

GI Dynamics, Inc. – ASX Announcement

Appendix 4E Preliminary Final Report Year ended 31 December 2015

LEXINGTON, Massachusetts, United States and SYDNEY, Australia – 26 February 2016 – GI Dynamics, Inc. (ASX: GID) (GI Dynamics or the Company), a medical device company developing innovative treatments for type 2 diabetes and obesity, today announced its preliminary financial results for the year ended 31 December 2015 ("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, Ernst & Young 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 31 March 2016.

Summary of the Results

- Revenue decreased to US\$1.3 million for the year ended 31 December 2015 compared to US\$2.8 million for the year ended 31 December 2014.
- Cost of revenue was US\$5.7 million for the year ended 31 December 2015 compared to US\$4.1 million for the year ended 31 December 2014.
- Operating expenses decreased to US\$30.1 million for the year ended 31 December 2015 compared to US\$46.9 million for the year ended 31 December 2014.
- Other income (expense) for the year ended 31 December 2015 was a loss of US\$0.6 million compared to a gain of US\$0.1 million for the year ended 31 December 2014.
- The Company recorded a net loss of US\$35.2 million for the year ended 31 December 2015 compared to US\$48.2 million for the year ended 31 December 2014.
- The Company had cash and cash equivalents of US\$19.6 million at 31 December 2015 compared to US\$51.2 million at 31 December 2014.

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

Robert Solomon Vice President, Finance & Company Secretary

About GI Dynamics

GI Dynamics, Inc. (ASX: GID) is the developer of EndoBarrier[®], the first endoscopically-delivered device therapy approved for the treatment of obese type 2 diabetes with BMI \geq 30 kg/m², or obese patients with BMI \geq 30 kg/m² with \geq 1 comorbidities, or obese patients with BMI \geq 35 kg/m². The liner is indicated for a maximum implant duration of 12 months. EndoBarrier is approved and commercially available in multiple countries outside the U.S. EndoBarrier is not approved for sale in the U.S. and is limited by federal law to investigational use only in the United States. Founded in 2003, GI Dynamics is headquartered in Lexington, Massachusetts. For more information, please visit www.gidynamics.com.

Forward-Looking Statements

This announcement contains forward-looking statements concerning: our development and commercialization plans; our potential revenues and revenue growth, costs, excess inventory, profitability and financial performance; our ability to obtain reimbursement for our products; our clinical trials, and associated regulatory submissions and approvals; the number and location of commercial centres offering the EndoBarrier, and our intellectual property position. These forward-looking statements are based on the current estimates and expectations of future events by the management of GI Dynamics, Inc. as of the date of this announcement and are subject to a number of 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 the consequences of terminating the ENDO Trial and the possibility that future clinical trials will not be successful or confirm earlier results; risks associated with obtaining funding from third parties; risks relating to the timing and costs of clinical trials, the timing of regulatory submissions, the timing, receipt and maintenance of regulatory approvals, the timing and amount of other expenses, and the timing and extent of third-party reimbursement; risks associated with commercial product sales, including product performance; competition; risks related to market acceptance of products; intellectual property risks; risks related to excess inventory; risks related to assumptions regarding the size of the available market, 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, you 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, future events or otherwise, unless required by law.

Investor Enquiries:

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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 2015 |

The previous corresponding period refers to the comparative amounts for the year ended 31 December 2014.

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 2015 Compared to Year Ended 31 December 2014

| 2.1 | Revenue from ordinary activities |
|-----|--|
| | Loss from operations |
| 2.2 | Loss from ordinary activities, after tax |
| 2.3 | Loss attributable to members |

| | | Amount of | |
|------------------|------------------|------------|------------|
| | D : 17 | _ | |
| Current Year | Prior Year | Increase | Percentage |
| 12 Months Ended | 12 Months Ended | or | Increase |
| 31 December 2015 | 31 December 2014 | (Decrease) | or |
| \$'ooo USD | \$'ooo USD | \$'ooo USD | (Decrease) |
| | | | |
| 1,316 | 2,828 | (1,512) | (53%) |
| (34,506) | (48,190) | (13,684) | (28%) |
| (35,161) | (48,205) | (13,044) | (27%) |
| (35,161) | (48,205) | (13,044) | (27%) |

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

We are a medical device company that is dedicated to restoring health and improving quality of life, through the design and application of device and management solutions for treatment of metabolic disease. Our near-term vision is to establish EndoBarrier® Therapy as a valued treatment option for patients suffering from type 2 diabetes and obesity by restoring more manageable blood sugar levels and reducing body weight. We are the developer of EndoBarrier, the first endoscopically-delivered device therapy approved for the treatment of

obese type 2 diabetes with BMI \geq 30 kg/m², or obese patients with BMI \geq 30 kg/m² with \geq 1 comorbidities, or obese patients with BMI >35 kg/m². EndoBarrier is the only proven, incision-free, non-anatomy altering solution designed to specifically mimic the duodenal-jejunal exclusion created by gastric bypass surgery. Since incorporation, we have devoted substantially all of our efforts to product commercialization, research and development, business planning, recruiting management and technical staff, acquiring operating assets, and raising capital. We began commercial sales of our product in 2011. In 2015, we terminated our U.S. pivotal trial of EndoBarrier Therapy, which we began in 2013, due to a higher than anticipated incidence of hepatic abscess.

Our revenue from ordinary activities was approximately \$1.3 million for the year ended 31 December 2015 as compared to approximately \$2.8 million for the year ended 31 December 2014, a decrease of approximately \$1.5 million, or 53%. The decrease in our revenue from ordinary activities was a result of a decrease in sales across all markets. This decrease was a result of the termination of the ENDO Trial in the third quarter of 2015. Additionally, as part of our reorganization efforts begun in the third quarter of 2015, we decided to focus sales activity on a limited number of countries while disengaging from others.

Our cost of revenue for the year ended 31 December 2015 was approximately \$5.7 million compared to approximately \$4.1 million for the year ended 31 December 2014, an increase of approximately \$1.6 million, or 40%. The increase in our cost of revenue was primarily a result of an increase in the expense for additional inventory reserves needed to write-down the net realizable value of our existing inventory due to lower anticipated commercial activity and increased expense resulting from manufacturing inefficiencies due to lower production volume, partially offset by a decrease in sales unit volume and personnel related expenses.

Our research and development expenses were approximately \$16.6 million for the year ended 31 December 2015 compared to approximately \$26.7 million for the year ended 31 December 2014, a decrease of \$10.1 million, or 38%. The decrease in research and development expenses was primarily a result of decreased expenses to support the ENDO Trial as a result of the ENDO Trial's enrollment hold and subsequent termination and decreased personnel related expenses. Our sales and marketing expenses were approximately \$5.1 million for the year ended 31 December 2015 compared to approximately \$10.0 million for the year ended 31 December 2014, a decrease of approximately \$4.9 million, or 49%. The decrease in sales and marketing expenses was the result of lower personnel related expenses, including stock-based compensation expense, and lower spending on marketing related activities. General and administrative expenses were approximately \$8.4 million for the year ended 31 December 2015 and approximately \$10.2 million for the previous year, a decrease of approximately \$1.8 million, or 18%. The decrease in general and administrative expenses was primarily due to decreases in personnel related expenses and professional and consulting expenses.

Our loss from ordinary activities, after tax, was approximately \$35.2 million for the year ended 31 December 2015 as compared to approximately \$48.2 million for the year ended 31 December 2014, a decrease of approximately \$13.0 million, or 27%, and was a result of the reasons described above, in addition to a decrease in other income (expense) of approximately \$0.7 million, or 1,138%. The decrease in other income (expense) was primarily associated with a decrease in the gain on remeasurement of the warrant liability, a decrease in interest income and an increase in foreign exchange loss due to the depreciation of the Australian dollar versus the U.S. dollar.

Our loss attributable to members was the same as our loss from ordinary activities, after tax, for the years ended 31 December 2015 and 2014.

At 31 December 2015 we had cash and cash equivalents of approximately \$19.6 million compared to approximately \$51.2 million at 31 December 2014, a decrease of approximately \$31.6 million.

