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

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2014

Or

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

Commission file number: 001-36545

INTERSECT ENT, INC.
(Exact name of registrant as specified in its charter)

Delaware	**20-0280837**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification Number)**
1555 Adams Drive Menlo Park, California	**94025**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (650) 641-2100

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

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

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒ (Do not check if a smaller reporting company)	Smaller reporting company	☐

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

The number of shares of Intersect ENT's common stock outstanding as of August 31, 2014 was 23,365,756.

INTERSECT ENT, INC.
Form 10-Q – QUARTERLY REPORT
For the Quarter Ended June 30, 2014

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PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

INTERSECT ENT, INC.
CONDENSED BALANCE SHEETS
(in thousands, except per share data)

	June 30, 2014 (unaudited)	December 31, 2013 (1)
Assets		
Current assets:		
Cash and cash equivalents	$ 2,745	$ 12,294
Accounts receivable, net	4,513	4,200
Inventory	2,768	2,197
Restricted cash	—	62
Prepaid expenses and other current assets	552	449
Total current assets	10,578	19,202
Property and equipment, net	1,677	1,707
Other non-current assets	2,230	126
Total assets	$ 14,485	$ 21,035
Liabilities, Convertible Preferred Stock and Stockholders' Deficit		
Current liabilities:		
Accounts payable	$ 2,659	$ 1,451
Accrued compensation	3,296	2,955
Equipment loans – current portion	715	696
Convertible preferred stock warrant liability	429	237
Other current liabilities	942	745
Total current liabilities	8,041	6,084
Equipment loans – non-current portion	393	756
Deferred rent	—	52
Total liabilities	8,434	6,892
Commitments and contingencies (note 13)		
Convertible preferred stock issuable in series, $0.001 par value;		
Authorized shares: 15,907 at December 31, 2013 and June 30, 2014;		
Issued and outstanding shares: 15,701 and 15,704 at December 31, 2013 and June 30, 2014, respectively	90,789	90,760
Stockholders' deficit		
Preferred stock, $0.001 par value;		
Authorized shares: none and 10,000 at December 31, 2013 and June 30, 2014;		
Issued and outstanding shares: none	—	—
Common stock, $0.001 par value;		
Authorized shares: 150,000 at December 31, 2013 and June 30, 2014;		
Issued and outstanding shares: 1,761 and 1,872 at December 31, 2013 and June 30, 2014	2	2
Additional paid-in capital	2,310	1,859
Note receivable from related party	—	(219)
Accumulated deficit	(87,050)	(78,259)
Total stockholders' deficit	(84,738)	(76,617)
Total liabilities, convertible preferred stock and stockholders' deficit	$ 14,485	$ 21,035

(1) Amounts have been derived from the December 31, 2013 audited financial statements included in the Company's registration statement on Form S-1 (No. 333-196974) filed with the Securities and Exchange Commission.

See accompanying notes to condensed financial statements.

INTERSECT ENT, INC.
CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(in thousands, except per share data)
(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
Revenue	$ 8,565	$ 3,936	$16,062	$ 6,680
Cost of sales	2,320	2,202	4,680	4,151
Gross profit	6,245	1,734	11,382	2,529
Operating expenses:				
Selling, general and administrative	8,291	4,087	14,949	7,437
Research and development	2,377	2,421	4,954	4,677
Total operating expenses	10,668	6,508	19,903	12,114
Loss from operations	(4,423)	(4,774)	(8,521)	(9,585)
Interest and other income	65	1	66	83
Interest and other expense	(24)	(112)	(336)	(136)
Net loss and comprehensive loss	$ (4,382)	$(4,885)	$ (8,791)	$ (9,638)
Net loss per share, basic and diluted	$ (2.36)	$ (3.69)	$ (4.84)	$ (8.15)
Weighted average common shares used to compute net loss per share, basic and diluted	1,860	1,323	1,817	1,182

See accompanying notes to condensed financial statements.

INTERSECT ENT, INC.
CONDENSED STATEMENTS OF CASH FLOWS
(in thousands)
(unaudited)

	Six Months Ended June 30,	
	2014	2013
Operating activities:		
Net loss	$ (8,791)	$ (9,638)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	281	246
Stock-based compensation expense	569	130
Change in fair value of convertible preferred stock warrants	221	—
Change in fair value of convertible preferred stock financing option	—	86
Forgiveness of notes receivable from related party	100	100
Changes in operating assets and liabilities:		
Accounts receivable, net	(313)	(1,051)
Inventory	(571)	(188)
Prepaid expenses and other current assets	(141)	26
Other non-current assets	(797)	(2)
Accounts payable	(103)	(104)
Accrued compensation	341	(158)
Other current liabilities and deferred rent	150	110
Net cash used in operating activities	(9,054)	(10,443)
Investing activities:		
Purchases of property and equipment	(246)	(196)
Net cash used in investing activities	(246)	(196)
Financing activities:		
Proceeds from issuance of common stock	94	46
Proceeds from capital lease financing	—	106
Repayments related to equipment loans	(328)	(317)
Repayments related to capital lease financing	(15)	(5)
Proceeds from the exercise of Series A convertible preferred warrants	—	82
Proceeds from issuance of Series D convertible preferred stock, net of issuance costs	—	20,715
Net cash (used in) provided by financing activities	(249)	20,627
Net (decrease) increase in cash and cash equivalents	(9,549)	9,988
Cash and cash equivalents:		
Beginning of the period	12,294	2,060
End of the period	$ 2,745	$ 12,048

See accompanying notes to condensed financial statements.

NOTES TO CONDENSED FINANCIAL STATEMENTS
(unaudited)

1. Organization

Description of Business

Intersect ENT, Inc. (the "Company") is incorporated in the state of Delaware and its facilities are located in Menlo Park, California. The Company is a commercial stage drug-device company committed to improving the quality of life for patients with ear, nose and throat conditions. The Company's sole commercial products are the PROPEL and PROPEL mini drug-eluting implants for patients undergoing sinus surgery to treat chronic sinusitis. The Company received approval from the U.S. Food and Drug Administration ("FDA") for PROPEL in August 2011 and for PROPEL mini in November 2012. In the first half of 2013, the Company began scaling its U.S. direct commercial presence and currently markets its products only in the United States.

Liquidity and Business Risks

As of June 30, 2014, the Company had cash and cash equivalents of $2.7 million, and an accumulated deficit of $87.1 million. In July 2014 the Company completed its initial public offering ("IPO") by issuing 5,750,000 shares of common stock at an offering price of $11.00 per share, for net proceeds of approximately $55.8 million, after deducting underwriting discounts and commissions and offering expenses. The Company has financed its operations with a combination of debt and equity financing arrangements. The Company expects its cash and cash equivalents, revenue and available debt financing arrangements, together with the net proceeds from the IPO, will be sufficient to fund its operations through at least the next twelve months.

2. Summary of Significant Accounting Policies

Basis of Preparation

The financial statements have been prepared in accordance with U.S. generally accepted accounting principles ("U.S. GAAP") and pursuant to the rules and regulations of the United States Securities and Exchange Commission ("SEC").

The interim financial data as of June 30, 2014, is unaudited and is not necessarily indicative of the results for a full year or any interim period. In the opinion of the Company's management, the interim data includes only normal and recurring adjustments necessary for a fair statement of the Company's financial results for the three and six months ended June 30, 2014. Certain information and footnote disclosures normally included in annual financial statements prepared in accordance with GAAP have been condensed or omitted pursuant to SEC rules and regulations relating to interim financial statements.

The accompanying condensed financial statements should be read in conjunction with the Company's audited financial statements and notes thereto included in the Company's final prospectus filed pursuant to Rule 424(b) under the Securities Act of 1933, as amended, relating to the Company's final prospectus (No. 333-196974) ("Final Prospectus"), filed with the SEC on July 24, 2014.

