stock – subscribed but unissued and the cash was received on October 1, 2019.

On October 31, 2019, Crystal Amber, a Related Party, exercised another portion of May 2019 Warrant totaling 78,740,157 CDIs (equivalent to approximately 1,574,803 shares of common stock) for an aggregate cash payment of \$1 million. Cash was received on October 31, 2019.

13. Share-Based Compensation

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

In August 2011, the Board of Directors adopted the 2011 Employee, Director and Consultant Equity Incentive Plan (the “2011 Plan”, together with the 2003 Plan, the “Plans”) as the successor to the 2003 Plan. Under the 2011 Plan, the Company may grant incentive stock options, nonqualified stock options, restricted and unrestricted stock awards and other stock-based awards. The Company had initially reserved 450,000 shares (after adjusting for the 2015 reverse stock split) of its common stock for issue under the 2011 Plan. Awards that are returned to the Company’s 2003 Plan as a result of their forfeiture, expiration or cancellation without delivery of common stock shares or that result in the forfeiture of shares back to the Company on or after August 1, 2011, the date the 2011 Plan became effective, are automatically made available for issuance under the 2011 Plan. At August 1, 2011, 80,235 split adjusted shares available for grant under the 2003 Plan were transferred to the 2011 Plan. At September 30, 2019, there were 214,866 shares available for future grant under the 2011 Plan.

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

- a. 500,000 shares (adjusted for the 2015 reverse split);
- b. 4% of the number of common shares outstanding as of such date; and
- c. an amount determined by the Board of Directors or the Company’s compensation committee.

Accordingly, on January 1, 2019, 500,000 shares available for future grant were added to the 2011 Plan.

Stock-Based Compensation

Stock-based compensation is reflected in the consolidated statements of operations as follows for the three and nine months ended September 30, 2019 and 2018 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Research and development	\$ 15	\$ 1	\$ 47	\$ 6
Sales and marketing	—	5	—	15
General and administrative	43	16	127	65
	<u>\$ 58</u>	<u>\$ 22</u>	<u>\$ 174</u>	<u>\$ 86</u>

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

In calculating stock-based compensation costs, the Company estimates the fair value of stock options using the Black-Scholes option-pricing model. The Black-Scholes option-pricing model was developed for use in estimating the fair value of short-lived, exchange-traded options that have no vesting restrictions and are fully transferable. Such costs are then recognized over the requisite service period of the awards on a straight-line basis.

Determining the fair value of stock-based awards using the Black-Scholes option-pricing model requires the use of highly subjective assumptions, including the expected term of the award and expected stock price volatility. The weighted-average assumptions used to estimate the fair value of employee stock options using the Black-Scholes option-pricing model were as follows for the three and nine months ended September 30, 2019 and 2018:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Expected volatility	126.1%	119.4%	126.1%	117.1%
Expected term (in years)	6.05	6.05	6.05	6.05
Risk-free interest rate	1.7%	2.6%	1.7%	2.5%
Expected dividend yield	0%	0%	0%	0%

Stock Options

The following table summarizes option activity under the Company Plans for the nine months ended September 30, 2019:

	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, 2018	985,224	\$ 2.24	8.48	\$ —
Granted	1,874,771	\$ —	—	\$ 787
Exercised	—	\$ —	—	\$ —
Cancelled	(1,500)	\$ —	—	\$ —
Outstanding at September 30, 2019	<u>2,858,495</u>	<u>\$ 2.24</u>	<u>8.24</u>	<u>\$ 1,501</u>
Vested or expected to vest at September 30, 2019	<u>2,858,495</u>	<u>\$ 2.24</u>	<u>8.24</u>	<u>\$ 1,501</u>
Exercisable at September 30, 2019	<u>486,916</u>	<u>\$ 4.87</u>	<u>6.87</u>	<u>\$ 317</u>

As of September 30, 2019, there was approximately \$444 thousand of unrecognized stock-based compensation related to unvested stock option grants having service-based vesting under the Plans which is expected to be recognized over a weighted-average period of 2.2 years. The intrinsic value in the table above represents the difference between the fair value of the Company's common stock on the measurement date and the exercise price of the stock option.

The Plans provide that grantees may have the right to exercise an option prior to vesting. Shares purchased upon the exercise of unvested options will be subject to the same vesting schedule as the underlying options and are subject to repurchase at the original exercise price by the Company should the grantee discontinue providing services to the Company for any reason, prior to becoming fully vested in such shares.

Restricted Stock Units & Performance Stock Units

Each restricted stock unit ("RSU") and performance stock unit ("PSU") issued under the Company Plans represents a contingent right to receive one share of the Company's common stock. No RSUs have been outstanding since 2016. There is no consideration payable on the vesting of PSUs issued. Upon vesting, PSUs are exercised automatically and settled in shares of the Company's common stock.

The following table summarizes information related to PSU activity for the nine months ended September 30, 2019:

	Number of Units	Weighted- Average Contractual Life <i>(in years)</i>	Aggregate Intrinsic Value <i>(in thousands)</i>
Outstanding at December 31, 2018	250,000	7.23	\$ 141
Granted	—	—	\$ —
Exercised	—	—	\$ —
Cancelled	—	—	\$ —
Outstanding at September 30, 2019	<u>250,000</u>	<u>6.48</u>	<u>\$ 371</u>

The aggregate intrinsic value at September 30, 2019 and December 31, 2018 noted in the table above represents the closing price of the Company's common stock multiplied by the number of PSUs outstanding. The fair value of each PSU award equals the closing price of the Company's common stock on the date of grant.

At September 30, 2019, the PSUs outstanding are subject to performance-based vesting criteria as described in the applicable award agreement. For these awards, vesting will occur upon the achievement of certain product revenue, regulatory and reimbursement milestones. When achievement of the milestone is deemed probable, the Company expenses the compensation of the respective stock award over the remaining implicit service period.

At September 30, 2019 and 2018, no PSUs that have performance-based vesting criteria are considered probable of achievement. For the three and nine months ended September 30, 2019 and 2018, the Company did not recognize any stock-based compensation for PSUs subject to performance-based vesting criteria.

As of September 30, 2019, there remains approximately \$250 thousand of unrecognized stock-based compensation related to PSUs as the performance criteria have not become probable of achievement.

14. Segment Reporting

Operating segments are components of an enterprise for which separate financial information is available and is evaluated regularly by the Company's chief operating decision-maker in deciding how to allocate resources and in assessing performance. The Company has one reportable segment which designs, develops, manufactures and markets medical devices for non-surgical approaches to treating type 2 diabetes and obesity.

Geographic Reporting

The Company has historically reported various geographic segments but does not do so currently as the right-of-use asset of approximately \$462 thousand and all long-lived assets, comprised of property and equipment of approximately \$50 thousand are all held in the U.S. at September 30, 2019. Additionally, the Company did not have revenue in any geography for the three and nine months ended September 30, 2019 and 2018, respectively.

Major Customers

The Company did not recognize any revenue for the three and nine months ended September 30, 2019 and 2018, respectively.

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, 2018 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, Inc. is a clinical stage medical device company located in Boston, Massachusetts. The Company has developed EndoBarrier[®], a medical device intended for treatment of patients with type 2 diabetes and obesity, and the Company is engaged in achieving the steps necessary to obtain the regulatory approvals required to market this product. In order to market EndoBarrier[®] in the U.S., the Company must obtain approval from the FDA and in order to market EndoBarrier[®] outside of the U.S., the Company is required to comply with various regulations imposed by the countries in which the Company intends to sell the product.

In 2010, EndoBarrier[®] received CE Marking for sale in the European Union and in 2011, EndoBarrier[®] was listed on the ARTG. As a result, during 2013 and 2014, the Company received approximately \$2.8 million and \$2.3 million in revenue, respectively, from the sale of EndoBarrier[®] in Europe, South America and the Asia Pacific region. In the U.S. in 2013, the Company initiated 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 their 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, the Company received formal notification from the Therapeutic Goods Administration 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 the Company's 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 Company employees.

Following the decision to discontinue the ENDO Trial, the Company undertook significant investigational and scientific analyses with the goal of reducing the incidence rate and severity of hepatic abscess that present concurrently with the EndoBarrier[®] treatment. This investigational work focused on understanding the root cause of hepatic abscess and how to reduce the rate of occurrence. Investigation included: comparative bacterial DNA analysis between EndoBarrier[®] removals from uncomplicated patients and patients who developed hepatic abscess, numerous meta-analyses and responder cohort analyses, investigation into the contributing factors associated with proton pump inhibitors (PPIs), leaky gut syndrome and microbiome analyses, among other research topics. This allowed the Company to modify the medications utilized with EndoBarrier[®], most notably discontinuation of chronic double-dose PPI usage during EndoBarrier[®] implant.

In July 2018, the Company submitted to the FDA an application for investigational device exemption, or IDE, to commence a new pivotal trial evaluating the safety and efficacy of EndoBarrier[®] in the United States pending Institutional Review Board, or IRB, approval. In August 2018, the Company received approval of an IDE from the FDA to begin enrollment in this pivotal trial, and IRB approval was granted in February 2019. In this report, this pivotal trial is referred to as the GID STEP-1 clinical trial.

For financial reporting purposes, the Company has one reportable segment, which designs, manufactures and plans to market EndoBarrier[®].

To date, the Company has devoted substantially all its efforts to research and development, business planning, clinical research, clinical study management, reimbursement development, product commercialization, acquiring operating assets and raising capital. The Company has incurred significant operating losses since inception in 2003. As of September 30, 2019, the Company had an accumulated deficit of approximately \$282 million. The Company expects to incur net losses for the next several years while the Company continues to evaluate which markets are appropriate to continue pursuing regulatory approval, reimbursement, market awareness and general market development efforts, and continue to restructure the business and costs, establish new priorities, continue limited research, and evaluate strategic options.

To date, the Company has raised net proceeds of approximately \$277 million through the issuance of convertible debt and sales of the Company's equity. See Note 1 of these Consolidated Financial Statements (Nature of Business — Financing History) for a detailed description of the Company's financing history.

The Company's corporate headquarters are in Boston, Massachusetts. The Company executed a three-year lease commencing May 1, 2019, allowing the termination of the Company's former short-term lease and associated move from the Company's former office space as of May 31, 2019.

Critical Accounting Policies and Estimates

The discussion and analysis of the Company's 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 U.S. The preparation of these financial statements requires the Company to make certain estimates and assumptions that may affect the reported amounts of assets and liabilities, and the reported amounts of revenues and expenses during the reported periods and related disclosures. These estimates and assumptions, including those related to income taxes including the valuation allowance for deferred tax assets, research and development expenses, contingencies, stock-based compensation, going concern considerations, lease liabilities and derivative valuations are monitored and analyzed by the Company for changes in facts and circumstances, and material changes in these estimates could occur in the future. Estimates are based on historical experience and various other assumptions that are believed to be reasonable under the circumstances. Actual results may differ from estimates under different assumptions or conditions. See Note 2 of these Consolidated Financial Statements (Summary of Significant Accounting Policies and Basis of Presentation — New Accounting Pronouncements) for a detailed discussion of new accounting pronouncements, their adoption by the Company, and their impact (if any) on the Company's financial statements.

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 September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
	(in thousands)		(in thousands)	
Operating expenses:				
Research and development	\$ 1,391	\$ 494	\$ 3,011	\$ 1,121
Sales and marketing	—	167	22	683
General and administrative	1,260	1,338	3,997	3,378
Total operating expenses	2,651	1,999	7,030	5,182
Loss from operations	(2,651)	(1,999)	(7,030)	(5,182)
Other income (expense):				
Interest income	—	7	3	23
Interest expense	(109)	(201)	(6,198)	(489)
Foreign exchange gain (loss)	6	2	12	10
Gain on write-off of accounts payable	1	—	91	—
Re-measurement of derivative liabilities	(10)	10	(1,698)	13
Other income (expense), net	(112)	(182)	(7,790)	(443)
Loss before income tax expense	(2,763)	(2,181)	(14,820)	(5,625)
(Benefit from) Provision for income taxes	—	2	32	(1)
Net loss	\$ (2,763)	\$ (2,183)	\$ (14,852)	\$ (5,624)
Basic and diluted net loss per common share	(0.09)	\$ (0.17)	(0.48)	\$ (0.46)
Weighted-average number of common shares used in basic and diluted net loss per common share	31,239,071	12,691,797	31,239,071	12,279,294

Three and nine months ended September 30, 2019 compared to three and nine months ended September 30, 2018

Revenue. The Company did not record any revenues or associated cost of revenue during the three and nine months ended September 30, 2019 and 2018, respectively.

Operating expenses

	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2019	2018	\$	%	2019	2018	\$	%
	(dollars in thousands)				(dollars in thousands)			
Research and development	\$ 1,391	\$ 494	\$ 897	181.6%	\$ 3,011	\$ 1,121	\$ 1,890	168.6%
Sales and marketing	—	167	(167)	(100.0)%	22	683	(661)	(96.8)%
General and administrative	1,260	1,338	(78)	(5.8)%	3,997	3,378	619	18.3%
Total operating expenses	\$ 2,651	\$ 1,999	\$ 652	32.6%	\$ 7,030	\$ 5,182	\$ 1,848	35.7%

Research and Development Expense. The increase in research and development expense for the three and nine months ended September 30, 2019 compared to the three and nine months ended September 30, 2018 was primarily due to an increase in spending on internal and external resources as the Company initiated the STEP-1 trial in the United States, the I-Step trial in India (under joint venture with Apollo Sugar) and file for CE Mark designation. In the same period in 2018, the Company had just received the IDE from the FDA and had not moved from the planning stages on all three strategic priorities.

Sales and Marketing Expense. The decrease in sales and marketing expense for the three and nine months ended September 30, 2019 compared to the three and nine months ended September 30, 2018 was primarily due to a decrease in overall sales and marketing activities and a reclassification of existing overseas employee efforts to research and development.

General and Administrative Expense. The decrease in general and administrative expense for the three months ended September 30, 2019 compared to the three months ended September 30, 2018 was primarily due to lower corporate legal expenses. There were fewer overall legal expenses in 2019 and the Company changed corporate lawyers which resulted in significant savings.

The increase in general and administrative expense for nine months ended September 30, 2019 compared to the nine months ended September 30, 2018 was primarily related to increased insurance costs, increased support costs for higher headcount and additional legal and insurance costs related to transacting multiple financing events as a public company subject to reporting in two jurisdictions.