Net cash used in operations was approximately \$31.4 million for the year ended 31 December 2015. The primary use of cash was our net loss of approximately \$35.2 million and a net negative adjustment to cash flow from changes in working capital of approximately \$3.4 million resulting primarily from a decrease in accrued expenses associated with the clinical trial accruals and payroll related accruals, as well as net positive adjustment to cash flow from non-cash items of approximately \$7.2 million, due primarily to stock-based compensation expense and increases in inventory reserves resulting from charges for excess and obsolete inventory.

Net cash used in investing activities for the year ended 31 December 2015 was approximately \$0.2 million and resulted primarily from the purchase of property and equipment.

There was no net cash provided by financing activities for the year ended 31 December 2015.

3. Statement of Financial Performance

Please see our unaudited consolidated financial statements, with accompanying notes, which are attached hereto.

4. Statement of Financial Position

Please see our unaudited consolidated financial statements, with accompanying notes, which are attached hereto.

5. Statement of Cash Flows

Please see our unaudited consolidated financial statements, with accompanying notes, which are attached hereto.

6. Dividends per Security

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

7. Dividend or Distribution Reinvestment Plans

Not applicable; we have no dividend or distribution reinvestment plans.

8. Statement of Retained Earnings

Please see our unaudited consolidated financial statements, with accompanying notes, which are attached hereto.

9. Net Tangible Assets per Security

Net tangible assets (in \$'000 USD)

Issued equity (common stock and APIC) (in \$'000 USD)

Number of shares of common stock on issue at reporting date*

Net tangible assets per security (common share)*

| Current Year | Prior Year |
|----------------------------|----------------------------|
| 31 December 2015 | 31 December 2014 |
| 18,258 | 50,178 |
| 253,345 | 250,104 |
| 9,505,389 | 9,480,171 |
| \$1.92 (\$0.04 per CDI) | \$5.29 (\$0.11 per CDI) |

^{*} On 9 April 2015, the one-for-ten reverse stock split previously approved by shareholders became effective. The number of shares of common stock on issue and the net tangible assets per security (common share) at 31 December 2014 have been retroactively adjusted to reflect this reverse stock split.

10. Acquisitions and Divestments

Not applicable; no entities were acquired or disposed during 2015.

11. Joint Ventures

Not applicable; we are not and have not been party to any joint ventures.

12. Other Information

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

13. Foreign Entity Accounting Standards

Our 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 2015

Please see Section 2 above and our unaudited consolidated financial statements, with accompanying notes, which are attached hereto. We operated in one segment only in 2015.

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 2015 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 31 March 2016.

16. Audit Report (Unaudited Financials)

An audit of our financial statements is currently in process. We anticipate that our audited financial statements will contain an independent audit report which includes a paragraph stating that because we have 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 our operations, there is substantial doubt about our ability to continue as a going concern.

17. Audit Report (Audited Financials)

Not applicable; an audit of our financial statements is still in process.



Preliminary Final Report

Unaudited Financial Statements

Year ended 31 December 2015

GI Dynamics, Inc., is a corporation incorporated in Delaware, USA, whose stockholders have limited liability. ARBN 151 239 388

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Consolidated Balance Sheets

(In thousands, except share and per share amounts)

| December 3 | 31, |
|---|----------|
| 2015 | 2014 |
| Assets | |
| Current assets: | |
| Cash and cash equivalents | 51,191 |
| Accounts receivable, net | 470 |
| Inventory | 5,488 |
| Prepaid expenses and other current assets | 1,165 |
| Total current assets | 58,314 |
| Property and equipment, net | 1,089 |
| Other long-term assets | 97 |
| Total assets | 59,500 |
| | |
| Liabilities and stockholders' equity Current liabilities: | |
| Accounts payable | 882 |
| Accrued expenses | 7,674 |
| Deferred revenue | 412 |
| Other current liabilities | 175 |
| Total current liabilities | 9,143 |
| Deferred rent, net of current portion | 166 |
| Other liabilities | 4 |
| Warrants to purchase common stock | 9 |
| Commitments (Note 11) | |
| Stockholders' equity: | |
| Preferred stock, \$0.01 par value – 500,000 shares authorized; no shares issued and | |
| outstanding at December 31, 2015 and 2014 | _ |
| Common stock, \$0.01 par value – 13,000,000 shares authorized; 9,505,557 shares | |
| issued and 9,505,389 shares outstanding at December 31, 2015 and 9,483,671 | |
| shares issued and 9,480,171 shares outstanding at December 31, 2014 95 | 95 |
| Class B common stock, \$0.01 par value – 1,000,000 shares authorized; no shares | |
| issued and outstanding at December 31, 2015 and 2014 | |
| 1 | 250,009 |
| Accumulated deficit | 199,926) |
| Total stockholders' equity | 50,178 |
| Total liabilities and stockholders' equity | 59,500 |

Consolidated Statements of Operations and Comprehensive Loss

(In thousands, except share and per share amounts)

| | Years Ended December 31, | | |
|---|--------------------------|----------------------------|-----------------------------|
| | 2015 | 2014 | 2013 |
| Revenue | \$ 1,316 5,723 | \$ 2,828 4,089 | \$ 2,255 2,492 |
| Gross loss | (4,407) | (1,261) | (237) |
| Operating expenses: Research and development Sales and marketing General and administrative | 16,635 5,073 8,391 | 26,654 10,023 10,252 | 14,676 11,011 8,932 |
| Total operating expenses | 30,099 | 46,929 | 34,619 |
| Loss from operations | (34,506) | (48,190) | (34,856) |
| Other income (expense): Interest income Interest expense Foreign exchange gain (loss) Remeasurement of warrant liability | 68 (1) (647) | 253 (1) (514) 317 | 366 (5) (955) (32) |
| Other income (expense), net | (571) | 55 | (626) |
| Loss before income tax expense | (35,077) | (48,135) 70 | (35,482) |
| Net loss | \$ (35,161) | \$ (48,205) | \$ (35,578) |
| Basic and diluted net loss per common share | \$ (3.71) | \$ (5.36) | \$ (5.26) |
| Weighted-average number of common shares used in basic and diluted net loss per common share | 9,488,063 \$ (35,161) | 8,997,754 \$ (48,205) | 6,767,696 \$ (35,578) |

Consolidated Statements of Stockholders' Equity

(In thousands, except share amounts)

| | Common Stock | | Additional Paid-in Accumulated | | Total Stockholders' |
|---|--------------|-----------|--------------------------------|-------------|------------------------|
| | Shares | Par Value | Capital | Deficit | Equity |
| Balance at December 31, 2012 | 5,736,107 | \$ 57 | \$157,794 | \$(116,143) | \$ 41,708 |
| stock options Issuance of shares upon private placement and share purchase plan, net of issuance | 14,092 | _ | 53 | _ | 53 |
| costs of approximately \$2.1 million | 2,258,573 | 23 | 52,474 | _ | 52,497 |
| Stock-based compensation expense | | _ | 3,705 | _ | 3,705 |
| Net loss | | | | (35,578) | (35,578) |
| Balance at December 31, 2013 | 8,008,772 | 80 | 214,026 | (151,721) | 62,385 |
| stock options Issuance of shares upon private placement, net of issuance costs of approximately | 152,374 | 2 | 544 | _ | 546 |
| \$1.4 million | 1,319,025 | 13 | 30,769 | | 30,782 |
| Stock-based compensation expense | | _ | 4,670 | _ | 4,670 |
| Net loss | | | | (48,205) | (48,205) |
| Balance at December 31, 2014 Issuance of common stock upon exercise of stock options and vesting of restricted | 9,480,171 | 95 | 250,009 | (199,926) | 50,178 |
| stock | 21,886 | _ | 2 | _ | 2 |
| shares subject to repurchase | 3,332 | _ | 78 | _ | 78 |
| Stock-based compensation expense | | _ | 3,161 | _ | 3,161 |
| Net loss | | | | (35,161) | (35,161) |
| Balance at December 31, 2015 | 9,505,389 | \$ 95 | \$253,250 | \$(235,087) | \$ 18,258 |

