

Boston, United States Sydney, Australia 27 February 2018 AEDT

## Appendix 4E: Preliminary Final Report Year Ended 31 December 2017

BOSTON, Massachusetts, United States and SYDNEY, Australia – 27 February 2018 AEDT.

GI Dynamics, Inc. (ASX:GID) (the Company), is the developer of EndoBarrier, the first endoscopically-delivered device therapy used for the treatment of type 2 diabetes and obesity today announces its preliminary financial results for the year ended 31 December 2017 ("Results"). The Appendix 4E, which has been prepared in U.S. dollars and in accordance with U.S. GAAP, is attached; the Results disclosed in the Appendix 4E are unaudited. The financial results are currently being audited by the Company's auditors, Moody, Famiglietti & Andronico, LLP, with final audited results to be filed as part of the Annual Report on Form 10-K with the U.S. Securities and Exchange Commission and the Australian Securities Exchange on or before 30 March 2018.

#### **Summary of the Results**

- Revenue decreased to US\$0.3 million for the year ended 31 December 2017 compared to US\$0.5 million for the year ended 31 December 2016.
- Loss from Operations was US\$10.5 million for the year ended 31
  December 2017 compared to US\$13.1 million for the year ended 31
  December 2016.
- Loss from Ordinary Activities after tax was US\$10.7 million for the year ended 31 December 2017 compared to US\$13.1 million for the year ended 31 December 2016.
- The Company had cash and cash equivalents of US\$3.0 million at 31 December 2017 compared to US\$8.3 million at 31 December 2016.

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Please refer to the attached Appendix 4E, including the unaudited consolidated financial statements, for additional explanation and details.

#### **Houry Youssoufian**

**Vice President, Finance and Company Secretary** 

#### **About GI Dynamics**

GI Dynamics is a medical device company focused on the clinical development and commercialization of EndoBarrier ®, a medical device indicated for treatment of patients with type 2 diabetes and obesity or obesity alone. GI Dynamics, Inc. (the "Company") was incorporated on March 24, 2003, as a Delaware corporation, with operations based in Boston, Massachusetts.

#### **Forward-Looking Statements**

This announcement may contain forward-looking statements. Forward-looking statements are based on GI Dynamics management's current estimates and expectations of future events as of the date of this announcement. Furthermore, the estimates are subject to several risks and uncertainties that could cause actual results to differ materially and adversely from those indicated in or implied by such forward-looking statements. These risks and uncertainties include, but are not limited to, risks associated with our ability to continue to operate as a going concern, our ability to maintain compliance with our obligations under the Convertible Loan Note executed with Crystal Amber Fund Limited; obtaining funding from third parties; the consequences of stopping the ENDO trial and the possibility that future clinical trials will not be successful or confirm earlier results; the timing and costs of clinical trials; the timing of regulatory submissions; the timing, receipt and maintenance of regulatory

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Boston, United States Sydney, Australia 27 February 2018 AEDT approvals; the timing and amount of other expenses; the timing and extent of third-party reimbursement; intellectual-property risk; risks related to excess inventory; and risks related to assumptions regarding the size of the available market, the benefits of our products, product pricing, timing of product launches, future financial results and other factors, including those described in our filings with the U.S. Securities and Exchange Commission. Given these uncertainties, one should not place undue reliance on these forward-looking statements. We do not assume any obligation to publicly update or revise any forward-looking statements, whether as a result of new information or future events or otherwise, unless we are required to do so by law.

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Rule 4.3A

# Appendix 4E

## **Preliminary Final Report**

## 1. Company Information

Name of entity	
GI Dynamics, Inc.	
ABN	Year ended ("current year")
151 239 388	31 December 2017

The previous corresponding period refers to the comparative amounts for the year ended 31 December 2016.

All values contained in this report are stated in U.S. dollars and have been rounded to the nearest thousand, unless otherwise stated.

#### 2. Results for Announcement to the Market

Year Ended 31 December 2017 Compared to Year Ended 31 December 2016

		Current Year 12 Months Ended 31 December 2017 \$'000 USD	Prior Year 12 Months Ended 31 December 2016 \$'000 USD	Amount of Increase or (Decrease) \$'000 USD	Percentage Increase or (Decrease)
2.1	Revenue from ordinary activities	255	545	(290)	-53%
	Loss from operations	(10,503)	(13,118)	(2,615)	-20%
2.2	Loss from ordinary activities, after tax	(10,688)	(13,116)	(2,428)	-19%
2.3	Loss attributable to members	(10,688)	(13,116)	(2,428)	-19%

The Company does not propose to pay dividends to common stock or CDI holders at this time. As such, there is no franking or applicable record date.

GI Dynamics, Inc. (the "Company") was incorporated on 24 March 2003, as a Delaware corporation, with operations based in Boston, Massachusetts. The Company is dedicated to restoring health and improving quality of life through the design and application of device and disease management solutions for treatment of metabolic disease. The Company's near and long-term goal is to establish EndoBarrier

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as a vital treatment option for patients suffering from type 2 diabetes and obesity by restoring more manageable blood sugar levels and reducing body weight. The Company is the developer of EndoBarrier®, the first endoscopically-delivered device intended for the treatment of type 2 diabetes and obesity. EndoBarrier is the only proven, incision-free, non-anatomy altering solution and is specifically designed to mimic the duodenal-jejunal exclusion created by gastric bypass surgery without the permanent safety issues associated with gastric bypass.

Since incorporation, the Company has devoted substantially all of its efforts to product research and development, clinical studies, regulatory approvals, commercialization, business planning, recruiting management and technical staff, acquiring operating assets, and raising capital. During the year ended 31 December 2017, the Company operated in one reportable business segment which designs, manufactures and markets medical devices.

The Company began commercial sales of its product in 2011. In 2015, it stopped the U.S. pivotal trial of EndoBarrier, known as the ENDO Trial, which began in 2013. In 2016 the Company received final cancellation notification from the Therapeutic Goods Administration 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 its EndoBarrier system had been suspended pending closure of non-conformances related to its quality management system required under International Organization for Standardization ("ISO") regulations. On 10 November 2017 the Company received notification from SGS that it would withdraw the CE Certificate of Conformity for EndoBarrier effective 12 November 2017. Withdrawal of the CE Certificate of Conformity means that the Company will not be able to affix the CE Mark and sell EndoBarrier in European Union countries until another Certificate of Conformity is issued by another notified. The Company is evaluating its options including grounds for appeal of the decision and is consulting with its advisors on certain procedural and substantive matters relating to the notice.

The Company's revenue from ordinary activities was approximately \$0.25 million for the year ended 31 December 2017 as compared to approximately \$0.55 million for the year ended 31 December 2016, a decrease of approximately \$0.3 million, or 53%. The decrease in revenue from ordinary activities was a result of a decrease in sales across all markets and having the EndoBarrier CE mark suspended effective 15 May 2017.

The Company's loss from operations decreased by \$2.6 million for the twelve months ended 31 December 2017 as compared with the 2016 and is due primarily to a reduction of \$1.2 million in general and administrative costs, a reduction of \$0.37 million in EndoBarrier sales and marketing efforts and reduction of \$0.3 million in research and development efforts.

The decrease in the Company's gross loss was primarily a result of a \$1.0 million decrease in cost of revenue due to a decrease in sales unit volume and personnel-related expenses and offset by the decrease in revenue described above.

The decrease in research and development expenses was primarily a result of decreased expenses to support the ENDO Trial and decreased personnel-related expenses.

The decrease in sales and marketing expenses was the result of lower personnel-related expenses, including stock-based compensation expense, lower spending on marketing related activities, and lower expenses as fewer products were provided free of charge.

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The decrease in general and administrative expenses was primarily due to decreases in personnel-related expenses and professional and consulting expenses.

The Company's after tax loss from ordinary activities, was approximately \$10.7 million for the year ended 31 December 2017 as compared to approximately \$13.1 million for the year ended 31 December 2016, a decrease in loss of approximately \$2.4 million, or 19%, and was a result of the reasons described above, in addition to a decrease in other income (expense) of approximately \$0.2 million, primarily due to accrued interest and amortization of fees related to the \$5.0 million Note Purchase Agreement by and between the Company, as borrower, and Crystal Amber Fund Limited, as purchaser.

The Company's loss attributable to members was the same as the Company's loss from ordinary activities, after tax, for the years ended 31 December 2017 and 2016.