Certain amounts in the financial statements have been reclassified to conform to the current year presentation.

1-for-4 Reverse Stock Split

On July 10, 2014, the Board of Directors and stockholders approved, and on July 11, 2014, the Company filed, an amended and restated certificate of incorporation effecting a 1-for-4 reverse stock split of common stock and all convertible preferred stock. The par value of the common and convertible preferred stock was not adjusted as a result of the reverse stock split. All issued and outstanding common stock, convertible preferred stock, warrants for preferred stock, and per share amounts contained in the financial statements have been retroactively adjusted to reflect this reverse stock split for all periods presented.

Initial Public Offering

In July 2014, the Company completed its IPO by issuing 5,750,000 shares of common stock at an offering price of $11.00 per share, for net proceeds of approximately $55.8 million, after deducting underwriting discounts and commissions and offering expenses. In connection with the IPO, the Company's outstanding shares of convertible preferred stock were automatically converted into 15,703,875 shares of common stock and warrants exercisable for convertible preferred stock were automatically converted into warrants exercisable for 53,357 shares of common stock, resulting in the reclassification of the related redeemable convertible preferred stock warrant liability of $0.4 million to additional paid-in capital.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts and disclosures reported in the financial statements. Management uses significant judgment when making estimates related to its common stock valuation and related stock-based compensation, the valuations of the convertible preferred

stock warrant liability, convertible preferred stock financing option, clinical trial accruals, as well as certain accrued liabilities. Management bases its estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results could differ from those estimates.

Significant Accounting Policies

There have been no significant changes to the accounting policies during the three and six months ended June 30, 2014, as compared to the significant accounting policies described in Note 2 of the "Notes to Financial Statements" in the Company's audited financial statements included in the Final Prospectus other than those listed below.

Short-term Investments

Short-term investments, available-for-sale, represent highly liquid debt instruments with maturities greater than 90 days at date of purchase. Such investments are recorded at fair value and unrealized holding gains and losses are reported as a separate component of comprehensive income (loss) in stockholders' equity until realized. The Company reviews its investment portfolio periodically to assess for other-than-temporary impairment. Should the Company determine that any unrealized losses on the investments are other-than-temporary, the amount of that impairment to be recognized in earnings will depend on whether the Company intends to sell the security or more likely than not will be required to sell the security before recovery of its amortized cost basis less any current period credit loss. The specific identification method is used to determine the cost of securities disposed of, with realized gains and losses reflected in interest and other income (expense) in the statement of operations

Deferred Offering Costs

Deferred offering costs, primarily consisting of legal, accounting and other direct fees and costs relating to the IPO, are capitalized. The deferred offering costs were offset against the IPO proceeds upon the closing of the offering in July 2014. As of June 30, 2014, there was $2.1 million in deferred offering costs capitalized in other non-current assets on the condensed balance sheet. There were no deferred offering costs capitalized as of December 31, 2013.

Comprehensive Loss

Comprehensive loss comprises net loss and other comprehensive income (loss). The Company has no components of other comprehensive income (loss). Therefore net loss equals comprehensive loss for all periods presented.

Recent Accounting Pronouncements

In June 2014, the Financial Accounting Standard Board ("FASB") issued Accounting Standards Update ("ASU") No. 2014-12, *Accounting for Share-Based Payments When the Terms of an Award Provide That a Performance Target Could Be Achieved after the Requisite Service Period* ("ASU 2014-12"). ASU 2014-12 requires that a performance target that affects vesting of share-based payment awards and that could be achieved after the requisite service period be treated as a performance condition. Compensation cost should be recognized in the period in which it becomes probable that the performance target will be achieved and should represent the compensation cost attributable to the periods for which the requisite service has already been rendered. If the performance target becomes probable of being achieved before the end of the requisite service period, the remaining unrecognized compensation cost should be recognized prospectively over the remaining requisite service period. The total amount of compensation cost recognized during and after the requisite service period should reflect the number of awards that are expected to vest and should be adjusted to reflect those awards that ultimately vest. The requisite service period ends when the employee can cease rendering service and still be eligible to vest in the award if the performance target is achieved. ASU 2014-12 is effective for all entities for annual periods and interim periods within those annual periods beginning after December 15, 2015. Early adoption is permitted. An entity may apply the amendments in ASU 2014-12 either (i) prospectively to all awards granted or modified after the effective date or (ii) retrospectively to all awards with performance targets that are outstanding as of the beginning of the earliest annual period presented in the financial statements and to all new or modified awards thereafter. The adoption of ASU 2014-12 is not expected to have a material impact on the Company's financial condition or results of operations.

In May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers* ("ASU 2014-09"), which requires an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers. ASU 2014-09 will replace most existing revenue recognition guidance in U.S. GAAP when it becomes effective. In doing so, companies will need to use more judgment and make more estimates than under current guidance. These may include identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligation. ASU 2014-09 is effective for all entities for annual reporting periods beginning after December 15, 2016, including interim periods within that reporting period. Early adoption is not permitted. The standard permits the use of either the retrospective or cumulative effect transition method. The Company is evaluating the effect that ASU 2014-09 will have on its financial statements and related disclosures.

3. Composition of Certain Financial Statement Items

Inventory (in thousands):

	June 30, 2014	December 31, 2013
Raw materials	$ 853	$ 472
Work-in-process	166	241
Finished goods	1,749	1,484
	$2,768	$ 2,197

Property and Equipment (in thousands):

	June 30, 2014	December 31, 2013
Computer equipment and software	$ 534	$ 398
Furniture and office equipment	255	252
Laboratory equipment	2,370	2,262
Leasehold improvements	128	124
	3,287	3,036
Less: accumulated depreciation and amortization	(1,610)	(1,329)
	$ 1,677	$ 1,707

Depreciation and leasehold improvements and capital lease amortization expenses was $0.2 million and $0.3 million during the three and six months ended June 30, 2014, respectively, and $0.1 million and $0.2 million during the three and six months ended June 30, 2013, respectively. Amortization for the office equipment purchased on a capital lease entered into in April 2013 was $5,000 and $11,000 during the three and six months ended June 30, 2014, respectively, and $5,000 during both of the three and six months ended June 30, 2013.

Prepaid Expenses and Other Current and Non-current Assets (in thousands):

	June 30, 2014	December 31, 2013
Prepaid expenses	$ 552	$ 349
Note receivable from related party	—	100
Other	—	—
Prepaid expenses and other current assets	$ 552	$ 449

As of December 31, 2013, other non-current assets consisted of two-thirds of the security deposit on the Company's operating lease for its headquarters in Menlo Park, California of $0.1 million. As of June 30, 2014, other non-current assets consisted of deferred offering costs of $2.1 million and two-thirds of the security deposit on the Company's operating lease for its headquarters of $0.1 million.

Other Current Liabilities (in thousands):

	June 30, 2014	December 31, 2013
Manufacturing expenses	$ 324	$ 213
Sales and use tax	229	104
Deferred rent	114	115
Deferred gross margin	104	54
Facilities expenses	75	104
Other	96	155
	$ 942	$ 745

Interest and Other Income (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
Interest income	$ —	$ 1	$ 1	$ 4
Decrease in fair value of convertible preferred stock warrant	65	—	65	—
Other	—	—	—	79
	$ 65	$ 1	$ 66	$ 83

Interest and Other Expense (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
Interest expense	$ 24	$ 26	$ 50	$ 50
Increase in fair value of convertible preferred stock warrant	—	—	286	—
Increase in fair value of convertible preferred stock financing option	—	86	—	86
	$ 24	$ 112	$ 336	$ 136

4. Fair Value of Financial Instruments

The Company measures certain financial assets and liabilities at fair value on a recurring basis, including cash equivalents, the convertible preferred stock warrant liability and the convertible preferred stock financing option. Fair value is an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or a liability. A three-tier fair value hierarchy is established as a basis for considering such assumptions and for inputs used in the valuation methodologies in measuring fair value:

Level 1– Observable inputs such as quoted prices (unadjusted) for identical assets or liabilities in active markets.