Consolidated Statements of Cash Flows (In thousands)

| Operating activities (\$15,10) \$24,200 \$35,788 Net loss \$(\$5,161) \$(\$48,205) \$(\$5,578) Adjustments to reconcile net loss to net cash used in operating activities: 2486 656 441 Depreciation and amortization 486 656 441 Impairment of fixed assets 389 — — Stock-based compensation expenses 3,161 4,670 3,705 Remeasurement of warrant liability 9 (317) 32 Gain on sale of property and equipment — — (10) Changes in inventory reserve 3,155 1,527 149 Changes in operating assets and liabilities: 4430 120 (187) Prepaid expenses and other current assets 4430 120 (187) Prepaid expenses and other current assets 4430 120 (187) Other assets 97 (97) — Other assets 440 (385) 857 Accounts payable 4447 (385) 485 Act cash used in op | | Years Ended December 31, | | |
|--|--|--------------------------|------------|-----------------------------|
| Net loss (\$35,161) \$(48,205) \$(35,787) Adjustments to reconcile net loss to net cash used in operating activities: 486 656 441 Depreciation and amortization 486 656 441 Impairment of fixed assets 389 — — Stock-based compensation expense 3,161 4,670 3,705 Remeasurement of warrant liability 9 3,155 1,527 149 Changes in inventory reserve 3,155 1,527 149 Changes in operating assets and liabilities: 430 190 (187) Accounts receivable 4439 123 (450) Inventory 1,308 256 (2,061) Other assets 97 (97) — Accounts payable (4623) 3,214 (1,296) Deferred revenue (401) (310) 1 Deferred revenue (401) (310) 1 Investing activities (31,422) (38,522) (34,152) Proceeds from sale of property and equipment | | 2015 | 2014 | 2013 |
| Net loss \$(35,161) \$(48,205) \$(35,7878) Adjustments to reconcile net loss to net cash used in operating activities: 486 656 441 Depreciation and amortization 486 656 441 Impairment of fixed assets 389 — — Stock-based compensation expense 3,161 4,670 3,705 Remeasurement of warrant liability (9) 3,157 32 Gain on sale of property and equipment — — (10 Changes in inventory reserve 3,155 1,527 149 Changes in operating assets and liabilities: 430 190 (187) Accounts receivable 4439 123 (450) Inventory 1,308 256 (2,061) Other assets 97 (97) — Accounts payable (447) (385) 857 Accumed expenses (4,623) 3,214 (1,290) Deferred revenue (401) (310) 1 Investing activities (31,22) (38,522) <th>Operating activities</th> <th></th> <th></th> <th></th> | Operating activities | | | |
| Depreciation and amortization 486 Impairment of fixed assets 389 — — — Stock-based compensation expense 3,161 4,670 3,705 3,705 Remeasurement of warrant liability (9) (317) 32 32 Gain on sale of property and equipment — — (19) 149 Changes in operating assets and liabilities: — — (19) (187) 149 Changes in operating assets and liabilities: — — (450) (187) 149 Prepaid expenses and other current assets 430 190 (187) 159 (450) Inventory 1,308 256 (2,061) 256 (2,061) (467) (385) 857 Accounts payable (447) (385) 857 857 Accounts payable (447) (385) 857 857 Accured expenses (4623) 3,214 (1,296) 1 1 Deferred revenue (401) (310) 1 | | \$(35,161) | \$(48,205) | \$(35,578) |
| Impairment of fixed assets 389 — — Stock-based compensation expense 3,161 4,670 3,705 Remeasurement of warrant liability (9) (317) 32 Gain on sale of property and equipment — — (1) Change in inventory reserve 3,155 1,527 149 Changes in operating assets and liabilities: 430 190 (187) Prepaid expenses and other current assets 439 123 (450) Inventory 1,308 256 (2,061) Other assets 97 (97) — Accounts payable (447) (385) 857 Accrued expenses (4,623) 3,214 (1,296) Deferred revenue (449) 59 2,36 Other liabilities (97) 97 — Net cash used in operating activities (31,422) (38,522) (34,152) Investing activities (179) (255) (1,230) Proceeds from sale of property and equipment — — | | | | |
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| Remeasurement of warrant liability (9) (317) 32 Gain on sale of property and equipment — — (1) Change in inventory reserve 3,155 1,527 149 Changes in operating assets and liabilities: **** **** **** Accounts receivable 430 190 (187) Prepaid expenses and other current assets 439 123 (450) Inventory 1,308 256 (2,061) Other assets 97 97 — Accounts payable (447) (385) 857 Accrued expenses (4,623) 3,214 (1,296) Deferred revenue (401) (310) 1,296 Other liabilities (97) 97 — Net cash used in operating activities (31,422) (38,522) (34,152) Investing activities (179) (255) (1,230) Proceeds from sale of property and equipment — — 1 Change in restricted cash — 1 2 | Impairment of fixed assets | 389 | _ | |
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| Changes in operating assets and liabilities: Accounts receivable 430 190 (187) Prepaid expenses and other current assets 439 123 (450) Inventory 1,308 256 (2,061) Other assets 97 (97) — Accounts payable (447) (385) 857 Accrued expenses (4623) 3,214 (1,296) Deferred revenue (401) (310) 1 Deferred rent (149) 59 236 Other liabilities (97) 97 — Net cash used in operating activities (31,422) (38,522) (34,152) Investing activities Purchases of property and equipment — — 1 Change in restricted cash — — 33 Net cash used in investing activities — — 33 Proceeds from exercise of stock options 2 628 53 Proceeds from exercise of stock options 2 628 53 </td <td>* * *</td> <td>_</td> <td>_</td> <td>(1)</td> | * * * | _ | _ | (1) |
| Accounts receivable 430 190 (187) Prepaid expenses and other current assets 439 123 (450) Inventory 1,308 256 (2,061) Other assets 97 (97) — Accounts payable (447) (385) 857 Accrued expenses (4,623) 3,214 (1,296) Deferred revenue (401) (310) 1 Deferred rent (149) 59 236 Other liabilities (97) 97 — Net cash used in operating activities (31,422) (38,522) (34,152) Investing activities (179) (255) (1,230) Proceeds from sale of property and equipment (179) (255) (1,230) Proceeds from sale of property and equipment — — 1 Change in restricted cash (179) (255) (1,230) Proceeds from exercise of stock options 2 628 53 Proceeds from exercise of stock options 2 628 53 <td></td> <td>3,155</td> <td>1,527</td> <td>149</td> | | 3,155 | 1,527 | 149 |
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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 Lexington, Massachusetts. The Company is dedicated to restoring health and improving quality of life through the design and application of device and management solutions for treatment of metabolic disease. The Company's near-term goal is to establish EndoBarrier Therapy as a valued treatment option for patients suffering from type 2 diabetes and obesity by restoring more manageable blood sugar levels and reducing body weight. The Company is the developer of EndoBarrier®, the first endoscopically-delivered device therapy approved for the treatment of obese type 2 diabetes with BMI \geq 30 kg/m², or obese patients with BMI \geq 30 kg/m² with \geq 1 comorbidities, or obese patients with BMI \geq 35 kg/m². EndoBarrier is the only proven, incision-free, non-anatomy altering solution designed to specifically mimic the duodenal-jejunal exclusion created by gastric bypass surgery. Since incorporation, the Company has devoted substantially all of its efforts to product commercialization, research and development, business planning, recruiting management and technical staff, acquiring operating assets, and raising capital. The Company currently operates in one reportable business segment which designs, manufactures and markets medical devices.

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

In the U.S., the Company received approval from the Food and Drug Administration ("FDA"), to commence its pivotal trial of EndoBarrier Therapy (the "ENDO Trial"), which the Company began in 2013. The multicenter, 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.

On March 5, 2015, the Company announced that the FDA recommended discontinuing placement of any additional devices in the ENDO Trial as a result of, at that date, four cases of hepatic abscess among the 325 subjects then enrolled in the ENDO Trial. Hepatic abscess, a bacterial infection of the liver, is a known event related to the use of EndoBarrier. As a result, the Company halted enrollment in the ENDO Trial, although monitoring and data collection of patients then enrolled in the ENDO Trial continued.

On July 30, 2015, the Company announced its decision to discontinue the ENDO Trial. The decision followed discussions with the FDA regarding resumption of ENDO Trial enrollment, which despite collaborative efforts by both parties were unable to yield a feasible path forward for the mitigation of a higher than anticipated incidence of hepatic abscess. The Company concluded that terminating the ENDO Trial was in the best interest of all stakeholders.