At 31 December 2017 the Company had cash and cash equivalents of approximately \$3.0 million compared to approximately \$8.3 million at 31 December 2016, a decrease of approximately \$5.3 million. The decrease is primarily attributable to net cash used in operating activities of \$10.1 million offset by net cash provided by financing activities, primarily attributable to proceeds from our \$5.0 million Note Purchase Agreement referenced earlier.

## 3. Statement of Financial Performance

Please see the Company's unaudited consolidated financial statements, with accompanying notes, which are attached hereto.

#### 4. Statement of Financial Position

Please see the Company's unaudited consolidated financial statements, with accompanying notes, which are attached hereto.

## 5. Statement of Cash Flows

Please see the Company's unaudited consolidated financial statements, with accompanying notes, which are attached hereto.

## 6. Dividends per Security

The Company did not declare or pay any dividends on common stock (or CDIs) and it do not propose to pay any such dividends at this time.

## 7. Dividend or Distribution Reinvestment Plans

Not applicable; the Company have no dividend or distribution reinvestment plans.

## 8. Statement of Retained Earnings

Please see the Company's unaudited consolidated financial statements, with accompanying notes, which are attached hereto.

## 9. Net Tangible Assets per Security

	Current Year	Prior Year
	31 December 2017	31 December 2016
Net tangible assets (in \$'000 USD)	-3,512	6,790
Issued equity (common stock and APIC) (in \$'000 USD)	255,406	254,993
Number of shares of common stock on issue at reporting date	11,157,489	10,907,857
Net tangible assets per security (common share)	(\$0.31)	\$0.62
	(\$0.01 per CDI)	(\$0.01 per CDI)

## 10. Acquisitions and Divestments

Not applicable; no entities were acquired or disposed of during 2017.

## 11. Joint Ventures

Not applicable; the Company is not and have not been party to any joint ventures.

## 12. Other Information

Please see the Company's unaudited consolidated financial statements, with accompanying notes, which are attached hereto. Please also see the Company's other documents on file with the ASX.

## 13. Foreign Entity Accounting Standards

The Company's financial statements are presented in accordance with accounting principles generally accepted in the United States and are denominated in U.S. dollars.

## 14. Commentary on Results for 2017

Please see Section 2 above and the Company's unaudited consolidated financial statements, with accompanying notes, which are attached hereto. The Company operated in one segment only in 2017.

## 15. Status of Audit or Review

The financial statements, including accompanying notes, attached hereto are in the process of being audited. Such audit will be finalized and the audited consolidated financial statements as of and for the 12 months ended 31 December 2017 will be filed as part of the Annual Report on Form 10-K with the U.S. Securities and Exchange Commission and the ASX on or before 30 March 2018.

## 16. Audit Report (Unaudited Financials)

An audit of the Company's financial statements is currently in process. The Company anticipates that its audited financial statements will contain an independent audit report which includes a paragraph stating that because it has incurred operating losses and negative cash flows from operations since inception and will be required to obtain additional financing, alternative means of financial support or both in order to continue to fund the Company's operations, there is substantial doubt about its ability to continue as a going concern.

## 17. Audit Report (Audited Financials)

Not applicable; an audit of the Company's financial statements is still in process.

## GI Dynamics, Inc. and Subsidiaries

## **Consolidated Balance Sheets**

## (In thousands, except share and per share amounts)

	December 31,			
		2017		2016
Assets				
Current assets:				
Cash and cash equivalents	\$	3,034	\$	8,293
Restricted Cash		30		30
Accounts receivable, net		40		30
Inventory		-		213
Prepaid expenses and other current assets		265		483
Total current assets		3,369		9,049
Property and equipment, net		97		149
Total assets	\$	3,466	\$	9,198
Liabilities and stockholders' equity				
Current liabilities:				
Accounts payable	\$	1,191	\$	1,006
Accrued expenses		819		1,160
Deferred revenue		11		11
Short term debt-related party, net of debt issuance costs		4,929		-
Other current liabilities		-		214
Total current liabilities		6,950		2,391
Warrants liability		29		17
Commitments (Note 12)				
Stockholders' equity (deficit):				
Preferred stock, \$0.01 par value – 500,000 shares authorized; no shares				
issued and outstanding at December 31, 2017 and 2016		_		_
Common stock, \$0.01 par value – 50,000,000 and 13,000,000 shares				
authorized at December 31, 2017 and December 31, 2016; 11,157,489				
shares issued and outstanding at December 31, 2017 and 10,907,857				
shares issued and outstanding at December 31, 2016		112		109
Class B common stock, \$0.01 par value – zero and 1,000,000 shares				
authorized at December 31, 2017 and December 31, 2016; no shares				
issued and outstanding at December 31, 2017 and 2016		_		_
Additional paid-in capital		255,294		254,884
Accumulated deficit		(258,919)		(248,203)
Total stockholders' equity (deficit)		(3,513)		6,790
Total liabilities and stockholders' equity	\$	3,466	\$	9,198

## GI Dynamics, Inc. and Subsidiaries

## **Consolidated Statements of Operations and Comprehensive Loss**

## (In thousands, except share and per share amounts)

	Years Ended December 31,			
		2017		2016
Revenue	\$	255	\$	545
Cost of revenue		265		1,291
Gross loss		(10)		(746)
Operating expenses:				
Research and development		3,597		3,928
Sales and marketing		1,821		2,194
General and administrative		5,074		6,250
Total operating expenses		10,492		12,372
Loss from operations		(10,502)		(13,118)
Other income (expense):				
Interest income		33		42
Interest expense		(183)		_
Foreign exchange loss		(10)		10
Re-measurement of warrant liability		(12)		(17)
Other income (expense), net		(172)		35
Loss before income tax expense		(10,674)		(13,083)
Income tax expense		14		33
Net loss	\$	(10,688)	\$	(13,116)
Basic and diluted net loss per common share		(0.96)		(1.37)
Weighted-average number of common shares used in basic and diluted net loss per common share		11,157,489		9,555,246
Comprehensive loss	\$	(10,688)	\$	(13,116)

# GI Dynamics, Inc. and Subsidiaries Consolidated Statements of Stockholders' Equity (In thousands, except share amounts)

	Common Stock		Additional	Total	
Balance at December 31, 2015	Shares 9,505,389	Par Value 95	Paid-in Capital 253,250	Accumulated Deficit (235,087)	Equity (deficit)  18,258
	7,505,507	)3	255,250	(233,007)	10,230
Issuance of common stock upon exercise of stock options and vesting of restricted stock	5,000	_	_	_	_
Issuance of common stock upon vesting of shares subject to repurchase	168	_	3	_	3
Issuance of shares upon private placement, net of issuance costs of approximately					
\$0.1 million	1,397,300	14	964	_	978
Stock-based compensation expense	_	_	667	_	667
Net loss				(13,116)	(13,116)
Balance at December 31, 2016	10,907,857	109	254,884	(248,203)	6,790
Issuance of shares upon private placement	249,632	3	196	_	199
Share-based compensation expense related to accounting change with respect to forfeiture					
rate	_	_	28	(28)	_
Stock-based compensation expense	_	_	186	_	186
Net loss	_			(10,688)	(10,688)
Balance at December 31, 2017	11,157,489	112	255,294	(258,919)	(3,513)

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

	Years Ended December 31,			ber 31,
		2017		2016
Operating activities:				
Net loss	\$	(10,688)	\$	(13,116
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation and amortization		57		190
Impairment and abandonment of fixed assets		-		145
Stock-based compensation expense		187		667
Amortization of debt offering costs		44		-
Re-measurement of warrant liability		12		17
Loss on sale of property and equipment		-		7
Change in inventory reserve		(76)		(77
Changes in operating assets and liabilities:				
Accounts receivable		(10)		10
Prepaid expenses and other current assets		218		243
Inventory		289		889
Accounts payable		185		571
Accrued expenses		(341)		(1,908
Net cash used in operating activities		(10,123)		(12,362
Investing activities				
Purchases of property and equipment		(5)		(94
Proceeds from sale of property and equipment				3
Change in restricted cash				(30
Net cash used in investing activities		(5)		(121
Financing activities				
Proceeds from issuance of common stock		198		978
Proceeds from borrowings		5,000		305
Debt issuance costs		(115)		-
Payments on capital leases		_		(2
Payments on long-term debt		(214)		(95
Net cash provided by financing activities		4,869		1,186
Net decrease in cash and cash equivalents		(5,259)	_	(11,297
Cash and cash equivalents at beginning of year		8,293		19,590
Cash and cash equivalents at end of year	\$	3,034	\$	8,293
Supplemental cash flow disclosures		<u>_</u>		
Income taxes paid	\$	40	\$	73
Issuance of common stock upon vesting of shares subject to repurchase	\$	-	\$	3

#### GI Dynamics, Inc. and Subsidiaries

#### **Notes to Consolidated Financial Statements**

#### 1. Nature of Business

GI Dynamics, Inc. (the "Company") was incorporated on March 24, 2003, as a Delaware corporation, with operations based in Boston, Massachusetts.