Level 2– Include other inputs that are based upon quoted prices for similar instruments in active markets, quoted prices for identical or similar instruments in markets that are not active and model-based valuation techniques for which all significant inputs are observable in the market or can be derived from observable market data. Where applicable, these models project future cash flows and discount the future amounts to a present value using market-based observable inputs including interest rate curves, foreign exchange rates, and credit ratings.

Level 3– Unobservable inputs that are supported by little or no market activities, which would require the Company to develop its own assumptions.

The fair value hierarchy also requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value.

As of December 31, 2013 and June 30, 2014, cash equivalents were all categorized as Level 1 and primarily consisted of money market funds, and convertible preferred stock warrant liabilities and convertible preferred stock financing option were categorized as Level 3.

There were no transfers in and out of Level 1 and Level 2 fair value measurements during the year ended December 31, 2013, and the three and six months ended June 30, 2014.

Convertible Preferred Stock Warrants

The following table sets forth a summary of the changes in the estimated fair value of the Company's convertible preferred stock warrants, which represents financial instruments with valuations classified as Level 3. When a determination is made to classify a financial instrument within Level 3, the determination is based upon the significance of the unobservable inputs to the overall fair value measurement. However, Level 3 financial instruments typically include, in addition to the unobservable inputs, observable inputs (that is, components that are actively quoted and can be validated to external sources). Accordingly, the expense in the table below includes changes in fair value due in part to observable factors that are part of the Level 3 methodology (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
Beginning of the period	$ 494	$ 93	$ 237	$ 93
Issued	—	—	—	—
Exercised	—	—	(29)	—
Expired	—	—	—	—
Change in fair value	(65)	—	221	—
End of the period	$ 429	$ 93	$ 429	$ 93

The fair value of the convertible preferred stock warrants was determined using the option pricing method or the probability weighted expected return method using the following assumptions:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
Expected life (years)	2.0	3.0	2.0	3.0
Expected volatility	47%	58%	46%	58%
Risk-free interest rate	0.4%	0.4%	0.5%	0.4%
Dividend yield	0.0%	0.0%	0.0%	0.0%

Series D Convertible Preferred Stock Financing Option

The Series D convertible preferred stock contained a provision that obligated the investors to purchase additional shares ("convertible preferred stock financing option") at the same price as the initial closing upon notification by the Company that it had achieved an annualized revenue rate of at least $16.0 million over a trailing three month period. This convertible preferred stock financing option to purchase Series D convertible preferred stock in the future tranche was considered to be a freestanding financial instrument for accounting purposes. Therefore, in February 2013, the Company recorded a financing liability of $0.9 million representing the fair value of this convertible preferred stock financing option at the time of issuance. In October 2013, shortly after achieving the annualized revenue rate, the Company issued the additional 1,369,008 shares of Series D convertible preferred stock to the investors for net proceeds of $9.4 million. Since the convertible preferred stock financing option expired in October 2013 as a result of the issuance of Series D convertible preferred stock, the carrying and fair value of the convertible preferred stock financing option of $1.1 million in October 2013 was reclassified from liability to Series D convertible preferred stock. The Company recorded total charges related to the change in fair value during the year ended December 31, 2013 of $0.2 million related to this financing option liability.

The following table sets forth a summary of the changes in the estimated fair value of the Company's convertible preferred stock financing option, which represents financial instruments with valuations classified as Level 3 (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
Beginning of the period	$ —	$ 885	$ —	$ —
Issued	—	—	—	885
Exercised	—	—	—	—
Expired	—	—	—	—
Change in fair value	—	86	—	86
End of the period	$ —	$ 971	$ —	$ 971

The fair value of the convertible preferred stock financing liability was determined using the present value methodology with the following assumptions which are categorized as Level 3:

	February 2013	June 2013
Total consideration per share	$ 1.72	$1.72
Additional investment per share	1.72	1.72
Discount rate	20.0%	20.0%
Probability of achievement	95.0%	95.0%
Years until milestone achieved	0.5	0.6

5. Notes Receivable from Related Parties

In April 2013, options held by the President and Chief Executive Officer, Ms. Earnhardt, a related party, were modified to permit exercise with promissory notes of up to $0.5 million. The promissory notes were issued in May 2013 for $0.5 million. Under the terms of the notes, one quarter of the principal and interest was to be forgiven on each anniversary date of the note as long as Ms. Earnhardt remained the Company's Chief Executive Officer. In addition, the entire principal and interest of the notes was to be forgiven on the earlier of an initial public offering or the closing of a liquidation event (as defined in the certificate of incorporation) where total proceeds payable to the Company or its stockholders is greater than $200.0 million. The Company had the option to accelerate the maturity date if, at the Company's reasonable discretion, such acceleration may be necessary due to any applicable law, rule or regulation, including, without limitation, the Sarbanes-Oxley Act of 2002. The entire principal amount and all accrued and unpaid interest of the loan was forgiven in full in June 2014.The full recourse promissory notes were secured by a pledge of the exercised shares.

In January 2007, the Company loaned amounts to its Chief Operation Officer, Mr. Kaufman, a related party in connection with the commencement of Mr. Kaufman's employment with the Company. The loan was evidenced by a promissory note for $0.3 million. The note bore interest at the applicable federal rate and interest was determined in accordance with Section 7872 of the Internal Revenue Code and had been reflected as income to the employee. Pursuant to the terms of the promissory note, provided Mr. Kaufman remained a continuous, full-time employee of the Company, repayment of the notes was to begin after the third year of employment when 50% of Mr. Kaufman's annual bonus would have been applied to the loan balance until the loan was paid in full. The note matures and become immediately due and payable within 30 days following the date on which Mr. Kaufman ceases, voluntarily or involuntarily, to be employed by the Company. No payment was received in the year ended December 31, 2011, since the Company did not pay an annual bonus in that year. In February 2011, the Company agreed to forgive Mr. Kaufman's loan over three years, provided Mr. Kaufman remained employed by the Company, with $0.1 million forgiven in January 2012, $0.1 million in January 2013 and $0.1 million in January 2014. The notes were secured by any stock and options Mr. Kaufman held in the Company. The note receivable balance outstanding at December 31, 2013 was $0.1 million. Mr. Kaufman's note was fully forgiven in January 2014.

6. Loan and Security Agreement

In August 2013, the Company entered into a loan and security agreement ("Loan Agreement") with Silicon Valley Bank ("SVB") for a total commitment of $12.0 million. The commitment consists of an $8.0 million growth capital facility and a $4.0 million revolving accounts receivable line of credit.

The $8.0 million growth capital facility consists of two $4.0 million tranches. The first $4.0 million tranche was available immediately upon execution of the Loan Agreement and will continue to be available until October 31, 2014. The second $4.0 million tranche was contingent upon the Company achieving a trailing three-month revenue of at least $7.0 million. The Company achieved that condition as of January 31, 2014, and therefore the second tranche will be available until March 31, 2015. Payment under both tranches will be interest-only until March 31, 2015, at which time the outstanding balance will convert to a 30-month fully amortizing loan. The interest rate will be fixed at the time of advance and will be the greater of 3.65% or the three-year U.S. Treasury note plus 3%. At the end of the amortization period, the Company will make a final payment of 3.9% of the advanced amounts. There is a prepayment penalty of 2% of the prepaid principal during the first year, 1% during the second year and no prepayment penalty during the third year.