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 the termination of the ENDO Trial and to ensure sufficient cash remains available for it to establish new priorities, continue limited market development and research, and to evaluate strategic options.

The Company is subject to a number of risks similar to other medical device companies, including, but not limited to, market acceptance of the Company's products, development by its competitors of new technological innovations, safety and efficacy of the products in clinical trials, the regulatory approval process governing medical devices and protection of proprietary technology. In addition, the Company will require additional funding to support its long-term operations. Any such financing may or may not be similar to transactions in which it has engaged in the past and there can be no assurance that any such financing opportunities will be available on acceptable terms, if at all.

Notes to Consolidated Financial Statements (continued)

1. Nature of Business (continued)

The Company has incurred operating losses since inception and at December 31, 2015, had an accumulated deficit of approximately \$235.1 million. Based on the Company's decision to conclude the ENDO Trial, it has begun to evaluate which markets are appropriate to continue pursuing reimbursement, market awareness and general market development efforts, and started restructuring its business and costs, establishing new priorities, continuing limited research, and evaluating strategic options. As a result, the Company expects to incur significant operating losses for the next several years. At December 31, 2015, the Company had approximately \$19.6 million in cash and cash equivalents, which it believes is sufficient to fund its operations through December 2016. 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 and complete development of an improved EndoBarrier for its current use and potential new indications. The Company will need to raise additional funding in order to implement its new business objectives and to continue to fund its operations beyond December 2016. 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.

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 sold 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.

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

Notes to Consolidated Financial Statements (continued)

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

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, 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 \$17.2 million and \$38.5 million at December 31, 2015 and 2014, respectively.

At December 31, 2015 and 2014, the Company had approximately \$0.2 million and \$5.9 million, respectively, of cash and cash equivalents denominated in Australian dollars that is subject to foreign currency gain and loss. At December 31, 2015 and 2014, the Company had approximately \$0.5 million and \$1.3 million, respectively, of cash and cash equivalents denominated in euros that is subject to foreign currency gain and loss.

Investments

The Company classifies all short-term investments with an original maturity when purchased of greater than three months as held-to-maturity as the Company has the intent and ability to hold these investments to maturity. The net carrying value of securities classified as held-to-maturity is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization is computed under the effective interest method and is included in interest income along with any declines in value judged to be other than temporary. The Company classifies all investments that mature in less than one year from the balance sheet date as short-term investments. Investments that mature in more than one year are classified as long-term, held-to-maturity investments within the consolidated balance sheets.

To determine whether an other-than-temporary impairment exists, the Company considers whether it has the ability and intent to hold the investment until a market price recovery and whether evidence indicating the recoverability of the cost of the investment outweighs evidence to the contrary. There were no other-than-temporary impairments for the years ended December 31, 2015, 2014 and 2013.

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:

| Asset Description | Estimated Useful Life (In Years) |
|--|-------------------------------------|
| Laboratory and manufacturing equipment | 5 |
| Computer equipment and software | 3 |
| Office furniture and equipment | 5 |

Notes to Consolidated Financial Statements (continued)

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

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 collectibility 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 collectibility 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. In the event the Company is unable to reasonably estimate future returns, it recognizes revenue when the right of return lapses. Prior to the fourth quarter of 2013, the Company did not have sufficient historical experience on which to base an estimate of returns, and therefore recognized revenue when the right of return lapsed. The Company determined this point to be when the product was implanted or otherwise consumed and payment was received from the customer, which indicated that the Company had no further obligations to the customer and that the sale was complete. As a result, starting in the fourth quarter of 2013, the

Notes to Consolidated Financial Statements (continued)

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

Company began to recognize revenue at the time of delivery net of these return estimates. 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, 2015 and 2014, the Company had deferred revenue of approximately \$11,000 and \$0.4 million, respectively.

In addition, the Company has entered into consignment arrangements in which the Company delivers the product to the customer but retains title to the product until it is implanted or otherwise consumed. In these arrangements, the Company recognizes revenue once it receives proof of third party purchase, usually in the form of a customer purchase order.

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, 2015, no such costs had been capitalized since inception of the Company. The Company has expensed approximately \$0.5 million, \$0.5 million and \$0.4 million of patent costs within general and administrative expenses in the consolidated statements of operations and comprehensive loss for the years ended December 31, 2015, 2014 and 2013, respectively.

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.

Notes to Consolidated Financial Statements (continued)

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

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 stock award 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

Notes to Consolidated Financial Statements (continued)

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

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.

The Company leases office space under several non-cancelable operating leases (Note 11). The Company has standard indemnification arrangements under these leases that require it to indemnify its landlords against all costs, expenses, fines, suits, claims, demands, liabilities, and actions directly resulting from any breach, violation, or nonperformance of any covenant or condition of the respective lease. The aggregate maximum potential future liability of the Company under such indemnification provisions is uncertain.

As of December 31, 2015 and 2014, 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.

Reverse Stock Split

In November 2014, the Company's stockholders approved a one-for-ten reverse stock split of the Company's common stock that was effective April 9, 2015. All share and per share amounts in the consolidated financial statements and notes thereto have been retroactively adjusted, where necessary, to reflect this reverse stock split. Because the par value of the Company's shares of common stock remain unchanged after the date of the split, the total stated par value and additional paid-in capital changed by offsetting amounts. The stated par value was reduced to one-tenth of the amount before the split and the additional paid-in capital was increased the same amount.

Notes to Consolidated Financial Statements (continued)

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

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 that ASU 2014-09 may have on its consolidated financial statements.

In August 2014, the FASB issued ASU No. 2014-15, *Presentation of Financial Statements-Going Concern: Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern* ("ASU 2014-15"). This new standard gives a company's management the final responsibilities to decide whether there is substantial doubt about the company's ability to continue as a going concern and to provide related footnote disclosures. The standard provides guidance to management, with principles and definitions that are intended to reduce diversity in the timing and content of disclosures that companies commonly provide in their footnotes. Under the new standard, management must decide whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the company's ability to continue as a going concern within one year after the date that the financial statements are issued, or within one year after the date that the financial statements are available to be issued when applicable. This guidance is effective for annual reporting beginning after December 15, 2016, including interim periods within the year of adoption, with early application permitted. The Company does not expect that the adoption of ASU 2014-15 will have a material impact on its financial position, results of operations or cash flows.

In April 2015, the FASB issued ASU No. 2015-05, *Intangibles – Goodwill and Other – Internal-Use Software* ("ASU 2015-05"). This new standard provides guidance to customers about whether a cloud computing arrangement includes a software license. If a cloud computing arrangement includes a software license, then the customer should account for the software license element of the arrangement consistent with the acquisition of other software licenses. If a cloud computing arrangement does not include a software license, the customer should account for the arrangement as a service contract. ASU 2015-05 will be effective for the Company for

Notes to Consolidated Financial Statements (continued)

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

reporting periods beginning after December 15, 2015. Early adoption is permitted and a company can elect to adopt ASU 2015-05 either (1) prospectively to all arrangements entered into or materially modified after the effective date or (2) retrospectively. Accordingly, the standard is effective for the Company on January 1, 2016. The adoption of this guidance is not expected to have a material impact on the Company's consolidated financial statements.

In July 2015, the FASB issued ASU No. 2015-11, *Simplifying the Measurement of Inventory* ("ASU 2015-11"). ASU 2015-11, which simplifies the measurement of inventories valued under most methods, including the Company's inventories valued under FIFO – the first-in, first-out cost method. Inventories valued under LIFO – the last-in, first-out method – are excluded. Under this new guidance, inventories valued under these methods would be valued at the lower of cost and net realizable value, with net realizable value defined as the estimated selling price less reasonable costs to sell the inventory. This guidance is effective for annual reporting beginning after December 15, 2016, including interim periods within the year of adoption, with early application permitted. The adoption of this guidance is not expected to have a significant impact on the Company's consolidated financial statements.