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. The Company expects operating expenses for the fourth quarter of 2019 to approximate those of the third quarter of 2019 as the start of the STEP-1 clinical trial approaches.

Other income (expense)

	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2019	2018	\$	%	2019	2018	\$	%
	(dollars in thousands)				(dollars in thousands)			
Other income (expense):								
Interest income	\$ —	\$ 7	\$ (7)	(100.0)%	\$ 3	\$ 23	\$ (20)	(87.0)%
Interest expense	(109)	(201)	92	(45.8)%	(6,198)	(489)	(5,709)	1,167.5%
Foreign exchange gain (loss)	6	2	4	200.0%	12	10	2	20.0%
Gain on write-off of accounts payable	1	—	1	(100)%	91	—	91	(100)%
Re-measurement of derivative liabilities	(10)	10	(20)	(200.0)%	(1,698)	13	(1,711)	(13,161.5)%
Total other income (expense), net	<u>\$ (112)</u>	<u>\$ (182)</u>	<u>\$ 70</u>	<u>(38.5)%</u>	<u>\$ (7,790)</u>	<u>\$ (443)</u>	<u>\$ (7,347)</u>	<u>1,658.5%</u>

Other income (expense). The change to other income (expense), net, for the three and nine months ended September 30, 2019 compared to the three and nine months ended September 30, 2018 is primarily due to the change in fair value of derivative liabilities and the conversion of the 2018, March 2019 and May 2019 Notes Payable to Crystal Amber, a Related Party.

Liquidity and Capital Resources

The Company has incurred losses since inception in March 2003 and as of September 30, 2019, the Company had an accumulated deficit of approximately \$282 million. The Company has financed operations from a combination of sales of equity securities and issuances of convertible term notes. As of September 30, 2019, the Company had approximately \$1.4 million of cash and cash equivalents with an equity subscription receivable of \$2 million.

In June 2017, the Company completed a convertible term promissory note (the "2017 Note") secured financing with Crystal Amber, a Related Party. The 2017 Note was placed for a gross amount of \$5 million and accrues annually compounded interest at 5% per annum. The 2017 Note was originally due on December 31, 2018 but was extended to March 31, 2019 in December 2018 (in exchange for payment of \$394 thousand, the total accrued interest on the 2017 Note at December 31, 2018) and further extended to May 1, 2019 in March 2019, July 1, 2019 in April 2019, October 1, 2019 in June 2019 and March 31, 2020 in August 2019. The 2017 Note is subject to security arrangements in favor of Crystal Amber, a Related Party (See Note 10 of these Consolidated Financial Statements for a more complete description of the terms and conditions of the financing).

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

In May 2018, the Company completed a convertible term promissory note (the "2018 Note") and warrant (the "2018 Warrant") financing with Crystal Amber, a Related Party, for a gross amount of \$1.8 million. The 2018 Note accrued interest at 10% per annum compounded annually and was converted into 134,852,549 CDIs (representing 2,697,050 shares of common stock) on June 30, 2019. The 2018 Warrant allowed Crystal Amber, a Related Party, to purchase 97,222,200 CDIs (representing 1,944,444 shares of common stock) at an initial exercise price of \$0.018 per CDI. In September 2018, the warrant exercise price was subsequently automatically adjusted to \$0.0144 per CDI.

In 2018, the Company received commitments for two private placements to sophisticated and professional investors in Australia, the United States and the United Kingdom, consisting of U.S. and non-U.S. persons (as defined in Regulation S of the Securities Act) to raise up to approximately \$6.6 million (the “2018 Placements”). The first placement (“First Quarter 2018 Placement”) consisted of a total of 406,002,869 fully paid CDIs of the Company (representing 8,120,057 shares of common stock) at an issue price of A\$0.035 per CDI. The issue of CDIs under the First Quarter 2018 Placement occurred in two tranches. The first tranche closed on January 22, 2018 (US Eastern time), pursuant to which the Company issued 28,467,063 CDIs (representing 569,341 shares of common stock) resulting in gross proceeds of approximately \$781 thousand and related issuance costs of \$63 thousand. The closing of the second tranche of the First Quarter 2018 Placement resulted in gross proceeds of \$824 thousand and related issuance costs of \$39 thousand by the issue of 30,313,556 CDIs (representing 606,271 shares of common stock) following stockholder approval granted on February 27, 2018. There were two participants in the First Quarter 2018 Placement second tranche; Crystal Amber, a Related Party, purchased 27,391,756 CDIs. A Board member of the Company purchased 2,921,800 CDIs.

The second placement (“Autumn 2018 Placement”) consisted of a total of 347,222,250 fully paid CDIs of the Company (representing 6,944,445 shares of common stock) at an issue price of A\$0.020 per CDI. The investors in the Autumn 2018 Placement included certain existing investors. The issue of these CDIs occurred in two tranches. The first tranche closed on September 20, 2018 (US Eastern time), pursuant to which the Company issued 150,000,000 CDIs (representing 3,000,000 shares of common stock) resulting in gross proceeds of approximately \$2.2 million and related issuance costs of \$56 thousand. The closing of the second tranche resulted in gross proceeds of \$2.8 million by the issue of 197,222,250 CDIs (representing 3,944,445 shares of common stock) following stockholder approval at the adjourned Special Meeting of Stockholders on October 29, 2018. There were three participants in the second tranche; Crystal Amber, a Related Party, purchased 168,194,450 CDIs. Existing investors in the United States and Australia also purchased 23,819,450 and 5,208,350 CDIs, respectively. All second tranche CDIs were allotted to investors in November 2018.

In March 2019, the Company completed a convertible term promissory note (the “March 2019 Note”) and warrant (the “March 2019 Warrant”) financing with Crystal Amber, a Related Party, for a gross amount of \$1 million. The March 2019 Note accrued interest at 10% per annum compounded annually and notice of conversion was provided by Crystal Amber, a Related Party, on June 30, 2019 into 81,070,003 CDIs (representing 1,621,400 common shares). The March 2019 Warrant was approved by stockholders and issued on June 30, 2019 and allowed Crystal Amber, a Related Party, to purchase 78,984,823 CDIs (representing 1,579,696 shares of common stock) at an initial exercise price of \$0.0127 per CDI (See Note 10 of these Consolidated Financial Statements for a more complete description of the terms and conditions of the financing).

In May 2019, the Company completed a convertible term promissory note (the “May 2019 Note”) and warrant (the “May 2019 Warrant”) financing with Crystal Amber, a Related Party, for a gross amount of up to \$3 million. The May 2019 Note accrued interest at 10% per annum, computed on the daily funded balance until completion of funding on June 28, 2019, when interest began to compound annually at 10% per annum and notice of conversion was provided by Crystal Amber, a Related Party, on June 30, 2019 into 237,687,411 CDIs (representing 4,753,747 shares of common stock). The May 2019 Warrant was approved by stockholders and issued on June 30, 2019 and allowed Crystal Amber, a Related Party, to purchase 236,220,472 CDIs (representing 4,724,409 shares of common stock) at an initial exercise price of \$0.0127 per CDI (see Note 10 of these Consolidated Financial Statements for a more complete description of the terms and conditions of the financing).

On June 30, 2019, Crystal Amber, a Related Party, elected to convert the 2018 Note, the March 2019 Note and the May 2019 Note to CDIs. Under the terms of the respective notes, an aggregate of 453,609,963 CDIs (representing approximately 9,072,199 shares of common stock) were subscribed but unissued on conversion and concurrent cancellation of the 2018 Note, the March 2019 Note and the May 2019 Note. The CDIs were issued on July 3, 2019.

On August 21, 2019, the Company and Crystal Amber, a Related Party, 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 is comprised of scheduled warrant exercises between August 25, 2019 and November 15, 2019 of the 2018 Warrants, the March 2019 Warrants, and the May 2019 Warrants held by Crystal Amber, a Related Party. The remaining amount, up to \$4.6 million, is to be funded on or before December 6, 2019, at the request of the Company, pursuant to the terms of a convertible term promissory note (the “August 2019 Note”) in substantially the same form as the March 2019 and May 2019 convertible term promissory note. The Company, at its sole discretion, may elect to request any of the \$4.6 million to be funded. In connection with the August 2019 Note, the Company agreed to issue Crystal Amber, a Related Party, a warrant (the “August 2019 Warrant”) to purchase CDIs or common stock as set forth in the August 2019 Warrant, subject to the receipt of required stockholder approval approving the issuance of the August 2019 Warrant and the funding of the August 2019 Note. Stockholder approval will be required to enable certain specific conversion features and to issue the related August 2019 Warrant (see Note 10 of these Consolidated Financial Statements for a more complete description of the terms and conditions of the financing).

On August 25, 2019, Crystal Amber, a Related Party, exercised the 2018 Warrant totaling 97,222,200 CDIs (representing 1,944,444 shares of common stock) and a portion of the March 2019 Warrant totaling 47,244,119 CDIs (equivalent to approximately 944,882 shares of common stock) for an aggregate cash payment of \$2 million.

On September 30, 2019, Crystal Amber, a Related Party, exercised the remaining March 2019 Warrant totaling 31,740,704 CDIs (equivalent to 634,814 shares of common stock) and a portion of the May 2019 Warrant totaling 125,739,610 CDIs (equivalent to 2,514,792 shares of common stock) for an aggregate cash payment due of \$2 million and recorded as a subscription receivable from related party. The cash was received on October 1, 2019.

On October 31, 2019, Crystal Amber, a Related Party, exercised another portion of the May 2019 totaling 78,740,157 CDIs (equivalent to approximately 1,574,803 shares of common stock) for an aggregate cash payment of \$1 million.

During the nine months ended September 30, 2019, the Company’s cash and cash equivalents balance decreased primarily as a result of funds utilized to support operations offset by proceeds from financing activities.

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

	Nine Months Ended September 30,	
	2019	2018
	(in thousands)	
Net cash (used in) provided by:		
Operating activities	\$ (8,305)	\$ (5,202)
Investing activities	(11)	-
Financing activities	5,913	5,272
Net increase (decrease) in cash and cash equivalents	<u>\$ (2,403)</u>	<u>\$ 70</u>

Cash Flows Used in Operating Activities

The primary uses of cash for operating activities for the nine months ended September 30, 2019 were:

- to fund the Company's net loss of approximately \$14.9 million;
- a net positive adjustment to cash flow from non-cash items of approximately \$8 million, primarily from non-cash interest expense of approximately \$6.2 million, re-measurement of derivative liabilities of approximately \$1.7 million, stock-based compensation expense of approximately \$174 thousand and depreciation and amortization of approximately \$24 thousand; and
- a net negative adjustment to cash flow from changes in working capital of approximately \$1.5 million resulting primarily from an increase in prepaid expenses predominantly related to trial start up pre-payments and decreases in accounts payable and accrued expenses.

The primary uses of cash for operating activities for the nine months ended September 30, 2018 were:

- to fund the Company's net loss of approximately \$5.6 million;
- a net positive adjustment to cash flow from non-cash items of approximately \$583 thousand, primarily from non-cash interest expense of approximately \$486 thousand, stock-based compensation expense of approximately \$86 thousand and depreciation and amortization of \$11 thousand; and
- a net negative adjustment to cash flow from changes in working capital of approximately \$150 thousand resulting primarily from a decrease in accounts payable partially offset by an increase in accrued expenses.

Cash Flows Used in Investing Activities

Cash used in investing activities for the nine months ended September 30, 2019 was approximately \$11 thousand related to capital expenditures. No cash was used in investing activities for the nine months ended September 30, 2018.

Cash Flows Provided by Financing Activities

Cash provided by financing activities for the nine months ended September 30, 2019 totaled approximately \$5.9 million and primarily resulted from proceeds received from the March 2019 Note and the May 2019 Note payable to a Related Party and the warrants that were exercised in August 2019, offset by related issuance costs. An additional \$2 million was due from Crystal Amber, a Related Party, after receiving notices of exercise of warrants on September 30, 2019 but the cash had not been received by the Company and was thus recorded in subscription receivable from related party. The cash was received on October 1, 2019.

Cash provided by financing activities for the nine months ended September 30, 2018 totaled approximately \$5.3 million and primarily resulted from net proceeds received from the 2018 Note payable to Crystal Amber, a Related Party, and net proceeds from the private placement of CDIs offset by related issuance costs.

Funding Requirements

As of September 30, 2019, the Company's primary source of liquidity is its cash and cash equivalents balances. The Company continues to evaluate which markets are appropriate to pursue regulatory approvals, pursue reimbursement, raise market awareness and conduct general market development efforts. The Company continues to restructure its business and costs, establish new priorities, and evaluate strategic options. As a result, if the Company remains in business, it expects to incur significant operating losses for the next several years. The Company has incurred operating losses since inception and at September 30, 2019 had an accumulated deficit of approximately \$282 million, a working capital deficit of approximately \$2.3 million, cash used in 2019 for operating activities of approximately \$8.3 million and cash, restricted cash, and cash equivalents of approximately \$1.4 million. Cash provided by these activities will be used predominantly to prepare for and conduct the Company's clinical trials, which will result in increased expenses. The August 2019 Note and August 2019 Warrant are potential future capital resources. As of the issuance date of the financial statements included herein, notice had not been given by the Company to Crystal Amber, a Related Party, representing a request to fund the August 2019 Note. The Company does not expect its current cash balances will be sufficient to operate beyond the end of February 2020. The Company will need to raise additional funds through any combination of collaborative arrangements, strategic alliances, and additional equity and debt financings or from other sources. Furthermore, if the Company raises insufficient funds or is required to make payment to Crystal Amber, a Related Party, under the 2017 Note on its maturity date of March 31, 2020, the Company will be required either to renegotiate the maturity date of the loan or to potentially cease operations. The Company expects to discuss a further extension of the maturity date of the 2017 Note with Crystal Amber, a Related Party, but there can be no assurance that any extension will occur.

The forecast of the period of time through which the Company's financial resources will be adequate to support operations are forward-looking statements and involve risks and uncertainties, and actual results could vary materially and negatively as a result of a number of factors, including the factors discussed in the "Risk Factors" in Item 1A. of the Company's Annual Report on Form 10-K, which is incorporated by reference herein. Estimates are based on assumptions that may prove to be wrong, and the Company could utilize available capital resources sooner than currently expected.