GI Dynamics is a medical device company focused on the development and commercialization of EndoBarrier, a medical device indicated for treatment of patients with type 2 diabetes and obesity or obesity alone.

Diabetes mellitus type 2 (also known as type 2 diabetes) is a long-term progressive metabolic disorder characterized by high blood sugar, insulin resistance, and reduced insulin production. People with type 2 diabetes represent 90% 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. Obesity and its comorbidities contribute to the progression of type 2 diabetes. Many experts believe obesity contributes to higher levels of insulin resistance, which creates a feedback loop that increases the severity of type 2 diabetes.

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

#### EndoBarrier® is the first medical device intended for the treatment of both type 2 diabetes and obesity.

The current treatment paradigm for type 2 diabetes is pharmacological, whereby treating clinicians prescribe a treatment regimen of 1–4 concurrent medications that could include insulin for patients with higher levels of blood sugar. Insulin carries a significant risk of increased mortality and directly contributes to weight gain, which in turn leads to higher levels of insulin resistance and diabetes. In other words, the primary drug used to treat severe type 2 diabetes raises risk significantly and increases the downstream progression of the disease by increasing obesity. Fewer than 50% of patients treated pharmacologically for type 2 diabetes are adequately managed, meaning that medication does not halt the progressive nature of diabetes.

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

Our vision is to make EndoBarrier the essential nonpharmacological and nonsurgical treatment for patients with type 2 diabetes and obesity. We intend to achieve this vision by providing a safe and effective device, focusing on patient safety, supporting treating clinicians, adding to the extensive body of clinical evidence around EndoBarrier, gaining appropriate regulatory approvals, continuing to improve our products and systems, operating the company in a lean fashion, and maximizing shareholder value.

Since incorporation, the Company has devoted substantially all of its efforts to product commercialization, research and development, business planning, recruiting management and technical staff, acquiring operating assets, and raising capital. The Company currently operates in one reportable business segment which designs, manufactures and markets medical devices.

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

In the U.S., the Company received approval from the Food and Drug Administration ("FDA"), to commence its pivotal trial of EndoBarrier (the "ENDO Trial"), which the Company began in 2013. The multi- center, randomized, double-blinded study planned to enroll 500 patients with uncontrolled type 2 diabetes and obesity at 25 sites in the U.S. The primary endpoint was improvement in diabetes control as measured by HbA1c levels. In the second half of fiscal year 2015, the Company announced its decision to stop the ENDO Trial.

On August 21, 2015, the Company announced that it was reducing headcount by approximately 46% as part of its efforts to restructure its business and expenses in response to stopping the ENDO Trial and to ensure sufficient cash remained available for it to establish new priorities, continue limited market development and research, and to evaluate strategic options.

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

In October 2016, the Company received final cancellation notification from the Therapeutic Goods Administration ("TGA") for the listing of EndoBarrier on the Australian Register of Therapeutic Goods ("ARTG").

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.

In June 2017, the Company announced that it had entered into a Convertible Loan Note Financing with its largest shareholder Crystal Amber for a total of \$5 million. Crystal Amber is deemed a Related Party of the Company due to the size of its ownership position.

On November 11, 2017, the Company received notification from its notified body SGS United Kingdom Limited ("SGS") that the SGS planned to withdraw the Certificate of Conformance for EndoBarrier, ending the CE Marking of EndoBarrier in Europe and select Middle East countries.

#### **Going Concern Evaluation**

As of December 31, 2017, the Company's primary source of liquidity is its cash and cash equivalents balances. The Company continues to evaluate which markets are appropriate to continue pursuing reimbursement, market awareness and general market development and selling efforts, and continue to restructure its business and costs, establish new priorities, and evaluate strategic options. As a result, if the Company remains in business, it expects to incur significant operating losses for the next several years.

The Company does not expect its current cash balances will be sufficient to continue to fund its operations after March 2018. In addition, as previously disclosed, 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 ISO 13485:2003 and 93/42/EEC. On November 10, 2017, the Company received notification from SGS that it would withdraw the CE Certificate of Conformity for EndoBarrier effective November 12, 2017. Withdrawal of the CE Certificate of Conformity means that the Company cannot affix the CE Mark and sell EndoBarrier in European Union countries until another Certificate of Conformity is issued by r another notified body.

The Company will need to raise additional capital before March 2018 in order to continue to pursue its current business objectives as planned and to continue to fund its operations. The Company is looking to raise additional funds through any combination of additional equity and debt financings or from other sources. However, the Company has no guaranteed source of capital that will sustain operations after April 2018, and there can be no assurance that any such potential financing opportunities will be available on acceptable terms, if at all. If the Company is unable to raise capital when needed, it could be forced to cease operations, including discontinuing research and development activities and further commercialization of EndoBarrier. As such, if access to capital is not achieved in the near term, it will materially harm the Company's business, financial condition and results of operations. These factors raise substantial doubt about the Company's ability to continue as a going concern.

The Company has incurred operating losses since inception and at December 31, 2017, had an accumulated deficit of approximately \$259 million. GI Dynamics expects to incur significant operating losses for the next several years. At December 31, 2017, the Company had approximately \$3 million in cash and cash equivalents and restricted cash. The Company does not expect its current cash balances will be sufficient to enable it to conduct an additional clinical trial for the purpose of seeking regulatory approval from the FDA. The Company will need to raise additional funding prior to March 31, 2018 in order to continue to pursue its current business objectives as planned and to continue to fund its operations. These factors raise substantial doubt about the Company's ability to continue as a going concern. The Company may seek to raise additional funds through any combination of collaborative

arrangements, strategic alliances, and additional equity and debt financings or from other sources. There can be no assurance that any such financing opportunities will be available on acceptable terms, if at all. If the Company is unable to raise capital when needed, it could be forced to significantly delay or discontinue research and development activities and further commercialization of EndoBarrier, which could have a material adverse effect on its business, financial condition and results of operations. In addition, the Company could be required to cease operations if it is unable to raise capital when needed.

The accompanying 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 for the year ended December 31, 2017 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.

In September 2011, the Company completed its initial public offering ("IPO") of common stock in the form of CHESS Depositary Interests ("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 \$6.0 million of the Company's Convertible Term Promissory Notes. Additionally, in July and August 2013, the Company issued CDIs on the Australian Securities Exchange ("ASX") through a private placement and Share Purchase Plan ("SPP"), which raised a total of approximately \$52.5 million, net of expenses. In May 2014, the Company raised an additional approximately \$30.8 million, net of expenses, when it sold CDIs on the ASX through a private placement.

On December 20, 2016, the Company completed a private placement issue of 69,865,000 CDIs (1,397,300 shares) at an issue price of \$0.22 per CDI raising approximately \$1.0 million, net of expenses. In January 2017, the Company completed the issue of 12,481,600 CDI's (249,632 shares) to eligible investors under a Security Purchase Plan for approximately \$0.83 per share resulting in net proceeds after expenses of approximately \$0.2 million.

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

#### 2. Summary of Significant Accounting Policies and Basis of Presentation

#### **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.

The functional currency of GID Europe Holding B.V., GID Europe B.V., GID Germany GmbH and GI Dynamics Australia Pty Ltd is the U.S. dollar. Consolidated balance sheet accounts of the Company's subsidiaries are translated into U.S. dollars using the exchange rate in effect at the consolidated balance sheet date while expenses are translated using the average exchange rate in effect during the period. Gains and losses arising from translation of the wholly owned subsidiaries' financial statements are included in the determination of net loss.