In November 2015, the FASB issued ASU 2015-17, *Income Taxes – Balance Sheet Reclassification of Deferred Taxes (Topic 740)* ("ASU 2015-17"). ASU 2015-17 requires that deferred tax liabilities and assets, and any related valuation allowances, be classified as noncurrent in a classified statement of financial position. The classification change for all deferred taxes as noncurrent simplifies entities' processes as it eliminates the need to separately identify the net current and net noncurrent deferred tax asset or liability in each jurisdiction and allocate valuation allowances. ASU 2015-17 is effective for financial statements issued for annual periods beginning after December 15, 2016, and interim periods within those annual periods. Early adoption is permitted and the amendments may be applied either prospectively to all deferred tax liabilities and assets or retrospectively to all periods presented. The Company early adopted ASU 2015-17 in the fourth quarter of 2015 on a prospective basis and included the current portion of deferred tax assets within the non-current portion of deferred tax assets within its consolidated balance sheets resulting in a reduction of other long-term assets and other current liabilities of approximately \$97,000 as of December 31, 2015. The prior period balances were not retrospectively adjusted.

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, 2015, 2014 and 2013, 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.

Notes to Consolidated Financial Statements (continued)

3. Net Loss per Common Share (continued)

The following potentially dilutive securities have been excluded from the computation of diluted weighted-average shares outstanding as of December 31, 2015, 2014 and 2013, as they would be anti-dilutive:

| | Years Ended December 31, | | |
|---|--------------------------|-----------|-----------|
| | 2015 | 2014 | 2013 |
| Warrants to purchase common stock Options to purchase common stock and other stock- | 50,000 | 50,000 | 50,000 |
| based awards | 1,041,322 | 1,410,736 | 963,455 |
| Total | 1,091,322 | 1,460,736 | 1,013,455 |

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 will expire on the fifth anniversary of their date of grant. The warrants may be converted on a cashless basis at the option of the holder. The Company has reserved 50,000 shares of common stock related to these warrants.

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, 2015 and 2014, 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.

Notes to Consolidated Financial Statements (continued)

5. Fair Value of Financial Instruments (continued)

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 | | |
|--|----------------------|---|--|--|
| Description | December 31, 2015 | Quoted Prices in Active Markets for Identical Assets (Level 1) | Significant Other Observable Inputs (Level 2) | Significant Unobservable Inputs (Level 3) |
| Assets | | | | |
| Money market funds (included in cash and cash equivalents) | \$17,207 | \$17,207 | \$ | \$ <u> </u> |
| Total assets | \$17,207 | <u>\$17,207</u> | <u>\$</u> | <u>\$</u> |
| Liabilities | | | | |
| Warrants to purchase common | | | | |
| stock | \$ — | \$ — | \$ | \$ |
| Total liabilities | \$ | <u>\$</u> | <u>\$—</u> | \$ |

| | | Fair Value Measurements at Reporting Date Using | at | |
|--|----------------------|---|--|--|
| Description | December 31, 2014 | Quoted Prices in Active Markets for Identical Assets (Level 1) | Significant Other Observable Inputs (Level 2) | Significant Unobservable Inputs (Level 3) |
| Assets | | | | |
| Money market funds (included in cash and cash equivalents) | \$38,454 | \$38,454 | <u>\$—</u> | <u>\$—</u> |
| Total assets | \$38,454 | \$38,454 | \$— <u> </u> | <u>\$</u> |
| Liabilities | | | | |
| Warrants to purchase common stock | \$ 9 | \$ — | \$ | \$ 9 |
| Total liabilities | \$ 9 | \$ — | <u>\$—</u> | \$ 9 |

The assumptions used in the Black-Scholes option pricing model to determine the fair value of the common stock warrants at December 31, 2015, 2014 and 2013 were as follows:

| | December 31, | | |
|---|--------------|---------|---------|
| | 2015 | 2014 | 2013 |
| Exercise price (A\$55.00 at the then current exchange rate) | \$40.18 | \$45.11 | \$49.21 |
| Fair value of common stock | \$ 1.06 | \$ 9.84 | \$33.56 |
| Expected volatility | 165.6% | 62.2% | 48.7% |
| Expected term (in years) | 0.7 | 1.7 | 2.7 |
| Risk-free interest rate | 0.5% | 0.5% | 0.7% |
| Expected dividend yield | — % | — % | — % |

Notes to Consolidated Financial Statements (continued)

5. Fair Value of Financial Instruments (continued)

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, 2013 | \$ 326 |
|---|-------------|
| Decrease in fair value of warrants upon remeasurement included in other | |
| income (expense) | (317) |
| Balance at December 31, 2014 | 9 |
| Decrease in fair value of warrants upon remeasurement included in other | |
| income (expense) | (9) |
| Balance at December 31, 2015 | <u>\$ —</u> |

Cash equivalents, accounts receivable, prepaid expenses and other current assets, accounts payable, accrued expenses and other current liabilities at December 31, 2015 and 2014 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 have a rating of not less than A, 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.

At December 31, 2015, one health care provider accounted for approximately 15% of the Company's accounts receivable and two health care providers accounted for approximately 11% each and a fourth health care provider accounted for approximately 10%. At December 31, 2014, one distributor accounted for approximately 32% of the Company's accounts receivable. No other customer accounted for greater than 10% of the Company's accounts receivable at December 31, 2015 and 2014.

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 \$31,000 in the year ended December 31, 2015 and none in 2014 and 2013. As of December 31, 2015, the Company believes its allowance for doubtful accounts of approximately \$59,000 is adequate based on its review.

Notes to Consolidated Financial Statements (continued)

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

In certain circumstances the Company allows customers to return defective or nonconforming products for credit or replacement products. Defective or nonconforming products typically include those products that resulted in an unsuccessful implant procedure. The Company records an estimate for product returns based upon historical trends. The associated reserve for product returns is recorded as a reduction of the Company's accounts receivable.

The following table shows the components of the Company's accounts receivable at December 31, 2015 and 2014 (in thousands):

| | December 31, | |
|---------------------------------------|--------------|-------|
| | 2015 | 2014 |
| Accounts receivable | \$121 | \$555 |
| Less: allowance for doubtful accounts | (59) | (41) |
| Less: allowance for sales returns | (22) | (44) |
| Total | \$ 40 | \$470 |

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

| | Year Ended December 31, | | |
|---------------------------|-------------------------|-------|------------|
| | 2015 | 2014 | 2013 |
| Beginning balance | \$ 41 | \$ | \$ |
| Net charges to expenses | 49 | 41 | _ |
| Utilization of allowances | (31) | | |
| Ending balance | \$ 59 | \$ 41 | <u>\$—</u> |

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

Notes to Consolidated Financial Statements (continued)

7. Inventory (continued)

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, 2015, the Company has a reserve totaling approximately \$5.0 million of which approximately \$3.3 million was for its inventory of sleeve material. The Company continues to review any evidence that may indicate that the utility of additional amounts of inventory, as it was expected to be used, will be less than cost.

In 2014, the Company determined that its raw material sleeve inventory was in excess of its anticipated commercial demand for future sales. Accordingly, for the year ended December 31, 2014, the Company recorded a provision for excess inventory of approximately \$1.6 million to reduce the carrying value of the raw material sleeve inventory.

Inventory at December 31, 2015 and 2014 was as follows (in thousands):

| | December 31, | |
|-----------------|--------------|---------|
| | 2015 | 2014 |
| Finished goods | \$ 391 | \$ 733 |
| Work-in-process | 605 | 2,401 |
| Raw materials | 29 | 2,354 |
| Total | \$1,025 | \$5,488 |

The Company has entered into consignment arrangements in which the Company delivers product to the customer but retains title to the product until it is implanted or otherwise consumed. At December 31, 2015 and 2014, approximately 2% and 4% of the finished goods inventory was at customer locations pursuant to these arrangements.