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[®]. The Company's funding requirements will depend on many factors, including, but not limited to, the following:

- the rate of enrollment of patients in the Company's clinical trial and the timely completion of clinical trials;
- the rate of progress and cost of the Company's commercialization activities;
- the expenses potentially incurred in efforts to market and sell EndoBarrier[®] subject to future regulatory approvals;
- the timing and decisions of payer organizations related to reimbursement;
- the revenue generated by sales of EndoBarrier[®];
- the product performance from a safety and efficacy standpoint in addressing diabetes and obesity;
- the success of the Company's investment in manufacturing and supply chain infrastructure;
- the time and costs involved in obtaining regulatory approvals for EndoBarrier[®] in new markets;
- the success of the Company's research and development efforts;
- 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.

The Company will continue to manage its capital structure and to consider all financing opportunities, whenever they may occur, that could strengthen the Company's 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. There can be no assurance that any such financing opportunities will be available on acceptable terms, if at all. In addition, the Company could be required to cease operations if it is unable to raise capital when needed.

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.

There have been no material changes from the contractual commitments and obligations previously disclosed in the Company's Annual Report on Form 10-K.

Recent Accounting Pronouncements

For a discussion of recent accounting pronouncements please refer to Note 2, "Summary of Significant Accounting Policies and Basis of Presentation," to the consolidated financial statements included in this Quarterly Report on Form 10-Q.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

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

Interest Rate Sensitivity

The Company's cash and cash equivalents of approximately \$1.4 million at September 30, 2019, consisted of cash and money market funds, all of which will be used for working capital purposes. The Company does not enter into investments for trading or speculative purposes. The goals of the Company's investment policy are preservation of capital, fulfillment of liquidity needs and fiduciary control of cash and investments. The Company also seeks to maximize income from investments without assuming significant risk. The Company's primary exposure to market risk is interest income sensitivity, which is primarily affected by changes in the general level of interest rates in the U.S. and Australia. Due to the short-term nature of the Company's cash and cash equivalents, the Company does not have material exposure to changes in fair value as a result of changes in interest rates. The continuation of historically low interest rates in the U.S. limit future earnings on investments held in U.S. dollars.

Foreign Currency Risk

The Company conducts business in foreign countries. For U.S. reporting purposes, the Company translates all assets and liabilities of non-U.S. subsidiaries at the period-end exchange rate and revenue and expenses at the average exchange rates in effect during the periods. The net effect of these translation adjustments is shown in the accompanying consolidated financial statements as a component of net loss.

Fluctuations in the exchange rate of the U.S. dollar against major foreign currencies, including the euro, British Pound and Australian dollar, can result in foreign currency exchange gains and losses that may significantly impact the Company's financial results. These foreign currency transaction and translation gains and losses are presented as a separate line item in the Company's consolidated statements of operations. Continued fluctuation of these exchange rates could result in financial results that are not comparable from quarter to quarter. Foreign currency contracts are not currently used to mitigate the gains and losses generated by the re-measurement of non-functional currency assets and liabilities and currently only hold immaterial cash balances in non-U.S. currencies.

All proceeds from the Company's 2011, 2013, 2014, and 2016 equity offerings, along with a portion of the Company's 2017 and 2018 offerings, were denominated in Australian dollars and as of September 30, 2019, the Company held an immaterial amount denominated in Australian dollars and Euros. Accordingly, the Company has had and will continue to have minor exposure to foreign currency exchange rate fluctuations. A change of 10% or more in foreign currency exchange rates of the Australian dollar or the euro would not have a material impact on the Company's financial position and results of operations.

Effects of Inflation

The Company does not believe that inflation and prices fluctuations over the three and nine months ended September 30, 2019 and 2018 had a significant impact on the results of operations.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

As required by Rule 13a-15(b) of the Securities Exchange Act of 1934, or the Exchange Act, the Company's management, including the principal executive officer and the principal financial and accounting officer, conducted an evaluation as of the end of the period covered by this Quarterly Report on Form 10-Q of the effectiveness of the design and operation of the Company disclosure controls and procedures. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by the Company in the reports required to be filed or submitted under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms, and such information required to be disclosed by the Company in the reports filed under the Exchange Act is accumulated and communicated to Company management, including the principal executive officer and principal financial and accounting officer, as appropriate to allow timely decisions regarding required disclosure. The Company's principal executive officer and principal financial and accounting officer have concluded that, based on and as of the time of such evaluation, the Company's disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control

As required by Rule 13a-15(d) of the Exchange Act, Company management, including the principal executive officer and the principal financial and accounting officer, conducted an evaluation of the internal control over financial reporting and concluded that there have not been any changes during the quarter ended September 30, 2019 that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

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

PART II – OTHER INFORMATION

Item 1. Legal Proceedings

None

Item 1A. Risk Factors.

In addition to the other information contained elsewhere in this Quarterly Report on Form 10-Q, you should carefully consider the factors discussed in “Item 1A. Risk Factors” in the Company Annual Report on Form 10-K, which could materially affect the Company business, financial condition or future results. The risks described in the Company’s Annual Report on Form 10-K are not the only risks faced by the Company. Additional risks that we do not presently know or that we currently believe are immaterial could also materially and adversely affect any of the Company business, financial condition or future results. The trading price of the Company’s CDIs may decline due to these risks.

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

Other than as previously disclosed on the Company’s Current Reports on Form 8-K filed with the SEC, the Company did not issue any unregistered equity securities during the three months ended September 30, 2019.

Item 6. Exhibits.

<u>Exhibit No:</u>	<u>Description</u>
10.1*	<u>Fifth Amendment to Note Purchase Agreement, dated June 15, 2017, between GI Dynamics, Inc. and Crystal Amber Fund Limited, as purchaser, dated August 21, 2019.</u>
10.2*	<u>Fifth Amendment to Senior Secured Convertible Promissory Note, dated June 15, 2017, by and between GI Dynamics, Inc. and Crystal Amber Fund Limited, dated August 21, 2019.</u>
10.3*	<u>Securities Purchase Agreement, dated August 21, 2019, between GI Dynamics, Inc. and Crystal Amber Fund Limited, as purchaser.</u>
10.4*	<u>Senior Unsecured Convertible Promissory Note, dated August 21, 2019, between GI Dynamics, Inc. and Crystal Amber Fund Limited.</u>
10.5*	<u>Form of Warrant to Purchase up to 229,844,650 CHES Depository Interests of GI Dynamics, Inc., between GI Dynamics, Inc. and Crystal Amber Fund Limited.</u>
10.6†	<u>Amended and Restated Offer Letter Agreement, dated September 19, 2019, by and between Scott Schorer and the Company, incorporated by reference to Exhibit 10.1 of GI Dynamics, Inc.’s Current Report on Form 8-K filed with the SEC on September 20, 2019.</u>
10.7†	<u>Offer Letter Agreement, dated September 19, 2019, by and between Charles Carter and the Company, incorporated by reference to Exhibit 10.2 of GI Dynamics, Inc.’s Current Report on Form 8-K filed with the SEC on September 20, 2019.</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.

† Management contract or compensatory plan or arrangement.

SIGNATURES

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

GI Dynamics, Inc.

Date: November 8, 2019

By: /s/ SCOTT W. SCHORER

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

Date: November 8, 2019

By: /s/ CHARLES R. CARTER

Charles R. Carter
Chief Financial Officer, Secretary
(principal financial and accounting officer)

GI DYNAMICS, INC.

FIFTH AMENDMENT TO NOTE PURCHASE AGREEMENT

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

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

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

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

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

[Signature pages follow]

IN WITNESS WHEREOF, the parties have executed this Amendment as of the date first above written.

COMPANY:

GI DYNAMICS, INC.

By: /s/ Scott Schorer

Name: Scott Schorer

Title: Chief Executive Officer

[Signature Page to Fifth Amendment to Note Purchase Agreement]

IN WITNESS WHEREOF, the parties have executed this Amendment as of the date first above written.

PURCHASER:

CRYSTAL AMBER FUND LIMITED

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

By: /s/ Laurence McNairn

Name: Laurence McNairn

Title: Director

[Signature Page to Fifth Amendment to Note Purchase Agreement]

EXHIBIT A

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

[See Exhibit 10.2 to this Quarterly Report on Form 10-Q.]

FIFTH AMENDMENT TO SENIOR SECURED CONVERTIBLE PROMISSORY NOTE

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

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

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

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

1. Amendments to Existing Note. Sections 1(b), 2(a), 2(b) and 2(c) of the Existing Note are hereby amended with immediate effect to change the dates referred to in each such section (including, for the avoidance of doubt, the Maturity Date) from “October 1, 2019” to “March 31, 2020”.

2. Waiver. The Holder hereby waives the application of the definition of Qualified Financing with respect to the financing (the “**Financing**”) to be completed pursuant to the terms and conditions of that certain Securities Purchase Agreement, dated of even date herewith (as amended, restated, supplemented, or otherwise modified from time to time, the “**August 2019 SPA**”), by and between the Payor and the Holder. For the avoidance of doubt, the Financing being conducted pursuant to the August 2019 SPA and any proceeds received by the Payor for the securities issued in connection with the Financing shall not trigger an automatic conversion pursuant to Section 2(a) of the Existing Note.

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

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

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

[Signature Pages Immediately Follow]

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

PAYOR:

GI DYNAMICS, INC.

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

[Signature Page to Fifth Amendment to Promissory Note]

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

HOLDER:

CRYSTAL AMBER FUND LIMITED

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

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

[Signature Page to Fifth Amendment to Promissory Note]

GI DYNAMICS, INC.

SECURITIES PURCHASE AGREEMENT

GI DYNAMICS, INC.

SECURITIES PURCHASE AGREEMENT

THIS SECURITIES PURCHASE AGREEMENT (this "*Agreement*") is made as of the 21st day of August, 2019 (the "*Effective Date*") by and between GI DYNAMICS, INC., a Delaware corporation (the "*Company*"), and CRYSTAL AMBER FUND LIMITED (the "*Purchaser*"). Capitalized terms used herein and not otherwise defined herein shall have the respective meanings given to them in the Note (as defined below).

The parties hereby agree as follows:

1. TERMS OF THE SECURITIES

1.1 The Financing. Subject to the terms of this Agreement, the Purchaser agrees to (i) exercise certain outstanding warrants issued on May 30, 2018 and June 30, 2019 (the "*Existing Warrants*"), in accordance with the terms of such Existing Warrants, and purchase an aggregate of 412,427,495 Chess Depositary Interests (the "*Existing Warrants CDIs*") (subject to the effect of any rounding) (with each CDI representing 1/50th of a share of the Company's common stock, par value \$0.01 per share (the "*Common Stock*")), at an aggregate purchase price of Five Million Four Hundred Three Thousand One Hundred Six Dollars and Ninety Five Cents (US\$5,403,106.95) (the "*Aggregate Exercise Price*") and (ii) purchase from the Company, and the Company agrees to issue and sell to the Purchaser, an unsecured convertible promissory note in the aggregate principal amount of up to Four Million Five Hundred Ninety-Six Thousand Eight Hundred Ninety-Three Dollars (US\$4,596,893) (the "*Loan Amount*") in substantially the form attached hereto as *Exhibit A* (the "*Note*"). The Note may, subject to stockholder approval, be converted into CDIs as provided in such Note.

1.2 The Warrant. In order to induce the Purchaser to enter into this Agreement, to exercise the Existing Warrants, to purchase the Note and to make the loan evidenced thereby, the Company agrees, in accordance with the terms of this Agreement, to issue to the Purchaser a warrant to purchase CDIs or Common Stock as provided in such warrant and in substantially the form attached hereto as *Exhibit B* (the "*Warrant*"). The Warrant shall only be issuable (a) in the event of the Advance (as defined in the Note) under the Note and (b) in accordance with Section 2.3 of this Agreement following receipt of stockholder approval to issue the Warrant in accordance with the same stockholder approval process described in Section 2(c) of the Note, and if stockholder approval is obtained, shall have a term that expires on the fifth (5th) anniversary of the Funding Date (as defined in the Note). If stockholder approval for issuance of the Warrant is not obtained, the Warrant will not be capable of being issued and the Purchaser shall be entitled to the remedy described in Section 2(c) of the Note in accordance with the procedures described therein, in full satisfaction of all obligations under the Note and in lieu of issuance of the Warrant.

2. THE CLOSING

2.1 Closing Date. The closing of the transactions contemplated by this Agreement (the “*Closing*”) shall be held on the Effective Date or at such other time as the Company and the Purchaser shall agree (the “*Closing Date*”).

2.2 The Closing; Exercise of Existing Warrants; and Delivery of Note.

(A) At the Closing (i) in accordance with the terms of the Existing Warrants and this Agreement, the Purchaser will deliver to the Company a Notice of Exercise for a cash exercise of \$2,000,000 (“*Initial Exercise Price*”) in CDIs with respect to the Existing Warrants and a wire transfer of immediately available funds in an amount equal to the Initial Exercise Price; and (ii) the Company shall issue and deliver to the Purchaser (a) 144,466,319 Existing Warrant CDIs (subject to the effect of any rounding) required to be issued in connection with the delivery of the Initial Exercise Price and (b) the Note; and (iii) the Company shall execute and deliver such other documents as the Purchaser shall reasonably require.

(B) On September 30, 2019, or such earlier date as may be requested by the Company (the “*Second Exercise Date*”), in accordance with the terms of the Existing Warrants and this Agreement the Purchaser will deliver to the Company a Notice of Exercise for a cash exercise of \$1,999,999.99 (“*Second Exercise Price*”) in CDIs with respect to the Existing Warrants not exercised at the Closing and a wire transfer of immediately available funds in an amount equal to the Second Exercise Price and the Company shall issue and deliver to the Purchaser 157,480,314 Existing Warrant CDIs (subject to the effect of any rounding) required to be issued in connection with the delivery of the Second Exercise Price.

(C) On October 31, 2019, or such earlier date as may be requested by the Company (the “*Third Exercise Date*”), in accordance with the terms of the Existing Warrants and this Agreement, the Purchaser will deliver to the Company a Notice of Exercise for a cash exercise of \$1,000,000 (“*Third Exercise Price*”) in CDIs with respect to the Existing Warrants not exercised at the Closing or on the Second Exercise Date and a wire transfer of immediately available funds in an amount equal to the Third Exercise Price and the Company shall issue and deliver to the Purchaser 78,740,157 Existing Warrant CDIs (subject to the effect of any rounding) required to be issued in connection with the delivery of the Third Exercise Price.