#### **Use of Estimates**

The preparation of consolidated financial statements in accordance with generally accepted accounting principles in the U.S. requires the Company's management to make estimates and judgments that may affect the reported amounts of assets, liabilities, revenues and expenses, and the related disclosure of contingent assets and liabilities. On an ongoing basis, the Company's management evaluates its estimates, including those related to revenue recognition, allowance for doubtful accounts, inventory valuation including reserves for excess and obsolete inventory, impairment of long-lived assets, income taxes including the valuation allowance for deferred tax assets, research and development, contingencies, valuation of warrant 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 \$2.6 million and \$6.3 million at December 31, 2017 and 2016, respectively.

At December 31, 2017 and 2016, the Company had approximately \$0 and \$0.1 million, respectively, of cash and cash equivalents denominated in Australian dollars that is subject to foreign currency gain and loss. At December 31, 2017 and 2016, the Company had approximately \$0.3 million and \$0.2 million of cash and cash equivalents denominated in euros that is subject to foreign currency gain and loss.

#### **Property and Equipment**

Property and equipment, including leasehold improvements, are recorded at cost and are depreciated when placed in service using the straight-line method based on their estimated useful lives as follows:

	<b>Estimated Useful Life</b>
Asset Description	(In Years)
Laboratory and manufacturing equipment	5
Computer equipment and software	3
Office furniture and equipment	5

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 are 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 have been capitalized as construction in progress and will be depreciated in accordance with the above guidelines once placed into service. Maintenance and repair costs are expensed as incurred.

#### **Revenue Recognition**

The Company generates all of its revenue from sales of its EndoBarrier to health care providers and third-party distributors who resell the product to health care providers.

The Company considers revenue to be realized or realizable and earned when all of the following criteria are met: persuasive evidence of a sales arrangement exists, delivery has occurred or services have been rendered, the price is fixed or determinable, and collectability is reasonably assured. Revenue is recognized upon passage of title and risk of loss to customers, unless a consignment arrangement exists and provided an estimate can be made for sales returns.

With respect to these criteria:

- The evidence of an arrangement generally consists of a health care provider or distributor purchase order with the necessary approvals and acceptance by the Company.
- Transfer of title and risk and rewards of ownership are passed to the health care provider or third-party distributor upon delivery of the products.

The selling prices for all sales are fixed and agreed with the health care provider or third-party distributor.
 Provisions for discounts and rebates to customers are established as a reduction to revenue in the same period the related sales are recorded.

When doubt exists about collectability from specific customers, the Company defers revenue from sales of products to those customers until payment is received.

In certain circumstances the Company allows customers to return defective or nonconforming products for credit or replacement products. Defective or nonconforming products typically include those products that resulted in an unsuccessful implant procedure. The Company considers these transactions to be product returns and bases its estimate for sales returns upon historical trends and records the amount as a reduction to revenue upon the initial sale of the product. Prospectively, the Company will continue to evaluate whether it has sufficient data to determine return estimates as it enters new markets.

The Company has certain relationships in which title to delivered product passes to a buyer, but the substance of the transaction is that of a consignment arrangement. In these cases, the Company recognizes revenue when the product is implanted or otherwise consumed and payment is received from the customer, which indicates that the Company has no further obligations to the customer and that the sale is complete. For these transactions, revenue recognition is deferred until the sale is complete.

At December 31, 2017 and 2016, the Company had deferred revenue of approximately \$11 thousand.

#### **Shipping and Handling Costs**

Shipping and handling costs are included in costs of revenue.

#### **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 pre-approval regulatory and clinical trial expenses.

#### **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 December 31, 2017, no such costs had been capitalized since inception of the Company. The Company has expensed approximately \$0.4 million of patent costs within general and administrative expenses in the consolidated statements of operations and comprehensive loss for each year ended December 31, 2017 and 2016.

#### **Stock-Based Compensation**

The Company accounts for stock-based compensation in accordance with the Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("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 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 respective awards over the implicit service period.

Stock awards to non-employees are accounted for in accordance with ASC 505-50, *Equity-Based Payments to Non-Employees* ("ASC 505-50"). The measurement date for non-employee awards is generally the date performance of services required from the non-employee is complete. For non-employee awards that vest based on service conditions, the Company expenses the value of the awards over the related service period, provided they expect the service condition to be met. The Company records the expense of services rendered by non-employees based on the estimated fair value of the stock option using the Black-Scholes option pricing model over the contractual term of the non-employee. The fair value of unvested non-employee awards are remeasured at each reporting period and expensed over the vesting term of the underlying stock options on a straight-line basis.

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

#### **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.

#### **Comprehensive Loss**

Comprehensive loss is the change in equity of a company during a period from transactions and other events and circumstances, excluding transactions resulting from investments by owners and distributions to owners. The Company currently does not have any changes in equity from non-owner sources. As a result, comprehensive loss was equal to the net loss for all periods reported.

#### **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 should limit its exposure and enable it to recover a portion of any future amounts paid.

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

As of December 31, 2017 and 2016, the Company had not experienced any material losses related to these indemnification obligations, and no material claims with respect thereto were outstanding. The Company does not expect significant claims related to these indemnification obligations and, consequently, concluded that the fair value of these obligations is negligible. As a result, no related reserves have been established.

#### **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. There have been no subsequent events that have occurred through the date the Company issued its consolidated financial statements that require disclosure in or adjustment to its consolidated financial statements.

#### **New Accounting Pronouncements**

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

In May 2014, the FASB issued Accounting Standards Update ("ASU") No. 2014-09 ("ASU 2014-09"), *Revenue from Contracts with Customers*, which supersedes the revenue recognition requirements in ASC Topic 605, *Revenue Recognition*, and most industry-specific guidance. The new standard requires that an entity recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. ASU 2014-09 also requires additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to obtain or fulfill a contract. In July 2015, the FASB approved a one year deferral of the effective date of this standard to annual reporting periods, and interim reporting periods within those years, beginning after December 15, 2017. Early adoption is permitted to the original effective date of December 15, 2016, including interim reporting periods within those years. The Company is currently evaluating the potential impact of ASU 2014-09 and expect it to have no material impact on its consolidated financial statements.

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

expired before the earliest comparative period presented. Lessees may not apply a full retrospective transition approach. The adoption of this guidance is not expected to have a significant impact on our consolidated financial statements.

In March 2016, the FASB issued ASU No. 2016-09, Compensation—Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting ("ASU 2016-09"). ASU 2016-09 will simplify the income tax consequences, accounting for forfeitures and classification on the statements of consolidated cash flows. ASU 2016-09 is effective for annual periods beginning after December 15, 2016, and interim periods within those annual periods, with early adoption permitted. The Company elected to adopt ASU 2016-09 in the first quarter of 2017 retrospectively to January 1, 2017. As a result of adopting ASU No. 2016-09 during the year ended December 31, 2017, the Company adjusted its accumulated deficit related to the accounting policy election to recognize the impact of share-based award forfeitures only as they occur rather than by applying an estimated forfeiture rate as previously required. ASU No. 2016-09 requires that this change be applied using a modified-retrospective transition method by means of a cumulative-effect adjustment to accumulated deficit as of the beginning of the fiscal year in which the guidance is adopted. As a result of this adoption, the Company recorded a decrease to accumulated deficit of approximately \$28,000.

In August, 2016, the FASB issued ASU No. 2016-15, Classification of Certain Cash Receipts and Cash Payments (a consensus of the Emerging Issues Task Force), or ASU 2016-15. The amendments in ASU 2016-15 address eight specific cash flow issues and apply to all entities that are required to present a statement of cash flows under FASB Accounting Standards Codification 230, Statement of Cash Flows. The amendments in ASU 2016-15 are effective for public business entities for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. Early adoption is permitted, including adoption during an interim period. We are currently evaluating the impact of ASU No. 2016-15 and expect it to have limited impact on our consolidated financial statements for period ending March 31, 2018.

In November 2016, the FASB issued ASU No. 2016-18, *Statement of Cash Flows (Topic 230): Restricted Cash (a consensus of the FASB Emerging Issue Task Force)*, or ASU 2016-18. This new standard addresses the diversity that exists in the classification and presentation of changes in restricted cash on the statement of cash flows. The amendments in ASU 2016-18 require that a statement of cash flows explain the change during the period in the total of cash, cash equivalents, and amounts generally described as restricted cash or restricted cash equivalents. Therefore, amounts generally described as restricted cash and restricted cash equivalents should be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. This guidance is effective for fiscal years beginning after December 15, 2017, including interim periods within the year of adoption, with early adoption permitted. We do not expect that the adoption of ASU 20116-18 will have a material impact on our consolidated financial statements.