8. Property and Equipment

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

| | December 31, | | |
|--|--------------|----------|--|
| | 2015 | 2014 | |
| Laboratory and manufacturing equipment | \$ 457 | \$ 545 | |
| Computer equipment and software | 1,118 | 1,125 | |
| Office furniture and equipment | 229 | 221 | |
| Construction in process | _ | 48 | |
| Leasehold improvements | 848 | 921 | |
| | 2,652 | 2,860 | |
| Less accumulated depreciation and amortization | (2,251) | (1,771) | |
| Total | \$ 401 | \$ 1,089 | |

Notes to Consolidated Financial Statements (continued)

8. Property and Equipment (continued)

As part of the Company's restructuring in August 2015, the Company recognized a charge for impaired fixed assets as follows (in thousands):

| | Years Ended December 31 | | |
|----------------------------|-------------------------|------------|------|
| | 2015 | 2014 | 2013 |
| Cost of revenue | \$265 | - | \$— |
| Research and development | 100 | _ | _ |
| Sales and marketing | | | _ |
| General and administrative | 19 | _ | _ |
| | \$389 | <u>\$—</u> | \$ |

In January 2015, the Company entered into a capital lease for certain office equipment. As of December 31, 2015, the Company had approximately \$8,000 of assets under capital leases with an accumulated amortization balance of approximately \$2,000.

Depreciation and amortization expense of property and equipment, including equipment recorded under capital leases, totaled approximately \$0.5 million, \$0.7 million and \$0.4 million for the years ended December 31, 2015, 2014, and 2013, respectively.

9. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

| | December 31, | |
|---------------------------------|--------------|---------|
| | 2015 | 2014 |
| Clinical trials | \$1,809 | \$3,906 |
| Payroll and related liabilities | 501 | 2,629 |
| Professional fees | 454 | 634 |
| Deferred rent, current portion | 168 | 151 |
| Other | 136 | 354 |
| Total | \$3,068 | \$7,674 |

In 2015 and 2014, the Company recorded approximately \$0.6 million and \$1.5 million, respectively, of separation related expenses of which approximately \$0.1 million and \$1.3 million is included in payroll and related liabilities at December 31, 2015 and 2014, respectively, and which will be paid out through March 2016.

10. Debt

In January 2012, the Company entered into an unsecured credit facility of approximately \$0.2 million related to the Company's acquisition of its enterprise resource planning system. The credit facility was fully repaid in August 2014. Prior to its repayment, interest on the borrowings under the credit facility was at an annual interest rate of 5.6%.

Notes to Consolidated Financial Statements (continued)

11. Commitments and Contingencies

Lease Commitments

In June 2013, the Company entered into a noncancelable agreement to sublease 33,339 square feet of office, laboratory and manufacturing space in Lexington, Massachusetts. The sublease commenced in June 2013 and expires in December 2016, subject to earlier termination under certain conditions. Base rent during the initial rent period is approximately \$0.6 million per year and increases annually by approximately \$17,000. The space was delivered to the Company in June 2013 and rent payments commenced in May 2014. The rent expense, inclusive of the escalating rent payments and free rent period, is recognized on a straight-line basis over the term of the sublease agreement. In accordance with the terms of the sublease agreement, the Company maintains an unsecured letter of credit of approximately \$0.2 million securing its obligations under the sublease agreement.

In March 2012, the Company's subsidiary, GID Germany GmbH, entered into a noncancelable operating lease for office space in Dusseldorf, Germany. The lease was renewed in September 2013 and again in January 2015 and was extended through April 2016. The agreement was extended under substantially the same terms as the original agreement and is subject to earlier termination based on certain terms and conditions. The rent expense, inclusive of the free rent periods, is recognized on a straight-line basis over the term of the current lease agreement.

In July 2013, the Company's subsidiary, GI Dynamics Australia Pty Ltd, entered into a noncancelable operating lease for office space in Baulkham Hills, Australia. The initial term of the lease was for twelve months, which expired in July 2014. The Company exercised its option to renew the lease and extended the term through July 2015. In July 2015 the Company vacated this office space.

Rent expense on noncancelable operating leases was approximately \$0.5 million, \$0.5 million and \$0.6 million for the years ended December 31, 2015, 2014 and 2013, respectively.

In March 2015, the Company entered into a capital lease for certain office equipment totaling approximately \$8,000. The capital lease has a three-year term and an interest rate of 14.1%.

Future minimum lease payments under all noncancelable lease arrangements at December 31, 2015, are as follows (in thousands):

| Year Ending December 31, | |
|-------------------------------------|-------|
| 2016 | \$626 |
| 2017 | 3 |
| 2018 | 1 |
| Total future minimum lease payments | \$630 |

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 \$75,000 at execution, make payments of \$12,500 in 2004, and \$25,000 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 Company will cease paying royalties, if any, at the time the patent covered by the License Agreement expires in 2017.

Notes to Consolidated Financial Statements (continued)

11. Commitments and Contingencies (continued)

Supply Agreement

In July 2013, the Company and W.L. Gore & Associates, Inc. ("Gore") agreed to terminate their supply agreement ("Supply Agreement"). The Supply Agreement, entered into in 2004, was for the supply of a material used to manufacture the sleeve used in the Company's products.

Litigation

On January 9, 2013, the Company reached a settlement of litigation brought by Gore in the United States District Court for the District of Arizona in June 2010. In the litigation, Gore sought essentially the following declarations: (1) that it was the co-owner of all of the Company's patents and patent applications and (2) that the Supply Agreement (discussed above) was void. The Company strongly denied all of the claims made by Gore and also filed counterclaims against Gore alleging, among other claims, misuse and misappropriation by Gore of the Company's trade secrets. The Company also sought declarations that Gore was not the co-inventor or co-owner of any of the Company's patents.

Under the settlement, the Company retains exclusive ownership and control of its patent portfolio, and both parties have dismissed all claims against each other. The dismissed claims included Gore's claim that the Supply Agreement was void. The Company granted to Gore, a non-exclusive, royalty-free license to use the Company's patents, but only for application in the vasculature. Gore is not licensed to use the Company's patents for any applications in the gastrointestinal tract, which is the area of the body in which the Company's products are designed to be used. Neither side made any cash payments to the other, nor will any royalties be due.

12. Stockholders' Equity

On April 9, 2015, the Company amended its certificate of incorporation to reflect the one-for-ten reverse stock split approved by its shareholders. After giving effect to the reverse stock split, the authorized capital stock of the Company now consists of 14,500,000 shares, of which 13,000,000 shares are designated as common stock, 1,000,000 shares are designated as Class B common stock, and 500,000 shares are designated as preferred stock.

Common Stock

The Company authorized Class B common stock in order 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 is identical to and ranks equally with the common stock except that Class B common stock has no voting rights and is not entitled to any dividends. No shares of common stock are currently subject to such an escrow.

In July and August 2013, the Company sold approximately 108.5 million CDIs at an issue price of A\$0.53 per CDI in a private placement. In conjunction with the private placement, the Company initiated an SPP, in which eligible shareholders who held CDIs or shares of common stock in the Company at the record date were entitled to acquire up to A\$15,000 worth of additional CDIs at an issue price of A\$0.53 per CDI. The Company sold approximately 4.4 million CDIs in the SPP. As a result of the private placement and SPP, the Company raised approximately \$52.5 million, net of expenses.

Notes to Consolidated Financial Statements (continued)

12. Stockholders' Equity (continued)

In May 2014, the Company raised approximately \$30.8 million, net of expenses, in an offering of the Company's CDIs to sophisticated, professional and accredited investors in Australia, Hong Kong, the United Kingdom and certain other jurisdictions. The Company sold approximately 66.0 million CDI's at an issue price of A\$0.52 per CDI. The Company intends to use these proceeds to fund its U.S. pivotal clinical trial and for general working capital purposes.

13. Stock Plans

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, 2015, 921,969 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 2015 379,346 shares were added to the 2011 Plan.

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, 2015, 2014 and 2013 (in thousands):

| | Years Ended December 31, | | |
|----------------------------|--------------------------|---------|---------|
| | 2015 | 2014 | 2013 |
| Cost of revenue | \$ 89 | \$ 126 | \$ 69 |
| Research and development | 456 | 1,179 | 679 |
| Sales and marketing | 425 | 1,367 | 1,364 |
| General and administrative | 2,191 | 1,998 | 1,593 |
| | \$3,161 | \$4,670 | \$3,705 |

Notes to Consolidated Financial Statements (continued)

13. Stock Plans (continued)

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.

At December 31, 2014, the Company had options for the purchase of 20,000 shares of common stock subject to performance-based milestone vesting. During the years ended December 31, 2015 and 2014, the Company did not recognize any expense associated with options subject to performance-based milestones as the vesting of the underlying awards was not deemed probable. At December 31, 2015, there were no options subject to performance-based milestone vesting outstanding.