In addition, the Company issued a warrant to SVB to purchase up to 20,313 shares of the Company's Series D convertible preferred stock for an aggregate exercise price of 0.5% of the total growth capital facility commitment, or $40,000. As of June 30, 2014, this warrant was exercisable for 5,803 shares of the Company's Series D convertible preferred stock at an exercise price of $6.89 per share as of December 31, 2013, and June 30, 2014. Following any draw-downs under the growth capital facility, the warrant will become exercisable for additional shares of Series D convertible preferred stock equal to 1.25% of the advanced amounts under tranche one and two divided by $6.89. The initial value of the warrants issued was $10,000 and has been recognized as convertible preferred stock warrant liability and interest expense. In connection with the IPO, the warrants to purchase convertible preferred stock were converted to warrants to purchase common stock and any additional warrants that become exercisable under the terms of the Loan Agreement will be exercisable for common stock.

The $4.0 million revolving accounts receivable line of credit will expire in August 2016. Advances will be made for up to 80% of eligible accounts receivable. An annual loan fee of 0.75% will be paid at the beginning of each of the three years. The interest will be the greater of 4.25% or SVB Prime Rate plus 0.25%.

As of June 30, 2014, the Company had not received any advances under the Loan Agreement.

7. Equipment Loans

In September 2012, the Company entered into an equipment loan with an aggregate principal amount of $2.0 million, all of which was drawn down in December 2012. Payments were made in monthly installments over a 36-month period with an annual interest rate of 5.1%. A total of $14,000 and $30,000 was recorded as interest expense during the three and six months ended June 30, 2014, respectively, and $22,000 and $46,000 during the three and six months ended June 30, 2013, respectively. The amounts outstanding under this loan at December 31, 2013 and June 30, 2014, were $1.4 million and $1.0 million, respectively. In August 2014, the amount outstanding under this equipment loan was repaid.

In April 2013, the Company entered into a capital lease for a principal amount of $0.1 million. Payments will be made in monthly installments over a 38-month period with an interest rate of 14.88%. A total of $3,000 and $6,000 was recorded as interest expense during the three and six months ended June 30, 2014, respectively, and $4,000 during both of the three and six months ended June 30, 2013. The amounts outstanding under this loan at December 31, 2013 and June 30, 2014, were $87,000 and $72,000, respectively.

At December 31, 2013 and June 30, 2014, future minimum payments under these equipment loans are as follows (in thousands):

Year Ending December 31,	June 30, 2014	December 31, 2013
2014 (remaining)	$ 380	$ 761
2015	761	761
2016	21	21
Thereafter	—	—
Total minimum payments	1,162	1,543
Less: amount representing interest	(54)	(91)
Present value of future payments	1,108	1,452
Less: current portion	(715)	(696)
Non-current portion	$ 393	$ 756

8. Convertible Preferred Stock Warrant Liability

As of December 31, 2013 and June 30, 2014, the following warrants to purchase shares of convertible preferred stock were outstanding and exercisable (in thousands, except share and per share data):

Dates					Shares Outstanding at			Fair Value at	
Issuance	Expiration	In Connection With	Series	Exercise Price	June 30, 2014	December 31, 2013	Initial Value	June 30, 2014	December 31, 2013
Mar 2007	Mar 2014	Equipment loan	A	$ 3.68	—	4,076	$ 4	$ —	$ 17
Nov 2007	Nov 2017	Venture loan	A	$ 3.68	47,554	47,554	63	394	200
Aug 2013	Aug 2023	Loan Agreement	D	$ 6.89	5,803	5,803	10	35	20
					53,357	57,433		$ 429	$ 237

During the six months ended June 30, 2014, warrants to purchase 4,076 shares of Series A convertible preferred stock were exercised though a cashless exercise provision. Net shares of 2,431 were issued and the remaining 1,645 shares were withheld for the exercise price. During the six months ended June 30, 2013, warrants to purchase 22,418 shares of Series A convertible preferred stock were exercised at a price of $3.68 per share.

In connection with the execution of the Loan Agreement, warrants were issued to purchase the Company's Series D convertible preferred stock. The warrants were initially exercisable for 5,803 shares of Series D convertible preferred stock at an exercise price of $6.89 per share. Alternatively, the bank has the option to exercise the warrants to purchase shares of the class of equity sold to investors in a future round of equity financing with proceeds of at least $5.0 million. The exercise price would be the price paid by the lead investor in the new financing and the number of shares exercisable would be based on an aggregate exercise price of $40,000, representing 0.5% of the total growth capital facility. This represented a warrant for 5,803 shares at an exercise price of $6.89 per share as of December 31, 2013, and June 30, 2014. The warrants expire in August 2023 or upon the occurrence of an acquisition of the Company in exchange for cash or marketable securities. Following any draw-downs under the growth capital facility, the warrant would become exercisable for additional shares of Series D convertible preferred stock equal to 1.25% of the advanced amounts under tranche one and two divided by $6.89.

In connection with the IPO, the warrants for convertible preferred stock were converted to warrants for common stock and any additional warrants that become exercisable under the terms of the Loan Agreement will be for common stock.

9. Convertible Preferred Stock

A summary of the Company's convertible preferred stock is as follows:

	June 30, 2014			December 31, 2013		
Series	Shares Authorized	Shares Issued and Outstanding	Carrying Value (in thousands)	Shares Authorized	Shares Issued and Outstanding	Carrying Value (in thousands)
A	2,796,259	2,747,050	$ 10,016	2,796,259	2,744,619	$ 9,987
B	3,249,662	3,249,657	19,894	3,249,662	3,249,657	19,894
C	5,311,401	5,311,395	30,521	5,311,401	5,311,395	30,521
D	4,550,000	4,395,773	30,358	4,550,000	4,395,773	30,358
	15,907,322	15,703,875	$ 90,789	15,907,322	15,701,444	$ 90,760

Series D Convertible Preferred Stock

In February 2013, the Company completed the initial closing of the Series D convertible preferred stock financings. The total net cash proceeds from this initial closing totaled $18.2 million and 2,656,636 shares of Series D convertible preferred stock were issued. In March 2013, the Company completed an additional closing of the Series D convertible preferred stock financings. The total net cash proceeds from this additional closing totaled $2.5 million and 370,129 shares of Series D convertible preferred stock were issued. The March 2013 closing included 72,548 shares purchased by certain employees of the Company for $0.5 million.

The Series D convertible preferred stock financing contained a provision that obligated the investors to purchase additional shares ("convertible preferred stock financing option") at the same price as the initial closing upon notification by the Company that it had achieved an annualized revenue rate of at least $16.0 million over a trailing three-month period. This convertible preferred stock financing option to purchase Series D convertible preferred stock in the future tranche was considered to be a freestanding financial instrument for accounting purposes. Therefore, in February 2013, the Company recorded a financing liability of $0.9 million representing the fair value of this convertible preferred stock financing option at the time of issuance. In October 2013, shortly after

achieving the annualized revenue rate, the Company issued the additional 1,369,008 shares of Series D convertible preferred stock to the investors for net proceeds of $9.4 million. Since the convertible preferred stock financing option expired in October 2013 as a result of the issuance of Series D convertible preferred stock, the carrying and fair value of the convertible preferred stock financing option of $1.1 million in October 2013 was reclassified from liability to Series D convertible preferred stock. The Company recorded total charges related to the change in fair value during the year ended December 31, 2013 of $0.2 million related to this financing option liability.