(D) On November 15, 2019, or such earlier date as may be requested by the Company (the “*Fourth Exercise Date*”), in accordance with the terms of the Existing Warrants and this Agreement the Purchaser will deliver to the Company a Notice of Exercise for a cash exercise of \$403,106.96 (“*Fourth Exercise Price*”) in CDIs with respect to the Existing Warrants not exercised at the Closing or on the Second Exercise Date or the Third Exercise Date and a wire transfer of immediately available funds in an amount equal to the Fourth Exercise Price and the Company shall issue and deliver to the Purchaser 31,740,705 Existing Warrant CDIs (subject to the effect of any rounding) required to be issued in connection with the delivery of the Fourth Exercise Price.

2.3 Issuance and Delivery of Warrant. Subject to and conditioned upon receipt by the Company of the Advance under the Note, the Company shall issue and deliver the Warrant to the Purchaser within five business days of the date of the Company's receipt of stockholder approval of the issue of the Warrant in accordance with the same stockholder approval process described in Section 2(c) of the Note.

3. REPRESENTATIONS, WARRANTIES AND COVENANTS OF THE COMPANY

The Company hereby represents and warrants to the Purchaser, as of the date hereof and as of the Closing Date, as follows:

3.1 Organization; Good Standing and Qualification. The Company is a corporation duly organized, validly existing, and in good standing under the laws of the State of Delaware and has all requisite corporate power and authority to own its property and carry on its business as now conducted. The Company is duly qualified to transact business and is in good standing in the Commonwealth of Massachusetts and in each jurisdiction in which its ownership of property or the nature of the business conducted by it makes such qualification necessary.

3.2 Corporate Power. The Company has all requisite corporate power to (i) execute and deliver this Agreement, (ii) deliver the Existing Warrants CDIs, (iii) execute and deliver the Note and subject to the abovementioned stockholder approval, (iv) execute and deliver the Warrant in favor of the Purchaser and any other document provided for herein or by any of the foregoing (collectively, as the same may from time to time be amended, modified, supplemented or restated, the "**Financing Documents**") and to carry out and perform its obligations under the terms of the Financing Documents and to, subject to the abovementioned stockholder approval, issue CDIs in accordance with the terms thereof.

(a) Authorization. The execution and delivery of each of the Financing Documents by the Company and the consummation by the Company of the transactions contemplated hereby and thereby, including, without limitation, the issuance of the Note, the issuance of the Existing Warrants CDIs, the issuance of the Warrant, the reservation of the Common Stock underlying the CDIs issuable upon conversion of the Note (the "**Conversion CDIs**"), the reservation of the Common Stock underlying the CDIs issuable upon exercise of the Warrant (the "**Warrant CDIs**" and, together with the Note, the Existing Warrants CDIs, the Warrant, the Conversion CDIs and the Common Stock, "**Securities**") and the issuance of the Conversion CDIs and the Warrant CDIs, was duly authorized by the Company's board of directors. Other than those consents and authorizations obtained by the Company prior to the date hereof that are in full force and effect on the Closing Date and except for any required stockholder approval of the Company as set forth in Section 2(c) of the Note and in this Agreement, no further consent or authorization is required by the Company, its board of directors or its stockholders. Each of the Financing Documents has been (or in the case of the Warrant, will be) duly executed and delivered by the Company, and constitutes the legal, valid and binding obligations of the Company enforceable in accordance with its terms, subject to laws of general application relating to equitable principles, bankruptcy, insolvency and the relief of debtors. Upon conversion of the Note into Conversion CDIs in accordance with the provisions of this Agreement and the Note, the Conversion CDIs will be validly issued, fully paid and nonassessable and free of any liens or encumbrances (other than as set out in Section 2(f) of the Note). Upon the exercise of the Warrant in accordance with the provisions of this Agreement and the Warrant, the Warrant CDIs will be validly issued, fully paid and nonassessable and free of any liens or encumbrances (other than as set out in Section 5(b) of the Warrant). Upon exercise of the Existing Warrants, the Existing Warrants CDIs will be validly issued, fully paid and nonassessable and free of any liens or encumbrances (other than as set out in clause 5(b) of the Existing Warrants). The issuance of the Note (and the Conversion CDIs), the Warrant (and the Warrant CDIs), and the Existing Warrants CDIs pursuant to the provisions of this Agreement will not give rise to any preemptive rights or rights of first refusal granted by the Company, and the Note (and the Conversion CDIs), the Warrant (and the Warrant CDIs) and the Existing Warrants CDIs will be issued in compliance with all applicable federal and state securities laws, and will be free of any liens or encumbrances; *provided, however*, that the Note and the Warrant (and the underlying securities) may be subject to restrictions on transfer as set out in the Financing Documents or under state and/or federal securities laws as set forth herein or as otherwise required by such laws at the time the transfer is proposed. The issuance and sale of the Note (and the Conversion CDIs), the Warrant (and the Warrant CDIs) and the Existing Warrants CDIs do not and will not cause any dilution adjustment in any existing securities of the Company, and the Purchaser hereby waives any dilution adjustment that might otherwise result from the issuance and sale of the Note (and the Conversion CDIs) or the Warrant (and the Warrant CDIs) or the issuance of the Existing Warrants CDIs pursuant to the terms of any existing security held by the Purchaser.

3.3 Governmental Consents. All consents, approvals, orders, or authorizations of, or registrations, qualifications, designations, declarations, or filings with, any governmental authority, required on the part of the Company in connection with the valid execution and delivery of the Financing Documents, the offer, sale or issuance of the Note, the Conversion CDIs, the Warrant, the Warrant CDIs and the Existing Warrants CDIs, or the consummation of any other transaction contemplated hereby shall have been obtained and will be effective at the Closing, except for (i) any stockholder approval described by Section 2(c) of the Note and this Agreement and (ii) any notices required or permitted to be filed with certain foreign, state and/or federal securities commissions or stock exchanges, which notices will be filed on a timely basis.

3.4 No Conflicts. The execution, delivery and performance of the Financing Documents by the Company and the consummation by the Company of the transactions contemplated hereby and thereby (including, without limitation, the issuance of the Note, the Warrant and the Existing Warrants CDIs and the reservation for issuance and issuance of the Conversion CDIs and the Warrant CDIs) will not (i) result in a violation of the certificate of incorporation or by-laws of the Company or (ii) conflict with, or constitute a default (or an event which with notice or lapse of time or both would become a default) under, or give to others any rights of termination, amendment, acceleration or cancellation of, any material agreement, indenture or instrument to which the Company is a party or by which the Company is bound, or (iii) result in a violation of any law, rule, regulation, order, judgment or decree including federal and state securities laws and regulations applicable to the Company or by which any property or asset of the Company is bound or affected. For the avoidance of doubt, the Purchaser agrees that the execution, delivery and performance of the Financing Documents by the Company and the consummation by the Company of the transactions contemplated hereby and thereby shall not conflict with or constitute a default under the Note Purchase Agreement, dated as of June 15, 2017, and amended as of December 31, 2018, March 31, 2019, April 30, 2019, June 30, 2019 and of even date herewith, between the Company and the Purchaser, including, without limitation, the restriction on additional indebtedness set forth in Section 3.14 thereof.

3.5 Offering. Assuming the accuracy of the representations and warranties of the Purchaser contained in Section 4 hereof, the offer, issue, and sale of the Note and the Warrant and the issue and sale of the Existing Warrants CDIs are and will be exempt from the registration and prospectus delivery requirements of the Securities Act of 1933, as amended (the “*Act*”), and have been registered or qualified (or are exempt from registration and qualification) under the registration, permit, or qualification requirements of all applicable state securities laws.

3.6 Use of Proceeds. The Company shall use the proceeds from the exercise of the Existing Warrants and the sale and issuance of the Note to continue work on the three highest priority programs, comprised of STEP-1 (United States) clinical trial enrollment, I-STEP (India with Apollo Sugar) clinical trial enrollment, CE Mark, and for general corporate purposes advance for general corporate purposes.

3.7 Delivery of SEC Filings. The Company has provided the Purchaser with copies of the Company’s most recent Annual Report on Form 10-K for the fiscal year ended December 31, 2018, and all other reports filed by the Company pursuant to the Securities Exchange Act of 1934, as amended (the “*1934 Act*”) since the filing of the Annual Report on Form 10-K and prior to the date hereof (collectively, the “*SEC Filings*”); which reports represent all filings required of the Company pursuant to the 1934 Act for such period. During the two (2) years prior to the date hereof, the Company has filed all reports, schedules, forms, statements and other documents required to be filed by it with the SEC pursuant to the reporting requirements of 1934 Act (all of the foregoing filed prior to the date hereof or prior to the date of the Closing, and all exhibits included therein and financial statements, notes and schedules thereto and documents incorporated by reference therein being hereinafter referred to as the “*SEC Documents*”). As of their respective filing dates, or, if amended or superseded by a subsequent filing, as of the date of the last such amendment or superseding filing, the SEC Documents complied in all material respects with the requirements of the 1934 Act and the rules and regulations of the SEC promulgated thereunder applicable to the SEC Documents, and none of the SEC Documents, at the time they were filed or, if amended or superseded by a subsequent filing, as of the date of the last such amendment or superseding filing, with the SEC, contained any untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading. As of their respective filing dates, or, if amended or superseded by a subsequent filing, as of the date of the last such amendment or superseding filing, the financial statements of the Company included in the SEC Documents complied as to form in all material respects with applicable accounting requirements and the published rules and regulations of the SEC with respect thereto. Such financial statements have been prepared in accordance with generally accepted accounting principles, consistently applied, during the periods involved (except (i) as may be otherwise indicated in such financial statements or the notes thereto, or (ii) in the case of unaudited interim statements, to the extent they may exclude footnotes or may be condensed or summary statements) and fairly present in all material respects the financial position of the Company as of the dates thereof and the results of its operations and cash flows for the periods then ended (subject, in the case of unaudited statements, to normal year-end audit adjustments).

3.8 Conduct of Business; Regulatory Permits. To the knowledge of the Company, the Company is not in violation of any term of, or in default under, its Certificate of Incorporation, as amended and as in effect on the date hereof, or any certificate of designation of an outstanding series of stock of the Company or Bylaws, as amended and as in effect on the date hereof. The Company is not in violation of any judgment, decree or order or any statute, ordinance, rule or regulation applicable to the Company, and the Company does not and will not conduct its business in violation of any of the foregoing, except for possible violations which could not, individually or in the aggregate, reasonably be expected to have a material adverse effect on the Company. Without limiting the generality of the foregoing, the Company is not in violation of any of the rules, regulations or requirements of the ASX (defined below) and, assuming the Note, the Existing Warrants CDIs and the Warrant are issued, has no knowledge of any facts or circumstances that would reasonably lead to a suspension of its securities by the ASX in the foreseeable future. Except as set forth in its SEC Filings, the Company possesses all certificates, authorizations and permits issued by the appropriate federal, state or foreign regulatory authorities necessary to conduct its business, and the Company has not received any notice of proceedings relating to the revocation or modification of any such certificate, authorization or permit.

3.9 Absence of Litigation. There is no action, suit, proceeding, inquiry or investigation before or by the SEC, the ASX, any court, public board, government agency, self-regulatory organization or body pending or, to the knowledge of the Company, threatened against or affecting the Company or any of its subsidiaries or affiliates, the Securities or any of the Company's or its subsidiaries' officers or directors, whether of a civil or criminal nature or otherwise, which, if adversely determined, would have a material adverse effect on the Company's business or financial condition.

3.10 Securities Laws. The Company shall timely make all filings and reports relating to the issuance of the Securities required under applicable securities laws, including filing any notice of sale of securities required by applicable law or regulation and complying with any applicable "blue sky" laws of the states of the United States. The Company shall pay all fees and expenses in connection with satisfying its obligations under this Section 3.10. The Company shall not sell, offer for sale or solicit offers to buy or otherwise negotiate in respect of any "security" (as defined in the Act) that could be integrated with the issuance of the Note or the Warrant in a manner that could require the registration of the Note or the Warrant under the Act.

3.11 Efforts to Obtain Stockholder Approval. The Company shall use its commercially reasonable efforts to obtain any stockholder approval described in Section 2(c) of the Note in respect of the Note and the same form of approval in respect of the Warrant on or prior to December 31, 2019. The Company covenants that its proposal to stockholders in respect of approval of the Warrant issuance will be interconditional with its proposal to stockholders in respect of approval of issuance of CDIs upon conversion of the Note, such that if either proposal is not approved, then neither proposal may be approved.

4. REPRESENTATIONS AND WARRANTIES OF THE PURCHASER

The Purchaser hereby represents and warrants to the Company as follows:

4.1 Purchase for Own Account. The Purchaser understands that the Securities have not been registered under the Act and the Purchaser is acquiring the Securities for its own account and not with a view towards, or for resale in connection with, the public sale or distribution thereof, except pursuant to sales registered or exempted from registration. The Purchaser represents that its acquisition of any Securities under the Note, the Warrant or Existing Warrants will be acquired solely for its own account and beneficial interest for investment and not for sale or with a view to distribution of the Securities or any part thereof, has no present intention of selling (in connection with a distribution or otherwise), granting any participation in, or otherwise distributing the same.

4.2 Information and Sophistication. Without lessening or obviating the representations and warranties of the Company set forth in Section 3, the Purchaser hereby: (i) acknowledges that it has received all the information it has requested from the Company including, but not limited to, the SEC Filings, (ii) represents that it has had an opportunity to ask questions and receive answers from the Company regarding the Company, its business and the terms and conditions of the offering of the Securities and (iii) further represents that it has such knowledge and experience in financial and business matters that it is capable of evaluating the merits and risk of this investment.

4.3 Ability to Bear Economic Risk. The Purchaser acknowledges that investment in the Securities involves a high degree of risk, and represents that it is able, without materially impairing its financial condition, to hold the Securities for an indefinite period of time and to suffer a complete loss of its investment.

4.4 Rule 144. The Purchaser is aware that none of the Securities may be sold pursuant to Rule 144 adopted under the Act unless certain conditions are met, including, among other things, the existence of a public market for the shares, the availability of certain current public information about the Company, the resale following the required holding period under Rule 144 and the number of shares being sold during any three month period not exceeding specified limitations.

4.5 Accredited Investor Status. The Purchaser is an “*accredited investor*” as such term is defined in Rule 501 under the Act.