During the year ended December 31, 2013, an option granted in 2007, for the purchase of 13,000 shares of common stock, originally associated with a performance-based milestone, was modified by the Board of Directors to fully vest based upon services provided. The Company recorded approximately \$0.4 million of expense associated with the modification and vesting of this option grant in 2013.

During the year ended December 31, 2015, the Company modified the post-employment exercise period of stock awards previously granted to the Company's former chief financial officer in relation to his separation from the Company. The modification extended the exercise period to December 8, 2015. The modification resulted in an approximately \$19,000 increase in stock-based compensation in 2015. The Company accounted for the modification of these stock awards in accordance with the provisions of ASC 718.

Due to the absence of an active market for the Company's common stock, prior to the Company's IPO in September 2011, the Board of Directors was required to determine the fair value of the common stock for consideration in setting exercise prices for the options granted and in valuing the options granted. In determining the exercise prices for options granted, the Company's Board of Directors considered both quantitative and qualitative factors including the results obtained from an independent third-party valuation, the Company's financial position and historical financial performance, the status of technological developments within the Company's products, the composition and ability of the current research and management team, achievement of enterprise milestones, an evaluation or benchmark of the Company's competition, the current business climate in the marketplace, the illiquid nature of the common stock, arm's-length sales of the Company's capital stock (including convertible preferred stock), the effect of the rights and preferences of the preferred shareholders, and the prospects of a liquidity event, among others.

In calculating stock-based compensation costs, the Company estimated 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.

Notes to Consolidated Financial Statements (continued)

13. Stock Plans (continued)

Determining the fair value of stock-based awards using the Black-Scholes option-pricing model requires the use of highly subjective assumptions, including the expected term of the award and expected stock price volatility. The weighted-average assumptions used to estimate the fair value of employee stock options using the Black-Scholes option-pricing model were as follows for the years ended December 31, 2015, 2014 and 2013:

| | Years Ended December 31, | | |
|--------------------------|--------------------------|-------|-------|
| | 2015 | 2014 | 2013 |
| Expected volatility | 56.8% | 61.6% | 64.8% |
| Expected term (in years) | 6.04 | 6.05 | 6.05 |
| Risk-free interest rate | 1.6% | 2.1% | 1.1% |
| Expected dividend yield | — % | — % | — % |

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, 2015, 2014 and 2013, 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, 2015, 2014 and 2013.

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.

Forfeitures

Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from the Company's estimates. Subsequent changes in estimated forfeitures are recognized through a cumulative adjustment in the period of change and will also impact the amount of stock-based compensation expense in future periods. The Company uses historical data to estimate forfeiture rates. The Company's estimated forfeiture rates were 15.0%, 5.0% and 2.0% as of December 31, 2015, 2014 and 2013, respectively.

Notes to Consolidated Financial Statements (continued)

13. Stock Plans (continued)

Stock Options

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

| | Shares of Common Stock Attributable to Options | Weighted- Average Exercise Price | Weighted- Average Contractual Life | Aggregate Intrinsic Value |
|--|--|---|---|---|
| | | | (in years) | (in thousands) |
| Outstanding at December 31, 2014 | 1,201,496 | \$26.36 | 6.41 | \$1,406 |
| Granted | 246,604 | \$ 5.42 | | |
| Exercised | (1,000) | \$ 1.50 | | |
| Cancelled | (668,072) | \$21.52 | | |
| Outstanding at December 31, 2015 | 779,028 | \$23.92 | 7.64 | <u>\$ </u> |
| Vested or expected to vest at December 31, | | | | |
| 2015 | 718,278 | \$24.31 | 7.55 | <u>\$ —</u> |
| Exercisable at December 31, 2015 | 374,024 | \$28.98 | 6.45 | <u>\$ —</u> |

As of December 31, 2015, there was approximately \$3.7 million of unrecognized stock-based compensation, net of estimated forfeitures, 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 2.4 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, 2015, 2014 and 2013 was \$2.91, \$15.22 and \$19.01, respectively. The total intrinsic value of options exercised during the years ended December 31, 2015, 2014 and 2013 was approximately \$10,000, \$4.4 million and \$0.5 million, respectively. 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. Cash received from option exercises during the years ended December 31, 2015, 2014 and 2013 was approximately \$1,500, \$0.6 million and \$53,000, respectively. 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, 2015 and 2014, there were 168 and 3,500 shares of common stock, respectively, 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 \$4,000 and \$82,000, respectively, at December 31, 2015 and 2014. 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.

Notes to Consolidated Financial Statements (continued)

13. Stock Plans (continued)

Restricted Stock Units

Each restricted stock unit ("RSU") represents a contingent right to receive one share of the Company's common stock. The RSUs outstanding at December 31, 2015 vest on the first anniversary of the issuance date, vest on a pro-rata basis on each anniversary of the issuance date over four years or vest upon the achievement of certain product revenue, regulatory and reimbursement milestones. There is no consideration payable on the vesting of RSUs issued under the Plans. Upon vesting, the RSUs are exercised automatically and settled in shares of the Company's common stock. During the years ended December 31, 2015 and 2014, the Company awarded a total of 143,506 and 209,568 RSUs to employees and directors of the Company, respectively.

The following table summarizes information related to the RSUs and activity during the year ended December 31, 2015:

| | Number of Units | Weighted- Average Contractual Life | Aggregate Intrinsic Value |
|----------------------------------|-----------------|---|---------------------------------|
| | | (in years) | (in thousands) |
| Outstanding at December 31, 2014 | 205,740 | 5.43 | \$2,016 |
| Granted | 143,506 | | |
| Vested | (20,886) | | |
| Cancelled | (66,234) | | |
| Outstanding at December 31, 2015 | <u>262,126</u> | 4.30 | \$ 278 |

The aggregate intrinsic value at December 31, 2015 and 2014 noted in the table above represents the closing price of the Company's common stock multiplied by the number of RSUs outstanding.

The fair value of each RSU award equals the closing price of the Company's common stock on the date of grant. The weighted average grant date fair value per share of RSUs granted in the years ended December 31, 2015 and 2014 was \$5.39 and \$22.64, respectively.

At December 31, 2015, 193,468 of the RSUs outstanding are subject to performance-based vesting criteria as described above. 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 year ended December 31, 2015, the Company determined that a milestone previously deemed probable was now not probable of being achieved prior to the expiration of the award. This change in estimate was recognized through a cumulative adjustment in 2015, resulting in a reduction of stock-based compensation of approximately \$0.3 million, all of which was previously recognized in the year ended December 31, 2014.

During the years ended December 31, 2015 and 2014, the Company recognized stock-based compensation related to RSUs having service-based vesting of approximately \$0.5 million and \$0.1 million, respectively.

As of December 31, 2015, there was approximately \$1.0 million of unrecognized stock-based compensation expense, net of estimated forfeitures, related to non-vested RSU awards that have service-based vesting. This expense is expected to be recognized over a weighted average period of 2.5 years. At December 31, 2015, no RSUs that have performance-based vesting criteria are considered probable of achievement and there remains approximately \$2.4 million, net of estimated forfeitures, of unrecognized stock-based compensation, including the amount of the cumulative adjustment above.

Notes to Consolidated Financial Statements (continued)

13. Stock Plans (continued)

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, 2013, the Company granted options to purchase 30,000 shares of common stock to non-employees with an aggregate fair value of approximately \$0.6 million. During the years ended December 31, 2015 and 2014, the Company did not grant any options for 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 and a reduction of approximately \$0.2 million in the year ended December 31, 2013. 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 \$6,000, \$0.2 million and \$0.1 million during the years ended December 31, 2015, 2014 and 2013, respectively, which is included in the total stock-based compensation expense.

14. Segment Reporting

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

Geographic Reporting

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, 2015, long-lived assets, comprised of property and equipment, of approximately \$0.4 million are all held in the U.S.