10. Stockholder's Equity

2013 Equity Incentive Plan

Under the 2013 Equity Incentive Plan (the "2013 Plan") approved by the Company's Board of Directors in September 2013, 574,817 shares of common stock have been reserved for the issuance of incentive stock options ("ISOs"), non-statutory stock options ("NSOs"), stock bonuses and rights to acquire restricted stock to employees, officers, directors and consultants of the Company as of June 30, 2014. In June 2014, the Company authorized an additional 149,088 shares. ISOs and NSOs may be granted with exercise prices at no less than 100% and 85%, respectively, of the fair value of the common stock on the date of grant. Options granted to a 10% stockholder shall be at no less than 110% of the fair value and ISO stock option grants to such 10% stockholders expire five years from the date of grant. ISOs granted under the 2013 Plan generally vest 25% after the completion of 12 months of service and the balance vests in equal monthly installments over the next 36 months of service and expire 10 years from the grant date, unless subject to provisions regarding 10% stockholders. NSOs vest per the specific agreement and expire 10 years from the date of grant. There were 10,000 options issued with 100% of the shares vested as of the date of grant during the three and six months ended June 30, 2014 and no options issued with 100% of the shares vested as of the date of grant during the three and six months ended June 30, 2013. New shares are issued upon exercise of options under the stock plan.

The 2013 Plan is the successor to the 2003 Equity Incentive Plan ("2003 Plan") which expired in September 2013. Options available for grant under the 2003 Plan of 425,729 were incorporated into the 2013 Plan. Options outstanding under the 2003 Plan will be returned to the 2013 Plan upon forfeiture.

A summary of the Company's stock option activity and related information is as follows (options in thousands):

	Six Months Ended June 30, 2014	
	Options	Price
Outstanding, beginning of period	1,928	$ 1.08
Granted	466	10.03
Exercised	(111)	0.84
Forfeited	(59)	1.12
Expired	—	—
Outstanding, end of period	2,224	2.96
Vested and expected to vest	2,023	2.93
Exercisable	1,492	2.29

As of December 31, 2013 and June 30, 2014, the aggregate pre-tax intrinsic value of options outstanding and exercisable was $4.2 million and $13.2 million, respectively, and options outstanding were $6.1 million and $18.2 million, respectively. The aggregate pre-tax intrinsic value of options exercised was $0.9 million and $0.2 million during the six months ended June 30, 2014 and 2013, respectively. The aggregate pre-tax intrinsic value was calculated as the difference between the exercise prices of the underlying options and the fair market value of the common stock on the date of exercise. The total cash received upon the exercise of options was $0.1 million and $0.5 million during the six months ended June 30, 2014 and 2013, respectively.

Early Exercise of Stock Options

Stock options granted under the Plan may provide option holders the right to elect to exercise unvested options in exchange for restricted common stock. During the year ended December 31, 2013, employees exercised options with 69,037 unvested shares. As of December 31, 2013 and June 30, 2014, 53,796 and 41,145 shares, respectively, remained subject to a repurchase right held by the Company at the original issuance price in the event the optionees' service is voluntarily or involuntarily terminated. As of December 31, 2013 and June 30, 2014, the related liability was $31,000 and $24,000, respectively.

11. Stock-Based Compensation Expense

Total stock-based compensation expense recognized, before taxes, during the three and six months ended June 30, 2014 and 2013, are as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
Cost of sales	$ 13	$ 5	$ 22	$ 8
Sales and marketing	93	22	138	33
General and administrative	243	38	342	52
Research and development	38	27	67	37
	$ 387	$ 92	$ 569	$ 130

The amount of unearned stock-based compensation currently estimated to be expensed from now through the year 2018 related to unvested employee stock-based payment awards as of December 31, 2013 and June 30, 2014 is $1.5 million and $3.0 million, respectively. The weighted average period over which the unearned stock-based compensation is expected to be recognized as of December 31, 2013 and June 30, 2014, is 3.2 years and 3.6 years, respectively. If there are any modifications or cancellations of the underlying unvested securities, the Company may be required to accelerate, increase or cancel any remaining unearned stock-based compensation expense. Future stock-based compensation expense and unearned stock-based compensation will increase to the extent that the Company grants additional share-based payments.

The Company estimates the fair value of stock-based compensation on the date of grant using the Black-Scholes option-pricing model. The Black-Scholes model determines the fair value of stock-based payment awards based on the fair market value of the Company's common stock on the date of grant and is affected by assumptions regarding a number of highly complex and subjective variables. These variables include, but are not limited to, the fair value of the Company's common stock, volatility over the expected term of the awards and actual and projected employee stock option exercise behaviors. The Company has opted to use the "simplified method" for estimating the expected term of options, whereby the expected term equals the arithmetic average of the vesting term and the original contractual term of the option. Due to the Company's limited operating history and a lack of company specific historical and implied volatility data, the Company has based its estimate of expected volatility on the historical volatility of a group of similar companies that are publicly traded. When selecting these public companies on which it has based its expected stock price volatility, the Company generally selected companies with comparable characteristics to it, including enterprise value, stages of clinical development, risk profiles, position within the industry and with historical share price information sufficient to meet the expected life of the stock-based awards. The historical volatility data was computed using the daily closing prices for the selected companies' shares during the equivalent period of the calculated expected term of the share-based payments. The Company will continue to analyze the historical stock price volatility and expected term assumptions as more historical data for the Company's common stock becomes available. The risk-free rate assumption is based on the U.S. Treasury instruments with maturities similar to the expected term of the Company's stock options. The expected dividend assumption is based on the Company's history of not paying dividends and its expectation that it will not declare dividends for the foreseeable future.

As stock-based compensation expense recognized in the financial statements is based on awards ultimately expected to vest, it has been reduced for estimated forfeitures. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from estimates. Forfeitures are estimated based on estimated future employee turnover and historical experience.

The fair value of the options granted to employees or directors during the three and six months ended June 30, 2014 and 2013, was estimated as of the grant date using the Black-Scholes model assuming the weighted average assumptions listed in the following table:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
Expected life (years)	6.0	6.0	6.0	6.0
Expected volatility	58%	67%	59%	67%
Risk-free interest rate	2.0%	1.5%	2.0%	1.5%
Dividend yield	0.0%	0.0%	0.0%	0.0%
Expected forfeitures	5%	5%	5%	5%
Weighted average fair value	$ 6.16	$ 0.73	$ 5.60	$ 0.73

Option Modification

In April 2013, options held by the President and Chief Executive Officer, Ms. Earnhardt, a related party, were modified to permit exercise with promissory notes of up to $0.5 million. Under the terms of the notes, one quarter of the principal and interest was to be forgiven on each anniversary date of the note as long as Ms. Earnhardt remains the Company's Chief Executive Officer. In addition, the entire principal and interest of the notes was to be forgiven on the earlier of an initial public offering or the closing of a liquidation event (as defined in the certificate of incorporation) in each case where total proceeds payable to the Company or its stockholders is greater than $200.0 million. The Company had the option to accelerate the maturity date if, at the Company's reasonable discretion, such acceleration may be necessary due to any applicable law, rule or regulation, including, without limitation, the Sarbanes-Oxley Act of 2002. The economic effect of the modification was equivalent to converting options to purchase 0.6 million shares to a grant of restricted stock with four-year vesting and a contingent vesting acceleration provision. The incremental cost of the modification was $0.3 million, of which $19,000 and $31,000 was recognized during three and six months ended June 30, 2014, respectively, and $8,000 was recognized during both the three and six months ended June 30, 2013.

The entire principal amount and all accrued and unpaid interest of the loan was forgiven in full in June 2014. In connection with the forgiveness of the note, the unamortized modification cost relating to the vested options of $0.2 million was immediately recognized. The remaining unamortized modification cost of $0.1 million will be amortized over the remaining vesting period.