4.6 Regulation S. In issuing and selling the Securities, the Company may be relying upon the “safe harbor” provided by Regulation S and/or on Section 4(2) under the Act; it is a condition to the availability of the Regulation S “safe harbor” that the Securities not be offered or sold in the United States or to a U.S. person until the expiration of a one-year “distribution compliance period” (or a six-month “distribution compliance period,” if the issuer is a “reporting issuer,” as defined in Regulation S) following the closing; and notwithstanding the foregoing, prior to the expiration of the one-year “distribution compliance period” (or six-month “distribution compliance period,” if the issuer is a “reporting issuer,” as defined in Regulation S) after the closing (the “*Restricted Period*”), the Note, the Warrant and the underlying securities, and the Existing Warrants CDIs may, subject to any restrictions contained in the Note or the Warrant, as applicable, be offered and sold by the holder thereof only if such offer and sale is made in compliance with the terms of this Agreement and the Note or the Warrant, as applicable, and either: (A) if the offer or sale is within the United States or to or for the account of a U.S. person (as such terms are defined in Regulation S), the securities are offered and sold pursuant to an effective registration statement or pursuant to Rule 144 under the Act or pursuant to an exemption from the registration requirements of the Act; or (B) the offer and sale is outside the United States and to other than a U.S. person. If the Purchaser is not a United States person, the Purchaser hereby represents that the Purchaser is satisfied as to the full observance of the laws of the Purchaser’s jurisdiction applicable to the Purchaser in connection with any invitation to subscribe for the Securities, including (i) the legal requirements within the Purchaser’s jurisdiction for the purchase of the Securities, (ii) any foreign exchange restrictions applicable to such purchase, (iii) any governmental or other consents that may need to be obtained and (iv) the income tax and other tax consequences, if any, that may be relevant to the purchase, holding, redemption, sale or transfer of such Securities. The Purchaser’s subscription and payment for, and the Purchaser’s continued beneficial ownership of the Securities, will not violate any applicable securities or other laws of the Purchaser’s jurisdiction that are applicable to the Purchaser.

4.7 Rule 506(d). If the Purchaser beneficially owns twenty percent (20%) or more of the outstanding voting securities of the Company, calculated in accordance with Rule 506(d) of Regulation D of the Act, or may designate a director of the Company, the Purchaser hereby represents and warrants to the Company that the Purchaser has not been convicted of any of the felonies or misdemeanors or been subject to any of the orders, judgments, decrees or other conditions set forth in Rule 506(d) of Regulation D of the Act.

4.8 Further Limitations on Disposition. Without in any way limiting the representations set forth above and subject to any restrictions contained in the Note and the Warrant, as applicable, the Purchaser further agrees not to make any disposition of all or any portion of the Securities unless and until:

(a) There is then in effect a Registration Statement under the Act covering such proposed disposition and such disposition is made in accordance with such Registration Statement; or

(b) The Purchaser shall have notified the Company of the proposed disposition and shall have furnished the Company with a detailed statement of the circumstances surrounding the proposed disposition, and if reasonably requested by the Company, the Purchaser shall have furnished the Company with an opinion of counsel, reasonably satisfactory to the Company, that such disposition will not require registration under the Act or any applicable state securities laws.

(c) Notwithstanding the provisions of paragraphs (a) and (b) above, but subject to the terms of the Note and the Warrant, as applicable, no such registration statement or opinion of counsel shall be necessary for a transfer by the Purchaser to (i) any shareholder, partner, retired partner, member or former member of the Purchaser for no additional consideration or (ii) any affiliate, including affiliated funds, for no additional consideration, in each case if all transferees agree in writing to be subject to the terms hereof to the same extent as if they were the Purchaser hereunder.

(d) Notwithstanding the provisions of paragraphs (a) and (b) above, the Company acknowledges and agrees that the Securities may be pledged by the Purchaser, and its successors and assigns, in connection with a bona fide margin agreement or other loan or financing arrangement that is secured by the Securities, provided that any pledge of those Securities does not constitute an offer of those Securities for sale within 12 months after their issue such that it would require disclosure under section 707(3) of the *Corporations Act 2001* (Cth). The pledge of Securities shall not be deemed to be a transfer, sale or assignment of the Securities hereunder, and no Person effecting a pledge of Securities shall be required to provide the Company with any notice thereof or otherwise make any delivery to the Company pursuant to this Agreement or any other Financing Document. The Company hereby agrees to execute and deliver such documentation as a pledgee of the Securities may reasonably request, at the Purchaser's expense, in connection with a pledge of the Securities to such pledgee by the Purchaser and any successor or assignee.

4.9 Legends. The Purchaser understands that any securities issued upon conversion of the Note or exercise of the Warrant, and the Existing Warrants CDIs, may bear one or all of the following legends:

(a) “THE SECURITIES REPRESENTED BY THIS CERTIFICATE HAVE NOT BEEN REGISTERED UNDER THE U.S. SECURITIES ACT OF 1933, AS AMENDED (THE “SECURITIES ACT”), AND HAVE BEEN ACQUIRED FOR INVESTMENT AND NOT WITH A VIEW TO, OR IN CONNECTION WITH, THE SALE OR DISTRIBUTION THEREOF. NO SALE OR DISTRIBUTION OF SUCH SHARES MAY BE EFFECTED WITHOUT AN EFFECTIVE REGISTRATION STATEMENT RELATED THERETO OR AN OPINION OF COUNSEL IN A FORM SATISFACTORY TO THE COMPANY OR OTHER EVIDENCE REASONABLY SATISFACTORY TO THE COMPANY THAT SUCH REGISTRATION IS NOT REQUIRED UNDER THE SECURITIES ACT.”

(b) Any legend set forth in or required by another section of this Agreement, the Note or the Warrant, as applicable.

(c) Any legend required by the securities laws of any state or country to the extent such laws are applicable to the securities represented by the certificate so legended.

4.10 Market Standoff. The Purchaser agrees not to sell any of the Securities during a period specified by the representative of the underwriters of Common Stock (not to exceed one hundred eighty (180) days) following the effective date of the initial registration statement of the Company filed under the Act, so long as all officers, directors, and 1% stockholders have executed similar agreements and are similarly restricted from selling the Company’s stock.

4.11 Foreign Ownership Restrictions. The Purchaser acknowledges and agrees that in order to ensure that US persons do not purchase any CDIs that may be issued to them, a number of procedures governing the trading and clearing of CDIs, while the Company is listed on the ASX, will be implemented, including the application to any CDIs issued to them of the status of Foreign Ownership Restrictions securities under the ASX Settlement Operating Rules and the addition of the notation “FORUS” to the CDI description on ASX trading screens and elsewhere, which will inform the market of the prohibition of US persons acquiring CDIs.

5. EVENTS OF DEFAULT; REMEDIES

5.1 Events of Default. Each of the following shall constitute an event of default (each, an “*Event of Default*”) under this Agreement and the other Financing Documents:

(a) Any default in the payment, when the same becomes due and payable, of principal under or interest in respect of the Note or other amount due and payable under any other Financing Document including, but not limited to, the failure by the Company to pay on the Maturity Date, upon a Change of Control pursuant to Section 2(b) of the Note or to the extent due and payable under Section 2(c) of the Note, any and all unpaid principal, accrued interest and all other amounts owing under any Financing Document;

(b) The Company files any petition or action for relief under any bankruptcy, reorganization, insolvency or moratorium law or any other law for the relief of, or relating to, debtors, now or hereafter in effect, or makes any general assignment for the benefit of creditors or takes any corporate action in furtherance of any of the foregoing;

(c) An involuntary petition is filed against the Company (unless such petition is dismissed or discharged within sixty (60) days) under any bankruptcy statute now or hereafter in effect, or a custodian, receiver, trustee, assignee for the benefit of creditors (or other similar official) is appointed to take possession, custody or control of any property of the Company;

(d) The Company's stockholders (other than the Purchaser) or board of directors affirmatively vote to liquidate, dissolve, or wind up the Company or the Company otherwise ceases to carry on its ongoing business operations;

(e) If (i) a material portion of the Company's assets is attached, seized, levied on, or comes into possession of a trustee or receiver and the attachment, seizure or levy is not removed in thirty (30) days, (ii) the Company is enjoined, restrained, or prevented by a court order or other order of a governmental body from conducting its business, or (iii) notice of lien, levy, or assessment is filed against any material portion of the Company's assets by any court order or other order of any governmental body and it is not paid within sixty (60) days after the Company received notice thereof; or

(f) The Company shall fail in any material respect to observe or perform any covenant, obligation, condition or agreement contained in this Agreement or any other Financing Document (other than a failure to pay as specified in Section 5.1(a) hereof) and such failure shall continue for thirty (30) days after the Company's receipt of written notice thereof.

5.2 Remedies. Upon the occurrence or existence of any Event of Default (other than an Event of Default referred to in Sections 5.1(b) or 5.1(c) hereof) and at any time thereafter during the continuance of such Event of Default, the Purchaser or any holder of the Note may, by written notice to the Company, declare all outstanding obligations payable by the Company under the Note and the other Financing Documents to be immediately due and payable without presentment, demand, protest or any other notice of any kind, all of which are hereby expressly waived, anything contained herein to the contrary notwithstanding. Upon the occurrence or existence of any Event of Default described in Sections 5.1(b) or 5.1(c) hereof, immediately and without notice, all outstanding obligations payable by the Company hereunder shall automatically become immediately due and payable, without presentment, demand, protest or any other notice of any kind, all of which are hereby expressly waived, anything contained herein to the contrary notwithstanding. In the event of any Event of Default, the Company shall pay all reasonable attorneys' fees and costs incurred by the Purchaser in enforcing and collecting the Note and the other Financing Documents. No right or remedy conferred upon or reserved to the Purchaser under this Agreement is intended to be exclusive of any other right or remedy, and every right and remedy shall be cumulative and in addition to every other right and remedy given hereunder or now and hereafter existing under applicable law.

6. CONDITIONS TO CLOSING

6.1 Conditions to Purchaser's Obligations at the Closing. The obligations of the Purchaser under the Financing Documents are subject to the fulfillment on or before the Closing of each of the following conditions, which may be waived in writing by the Purchaser:

(a) **Representations and Warranties.** The representations and warranties of the Company contained in Section 3 shall be true on and as of the date when made and as of the Closing Date as though made at that time (except for representations and warranties that speak as of a specific date, which shall be true and correct as of such specified date).

(b) **Performance.** The Company shall have performed and complied with all agreements, obligations, and conditions contained in the Financing Documents that are required to be performed or complied with by it on or before the Closing.

(c) **Qualifications.** All authorizations, approvals, or permits, if any, of any governmental authority or regulatory body of the United States or of any state that are required in connection with the lawful issuance and sale of the Note, the Conversion CDIs, the Warrant, the Warrant CDIs and the exercise of the Existing Warrants CDIs shall be duly obtained and effective as of the Closing.

(d) **Proceedings and Documents.** All corporate and other proceedings in connection with the transactions contemplated at the Closing and all documents incident thereto shall be reasonably satisfactory in form and substance to the Purchaser's counsel, which shall have received all such counterpart original and certified copies of such documents as it may reasonably request.

6.2 Conditions to Company's Obligations at the Closing. The obligations of the Company under the Financing Documents are subject to the fulfillment on or before the Closing of each of the following conditions, which may be waived in writing by the Company:

(a) **Representations and Warranties.** The representations and warranties made by the Purchaser in Section 4 hereof shall be true and correct on the Closing Date.

(b) **Purchase Price.** The Purchaser shall have delivered to the Company the Initial Exercise Notice together with the Initial Exercise Price.

7. MISCELLANEOUS

7.1 Binding Agreement. The terms and conditions of this Agreement shall inure to the benefit of and be binding upon the respective successors and assigns of the parties. Nothing in this Agreement, expressed or implied, is intended to confer upon any third party any rights, remedies, obligations, or liabilities under or by reason of this Agreement, except as expressly provided in this Agreement.

7.2 Governing Law. This Agreement shall be governed by and construed under the laws of the State of New York.

7.3 Counterparts. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

7.4 Titles and Subtitles. The titles and subtitles used in this Agreement are used for convenience only and are not to be considered in construing or interpreting this Agreement.

7.5 Notices. All notices required or permitted hereunder shall be in writing and shall be deemed effectively given: (a) upon personal delivery to the party to be notified, (b) five (5) days after having been sent by registered or certified mail, return receipt requested, postage prepaid, or (c) one (1) day after deposit with a nationally recognized overnight courier, specifying next day delivery, with written verification of receipt. All communications shall be sent to the address set forth in this Section 7.5 or at such other address as the Company or the Purchaser may designate by ten (10) days advance written notice to the other parties hereto.

If to the Purchaser:

Crystal Amber Fund Limited
PO Box 286
Floor 2, Trafalgar Court
Les Banques
St Peter Port
Guernsey
GY1 4LY

With a copy (that shall not constitute notice) to:

Estera - GG - Crystal Amber Team
CrystalAmberTeam@estera.com

If to the Company:

GI DYNAMICS, INC.
320 Congress Street
Floor 3
Boston, MA 02205
Attention: Chief Executive Officer

With a copy (that shall not constitute notice) to:

Melanie Figueroa, Esq.
Mitchell Silberberg & Knupp LLP
437 Madison Avenue, 25th Floor
New York, New York 10022
Email: mxmf@msk.com

7.6 Amendment; Modification; Waiver. No amendment, modification or waiver of any provision of this Agreement or consent to departure therefrom shall be effective unless in writing and approved by the Company and the Purchaser provided that, while the Company is admitted to the Official List of the ASX, any proposed amendment, modification or waiver of any provision of this Agreement must not contravene the ASX Listing Rules.

7.7 Entire Agreement. This Agreement, the Exhibits hereto, and the Financing Documents constitute the full and entire understanding and agreement between the parties with regard to the subjects hereof and no party shall be liable or bound to any other party in any manner by any representations, warranties, covenants and agreements except as specifically set forth herein and therein.

IN WITNESS WHEREOF, the parties have executed this **SECURITIES PURCHASE AGREEMENT** as of the date first written above.

COMPANY:

GI DYNAMICS, INC.

By: /s/ Scott Schorer

Name: Scott Schorer

Title: Chief Executive Officer

PURCHASER:

CRYSTAL AMBER FUND LIMITED

By: /s/ Laurence McNairn

Name: Laurence McNairn

Title: Director

Executed by Crystal Amber Asset Management (Guernsey)
Ltd as Investment Manager of Crystal Amber Fund Limited

[SIGNATURE PAGE TO NOTE PURCHASE AGREEMENT]

EXHIBIT A

FORM OF UNSECURED CONVERTIBLE PROMISSORY NOTE

[See Exhibit 10.4 to this Quarterly Report on Form 10-Q.]