#### 3. Net Loss per Common Share

Basic net loss per common share is computed by dividing net loss by the weighted-average number of common shares outstanding during the period. Potential common stock equivalents are determined using the treasury stock method. For diluted net loss per share purposes, the Company excludes stock options and other stock-based awards, including shares issued as a result of option exercises but which are subject to repurchase by the Company, whose effect would be anti-dilutive from the calculation. During each of the years ended December 31, 2017 and 2016, common stock equivalents were excluded from the calculation of diluted net loss per common share, as their effect was anti-dilutive due to the net loss incurred. Therefore, basic and diluted net loss per share was the same in all periods presented.

The following potentially dilutive securities have been excluded from the computation of diluted weighted-average shares outstanding as of December 31, 2017 and 2016, as they would be anti-dilutive:

	Years Ended December 31,		
	2017	2016	
Warrants to purchase common stock	28,532	28,532	
Options to purchase common stock and other stock-			
based awards	1,504,938	1,152,072	
Total	1,533,470	1,180,604	

#### 4. Common Stock Warrants

In connection with the Company's IPO in September 2011, the Company issued warrants in an aggregate amount of 50,000 shares of common stock at an exercise price of A\$55.00 per share to the lead manager of the IPO and certain other investors. The warrants expired on the fifth anniversary of their date of grant.

On May 4, 2016, the Company entered into a consulting agreement pursuant to which the consulting firm will provide strategic advisory, finance, accounting, human resources and administrative functions, including chief financial officer services, to the Company. In connection with the consulting agreement, the Company granted the consulting firm a warrant ("Consultant Warrant," together with the IPO Warrants, the "Warrants") to purchase up to 28,532 shares of the Company's common stock at an exercise price per share equal to \$0.64. The Consultant Warrant vests on a monthly basis over two years and has a term of five years. The Company has reserved 28,532 shares of common stock related to the Consultant Warrant. As of December 31, 2016, no Consultant Warrants had been exercised.

The Company accounts for the warrants under ASC 815, *Derivatives and Hedging* ("ASC 815"). In accordance with the guidance included in ASC 815, because the Company's functional currency is the U.S. dollar and the exercise price of the warrants is in Australian dollars, the Company is exposed to currency exchange risk related to the warrants. As a result, the warrants are not considered indexed to the Company's own stock, and therefore, the warrants are classified as a liability and the fair value of the warrants must be remeasured at each reporting period. At the time the warrants were issued, the Company estimated the fair value of the warrants using the Black-Scholes option pricing model. The Company remeasured the fair value of the warrants at each reporting period using current assumptions and current foreign exchange rates, with changes in value recorded as other income or expense (Note 5).

#### 5. Fair Value of Financial Instruments

The tables below present information about the Company's assets and liabilities that are measured at fair value on a recurring basis as of December 31, 2017 and 2016, and indicates the fair value hierarchy of the valuation techniques the Company used to determine such fair value. In general, fair values determined by Level 1 inputs utilize observable inputs such as quoted prices in active markets for identical assets or liabilities. Fair values determined by Level 2 inputs utilize data points that are either directly or indirectly observable, such as quoted prices, interest rates and yield curves. Fair values determined by Level 3 inputs utilize unobservable data points in which there is little or no market data, requiring the Company to develop its own assumptions for the asset or liability.

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

			Fair Value Measurements at Reporting Date Using					
			Act	uoted Prices in tive Markets for lentical Assets		gnificant Other Observable Inputs	Signific Unobser Inpu	vable
Description	Decen	ber 31, 2017		(Level 1)		(Level 2)	(Leve	13)
Assets								
Money market funds (included in cash								
and cash equivalents)	\$	2,584	\$	2,584	\$	_	\$	_
Total assets	\$	2,584	\$	2,584	\$	_	\$	_
Liabilities	<del></del>							
Warrant liability	\$	29	\$	_	\$	_	\$	29
Total liabilities	\$	29	\$	_	\$	_	\$	29

		_	Fair Va Rep		
		A	Quoted Prices in Active Markets for Identical Assets	O	r Significant Unobservable Inputs
Description	Decen	nber 31, 2016	(Level 1)	(Level 2)	(Level 3)
Assets					
Money market funds (included in cash					
and cash equivalents)	\$	6,344 \$	6,344	\$ -	- \$ -
Total assets	\$	6,344 \$	6,344	\$ -	- \$ -
Liabilities				=	
Warrant liability	\$	17 \$	<u> </u>	\$	- \$ 17
Total liabilities	\$	17 \$	<u> </u>	\$ -	- \$ 17

The assumptions used in the Black-Scholes option pricing model to determine the fair value of the common stock warrants at December 31, 2017 and 2016 were as follows:

	December 31,			
		2017		2016
Exercise price (A\$55.00 at the then current				
exchange rate)	\$	0.64	\$	0.64
Fair value of common stock	\$	0.60	\$	0.59
Expected volatility		142.6%		90.5%
Expected term (in years)		3.34		4.34
Risk-free interest rate		2.02%		1.78%
Expected dividend yield		-%		-%

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

Balance at December 31, 2015	\$ _
Grant of Consulting warrants May 2016	\$ 12
Increase in fair value of warrants upon	
re-measurement included in other expense	 5
Balance at December 31, 2016	\$ 17
Increase in fair value of warrants upon	 
re-measurement included in other expense	12
Balance at December 31, 2017	\$ 29

Cash equivalents, accounts receivable, prepaid expenses and other current assets, accounts payable, accrued expenses and other current liabilities at December 31, 2017 and 2016 are carried at amounts that approximate fair value due to their short-term maturities and highly liquid nature of these instruments.

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

Financial instruments that subject the Company to credit risk primarily consist of cash and cash equivalents and accounts receivable. The Company maintains its cash and cash equivalent balances with high quality financial institutions, and consequently, the Company believes that such funds are subject to minimal credit risk. The Company's short-term investments potentially subject the Company to concentrations of credit risk. 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.

Accounts receivable primarily consist of amounts due from customers, including distributors and health care providers in different countries. In light of the current economic state of many foreign countries, the Company continues to monitor the creditworthiness of its customers.

In May 2017, the Company entered into a sales arrangement with certain distributors totaling \$517 thousand of EndoBarrier inventory. Due to certain extended right of return periods and payment terms, the Company determined that the revenue and related product costs associated with this transaction should be deferred for accounting purposes. As a result, the Company has recorded an adjustment to accounts receivable of \$559 thousand for the unpaid portion of deferred revenue which includes an adjustment of approximately \$40 thousand for revaluation of receivables denominated in foreign currency at December 31, 2017. The Company recognized revenue of \$80 thousand and related costs of \$27 thousand for this transaction.

At December 31, 2017, one health care provider accounted for approximately 26% of the Company's accounts receivable and three other health care providers accounted for approximately 70% of the Company's accounts receivable.

At December 31, 2016, one health care provider accounted for approximately 43% of the Company's accounts receivable and another health care provider accounted for approximately 22% of the Company's accounts receivable.

The Company grants credit to customers in the normal course of business but generally does not require collateral or any other security to support its receivables. The Company makes judgments as to its ability to collect outstanding receivables and provides an allowance for receivables when collection becomes doubtful. Provisions are made based upon a specific review of all significant outstanding invoices and the overall quality and age of those invoices not individually reviewed. Amounts determined to be uncollectible are written off against this reserve. The Company recorded write-offs of uncollectible accounts receivable of approximately \$22 thousand in the year ended December 31, 2017 and \$48 thousand in the year ended December 31, 2016. As of December 31, 2017, the Company believes its allowance for doubtful accounts of approximately \$40 thousand is adequate based on its review.

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

	December 31,			
	20	2017		
Accounts receivable	\$	85	\$	68
Less: allowance for doubtful accounts		(42)		(16)
Less: allowance for sales returns		(3)		(22)
Total	\$	40	\$	30

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

	Year Ended December 31,					
		2017			2016	
Beginning balance	\$		16	\$		59
Net charges to expenses			48			5
Utilization of allowances			(22)			(48)
Ending balance	\$		42	\$		16

#### 7. Inventory

The Company states inventory at the lower of first-in, first-out cost or market. The Company records a provision for excess, expired, and obsolete inventory based primarily on estimates of forecasted revenues. A significant change in the timing or level of demand for products as compared to forecasted amounts may result in recording additional provisions for excess, expired, and obsolete inventory in the future. When capitalizing inventory, the Company considers factors such as status of regulatory approval, alternative use of inventory, and anticipated commercial use of the product.