Performance-Based Options

Options issued in February 2011, included grants to certain employees totaling 289,253 shares that contained vesting conditions contingent on the achievement of certain milestones. Assuming continued service by the employee, the vesting would begin on the date both milestones were achieved and vest monthly thereafter over the following four years. The Company determined that it was probable that both milestones would be achieved and therefore began recording stock-based compensation expense related to these options in the year ended December 31, 2011. The milestones were achieved by the year ended December 31, 2013, and therefore began vesting accordingly. Stock-based compensation expense totaling $4,000 and $10,000 was recorded during the three and six months ended June 30, 2014, respectively, and $7,000 and $15,000 during the three and six months ended June 30, 2013, respectively.

Options issued in April 2013, included grants to certain employees totaling 363,000 shares that contained vesting conditions contingent on the achievement of certain milestones. Assuming continued service by the employee, the vesting would begin on the date both milestones were achieved and vest monthly over the following four years. The Company determined it was probable that both milestones would be achieved and therefore began recording stock-based compensation expense related to these options in the year ended December 31, 2013. The milestones were achieved by the year ended December 31, 2013, and therefore began vesting accordingly. Stock-based compensation expense totaling $22,000 and $50,000 were recorded during the three and six months ended June 30, 2014, respectively, and $22,000 during both the three and six months ended June 30, 2013, respectively.

Options Issued to Consultants

In September 2013, non-statutory options were issued to non-employees to purchase 5,000 shares of common stock for current and future services at weighted-average exercise prices of $1.20 per share, respectively. There were no options issued to non-employees during the three and six months ended June 30, 2014. The options were valued using the Black-Scholes model based on the following weighted average assumptions:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
Expected life (years)	9.0	9.0	9.0	9.0
Expected volatility	58%	66%	63%	66%
Risk-free interest rate	2.6%	2.3%	2.7%	2.1%
Dividend yield	0.0%	0.0%	0.0%	0.0%

The fair value of these options is expensed over the vesting period, which ranges from five months to three years. Stock-based compensation expense was $13,000 and $30,000 during the three and six months ended June 30, 2014, respectively, and $1,000 and $3,000 during the three and six months ended June 30, 2013, respectively, related to consultants was charged to expense in the statements of operations.

12. Net Loss per Share

Basic net loss per share is computed by dividing the net loss by the weighted average number of shares of common stock outstanding during the period. Diluted net loss per share is computed by dividing the net loss by the weighted average number of shares of common stock and dilutive potential shares of common stock outstanding during the period. Because the Company has reported a net loss for all periods presented, diluted net loss per share is the same as basic net loss per share for those periods as all potentially dilutive shares consisting of convertible preferred stock, stock options and warrants were antidilutive in those periods.

The Company allocates no loss to participating securities because they have no contractual obligation to share in the losses of the Company. The shares of the Company's convertible preferred stock participate in any dividends declared by the Company and are therefore considered to be participating securities.

Net loss per share was determined as follows (in thousands, except per share amounts):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
Net loss	$(4,382)	$(4,885)	$(8,791)	$(9,638)
Weighted average common stock outstanding	1,860	1,323	1,817	1,182
Net loss per share, basic and diluted	$ (2.36)	$ (3.69)	$ (4.84)	$ (8.15)

The following potentially dilutive securities outstanding have been excluded from the computations of diluted weighted average shares outstanding because such securities have an antidilutive impact due to losses reported, in common stock equivalent shares (in thousands):

	June 30,	
	2014	2013
Convertible preferred stock outstanding	15,704	14,332
Convertible preferred stock warrants	53	51
Common stock options	2,224	1,862
	17,981	16,245

13. Commitments and Contingencies

Contingencies

In the normal course of business, the Company enters into contracts and agreements that contain a variety of representations and warranties and provide for general indemnifications. The Company's exposure under these agreements is unknown because it involves claims that may be made against the Company in the future, but have not yet been made. The Company accrues a liability for such matters when it is probable that future expenditures will be made and such expenditures can be reasonably estimated.

Indemnification

The Company's amended and restated certificate of incorporation contains provisions limiting the liability of directors, and its amended and restated bylaws provide that the Company will indemnify each of its directors to the fullest extent permitted under Delaware law. The Company's amended and restated certificate of incorporation and amended and restated bylaws also provide its board of directors with discretion to indemnify its officers and employees when determined appropriate by the board. In addition, the Company has entered and expects to continue to enter into agreements to indemnify its directors and executive officers.

Litigation

The Company is not currently a party to any material legal proceedings. The Company may at times be involved in litigation and other legal claims in the ordinary course of business. When appropriate in the Company's estimation, it may record reserves in its financial statements for pending litigation and other claims.

Building Lease

As of December 31, 2013 and June 30, 2014, the Company has one leased facility under an operating lease agreement. Rental payments on operating leases are charged to expense on a straight-line basis over the period of the lease. The Company entered into this 36-month lease in March 2012, effective June 1, 2012, for a facility with larger production and office space. The lease agreement requires the Company to pay executory costs such as real estate taxes, insurance and repairs, and includes a renewal provision allowing the Company to extend this lease for an additional three years at 95% of the then-current fair market rental rate.

Future minimum annual operating lease payments are as follows (in thousands):

Year Ending December 31,	June 30, 2014	December 31, 2013
2014(remaining)	$ 468	$ 928
2015	390	390
Thereafter	—	—
	858	1,318

Rent expense was $0.3 million and $0.6 million during the three and six months ended June 30, 2014, respectively, and $0.5 million and $0.8 million during the three and six months ended June 30, 2013, respectively.

Purchase Commitments

The Company had commitments to suppliers for purchases totaling $0.5 million and $0.8 million as of December 31, 2013 and June 30, 2014, respectively.

14. Related Parties

In April 2013, options held by the President and Chief Executive Officer, Ms. Earnhardt, a related party, were modified to permit exercise with promissory notes of up to $0.5 million. The promissory notes were issued in May 2013 for $0.5 million. Under the terms of the notes, one quarter of the principal and interest was to be forgiven on each anniversary date of the note as long as Ms. Earnhardt remains the Company's Chief Executive Officer. In addition, the entire principal and interest of the notes was to be forgiven on the earlier of an initial public offering or the closing of a liquidation event (as defined in the certificate of incorporation) in each case where total proceeds payable to the Company or its stockholders is greater than $200.0 million. The Company had the option to accelerate the maturity date if, at the Company's reasonable discretion, such acceleration may be necessary due to any applicable law, rule or regulation, including, without limitation, the Sarbanes-Oxley Act of 2002. The entire principal amount and all accrued and unpaid interest of the loan was forgiven in full in June 2014. The full recourse promissory notes were secured by a pledge of the exercised shares.

In January 2007, the Company loaned amounts to its Chief Operation Officer, Mr. Kaufman, a related party in connection with the commencement of Mr. Kaufman's employment with the Company. The loan was evidenced by a promissory note for $0.3 million. The note bore interest at the applicable federal rate and interest was determined in accordance with Section 7872 of the Internal Revenue Code and had been reflected as income to the employee. Pursuant to the terms of the promissory note, provided Mr. Kaufman remained a continuous, full-time employee of the Company, repayment of the notes was to begin after the third year of employment when 50% of Mr. Kaufman's annual bonus would have been applied to the loan balance until the loan was paid in full. The note matures and becomes immediately due and payable within 30 days following the date on which Mr. Kaufman ceases, voluntarily or involuntarily, to be employed by the Company. No payment was received in the year ended December 31, 2011, since the Company did not pay an annual bonus in that year. In February 2011, the Company agreed to forgive Mr. Kaufman's loan over three years, provided Mr. Kaufman remained employed by the Company, with $0.1 million forgiven in January 2012, $0.1 million in January 2013 and $0.1 million in January 2014. The notes are secured by any stock and options Mr. Kaufman holds in the Company. The note receivable balance outstanding at December 31, 2013 was $0.1 million. Mr. Kaufman's note was fully forgiven in January 2014.