EXHIBIT B

FORM OF WARRANT

[See Exhibit 10.5 to this Quarterly Report on Form 10-Q.]

THIS UNSECURED CONVERTIBLE PROMISSORY NOTE (THIS “NOTE”) AND THE SECURITIES ISSUABLE UPON THE CONVERSION HEREOF HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE “SECURITIES ACT”), AND MAY NOT BE SOLD, TRANSFERRED, ASSIGNED, PLEDGED OR HYPOTHECATED EXCEPT IN ACCORDANCE WITH THE PROVISIONS OF REGULATION S PROMULGATED UNDER THE SECURITIES ACT, PURSUANT TO REGISTRATION UNDER THE SECURITIES ACT OR PURSUANT TO AN AVAILABLE EXEMPTION FROM REGISTRATION. HEDGING TRANSACTIONS INVOLVING THE SECURITIES REPRESENTED HEREBY MAY NOT BE CONDUCTED UNLESS IN COMPLIANCE WITH THE SECURITIES ACT. THE ISSUER OF THESE SECURITIES MAY REQUIRE AN OPINION OF COUNSEL REASONABLY SATISFACTORY TO THE ISSUER THAT SUCH OFFER, SALE OR TRANSFER OTHERWISE COMPLIES WITH THE ACT AND ANY APPLICABLE STATE SECURITIES LAWS OR LAWS OF ANY OTHER RELEVANT COUNTRY.

UNSECURED CONVERTIBLE PROMISSORY NOTE

US\$4,596,893

August 21, 2019
Boston, Massachusetts

FOR VALUE RECEIVED, **GI DYNAMICS, INC.**, a Delaware corporation (“*Payor*”), hereby promises to pay to the order of **CRYSTAL AMBER FUND LIMITED** (the “*Holder*”), an aggregate principal sum of Four Million Five Hundred Ninety-Six Thousand Eight Hundred Ninety Three Dollars (US\$4,596,893), or such lesser amount as may be advanced and outstanding pursuant to Section 1(d) hereof, or such greater amount as shall become due after giving effect to Section 2(b) or 2(c) hereof, with interest on the outstanding principal amount at the rate of ten percent (10%) per annum. Interest (i) shall commence with the date of receipt by Payor of the Advance Amount (as defined below) on the Funding Date (as defined below) and shall be compounded annually based on a 365-day year, and (ii) shall continue on the outstanding principal until paid in full or, if permitted by the terms of the Note, converted pursuant to Section 2 below.

1. PAYMENT AND MATURITY

(a) Reference is hereby made to the Securities Purchase Agreement (the “*Purchase Agreement*”), dated as of even date herewith, between Payor and the Holder. Capitalized terms used herein and not otherwise defined herein shall have the respective meanings given to them in the Purchase Agreement.

(b) If this Unsecured Convertible Promissory Note (this “*Note*”) has not already been paid in full or, if permitted by the terms of this Note, converted in accordance with the terms of Section 2(a) below, the entire outstanding principal balance of this Note and all unpaid accrued interest thereon shall be due and payable on the date which is the fifth anniversary of the Funding Date (the “*Maturity Date*”). All payments of interest and principal shall be in lawful money of the United States of America. All payments shall be applied first to accrued interest, and thereafter to principal. If any payments on this Note become due on a Saturday, Sunday or a public holiday under the laws of the State of New York, such payment shall be made on the next succeeding business day and such extension of time shall be included in computing interest in connection with such payment.

(c) Upon the occurrence and during the continuance of any Event of Default, the principal balance of this Note shall bear interest at the rate of sixteen percent (16%) per annum, including after the commencement of, and during the pendency of, any bankruptcy or other insolvency proceeding.

(d) Subject to the terms of this Note, the Holder shall make an advance (the “*Advance*”) to Payor on December 6, 2019 (or such earlier or later date as may be requested by Payor) (the “*Funding Date*”) in an amount equal to Four Million Five Hundred Ninety-Six Thousand Eight Hundred Ninety Three Dollars (US\$4,596,893), or such lesser amount as may be set forth in a notice delivered by Payor to the Holder not later than five (5) days prior to the Funding Date (the “*Advance Amount*”). Notwithstanding the foregoing, no Advance shall be made during the continuance of any Event of Default. In such an event, Advance to Payor may resume on the third (3rd) day, and shall resume no later than the seventh (7th) day, following the Holder’s receipt of notice delivered by Payor affirming that Payor has cured its Event of Default. The parties shall cause Schedule A to be updated as of the Funding Date. For the avoidance of doubt, the Holder and Payor may jointly waive any requirement set forth in this Section 1(d), provided, however, that only the Payor may waive the Holder’s obligation to deliver the Advance Amount.

2. CONVERSION

(a) Optional Conversion. Subject to Section 2(c) and Section 6(c) of this Note, the Holder shall have the option (the “*Conversion Option*”), but not the obligation, at any time after the Funding Date and prior to the Maturity Date, exercisable upon written notice to Payor, to (a) convert all (but not less than all) of the then outstanding unpaid principal amount of this Note together with any interest accrued but unpaid thereon (such principal amount and interest, the “*Outstanding Amount*”) into the number of CDIs equal to the quotient obtained by dividing (x) the Outstanding Amount by (y) US\$0.02 (such conversion price, the “*Conversion Price*”). In lieu of receiving CDIs, upon exercising the Conversion Option, the Holder may elect to instead receive the corresponding number of shares of Common Stock for the CDIs to be issued upon such conversion.

(b) Change of Control. Upon the consummation of a Change of Control prior to the Maturity Date, the Holder may, at its option, (i) receive an amount in cash equal to all unpaid interest that has accrued to date hereunder and 110% of the then outstanding unpaid principal amount of this Note in full satisfaction of all obligations under the Note, or (ii) subject to the provisions of Section 2(c) and Section 6(a) hereof, retain the Note, including, without limitation, the Conversion Option set forth in Section 2(a) hereof. A “*Change of Control*” means any transaction or series of related transactions that could result in any of the following: (i) the sale of all or substantially all of the assets of Payor to any person or related group of persons (other than the Holder or a person that directly or indirectly controls, is controlled by, or is under common control with, the Holder), (ii) the acquisition, directly or indirectly, by any person or related group of persons (other than Payor or the Holder or a person that directly or indirectly controls, is controlled by, or is under common control with, Payor or the Holder) of beneficial ownership of securities possessing more than fifty percent (50%) of the total combined voting power of the Payor’s outstanding securities pursuant to a tender or exchange offer made directly to Payor’s stockholders, (iii) a merger or consolidation of Payor, other than for the purpose of re-domiciling Payor, unless following such transaction or series of transactions, the holders of Payor’s securities prior to the first such transaction continue to hold more than fifty percent (50% percent) of the voting rights and equity interests in the surviving entity, (iv) a recapitalization, reorganization or other transaction involving Payor that constitutes or results in a transfer of more than one-third of the equity interests in Payor, unless following such transaction or series of transactions, the holders of Payor’s securities prior to the first such transaction continue to hold more than fifty percent (50%) of the voting rights and equity interests in the surviving entity or acquirer or (v) the execution by Payor or its controlling stockholders of an agreement providing for or reasonably likely to result in any of the foregoing events.

(c) Stockholder Approval. Notwithstanding anything to the contrary contained herein or in the Purchase Agreement, in the event that the rules of the Australian Securities Exchange (“**ASX**”) (or any other exchange on which the CDIs or Common Stock is then traded) require Payor to obtain stockholder approval to issue CDIs pursuant to Section 2(a) hereof, Payor shall use its commercially reasonable efforts to convene a meeting of stockholders on or prior to December 31, 2019 to seek approval to issue those CDIs or Common Stock. If such approval is not obtained at such meeting, the Holder shall instead become entitled to receive an amount in cash equal to all unpaid (and unconverted) interest that has accrued to date hereunder and 110% of the then outstanding unpaid (and unconverted) principal amount of this Note in full satisfaction of all obligations under the Note, and such amounts shall be due and payable upon the earlier of (i) the Maturity Date, or (ii) the date that is six months following the date of the stockholders’ meeting at which such approval is not obtained. For the avoidance of doubt, while Payor is listed on the ASX and the rules of the ASX require Payor to obtain stockholder approval to issue CDIs, no conversion may occur under this Note, and no CDIs or Common Stock may be issued pursuant to Section 2(a) hereof, unless and until Payor has obtained stockholder approval pursuant to this Section 2(c).

(d) Fractional Shares and Conversion Process. No fractional shares of Payor’s capital stock will be issued upon conversion of this Note. In lieu of any fractional share to which the Holder would otherwise be entitled, Payor will pay to the Holder in cash the amount of the unconverted principal and interest balance of this Note that would otherwise be converted into such fractional share. Upon valid conversion of this Note pursuant to Section 2, the Holder shall surrender this Note, duly endorsed, at the principal offices of Payor and Payor must, if the CDIs are quoted on the ASX, do the following:

- (i) allot and issue to CHES Depository Nominees Pty Ltd (“**CDN**”) the number of shares of Common Stock underlying the CDIs the subject of the conversion notice and procure CDN to allot and issue to the Holder the number of CDIs representing the Common Stock issued to CDN under this provision;
- (ii) enter CDN into Payor’s register of members as the holder of the relevant number of shares of Common Stock and procure CDN to enter the Holder into the register of CDI holders as the holder of the relevant number of CDIs;

- (iii) deliver to the Holder a holding statement showing the Holder as the holder of the relevant number of CDIs;
- (iv) apply for, and use its reasonable efforts to obtain, official quotation of the relevant number of CDIs (and underlying shares of Common Stock) on ASX as soon as practicable; and
- (v) deliver to the Holder a check payable to Holder for any cash amounts payable as a result of any fractional shares.

If, at the time of conversion, CDIs are no longer quoted on ASX, then on conversion of the Note Payor must issue directly to the Holder the number of shares of Common Stock over which the Note is convertible into and must procure that those shares be listed for trading on any securities exchange on which Payor's Common Stock is tradeable and deliver to the Holder a check payable to Holder for any cash amounts payable as a result of any fractional shares.

(e) Holder Representations and Warranties; Transfer and Assignment. The representations and warranties and rights and obligations of transfer and assignment of Holder that are set forth in Section 4 of the Purchase Agreement with respect to the shares of Common Stock or CDIs issuable to Holder are hereby made a part of this Note and incorporated herein by this reference.

(f) Restriction on Transfer. Notwithstanding any other provision of this Note or the Purchase Agreement, the Holder may not sell or transfer any shares of Common Stock or CDIs issued to the Holder pursuant to Section 2(a) hereof ("**Restricted Securities**"), or grant, issue or transfer interests in, or options over, any Restricted Securities, at any time within 12 months after the issue of those Restricted Securities ("**Restricted Period**") except as permitted by section 708 or any other applicable section of the *Corporations Act 2001* (Cth). Before commencement of the Restricted Period, to prevent any such restricted dealings in the Restricted Securities during the Restricted Period, the Holder agrees to (i) the application of a holding lock to the Restricted Securities by Payor's securities registry for the Restricted Period, and (ii) enter into any other documents reasonably necessary to prevent any such restricted dealings in the Restricted Securities during the Restricted Period.

3. DEFAULT; REMEDIES

(a) The occurrence of any Event of Default described in Section 5.1 of the Purchase Agreement shall be an Event of Default hereunder.

(b) Upon the occurrence and during the continuance of any Event of Default, all unpaid principal on this Note, accrued and unpaid interest thereon and all other amounts owing hereunder shall, at the option of the Holder, and, upon the occurrence of any Event of Default pursuant to Sections 5.1(b), (c) or (d) of the Purchase Agreement, automatically, be immediately due, payable and collectible by Holder pursuant to applicable law.

(c) Upon the occurrence and during the continuance of any Event of Default, Payor shall pay, on demand, all reasonable attorneys' fees and court costs incurred by Holder in enforcing and collecting this Note.

4. PREPAYMENT. Subject to Section 1(d), Payor may not prepay this Note prior to the Maturity Date without the consent of the Holder, except to the extent permitted pursuant to Section 2(b) and Section 2(c) hereof.

5. NON-TRANSFERABLE. The Holder may not sell or transfer this Note, or grant, issue or transfer interests in, or options over, this Note at any time within 12 months after the date hereof except as permitted by section 708 or any other applicable section of the *Corporations Act 2001* (Cth).

6. FUNDAMENTAL TRANSACTIONS; CORPORATE EVENTS.

(a) *Fundamental Transactions.* If, at any time while this Note is outstanding, (i) Payor effects any merger or consolidation of Payor with or into another person pursuant to which the Common Stock is effectively converted and exchanged, (ii) Payor effects any sale of all or substantially all of its assets in one or a series of related transactions pursuant to which the Common Stock is effectively converted and exchanged, (iii) any tender offer or exchange offer (whether by Payor or another person) is completed pursuant to which at least a majority of the outstanding Common Stock is tendered and exchanged for other securities, cash or property or (iv) Payor effects any reclassification of the Common Stock or any compulsory share exchange pursuant to which the Common Stock is effectively converted into or exchanged for other securities, cash or property (other than as a result of a subdivision or combination of shares of Common Stock) (in any such case, a “*Fundamental Transaction*”), then prior to any subsequent conversion of this Note, and subject to the provisions of Section 2(b) hereof, the Holder shall be entitled to require the surviving entity to issue to the Holder an instrument identical to this Note (with an appropriate adjustment to the conversion price(s)) such that the Holder may receive stock (or a beneficial interest in stock) of the surviving company’s stock. Subject to the provisions of Section 2(b) hereof, the terms of any agreement pursuant to which a Fundamental Transaction is effected shall include terms requiring any such successor or surviving entity to comply with the provisions of this paragraph (a) and insuring that this Note (or any such replacement security) will be similarly adjusted upon any subsequent transaction analogous to a Fundamental Transaction.