Notes to Consolidated Financial Statements (continued)

14. Segment Reporting (continued)

Product sales by geographic location for the years ended December 31, 2015, 2014 and 2013 are listed in the table below (in thousands).

| | December 31, | | | | |
|---------------|--------------|---------|---------|--|--|
| | 2015 | 2014 | 2013 | | |
| Europe | \$1,007 | \$1,687 | \$1,333 | | |
| Middle East | 146 | 247 | 255 | | |
| South America | 41 | 466 | 337 | | |
| Asia Pacific | 122 | 428 | 330 | | |
| Total | \$1,316 | \$2,828 | \$2,255 | | |

Germany and the United Kingdom comprised a significant component of revenue in Europe for the year ended December 31, 2015. Germany, Chile and Australia comprised a significant component of revenue in their respective regions for the year ended December 31, 2014. Germany, Netherlands, Chile and Australia comprised a significant component of revenue in their respective regions for the year ended December 31, 2013.

Major Customers

For the year ended December 31, 2015, one distributor accounted for approximately 15% of the Company's revenue. For the year ended December 31, 2014, one distributor accounted for approximately 16% of the Company's revenue. For the year ended December 31, 2013, one distributor accounted for approximately 15% of the Company's revenue and one health care provider accounted for approximately 13% of the Company's revenue. No other customer accounted for greater than 10% of the Company's revenue during the years ended December 31, 2015, 2014 and 2013.

15. 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 \$0.2 million, \$0.3 million and \$0.2 million for the years ended December 31, 2015, 2014 and 2013, 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 \$21,000, \$30,000 and \$0.1 million for the years ended December 31, 2015, 2014 and 2013, respectively, under this plan.

16. Income Taxes

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

| | Years Ended December 31, | | | | | |
|----------|--------------------------|------------|------------|--|--|--|
| | 2015 | 2014 | 2013 | | | |
| Domestic | \$(35,190) | \$(48,298) | \$(35,599) | | | |
| Foreign | 113 | 163 | 117 | | | |
| Total | \$(35,077) | \$(48,135) | \$(35,482) | | | |

Notes to Consolidated Financial Statements (continued)

16. Income Taxes (continued)

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, | | | |
|---------------------|--------------------------|-------|-------|--|
| | 2015 | 2014 | 2013 | |
| Current Provision: | | | | |
| Federal | \$ | \$ | \$ | |
| State | 2 | 3 | 39 | |
| Foreign | 59 | 90 | 57 | |
| Total | 61 | 93 | 96 | |
| Deferred Provision: | | | | |
| Federal | _ | | _ | |
| State | _ | _ | _ | |
| Foreign | 23 | (23) | | |
| Total | 23 | (23) | | |
| Total provision | \$ 84 | \$ 70 | \$ 96 | |

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, | | | | | | |
|--|--------------------------|------------|------------|--|--|--|--|
| | 2015 | 2014 | 2013 | | | | |
| Income tax benefit using U.S. federal statutory rate | \$(11,926) | \$(16,366) | \$(12,064) | | | | |
| Permanent differences | 23 | (60) | 40 | | | | |
| State income taxes, net of federal benefit | (383) | (2,254) | (1,612) | | | | |
| Stock compensation | 556 | 900 | 645 | | | | |
| Tax credits | (459) | (626) | (306) | | | | |
| Foreign tax rate differential | (2) | (11) | (11) | | | | |
| Change in the valuation allowance | 12,234 | 18,500 | 13,841 | | | | |
| Other | 41 | (13) | (437) | | | | |
| Total | \$ 84 | \$ 70 | \$ 96 | | | | |

Notes to Consolidated Financial Statements (continued)

16. Income Taxes (continued)

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

| | Decem | ber 31, |
|---|-----------|-----------|
| | 2015 | 2014 |
| Deferred tax assets: | | |
| Net operating loss carryforwards | \$ 73,260 | \$ 60,092 |
| Research and development credit carryforwards | 3,655 | 3,179 |
| Capitalized research and development costs | 2,196 | 3,140 |
| Capitalized start-up expenses | 5,105 | 5,621 |
| Depreciation and other | 6,883 | 6,854 |
| Total deferred tax assets | 91,099 | 78,886 |
| Valuation allowance | (91,099) | (78,863) |
| Net deferred tax asset | <u> </u> | \$ 23 |

In accordance with ASU No. 2015-17, at December 31, 2015, the Company reclassified its net current deferred tax asset to the net non-current deferred tax asset in our consolidated balance sheet. No prior periods were retrospectively adjusted.

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. As a result, a valuation allowance of approximately \$91.1 million and \$78.9 million was established at December 31, 2015 and 2014, respectively. The valuation allowance increased by approximately \$12.2 million during the year ended December 31, 2015, primarily due to the increase in the Company's net operating loss carryforwards.

At December 31, 2015, the Company had federal and state net operating loss carryforwards (excluding ASC 718 additional paid-in capital net operating losses) of approximately \$187.9 million and \$177.5 million, respectively. These operating loss carryforwards will expire at various times beginning in 2024 through 2035 for federal purposes and begin to expire in 2030 and will continue to expire through 2035 for state purposes. The Company has also recorded approximately \$4.6 million as a reduction to net operating losses carryforward that is attributable to excess stock option deductions as of December 31, 2015.

In addition, at December 31, 2015, the Company also has federal and state research and development tax credit carryforwards (excluding ASC 740, *Income Taxes* ("ASC 740"), reserve) of approximately \$3.6 million and \$2.0 million, respectively, to offset future income taxes. These tax credit carryforwards will expire at various times beginning in 2023 through 2035 for federal purposes and will expire at various times beginning in 2018 through 2030 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

Notes to Consolidated Financial Statements (continued)

16. Income Taxes (continued)

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, 2015, 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, 2015 and 2014, the Company had unrecognized tax liabilities of approximately \$1.4 million and \$1.3 million, respectively.

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

| | December 31, | | | |
|--|--------------|---------|--|--|
| | 2015 | 2014 | | |
| Unrecognized tax benefit – as of the beginning of the year | \$1,252 | \$1,025 | | |
| Gross increases – tax positions of the prior periods | _ | _ | | |
| Gross increases – current period tax positions | 174 | 227 | | |
| Unrecognized tax benefits – as of the end of the year | \$1,426 | \$1,252 | | |

The Company will recognize interest and penalties related to uncertain tax positions in income tax expense. As of December 31, 2015 and 2014, 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, 2015, 2014, 2013 and 2012, although carryforward attributes that were generated prior to tax year 2012 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, 2015, 2014, 2013 and 2012. 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.

Notes to Consolidated Financial Statements (continued)

17. Selected Quarterly Financial Information

| | Firs | t Quarter | Second Quarter | | | | Third Fourth Quarter Quarter | | Total Year | |
|---|------|-----------|-------------------|---------|----|---------|---------------------------------|----------|------------|---------|
| 2015 | | | | | | | | | | |
| Revenue | \$ | 616 | \$ | 310 | \$ | 175 | \$ | 215 | \$ | 1,316 |
| Gross loss* | | (270) | | (1,702) | | (743) | | (1,692) | | (4,407) |
| Loss from operations | | (9,870) | (| 10,252) | | (7,905) | | (6,479) | (| 34,506) |
| Net loss | (| 10,349) | (| 10,234) | | (8,089) | | (6,489) | (| 35,161) |
| Basic and diluted net loss per common share | \$ | (1.09) | \$ | (1.08) | \$ | (0.85) | \$ | (0.68) | \$ | (3.71) |
| 2014 | | | | | | | | | | |
| Revenue | \$ | 906 | \$ | 840 | \$ | 609 | \$ | 473 | \$ | 2,828 |
| Gross profit (loss)* | | 3 | | 290 | | 216 | | (1,770) | | (1,261) |
| Loss from operations | (| 10,094) | (| 12,641) | (| 11,699) | (| (13,756) | (| 48,190) |
| Net loss | | (9,681) | (| 12,300) | (| 12,130) | (| (14,094) | (| 48,205) |
| Basic and diluted net loss per common share | \$ | (1.20) | \$ | (1.38) | \$ | (1.28) | \$ | (1.49) | \$ | (5.36) |

^{*} In the second and fourth quarter of 2015, the Company recorded a charge to cost of revenue of approximately \$1.7 million and \$1.5 million, respectively, for excess, expired and obsolete inventory. In the fourth quarter of 2014, the Company recorded a charge to cost of revenue of approximately \$1.6 million for excess raw material sleeve inventory.