In March 2009, the Company purchased three sinus irrigation tool patents from Medilyfe Inc., a Canadian corporation. A member of the Company's Medical Advisory Board holds an executive-level position with Medilyfe Inc. The agreement called for a $40,000 payment upon execution of the agreement and an additional $35,000 upon the first anniversary of the agreement's effective date in addition to the issuance of a warrant to purchase 47,350 shares of the Company's common stock at $1.00 per share.

The warrant vested fully upon grant and will expire April 7, 2019. The value of the warrant was $30,000 determined using the Black-Scholes model. The cost of the patents is included in research and development expense, since substantial research and development efforts were required at the time of the payment of these amounts and there was no alternative future use of the technology rights. A $35,000 cash payment was made in 2012, since one additional patent claim was allowed by the U.S. Patent Office. The Company recorded $35,000 in research and development expense related to this agreement for the year ended December 31, 2012. An additional $80,000 cash payment will be due upon the first achievement of net sales of products incorporating this technology exceeding $1.0 million in a given calendar year. Such additional payment was not owed as of December 31, 2013 or June 30, 2014, since this technology is unrelated to the Company's current activities.

15. Subsequent Events

Initial Public Offering

In July 2014, the Company completed its IPO by issuing 5,750,000 shares of common stock, including 750,000 pursuant to the full exercise by the underwriters of their option to purchase these shares, at an offering price of $11.00 per share, for net proceeds of approximately $55.8 million, after deducting underwriting discounts and commissions of approximately $4.5 million and offering expenses of approximately $3.0 million. In connection with the IPO, the Company's outstanding shares of convertible preferred stock were automatically converted into 15,703,875 shares of common stock and warrants exercisable for convertible preferred stock were automatically converted into warrants exercisable for 53,357 shares of common stock, resulting in the reclassification of the related redeemable convertible preferred stock warrant liability of $0.4 million to additional paid-in capital.

1-for-4 reverse stock split

On July 11, 2014, the Board of Directors and stockholders approved, and the Company filed, an amended and restated certificate of incorporation effecting a 1-for-4 reverse stock split of common stock and all convertible preferred stock. The par value of the common and convertible preferred stock was not adjusted as a result of the reverse stock split. All issued and outstanding common stock, convertible preferred stock, warrants for preferred stock, and per share amounts contained in the financial statements have been retroactively adjusted to reflect this reverse stock split for all periods presented.

2014 Equity Incentive Plan

In July 2014, the Company's board of directors approved the 2014 Equity Incentive Plan ("2014 Plan"). The 2014 Plan became effective on the effective date of the IPO, at which time the Company ceased making awards under the 2013 Plan. Under the 2014 Plan, the Company may grant stock options, stock appreciation rights, restricted stock, restricted stock units and certain other awards to individuals who are employees, officers, directors or consultants of the Company. A total of 4,750,000 shares of common stock were initially reserved for issuance under the 2014 Plan. The number of shares of common stock reserved for issuance under the 2014 Plan will automatically increase on January 1 of each year, beginning on January 1, 2015, and continuing through and including January 1, 2024, by 3% of the total number of shares of our capital stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares determined by the Company's board of directors. The maximum number of shares that may be issued upon the exercise of ISOs under the 2014 Plan is 10.0 million.

2014 Employee Stock Purchase Plan

In July 2014, the Company's board of directors approved the 2014 Employee Stock Purchase Plan ("2014 ESPP"). The 2014 ESPP became effective on the effective date of the IPO. A total of 496,092 shares were initially reserved for issuance under the 2014 ESPP. Additionally, the number of shares of common stock reserved for issuance under the 2014 ESPP will increase automatically each year, beginning on January 1, 2015, and continuing through and including January 1, 2024, by the lesser of (1) 1% of the total number of shares of common stock outstanding on December 31 of the preceding calendar year; or (2) such lesser number as determined by the Company's board of directors.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion of our financial condition and results of operations contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Forward-looking statements include statements that may relate to our plans, objectives, goals, strategies, future events, future revenues or performance, capital expenditures, financing needs and other information that is not historical information. Forward-looking statements can often be identified by the use of terminology such as "subject to," "believe," "anticipate," "plan," "expect," "intend," "estimate," "project," "may," "will," "should," "would," "could," "can," the negatives thereof, variations thereon and similar expressions, or by discussions of strategy. All forward-looking statements are based upon our current expectations and various assumptions. These forward-looking statements involve risks and uncertainties that could cause our actual results to differ materially from those expressed or implied in our forward-looking statements. Such risks and uncertainties include, among others, those discussed in "Part II — Item 1A. Risk Factors" of this Quarterly Report on Form 10-Q as well as in our condensed financial statements, related notes, and the other information appearing elsewhere in this report and our other filings with the SEC. We do not intend, and undertake no obligation, to update any of our forward-looking statements after the date of this report to reflect actual results or future events or circumstances. Given these risks and uncertainties, readers are cautioned not to place undue reliance on such forward-looking statements. You should read the following Management's Discussion and Analysis of Financial Condition and Results of Operations in conjunction with the unaudited condensed financial statements and the related notes that appear elsewhere in this report, as well as our financial statements and related notes included in our final prospectus filed with the SEC pursuant to Rule 424(b) under the Securities Act on July 24, 2014.

When we refer to "we," "our," "us" or "Intersect ENT" in this Quarterly Report on Form 10-Q, we mean Intersect ENT, Inc., unless otherwise expressly stated or the context otherwise requires.

Overview

We are a commercial stage drug-device company committed to improving the quality of life for patients with ear, nose and throat conditions. We have developed a drug-eluting bioabsorbable implant technology that enables targeted and sustained release of therapeutic agents. This targeted drug delivery technology is designed to allow ear, nose and throat, or ENT, physicians to improve patient care. Our initial products, PROPEL and PROPEL mini, are the first and only drug-eluting implants approved by the U.S. Food and Drug Administration, or FDA, for use in patients with chronic sinusitis. Inserted by a physician during ethmoid sinus surgery, the self-expanding implants are designed to conform to and hold open the surgically enlarged sinus, while gradually releasing an anti-inflammatory steroid over a period of 30 days, before being fully absorbed into the body. Use of our PROPEL implants is clinically proven to improve surgical outcomes by maintaining the open pathways created in surgery and reducing the need for oral steroids and additional surgical procedures. In addition, we are using our drug-eluting bioabsorbable implant technology to develop new, less-invasive and more cost-effective treatment options for the management of chronic sinusitis in the physician office setting to provide benefits for patients, physicians and payors. Any new products we develop, or changes that we make in the therapeutic agent used in PROPEL or PROPEL mini, will require FDA approval prior to commercialization in the United States.

Our two commercial products, PROPEL and PROPEL mini, are designed to improve the outcomes of sinus surgery by reducing postoperative inflammation and scarring, both from the underlying condition as well as the surgery. Prior to obtaining FDA approval, we devoted substantially all of our resources to the design and clinical development of our steroid-eluting implants. Following approval, we commenced a limited commercial launch of PROPEL in the United States in September 2011, with four territory managers. In November 2012, we received FDA approval and commenced a limited commercial launch of PROPEL mini. In the first half of 2013 we began scaling our U.S. direct commercial presence. In addition to PROPEL and PROPEL mini, we are developing additional products using our drug-eluting bioabsorbable implant technology that are specifically designed to treat chronic sinusitis in the physician office setting during a routine visit.

Our direct sales force engages in sales efforts and promotional activities focused on ENT physicians. We increased the number of employees in our sales, marketing and reimbursement organizations from 21 as of December 31, 2012, to 72 as of June 30, 2014, and we expect to continue to expand this infrastructure to further penetrate the chronic sinusitis market.