(b) *Notice of Corporate Events.* If Payor (i) declares a dividend or any other distribution of cash, securities or other property in respect of its Common Stock, including without limitation any granting of rights or warrants to subscribe for or purchase any shares of Payor or any subsidiary, (ii) authorizes and publicly approves, or enters into any agreement contemplating or solicits stockholder approval for any Fundamental Transaction or (iii) publicly authorizes the voluntary dissolution, liquidation or winding up of the affairs of Payor, then Payor shall deliver to the Holder a notice describing the material terms and conditions of such transaction, at least ten (10) business days prior to the applicable record or effective date on which a person would need to hold Common Stock or CDIs in order to participate in or vote with respect to such transaction, and Payor will take all steps reasonably necessary in order to insure that the Holder is given the practical opportunity to convert this Note prior to such time so as to participate in or vote with respect to such transaction; provided, however, that the failure to deliver such notice or any defect therein shall not affect the validity of the corporate action required to be described in such notice.

(c) *Subsequent Equity Sales*. Notwithstanding any provision of this Note to the contrary, in the event that Payor issues any CDIs or Common Stock or any security that is exchangeable or convertible into CDIs or Common Stock ("**Additional Securities**") after the date hereof at a price per CDI (or the equivalent for shares of Common Stock) that is less than the Conversion Price (or the equivalent for shares of Common Stock) in an equity financing, then the Conversion Price shall be reduced to the lowest price per CDI (or the equivalent for shares of Common Stock) at which any Additional Security was issued or sold or deemed to be issued or sold. Payor agrees that it will provide a notice to the Holder describing the material terms and conditions of any issuance of Additional Securities promptly after the issuance thereof. For the avoidance of doubt, the price per CDI (or the equivalent for shares of Common Stock) at which any Additional Securities are issued by Payor to the Holder after the date hereof, including, without limitation, upon conversion into CDIs or Common Stock of the Senior Secured Convertible Promissory Note, dated June 15, 2017, and amended December 31, 2018, March 31, 2019, April 30, 2019, June 30, 2019 and of even date herewith, will have no effect on the Conversion Price.

7. WAIVER; PAYMENT OF FEES AND EXPENSES. Payor waives presentment and demand for payment, notice of dishonor, protest and notice of protest of this Note, and shall pay all costs of collection when incurred, including, without limitation, reasonable attorneys' fees, costs and other expenses. The right to plead any and all statutes of limitations as a defense to any demands hereunder is hereby waived to the full extent permitted by law. No delay by the Holder shall constitute a waiver, election or acquiescence by it.

8. CUMULATIVE REMEDIES. The Holder's rights and remedies under this Note and the Purchase Agreement shall be cumulative. No exercise by the Holder of one right or remedy shall be deemed an election, and no waiver by the Holder of any Event of Default shall be deemed a continuing waiver of such Event of Default or the waiver of any other Event of Default.

9. MISCELLANEOUS

(a) **Governing Law.** The terms of this Note shall be construed in accordance with the laws of the State of New York, as applied to contracts entered into by New York residents within the State of New York, and to be performed entirely within the State of New York.

(b) **Exclusive Jurisdiction.** All actions and proceedings arising out of, or relating to, this Agreement shall be heard and determined in any state or federal court sitting in the State of New York, County of New York. The undersigned, by execution and delivery of this Agreement, expressly and irrevocably consent and submit to the personal jurisdiction of any of such courts in any such action or proceeding; and (ii) waive any claim or defense in any such action or proceeding based on any alleged lack of personal jurisdiction, improper venue or forum non conveniens or any similar basis.

(c) **Successors and Assigns; Assignment.** The terms and conditions of this Note shall inure to the benefit of and be binding upon the respective successors and assigns of the parties. Payor may not assign this Note or delegate any of its obligations hereunder without the written consent of the Holder. Subject to Section 5 hereof, the Holder may assign this Note and its rights hereunder without the consent of Payor, subject to compliance with Section 4 of the Purchase Agreement.

(d) **Titles and Subtitles.** The titles and subtitles used in this Note are used for convenience only and are not to be considered in construing or interpreting the Note.

(e) **Notices.** All notices required or permitted hereunder by the Holder of this Note to Payor shall be in writing and shall be deemed effectively given: (a) upon personal delivery to the principal offices of Payor, to the attention of the Chief Executive Officer, (b) five (5) days after having been sent by registered or certified mail, return receipt requested, postage prepaid, or (c) one (1) day after deposit with a nationally recognized overnight courier, specifying next day delivery. Any refusal of delivery of a notice by Payor shall be deemed to have been delivered.

(f) **Amendment; Modification; Waiver.** No term of this Note may be amended, modified or waived without the written consent of Payor and the Holder provided that, while Payor is admitted to the Official List of the ASX, any amendment, modification or waiver must not contravene the ASX Listing Rules.

(g) **Counterparts.** This Note may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

(h) **Voting Rights.** This Note does not carry any voting rights at stockholder meetings of Payor unless and until the Note is converted.

(i) **Participation Rights.** The Holder is not by virtue of holding this Note entitled to participate in any new issue of securities made by Payor to stockholders without first converting the Note.

(j) **Equal Ranking.** The Common Stock and CDIs issued pursuant to a conversion of this Note will rank, from the date of issue, equally with the existing shares of Common Stock and CDIs of Payor in all respects.

(k) **Reorganisations.** While Payor is admitted to the Official List of the ASX, the rights of the Holder will be changed to the extent necessary to comply with the ASX Listing Rules applying to a reorganization of Payor's capital at the time of the reorganization.

[Signature page follows]

IN WITNESS WHEREOF, the parties have executed this **CONVERTIBLE PROMISSORY NOTE** as of the date first written above.

GI DYNAMICS, INC.

By: _____
Name: Scott Schorer
Title: Chief Executive Officer

AGREED TO AND ACCEPTED:

CRYSTAL AMBER FUND LIMITED

By: _____

Name: Laurence McNairn
Title: Director
Executed by Crystal Amber Asset Management (Guernsey) Ltd
as Investment Manager of Crystal Amber Fund Limited

SCHEDULE A

ADVANCE (in US\$)

Advance Date

Advance Amount

Will be determined on draw date

THIS WARRANT AND THE SECURITIES ISSUABLE UPON THE EXERCISE HEREOF HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "SECURITIES ACT"), AND MAY NOT BE SOLD, TRANSFERRED, ASSIGNED, PLEDGED OR HYPOTHECATED EXCEPT IN ACCORDANCE WITH THE PROVISIONS OF REGULATIONS PROMULGATED UNDER THE SECURITIES ACT, PURSUANT TO REGISTRATION UNDER THE SECURITIES ACT OR PURSUANT TO AN AVAILABLE EXEMPTION FROM REGISTRATION. HEDGING TRANSACTIONS INVOLVING THE SECURITIES REPRESENTED HEREBY MAY NOT BE CONDUCTED UNLESS IN COMPLIANCE WITH THE SECURITIES ACT. THE ISSUER OF THESE SECURITIES MAY REQUIRE AN OPINION OF COUNSEL REASONABLY SATISFACTORY TO THE ISSUER THAT SUCH OFFER, SALE OR TRANSFER OTHERWISE COMPLIES WITH THE ACT AND ANY APPLICABLE STATE SECURITIES LAWS OR LAWS OF ANY OTHER RELEVANT COUNTRY.

WARRANT TO PURCHASE CHESS DEPOSITARY INTERESTS

Issue Date: _____, 2019

This Warrant to Purchase CHESS Depositary Interests (the "*Warrant*") certifies that, for good and valuable consideration, CRYSTAL AMBER FUND LIMITED (along with its permitted assignees, the "*Holder*") is entitled to, and GI DYNAMICS, INC., a Delaware corporation (the "*Company*"), hereby grants the Holder the right to, purchase, as of the date of issuance set forth above (the "*Issue Date*"), up to such number of fully paid and non-assessable CHESS Depositary Interests (with each CDI representing 1/50th of a share of the Company's common stock, par value \$0.01 per share (the "*Common Stock*")) (the "*CDIs*") as determined pursuant to Section 1(a) below, at a price per CDI equal to the Exercise Price (as defined below), subject to the provisions and upon the terms and conditions set forth in this Warrant. This Warrant is issued pursuant to the Securities Purchase Agreement (the "*Purchase Agreement*"), dated as of August 21, 2019, by and between the Company and the Holder.

1. Number of CDIs; Exercise Price

(a) Number of CDIs. Subject to the terms of that certain Unsecured Convertible Promissory Note issued by the Company to the Holder on August 21, 2019 (the "*Note*"), upon receipt of the Advance (as defined in the Note) by the Company pursuant to the Note, and with effect from the Issue Date, this Warrant automatically shall become exercisable for the number of CDIs set forth on Schedule A hereto, which amounts represent a proportionate number of shares of Common Stock set forth on Schedule A. All CDIs for which this Warrant becomes exercisable from time to time pursuant to this Paragraph 1(a), and as may be adjusted from time to time in accordance with the provisions of this Warrant, are referred to herein cumulatively and collectively as the "*Warrant CDIs*."

(b) Exercise Price. With respect to each Warrant CDI for which this Warrant becomes exercisable pursuant to Paragraph 1(a) above, the purchase price therefor (the "*Exercise Price*") shall be US\$0.02.

2. Exercise; Payment.

(a) Method of Exercise. This Warrant may be exercised by the Holder at any time during the term (as set forth in Section 8) and in compliance with the provisions of this Warrant for all or any part of the Warrant CDIs, by the surrender of this Warrant together with the duly executed notice of exercise form attached hereto as Exhibit A (the "**Notice of Exercise**") at the principal office address of the Company. If this Warrant shall have been exercised in part, the Company shall, at the time of delivery of the Holding Statement or the book entry notice pursuant to Section 2(c), deliver to the Holder a new Warrant evidencing the rights of the Holder to purchase the then unpurchased, or remaining but not yet available for issuance, Warrant CDIs, which new Warrant shall in all other respects be identical to this Warrant, or at the request of the Holder, appropriate notation may be made on this Warrant and the same returned to the Holder.

(b) Cash Exercise. Upon exercise of this Warrant, the Holder shall pay the Company an amount ("**Exercise Payment**") equal to the product of the Exercise Price multiplied by the total number of Warrant CDIs purchased pursuant to such exercise of this Warrant, by wire transfer of immediately available funds or check payable to the order of the Company. In the manner set out in Paragraph (c) below, the Holder shall be deemed to have become the holder of record of, and shall be treated for all purposes as the record holder of, the Warrant CDIs represented by such exercise (and such Warrant CDIs shall be deemed to have been issued) immediately prior to the close of business on the date upon which the Exercise Payment is paid to the Company.

(c) Net Exercise. The Exercise Payment also may be paid at the Holder's election by surrender of all or a portion of the Warrant for the Warrant CDIs to be exercised under this Warrant ("**Net Exercise**"). If the Holder elects the Net Exercise method, the Company will issue Warrant CDIs in accordance with the following formula:

$$X = \frac{Y(A-B)}{A}$$

Where:

X = the number of Warrant CDIs to be issued upon the Net Exercise of the Warrant

Y = the number of Warrant CDIs to be surrendered

A = the fair market value of one (1) CDI on the date of exercise of this Warrant

B = the Exercise Price

For purposes of the above calculation, fair market value of CDIs shall mean the following (“**Fair Market Value**”):

(i) if CDIs are then quoted on the Australian Securities Exchange (“**ASX**”), then the Fair Market Value per share of one (1) CDI shall be equal to the volume weighted average closing price of the Company’s CDIs on the ASX for the five (5) trading days ending immediately prior to the business day on which the Company receives the Holder’s written Notice of Exercise (regardless if received during the trading hours or after);

(ii) if CDIs are not then quoted on the ASX, then if the Company’s Common Stock is traded on another national securities exchange, the Fair Market Value of the CDIs shall be equal to the result obtained by dividing (A) the volume weighted average closing price of the Company’s Common Stock on such securities exchange for the five (5) trading days ending immediately prior to the business day on which the Company receives the Holder’s written Notice of Exercise (regardless if received during the trading hours or after), by (B) the number of CDIs (or fraction thereof) which equal an interest in exactly one share of Common Stock on such dates;

(iii) if CDIs are not then quoted on the ASX and the Common Stock is not then traded on another securities exchange, then if the Common Stock is traded over-the-counter, the Fair Market Value of the CDIs shall be equal to the result obtained by dividing (A) the volume weighted average closing price of the Company’s Common Stock quoted on the principal market on which or through which the Common Stock is traded over the five (5) consecutive trading days ending immediately prior to the business day on which the Company receives the Holder’s written Notice of Exercise (regardless if received during the trading hours or after), by (B) the number of CDIs (or fraction thereof) which equal an interest in exactly one share of Common Stock on such dates; or

(iv) if CDIs are not then quoted on the ASX and the Common Stock is not then listed on any securities exchange or traded in the over-the-counter market, the Fair Market Value of the CDIs shall be as determined by its Board of Directors in its reasonable good faith judgment (which determination shall take into consideration any available appraisals).

If any of the amounts used to calculate the Fair Market Value are expressed in Australian dollars and not the United States dollar, then each such amount shall be converted into United States dollars based on the closing exchange rate published by the Reserve Bank of Australia in their Official Bulletin at 4 pm for the applicable date. The amounts used to calculate the Fair Market Value shall be equitably adjusted for the occurrence of any of the events for which an adjustment would be made pursuant to Section 4 but which is not otherwise fully reflected in the Fair Market Value calculation.

(d) Election to receive Common Stock. The Holder may include in its Notice of Exercise, the election to receive the corresponding number of shares of Common Stock for the Warrant CDIs to be purchased.

(e) Exercise Process including Holding Statement. In the event of the valid exercise of this Warrant, the Company must, if the CDIs are quoted on the ASX, do the following:

(i) allot and issue to CHES Depository Nominees Pty Ltd (“**CDN**”) the number of shares of Common Stock underlying the CDIs the subject of the Notice of Exercise and procure CDN to allot and issue to the Holder the number of CDIs representing the Common Stock issued to CDN under this provision;

(ii) enter CDN into the Company's register of members as the holder of the relevant number of shares of Common Stock and procure CDN to enter the Holder into the register of CDI holders as the holder of the relevant number of CDIs;

(iii) deliver to the Holder a holding statement showing the Holder as the holder of the relevant number of CDIs;

(iv) apply for, and use its reasonable efforts to obtain, official quotation of the relevant number of CDIs (and underlying shares of Common Stock) on ASX as soon as practicable; and

(v) deliver in accordance with Section 6 to the Holder a check payable to the Holder for any cash amounts payable as a result of any fractional shares.