The determination of obsolete or excess inventory requires the Company to estimate the future demand for its products within appropriate time horizons. The estimated future demand is compared to inventory levels to determine the amount, if any, of obsolete and excess inventory. The demand forecast includes the Company's estimates of market growth and various internal estimates, and is based on assumptions that are consistent with the plans and estimates the Company is using to manage its underlying business and short-term manufacturing plans. Forecasting demand for EndoBarrier in a market in which there are few, if any, comparable approved devices and for which reimbursement from third-party payers is limited has been difficult. To the extent the Company's demand forecast is less than its inventory on-hand, the Company could be required to record additional reserves for excess, expired or obsolete inventory in the future.

In 2015, the Company performed an analysis of its inventory on hand and due to current evidence that the utility of certain amounts of its inventory as it was expected to be used will be less than its cost recorded an approximately \$3.2 million charge for excess, expired and obsolete inventory. Factors contributing to the inventory write-down included: the effect that the ENDO Trial enrollment hold and subsequent termination had on commercial activity and the Company's inventory levels, the expected timing of third-party payer reimbursement in its commercial markets, its conclusion that certain inventory will not be used for sales inside or outside the U.S. and the historical accuracy of its demand forecasts. As of December 31, 2017 and 2016, the Company has a reserve totaling approximately \$5 million for each year. During 2017, the Company utilized the remaining balance of its inventory to offset cost of sales.

Inventory, net of reserves, at December 31, 2017 and 2016 was as follows (in thousands):

		December 31,			
	201	2017			
Finished goods	\$	_	\$	213	
Work-in-process		_		_	
Raw materials		_		_	
Total	\$	_	\$	213	

The Company entered into consignment arrangements in which the Company delivered product to the customer but retained title to the product until implanted or otherwise consumed. At December 31, 2017, approximately \$23 thousand of remaining inventory was used to offset recognized sales of \$80 thousand.

#### 8. Property and Equipment

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

	December 31,					
	2017			2016		
Laboratory and manufacturing equipment	\$	591	\$	591		
Computer equipment and software		1,179		1,174		
Office furniture and equipment		183		183		
Leasehold improvements		21		21		21
		1,974		1,969		
Less accumulated depreciation and amortization		(1,877)		(1,820)		
Total	\$	97	\$	149		

As part of the Company's restructuring in 2016 in connection with the abandonment of its Company headquarters in Lexington, Massachusetts, the Company recognized a charge for impaired fixed assets as follows (in thousands):

	December 31,
	2016
Cost of revenue	\$ 24
Research and development	79
General and administrative	42
	\$ 145

At December 31, 2017 and 2016, the Company had no assets under capital lease.

Depreciation and amortization expense of property and equipment totaled approximately \$57 thousand and \$0.2 million for the years ended December 31, 2017 and 2016.

#### 9. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	December 31,					
	2017			2016		
Clinical trials	\$	_	\$	16		
Payroll and related liabilities		180		430		
Professional fees		222		617		
Other		417		97		
Total	\$	819	\$	1,160		

In 2017 and 2016, the Company recorded \$0 and approximately \$0.6 million of separation-related expenses of which \$0 and \$0.1 million is included in payroll and related liabilities at December 31, 2017 and 2016, respectively.

#### 10. Short-Term Notes Payable

During the year ended December 31, 2016, the Company entered into a short-term loan agreement with First Insurance Funding Corp to borrow \$306,380 to purchase insurance. The agreement called for ten monthly payments of \$30,638 which included principal and interest. The annual interest rate on the borrowing was 1.95%. The outstanding balance at December 31, 2017 and 2016 was \$0 and \$214 thousand and was included in other current liabilities on the accompanying balance sheet.

#### 11. Short-Term Debt to Related Party

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

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

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

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

maintains the Purchaser's fully-diluted ownership percentage of the Company at the same level as existed immediately preceding the applicable subsequent equity financing.

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

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

The company has recorded the \$5.0 million note net of its debt issuance costs and will amortize this cost over life of the note. For the year ended December 31, 2017, the Company recognized interest expense of \$136 thousand and amortization of the issuance costs of \$43 thousand related to the Senior Secured Convertible Promissory Note.

#### 12. Commitments and Contingencies

#### **Lease Commitments**

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 expires in April 2018. Rent during the term is \$11.9 thousand per month.

Future minimum lease payments under all non-cancelable lease arrangements at December 31, 2017 are as follows (in thousands):

Year Ending December 31,	
2018	\$ 42
2019	_
2020	_
Total future minimum lease payments	\$ 42

Rent expense on non-cancelable operating leases was approximately \$0.1 million and \$0.5 million for the years ended December 31, 2017 and 2016, respectively.

#### License Agreement

In 2003, the Company entered into a license agreement ("License Agreement") for certain intellectual property. The License Agreement required the Company to pay \$75 thousand at execution, make payments of \$12.5 thousand in 2004, and \$25 thousand each year thereafter, until the date of first commercial sale of the product, as defined in the License Agreement. In 2011, the Company began commercial sales of the product as defined in the License Agreement and as a result ceased making the yearly payments. The royalty obligation begins with U.S. commercial sales of products as defined in the License Agreement, if any. The royalty percentage may vary on products covered by the License Agreement, but in any case, the royalties are not considered significant. The patent covered by the License Agreement expired in 2017.

#### 13. Stockholders' Equity (Deficit)

On April 9, 2015, the Company amended its certificate of incorporation to reflect the one-for-ten reverse stock split approved by its shareholders.

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

As of December 31, 2017, the Company has raised net proceeds of approximately \$232.8 million through sales of its equity from inception.

#### Common Stock

The Company had authorized Class B common stock in order to meet the Listing Rules of the ASX so far as they apply to escrowed securities. In the event that holders of common stock, who were subject to ASX-imposed escrow, breached the terms of their escrow agreement or the Listing Rules as they apply to escrowed securities, their common stock would have been automatically converted into Class B common stock until the earlier to occur of the expiration of the escrow period or the breach being rectified. The Class B common stock was identical to and ranked equally with the common stock except that Class B common stock had no voting rights and was not entitled to any dividends. Class B Common Stock of the Company was eliminated on May 22, 2017. No shares of common stock were subject to such an escrow.

In December 2016, GI Dynamics raised approximately \$1.0 million, net of expenses, in an offering of 69,865,000 CDIs (1,397,300 shares) to sophisticated and professional investors in Australia and certain other jurisdictions.

#### 14. Share-Based Compensation

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

In August 2011, the Board of Directors adopted the 2011 Employee, Director and Consultant Equity Incentive Plan (the "2011 Plan", together with the 2003 Plan, the "Plans") as the successor to the 2003 Plan. Under the 2011 Plan, the Company may grant incentive stock options, nonqualified stock options, restricted and unrestricted stock awards and other stock-based awards. The Company had initially reserved 450,000 shares 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 shares available for grant under the 2003 Plan were transferred to the 2011 Plan. At December 31, 2016, 1,060,920 shares were available for 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:

- 500,000 shares;
- 4% of the number of common shares outstanding as of such date; and
- an amount determined by the Board of Directors or the Company's compensation committee. Accordingly, during year ended December 31 2017 and December 31 2016, 436,314 and 380,222 shares were added to the 2011 Plan, respectively.

#### **Stock-Based Compensation**

Stock-based compensation is reflected in the consolidated statements of operations and comprehensive loss as follows for the years ended December 31, 2017 and 2016 (in thousands):

	Years Ended December 31,				
	2(	2017			
Operations	\$	_	\$	34	
Research and development		19		56	
Sales and marketing		75		159	
General and administrative		93		418	
	\$	187	\$	667	

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. The Company estimates the number of awards that will be forfeited in calculating compensation costs. Such costs are then recognized over the requisite service period of the awards on a straight-line basis.