If, at the time of exercise, CDIs are no longer quoted on ASX, then on exercise of the Warrant the Company must issue directly to the Holder the number of shares of Common Stock over which the Warrant is exercised and must procure that those shares be listed for trading on any securities exchange on which the Company's Common Stock is tradeable and in accordance with Section 6 deliver to the Holder a check payable to the Holder for any cash amounts payable as a result of any fractional shares.

3. Stock Fully Paid; Reservation of Shares. All of the Warrant CDIs or Common Stock issuable upon the exercise of this Warrant, upon issuance and receipt by the Company of the Exercise Price therefor (or upon Net Exercise thereof, as provided in Section 2(c)), shall be fully paid and nonassessable, and free from all preemptive rights, rights of first refusal or first offer, taxes, liens and charges with respect to the issuance thereof except as noted in Section 5. During the period within which the rights represented by this Warrant may be exercised, the Company shall at all times have authorized and reserved for issuance a sufficient number of shares of its Common Stock to provide for the exercise of this Warrant.

4. Adjustment of Exercise Price and Number of Shares. The number and kind of Warrant CDIs to be issued upon the exercise of this Warrant and the Exercise Price payable therefor shall be subject to adjustment from time to time upon the occurrence of certain events, as follows:

(a) Reclassification, Consolidation or Reorganization. Subject to Section 10, in case of any reclassification of the CDIs (other than as a result of a subdivision or combination), or in case of any consolidation or merger of the Company with or into another corporation or sale of all or substantially all of the Company's assets (any of which is a "**Reorganization Transaction**"), the Company, or such successor corporation as the case may be, shall execute a new warrant, providing that the Holder shall have the right to exercise such new warrant, and procure upon such exercise and payment of the same aggregate Exercise Price, in lieu of the Warrant CDIs then issuable upon exercise of this Warrant, the kind and amount of shares of stock, other securities, money and property as would be received by the Holder for such Warrant CDIs as if such Warrant CDIs were outstanding immediately prior to the consummation of the Reorganization Transaction.

(b) Stock Splits, Dividends and Combinations. Subject to Section 10, in the event that the Company shall at any time subdivide the outstanding shares of Common Stock, or shall issue a stock dividend on its outstanding shares of Common Stock, the number of Warrant CDIs issuable upon exercise of this Warrant immediately prior to such subdivision or to the issuance of such stock dividend shall be proportionately increased and the Exercise Price shall be proportionately decreased, and in the event that the Company shall at any time combine the outstanding shares of Common Stock, the number of Warrant CDIs issuable upon exercise of this Warrant immediately prior to such combination shall be proportionately decreased and the Exercise Price shall be proportionately increased, effective at the close of business on the date of such subdivision, stock dividend or combination, as the case may be such that in each case, the result obtained by multiplying the Exercise Price by the number of Warrant CDIs shall be the same immediately prior to, and immediately after, such event.

(c) Notice of Corporate Action. If the Company (i) declares a dividend (other than a cash dividend payable out of earnings or earned surplus legally available for the payment of dividends under the laws of the jurisdiction of incorporation of the Company) or other distribution, or any right to subscribe for or purchase any evidences of its indebtedness, any shares of stock of any class or any other securities or property, or to receive any other right; (ii) authorizes and publicly approves, or enters into any agreement contemplating or solicits stockholder approval for any Reorganization Transaction; or (iii) publicly authorizes the voluntary dissolution, liquidation or winding up of the affairs of the Company, then the Company shall deliver to the Holder a notice describing the material terms and conditions of such transaction, at least ten (10) business days prior to the applicable record or effective date on which a person would need to hold Common Stock or CDIs in order to participate in or vote with respect to such transaction, and the Company will take all steps reasonably necessary in order to insure that the Holder is given the practical opportunity to exercise this Warrant prior to such time so as to participate in or vote with respect to such transaction. Each such written notice shall be sufficiently given if addressed to the Holder at the last address of the Holder appearing on the books of the Company and delivered in accordance with Section 11(d); provided, however, that the failure to deliver such notice or any defect therein shall not affect the validity of the corporate action required to be described in such notice.

(d) Subsequent Equity Sales. Notwithstanding any provision of this Warrant to the contrary, in the event that the Company issues any CDIs or Common Stock or any security that is exchangeable or convertible into CDIs or Common Stock ("**Additional Securities**") after the date hereof at a price per CDI (or the equivalent for shares of Common Stock) that is less than the Exercise Price (or the equivalent for shares of Common Stock) in an equity financing, then the Exercise Price shall be reduced to the lowest price per CDI (or the equivalent for shares of Common Stock) at which any Additional Security was issued or sold or deemed to be issued or sold. The Company agrees that it will provide a notice to the Holder describing the material terms and conditions of any issuance of Additional Securities promptly after the issuance thereof. For the avoidance of doubt, the price per CDI (or the equivalent for shares of Common Stock) at which any Additional Securities are issued by the Company to the Holder after the date hereof, including, without limitation, upon conversion into CDIs or Common Stock of (i) the Senior Secured Convertible Promissory Note, dated June 15, 2017, and amended as of December 31, 2018, March 29, 2019, April 30, 2019, June 30, 2019 and August 21, 2019, issued to the Holder by the Company, will have no effect on the Exercise Price.

5. Holder Representations and Warranties; Transfer and Assignment.

(a) The representations and warranties and rights and obligations of transfer and assignment of the Holder that are set forth in Section 4 of the Purchase Agreement with respect to the shares of Common Stock or Warrant CDIs issuable to the Holder are hereby made a part of this Warrant and incorporated herein by this reference

(b) Notwithstanding any other provision of this Warrant or the Purchase Agreement, the Holder may not sell or transfer any shares of Common Stock or CDIs issued to the Holder pursuant to this Warrant (“**Restricted Securities**”), or grant, issue or transfer interests in, or options over, any Restricted Securities, at any time within 12 months after the issue of those Restricted Securities (“**Restricted Period**”) except as permitted by section 708 or any other applicable section of the *Corporations Act 2001* (Cth). Before commencement of the Restricted Period, to prevent any such restricted dealings in the Restricted Securities during the Restricted Period, the Holder agrees to (i) the application of a holding lock to the Restricted Securities by the Company’s securities registry for the Restricted Period, and (ii) enter into any other documents reasonably necessary to prevent any such restricted dealings in the Restricted Securities during the Restricted Period.

(c) The Holder may not sell or transfer this Warrant, or grant, issue or transfer interests in, or options over, this Warrant at any time within 12 months after the Issue Date except as permitted by section 708 or any other applicable section of the *Corporations Act 2001* (Cth).

6. Fractional Shares. No fractional shares of the Company’s capital stock will be issued in connection with any exercise of this Warrant, but in lieu of such fractional shares the Company shall make a cash payment therefor upon the basis of the Exercise Price then in effect.

7. Rights of Stockholders. The Holder shall not be entitled to vote or receive dividends or subscription rights or be deemed the holder of the CDIs, Common Stock or any other securities of the Company which may at any time be issuable on the exercise of this Warrant for any purpose, nor shall anything contained herein be construed to confer upon the Holder any of the rights of a stockholder of the Company or any right to vote for the election of directors or upon any matter submitted to stockholders at any meeting thereof, or to give or withhold consent to any corporate action (whether upon any recapitalization, issuance of stock, reclassification of stock, change of par value, consolidation, merger, conveyance, or otherwise) with respect to the Warrant CDIs until this Warrant shall have been exercised and the Warrant CDIs purchasable upon the exercise of this Warrant shall have become deliverable, as provided in Section 2(a).

8. Term of Warrant. This Warrant shall become exercisable on the Issue Date and shall terminate and no longer be exercisable from and after 5:00 p.m., Eastern Time, on the date that is the fifth (5th) anniversary of the Funding Date.

9. Registry of Warrants. The Company shall maintain a registry showing the name and address of the registered holder of this Warrant. The Holder's initial address, for purposes of such registry, is set forth below the Holder's signature on this Warrant. The Holder may change such address by giving written notice of such changed address to the Company.

10. ASX Listing Rules. Until such time as the Company is removed from the Official List of the ASX, the following additional provisions will apply to the Warrant notwithstanding any other provision of this Warrant:

(a) **Voting Rights.** The Warrant does not carry any voting rights at stockholder meetings of the Company unless and until the Warrant is exercised.

(b) **Participation Rights.** There are no participating rights or entitlements inherent in the Warrant and the Holder is not by virtue of holding the Warrant entitled to participate in any new issue of capital that may be offered to stockholders (except upon exercise of the Warrant).

(c) **Reorganizations.** The rights of the Holder will be changed to the extent necessary to comply with the ASX Listing Rules applying to a reorganization (including a reconstruction, consolidation, subdivision or reduction or return of capital) of the Company's capital at the time of the reorganization.

(d) **Bonus Issues.** If there is a bonus issue to the holders of CDIs, the number of CDIs representing shares of Common Stock over which the Warrant is exercisable will be increased by the number of CDIs which the Holder would have received if it had exercised the Warrant before the record date for the bonus issue.

(e) **Pro Rata Issue.** If the Company proceeds with a pro rata issue (except a bonus issue) of securities to stockholders after the date of issue of the Warrant, the Exercise Price of the Warrant will be reduced in accordance with the formula set out in ASX Listing Rule 6.22.2.

(f) **Not Quoted.** The Warrant will not be quoted on ASX or on any other securities exchange.

(g) **Equal Ranking.** The Common Stock and CDIs issued pursuant to an exercise of the Warrant will rank, from the date of issue, equally with the existing shares of Common Stock and CDIs of the Company in all respects.

(h) **Changes.** Other than as set out in this Warrant or the ASX Listing Rules, this Warrant does not confer the right to a change in the Exercise Price or a change in the underlying securities over which this Warrant can be exercised.

11. Miscellaneous.

(a) This Warrant shall be construed and enforced in accordance with and governed by the laws of the State of New York, without giving effect to principles of conflicts of laws.

(b) The headings in this Warrant are for purposes of reference only, and shall not limit or otherwise affect any of the terms hereof.

(c) The terms of this Warrant shall be binding upon and shall inure to the benefit of any successors or assigns of the Company and of the Holder and of the Warrant CDIs issued or issuable upon the exercise hereof.

(d) Any notice provided for or permitted under this Warrant shall be treated as having been given (i) upon receipt, when delivered personally, (ii) one day after sending, when sent by commercial overnight courier with written verification of receipt, (iii) upon confirmed transmission when sent via facsimile on a business day prior to 5:00 pm local time or, if sent after 5:00 pm local time, the next business day after confirmed transmission, or (iv) three business days after deposit with the United States Postal Service, when mailed postage prepaid by certified or registered mail, return receipt requested, in each case, addressed to the address or facsimile number set forth on the signature pages hereof or as otherwise furnished in writing.

(e) This Warrant, the Note and the Purchase Agreement constitute the full and entire understanding and agreement between the parties with regard to the matters contained herein.

(f) Upon receipt of evidence reasonably satisfactory to the Company of the loss, theft, destruction or mutilation of this Warrant and, in the case of any such loss, theft or destruction, upon delivery of an indemnity agreement reasonably satisfactory in form and amount to the Company or, in the case of any such mutilation, upon surrender and cancellation of such Warrant, the Company at the Holder's expense will execute and deliver to the holder of record, in lieu thereof, a new Warrant of like date and tenor.

(g) This Warrant and any provision hereof may be amended, waived or terminated only by an instrument in writing signed by the Company and the Holder provided that, while the Company is admitted to the Official List of the ASX, any proposed amendment, waiver or termination must not contravene the ASX Listing Rules.

[continued and to be signed on following page]

IN WITNESS WHEREOF, each of the Company and the Holder has caused this Warrant to be signed by its duly authorized officer, all as of the day and year first above written.

COMPANY:
a Delaware corporation

GI DYNAMICS, INC.

By: _____
Name: Scott Schorer
Title: Chief Executive Officer

Notice Address:

320 Congress St
Boston, MA 02210
U.S.A.
Attention: Chief Executive Officer

HOLDER:

CRYSTAL AMBER FUND LIMITED

By: _____
Name: _____
Title: Director
Crystal Amber Asset Management (Guernsey) Ltd

Notice Address:

P.O. Box 286
Floor 2
Trafalgar Court
St. Peter Port
Guernsey
GY1 4LY

With a copy (which shall not constitute notice) to:

Estera - GG - Crystal Amber Team CrystalAmberTeam@estera.com

SCHEDULE A

ISSUABLE WARRANT CDIS

CDIs

Common Stock



To be determined on August 2019 Note draw date



EXHIBIT A
NOTICE OF EXERCISE

TO: GI DYNAMICS, INC.

1. Cash Exercise. The undersigned hereby elects to purchase _____ CHESSE Depository Interests (with each CHESSE Depository Interest representing 1/50th of a share of the Company's common stock, par value \$0.01 per share (the "**Common Stock**") ("**CDIs**") of GI DYNAMICS, INC., a Delaware corporation (the "**Company**"), pursuant to the terms of Section 2(b) of the Warrant to Purchase CHESSE Depository Interests, dated _____, 2019 (the "**Warrant**"), and tenders herewith payment of the Exercise Price (as such term is defined in the Warrant) therefor.

2. Net Exercise. The undersigned hereby elects to effect a Net Exercise for _____ CDIs pursuant to Section 2(c) of the Warrant.

Please issue a Holding Statement certifying said _____ CDIs have been issued in the name of the undersigned or in such other name as is specified below:

Name: _____

Address: _____

3. Common Stock Election. By initialing here, the undersigned hereby elects to receive the number of shares of Common Stock corresponding to the CDIs noted above in lieu of the CDIs otherwise issuable: _____

The undersigned hereby represents and warrants that the aforesaid shares of Common Stock or CDIs, as the case may be, are being acquired for the account of the undersigned for investment and not with a view to, or for resale, in connection with the distribution thereof, and that the undersigned has no present intention of distributing or reselling such shares or CDIs.

Holder Name: _____

By: _____

Name: _____

Title: _____

Date: _____

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

I, Scott W. Schorer, certify that:

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

Date: November 8, 2019

/s/ SCOTT W. SCHORER

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

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

I, Charles R. Carter, certify that:

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

Date: November 8, 2019

/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 September 30, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Scott W. Schorer, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to my knowledge that:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ SCOTT W. SCHORER

Scott W. Schorer

Chief Executive Officer

(principal executive officer)

November 8, 2019

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

**CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of GI Dynamics, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2019 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)

November 8, 2019

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.