Determining the fair value of stock-based awards using the Black-Scholes option-pricing model requires the use of highly subjective assumptions, including the expected term of the award and expected stock price volatility. The weighted-average assumptions used to estimate the fair value of employee stock options using the Black-Scholes option-pricing model were as follows for the years ended December 31, 2017 and 2016:

	Years Ended Dec	ember 31,
	2017	2016
Expected volatility	93.3%	75.8%
Expected term (in years)	6.05	6.05
Risk-free interest rate	2.3%	2.1%
Expected dividend yield	0%	0%

#### **Expected Volatility**

Volatility measures the amount that a stock price has fluctuated or is expected to fluctuate during a period. As the Company was not publicly traded prior to September 2011 and therefore had no trading history, stock price volatility was estimated based on an analysis of historical and implied volatility of comparable public companies.

#### **Expected Term**

The Company has limited historical information to develop reasonable expectations about future exercise patterns and post-vesting employment termination behavior for its stock option grants. As a result, for stock option grants made during the years ended December 31, 2017 and 2016, the expected term was estimated using the "simplified method." The simplified method is based on the average of the contractual term of the option and the weighted-average vesting period of the option. For options granted to non-employees, the Company used the remaining contractual life to estimate the expected term of non-employee awards for the years ended December 31, 2017 and 2016.

#### **Risk-Free Interest Rate**

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.

#### **Expected Dividend Yield**

The Company has not paid and does not anticipate paying cash dividends on its shares of common stock in the foreseeable future; therefore, the expected dividend yield is assumed to be zero.

#### **Stock Options**

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

	Shares of Common Stock Attributable to Options	A E	eighted- Average Exercise Price	Weighted- Average Contractual Life	Aggregate Intrinsic Value
				(in years)	(in thousands)
Outstanding at December 31, 2016	748,571	\$	8.67	8.38	_
Granted	408,635	\$	1.07		
Exercised					
Cancelled	(164,985)	\$	11.81		
Outstanding at December 31, 2017	992,221	\$	4.88	7.57	_
Vested or expected to vest at December 31, 2017	992,221	\$	1.00	10.46	
Exercisable at December 31, 2017	388,007	\$	10.71	5.72	

As of December 31, 2017, there was approximately \$0.4 million of unrecognized stock-based compensation, related to unvested stock option grants having service-based vesting under the Plans which is expected to be recognized over a weighted-average period of 2 years. The total unrecognized stock-based compensation cost will be adjusted for future changes in estimated forfeitures.

The weighted-average grant date fair value of options granted during the years ended December 31, 2017 and 2016, was \$1.07 and \$1.00, respectively. The total intrinsic value of options exercised during the years ended December 31, 2017 and 2016 was \$0 for both years. The intrinsic value represents the difference between the fair value of the Company's common stock on the date of exercise and the exercise price of the stock option. There were no cash received from option exercises during the years ended December 31, 2017 and 2016. No tax benefits were realized from options and other stock-based payment arrangements during these periods.

The stock-based compensation plans provide that grantees may have the right to exercise an option prior to vesting. Shares purchased upon the exercise of unvested options will be subject to the same vesting schedule as the underlying options, and are subject to repurchase at the original exercise price by the Company should the grantee discontinue providing services to the Company for any reason, prior to becoming fully vested in such shares. At December 31, 2017 and 2016, there were no Common stock issued pursuant to the exercise of unvested options that remain unvested and subject to repurchase by the Company. The exercise of these shares is not substantive and as a result, the cash paid for the exercise price is considered a deposit or prepayment of the exercise price and is recorded as a liability. The liability related to these shares was approximately zero at December 31, 2017 and 2016. Additionally, while the shares of common stock subject to repurchase are included in the legally issued shares, they are excluded from the calculation of outstanding shares.

#### **Restricted Stock Units & Performance Stock Units**

Each restricted stock unit and performance stock unit ("RSU & PSU") represents a contingent right to receive one share of the Company's common stock. There is no consideration payable on the vesting of RSUs & PSUs issued under the Plans. Upon vesting, the RSUs & PSUs are exercised automatically and settled in shares of the Company's common stock. During the years ended December 31, 2017 and 2016, the Company awarded a total of 0 and 392,659 RSUs & PSUs to employees and directors of the Company, respectively.

The following table summarizes information related to RSU & PSU activity during the year ended December 31, 2017:

	Number of Units	Weighted- Average Contractual Life (in years)	Aggrega Intrinsi Value (in thousa	ic
Outstanding at December 31, 2016	403,501	9.11	\$	365
Granted				
Exercised				
Cancelled	(10,842)			
Outstanding at December 31, 2017	392,659	8.30	\$	429

The aggregate intrinsic value at December 31, 2017 and 2016 noted in the table above represents the closing price of the Company's common stock multiplied by the number of RSUs & PSUs outstanding.

The fair value of each RSU & PSU award equals the closing price of the Company's common stock on the date of grant. The weighted average grant date fair value per share of RSUs & PSUs granted in the years ended December 31, 2017 and 2016 was \$0 and \$0.75, respectively.

At December 31, 2017, 392,659 of the RSUs & PSUs outstanding are subject to performance-based vesting criteria. For these awards, the vesting will occur upon the achievement of certain product revenue, regulatory and reimbursement milestones. When achievement of the milestone is deemed probable, the Company expenses the compensation of the respective stock award over the implicit service period.

At December 31, 2016, 403,501 of the RSUs & PSUs outstanding are subject to performance-based vesting criteria. For these awards, the vesting will occur upon the achievement of certain product revenue, regulatory and reimbursement milestones. When achievement of the milestone is deemed probable, the Company expenses the compensation of the respective stock award over the implicit service period.

During the years ended December 31, 2017 and 2016, the Company recognized stock-based compensation related to RSUs & PSUs having service-based vesting of approximately \$0 and \$(0.1) million, respectively.

As of December 31, 2017, there was approximately \$243 thousand of unrecognized stock-based compensation expense related to non-vested RSU & PSU awards that have service-based vesting.

#### Non-employee awards

The Company accounts for non-employee awards in accordance with ASC 505-50. Stock-based compensation expense related to stock options granted to non-employees is recognized as services are rendered, generally on a straight-line basis. The Company believes that the fair value of the stock options is more reliably measurable than the fair value of the services rendered. The fair value of the stock options granted is remeasured at each reporting date using the Black-Scholes option pricing model as prescribed by ASC 718. During the year ended December 31, 2017, the Company granted options to purchase 115,500 shares of common stock to non-employees with an aggregate fair value of approximately \$171 thousand of which 46,500 shares with an aggregate fair value of approximately \$78 thousand were cancelled during year ending December 31, 2017. In 2016, the Company granted 50,000 stock options to purchase 50,000 shares of common stock to non-employees.

During the years ended December 31, 2014 and 2013, the Company modified the terms of stock awards previously granted to certain employees upon their change in status from employee to non-employee. The modifications included an extension of the exercise period after the status change with respect to certain of the awards and the extension of the vesting of certain options through the end of the respective expected service to the Company. These modifications resulted in increases in stock-based compensation of an immaterial amount in the year ended December 31, 2014. The Company accounted for the modifications of stock awards in accordance with the provisions of ASC 718. Stock awards that are modified and continue to vest when an employee has a change in employment status are subject to periodic revaluation over their vesting terms.

The Company has recorded non-employee stock-based compensation expense in accordance with ASC 505-50 of approximately \$38 thousand and \$0.5 million during the years ended December 31, 2017 and 2016, respectively, which is included in the total stock-based compensation expense.

#### 15. Segment Reporting

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

#### **Geographic Reporting**

All the Company's revenue is attributable to customers outside the U.S. The Company is dependent on favorable economic and regulatory environments for its products. Products are sold to customers located in Europe, the Middle East, the Asia Pacific region and South America and sales are attributed to a country or region based on the location of the customer to whom the products are sold.

At December 31, 2017, long-lived assets, comprised of property and equipment, of approximately \$0.1 million are all held in the U.S.

Product sales by geographic location for the years ended December 31, 2017 and 2016 are listed in the table below (in thousands).

	Years Ended December 31,					
	2017		2016			
Europe	\$	237	\$	309		
Middle East		18		154		
Asia Pacific		-		82		
Total	\$	255	\$	545		

#### **Major Customers**

For the year ended December 31, 2017, one distributor accounted for approximately 40% and another 11% of the Company's revenue. For the year ended December 31, 2016, a different distributor accounted for approximately 24% of the Company's revenue. No other customer accounted for greater than 10% of the Company's revenue during the year ended December 31, 2016.

#### 16. Retirement Plans

The Company has a 401(k) retirement and savings plan ("401(k) Plan") covering all qualified U.S. employees. The 401(k) Plan is a defined contribution plan and allows each participant to contribute up to 100% of the participant's

base wages up to an amount not to exceed an annual statutory maximum. The Company has made discretionary contributions to the 401(k) Plan and recorded expenses of approximately \$37 thousand and \$0.1 million for the years ended December 31, 2017 and 2016, respectively.

The Company maintains a defined contribution plan for certain international employees. The Company contributes 100% of the cost of the defined contribution. The Company recorded expenses of approximately \$38 thousand and \$26 thousand for the years ended December 31, 2017 and 2016, respectively, under this plan.

#### 17. Income Taxes

On December 22, 2017, the United States enacted new tax reform ("Tax Cuts and Jobs Act"). The Tax Cuts and Jobs Act contains provisions with separate effective dates but is generally effective for taxable years beginning after December 31, 2017. Included in the regulation are provisions which repatriate the aggregate of post-1986 earnings and profits of foreign corporations. The Company has estimated the impact of repatriation will reduce their Federal U.S. tax attributes by \$23 thousand for the year ended December 31, 2017. Beginning with the year ending December 31, 2018, the corporate statutory rates on U.S. earnings will be reduced from 34% to 21%. The impact of the future rate reduction resulted in a decrease to the deferred tax assets and an offset to the valuation allowance for the year ending December 31, 2017 by \$28.9 million relating to the revaluation of the net deferred tax asset.

Other than the repatriation tax and reduction in statutory rate, the Company does not anticipate the regulations will have a material impact on income taxes in future years.

Loss before provision for income taxes consisted of the following (in thousands):

	Years Ended December 31,				
	2017				
Domestic	\$ (10,720)	\$	(13,124)		
Foreign	46		41		
Total	\$ (10,674)	\$	(13,083)		

The provision for income taxes in the accompanying consolidated statements of operations and comprehensive loss consisted of the following (in thousands):

	Years Ended December 31,				
	2017	201	16		
Current Provision:					
Federal	\$ _	\$	_		
State	1		17		
Foreign	15		16		
Total	16		33		
Deferred (Benefit) Provision:					
Federal	_		_		
State	_		_		
Foreign	 (2)		_		
Total	(2)		_		
Total provision	\$ 14	\$	33		

A reconciliation of income taxes from operations computed using the U.S. federal statutory rate of 34% to that reflected in operations follows (in thousands):

	Years Ended December 31,				
		2017	2016		
Income tax benefit using U.S. federal statutory					
rate	\$	(3,629)	\$	(4,449)	
Rate Changes		28,918		-	
Permanent differences		35		16	
State income taxes, net of federal benefit		(130)		(661)	
Stock compensation		53		1,218	
Tax credits		(127)		(42)	
Foreign tax rate differential		(2)		1	
Change in the valuation allowance		(25,216)		1,303	
Unrealized gain		-		2,673	
Other		112		(26)	
Total	\$	14	\$	33	

Components of the Company's deferred tax assets and liabilities are as follows (in thousands):

	December 31,			31,
	2017		2016	
Deferred tax assets:				
Net operating loss carryforwards	\$	59,799	\$	79,648
Research and development credit carryforwards		4,005		3,713
Capitalized research and development costs	nt costs 464			1,366
Capitalized start-up expenses		2,846		4,594
Depreciation and other		1,889		3,081
Total deferred tax assets		69,003		92,402
Valuation allowance		(69,001)		(92,402)
Net deferred tax asset	\$	2	\$	_

Management of the Company has evaluated the positive and negative evidence bearing upon the realizability of the Company's deferred tax assets and determined that it is more likely than not that the Company will not recognize the benefits of the deferred tax assets related to the U.S. and the Netherlands. As a result, a valuation allowance of approximately \$69.0 million and \$92.4 million was established at December 31, 2017 and 2016, respectively. The valuation allowance decreased by approximately \$23.4 million during the year ended December 31, 2017, primarily due to the revaluation of the net deferred tax asset at the reduced 21% U.S. corporate income tax future rate.

At December 31, 2017, the Company had U.S. federal and state net operating loss carryforwards of approximately \$222.9 million and \$205.5 million, respectively. These operating loss carryforwards will expire at various times beginning in 2024 through 2037 for federal purposes and begin to expire in 2030 and will continue to expire through 2037 for state purposes.

In addition, at December 31, 2017, the Company also has U.S. federal and state research and development tax credit carryforwards (excluding ASC 740, *Income Taxes* ("ASC 740"), reserve) of approximately \$2.8 million and \$1.2 million, respectively, to offset future income taxes. These tax credit carryforwards will expire at various times beginning in 2023 through 2037 for federal purposes and will expire at various times beginning in 2018 through 2032 for state purposes.

Utilization of net operating loss carryforwards and research and development credit carryforwards may be subject to a substantial annual limitation due to ownership change limitations that have occurred previously or that could occur in the future in accordance with Section 382 of the Internal Revenue Code of 1986 ("IRC Section 382") and with Section 383 of the Internal Revenue Code of 1986, as well as similar state provisions. These ownership changes may limit the amount of net operating loss carryforwards and research and development credit

carryforwards that can be utilized annually to offset future taxable income and taxes, respectively. In general, an ownership change, as defined by IRC Section 382, results from transactions increasing the ownership of certain stockholders or public groups in the stock of a corporation by more than 50 percentage points over a three-year period. The Company has completed several financings since its inception, which may have resulted in a change in control as defined by IRC Section 382 or could result in a change in control in the future. As of December 31, 2017, the Company has not, as yet, conducted an IRC Section 382 study, which could impact its ability to utilize net operating loss and tax credit carryforwards annually in the future to offset the Company's taxable income, if any.

The Company applies ASC 740-10, which provides guidance on the accounting for uncertainty in income taxes recognized in financial statements and requires the impact of a tax position to be recognized in the financial statements if that position is more likely than not of being sustained by the taxing authority. When uncertain tax positions exist, the Company recognizes the tax benefit of tax positions to the extent that the benefit will more likely than not be realized. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position as well as consideration of the available facts and circumstances. At December 31, 2017 and 2016, the Company had unrecognized tax liabilities of approximately \$1.5 million.

The following is a roll forward of the Company's unrecognized tax benefits (in thousands):

	December 31,			1,
	2017		2016	
Unrecognized tax benefit – as of the beginning of the year	\$	1,449	\$	1,426
Gross increases – tax positions of the prior periods		_		_
Gross increases – current period tax positions		23		23
Unrecognized tax benefits – as of the end of the year	\$	1,472	\$	1,449

The Company will recognize interest and penalties related to uncertain tax positions, should they be assessed, in income tax expense. As of December 31, 2017 and 2016, the Company had no accrued interest or penalties related to uncertain tax positions, and no amounts have been recognized in the Company's consolidated statements of comprehensive loss.

The statute of limitations for assessment by the Internal Revenue Service ("IRS") and state tax authorities is open for tax years ended December 31, 2013 through December 31, 2017, although carryforward attributes that were generated prior to tax year 2013 may still be adjusted upon examination by the IRS or state tax authorities if they either have been or will be used in a future period. The statute of limitations for assessment by foreign tax authorities is open for tax years ended December 31, 2013 through December 31, 2017. There are currently no federal or state audits in progress.

The Company has not, as yet, completed a study of its research and development credit carryforwards. Once completed, this study may result in an adjustment to the Company's research and development credit carryforwards. A full valuation allowance has been provided against the Company's research and development credits, and if an adjustment is required at the time the study is completed, this adjustment would be offset by an adjustment to the deferred tax asset established for the research and development credit carryforward and the valuation allowance.

#### 18. Subsequent Events

On January 22, 2018, the Company announced that it had received commitments for a private placement of 58,780,619 fully paid CDIs of the Company (representing 1,175,612 shares of common stock) at an issue price of A\$0.035 per CDI 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 (the "Securities Act")) to raise up to approximately \$1.62.05 million (the "2018e Placement"). The issue of CDIs under the Private Placement is expected to occur in two tranches. The first tranche closed on January 22, 2018 (US EST), 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. The closing of the second tranche of the 2018 Placement, expected to result in the raising of \$830 thousand by the issue of 30,313,556 CDIs (606,271 shares), is subject to stockholder approval at the adjourned Special Meeting of stockholders on February 27 2018.