In July 2014, we completed our initial public offering, or IPO, by issuing 5,750,000 shares of common stock at an offering price of $11.00 per share, for net proceeds of approximately $55.8 million, after deducting underwriting discounts and commissions and offering expense.

Components of Our Results of Operations

Revenue

All of our revenue is currently derived from sales of PROPEL and PROPEL mini in the United States. We expect our revenue to increase as we expand our sales, marketing and reimbursement infrastructure and increase awareness of our products. We also expect our revenue to fluctuate from quarter to quarter due to a variety of factors. In the first quarter, our results can be impacted by adverse weather and by resetting of annual patient healthcare insurance plan deductibles, both of which may cause patients to delay elective procedures such as functional endoscopic sinus surgery, or FESS. In the second quarter, demand may be impacted by the seasonal nature of allergies and the resultant onset of sinus-related symptoms. In the third quarter, the number of FESS procedures nationwide is historically lower than other quarters throughout the year, which we believe is attributable to the summer vacations of ENT physicians and their patients. In the fourth quarter, demand may be impacted by the onset of the cold and flu season and related symptoms, as well as the desire of patients to spend their remaining balances in flexible-spending accounts or because they have met their annual deductibles under their health insurance plans.

Our currently approved products are commonly treated as general supplies utilized in sinus surgery and are paid for as part of the FESS procedure. We believe that establishment of reimbursement codes specific to the use of drug-eluting implants for chronic sinusitis is an important factor in expanding access to our products, especially in the physician office setting.

All of our revenue is based in the U.S. and no single customer accounted for more than 10% of our revenue during the three and six months ended June 30, 2014 and 2013.

Cost of Sales and Gross Profit

PROPEL and PROPEL mini are manufactured at our facility in Menlo Park, California. Cost of sales consists primarily of manufacturing overhead costs, material costs and direct labor. A significant portion of our cost of sales currently consists of manufacturing overhead costs. These overhead costs include the cost of quality assurance, material procurement, inventory control, facilities, equipment and operations supervision and management. We expect overhead costs as a percentage of revenue to become less significant as our production volume increases. Cost of sales also includes depreciation expense for production equipment and certain direct costs such as shipping costs. We expect cost of sales to increase in absolute dollars primarily as, and to the extent, our revenue grows.

We calculate gross margin as gross profit divided by revenue. Our gross margin has been and will continue to be affected by a variety of factors, primarily production volumes, manufacturing costs and product yields, and to a lesser extent the implementation of cost-reduction strategies. We expect our gross margin to increase over the long term as our production volume increases and as we spread the fixed portion of our manufacturing overhead costs over a larger number of units produced, thereby significantly reducing our per unit manufacturing costs. However, our gross margin will likely fluctuate from quarter to quarter.

Selling, General and Administrative Expenses

Selling, general and administrative, or SG&A, expenses consist primarily of compensation for personnel, including stock-based compensation, related to selling, marketing, business development, finance, information technology, and human resource functions. Other SG&A expenses include commissions, training, travel expenses, promotional activities, conferences, trade shows, professional services fees, audit fees, insurance costs and general corporate expenses including allocated facilities-related expenses. We expect SG&A expenses to continue to increase in absolute dollars for the foreseeable future as we expand our commercial infrastructure to both drive and support the anticipated growth in revenue and incur additional legal, accounting, insurance and other professional service fees associated with being a public company. However, for the foreseeable future we expect SG&A expenses to continue to decrease as a percentage of revenue.

Research and Development Expenses

Research and development, or R&D, expenses consist primarily of engineering, product development, clinical and regulatory affairs, consulting services, materials, depreciation and other costs associated with products and technologies in development. These expenses include employee and non-employee compensation, including stock-based compensation, supplies, materials, quality assurance expenses allocated to R&D programs, consulting, related travel expenses and facilities expenses. Clinical expenses include clinical trial design, clinical site reimbursement, data management and travel expenses, and the cost of manufacturing products for clinical trials. We expect R&D expenses to increase in absolute dollars for the foreseeable future as we continue to develop, enhance and commercialize new products and technologies. However, we expect R&D expenses as a percentage of revenue to vary over time depending on the level and timing of initiating new product development efforts as well as our clinical development activities.

Critical Accounting Policies and Estimates

Management’s discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of these financial statements requires us to make estimates and assumptions for the reported amounts of assets, liabilities, revenue, expenses and related disclosures. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions and any such differences may be material.

There have been no significant changes to our accounting policies during the three and six months ended June 30, 2014, as compared to the significant accounting policies described in our final prospectus (Registration No. 333-196974) filed with the SEC on July 24, 2014. We believe that the accounting policies discussed in that prospectus are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management’s judgments and estimates.

Recent Accounting Pronouncements

In June 2014, the Financial Accounting Standard Board, or FASB, issued Accounting Standards Update, or ASU, No. 2014-12, *Accounting for Share-Based Payments When the Terms of an Award Provide That a Performance Target Could Be Achieved after the Requisite Service Period*, or ASU 2014-12. ASU 2014-12 requires that a performance target that affects vesting of share-based payment awards and that could be achieved after the requisite service period be treated as a performance condition. Compensation cost should be recognized in the period in which it becomes probable that the performance target will be achieved and should represent the compensation cost attributable to the periods for which the requisite service has already been rendered. If the performance target becomes probable of being achieved before the end of the requisite service period, the remaining unrecognized compensation cost should be recognized prospectively over the remaining requisite service period. The total amount of compensation cost recognized during and after the requisite service period should reflect the number of awards that are expected to vest and should be adjusted to reflect those awards that ultimately vest. The requisite service period ends when the employee can cease rendering service and still be eligible to vest in the award if the performance target is achieved. ASU 2014-12 is effective for all entities for annual periods and interim periods within those annual periods beginning after December 15, 2015. Early adoption is permitted. An entity may apply the amendments in ASU 2014-12 either (i) prospectively to all awards granted or modified after the effective date or (ii) retrospectively to all awards with performance targets that are outstanding as of the beginning of the earliest annual period presented in the financial statements and to all new or modified awards thereafter. The adoption of ASU 2014-12 is not expected to have a material impact on our financial condition or results of operations.

In May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers* ("ASU 2014-09"), which requires an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers. ASU 2014-09 will replace most existing revenue recognition guidance in U.S. GAAP when it becomes effective. In doing so, companies will need to use more judgment and make more estimates than under current guidance. These may include identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligation. ASU 2014-09 is effective for all entities for annual reporting periods beginning after December 15, 2016, including interim periods within that reporting period. Early adoption is not permitted. The standard permits the use of either the retrospective or cumulative effect transition method. We are evaluating the effect that ASU 2014-09 will have on our financial statements and related disclosures.

Results of Operations

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
	(in thousands)			
Revenue	$ 8,565	$ 3,936	$16,062	$ 6,680
Cost of sales	2,320	2,202	4,680	4,151
Gross profit	6,245	1,734	11,382	2,529
Gross margin	*73%*	*44%*	*71%*	*38%*
Operating expenses:				
Selling, general and administrative	8,291	4,087	14,949	7,437
Research and development	2,377	2,421	4,954	4,677
Total operating expenses	10,668	6,508	19,903	12,114
Loss from operations	(4,423)	(4,774)	(8,521)	(9,585)
Interest and other income (expense), net	41	(111)	(270)	(53)
Net loss	$ (4,382)	$(4,885)	$ (8,791)	$ (9,638)

Comparison of the Three and Six Months Ended June 30, 2014 and 2013

Revenue

Revenue increased $4.7 million, or 118%, to $8.6 million during the three months ended June 30, 2014, compared to $3.9 million during the three months ended June 30, 2013. Revenue increased $9.4 million, or 140%, to $16.1 million during the six months ended June 30, 2014, compared to $6.7 million during the six months ended June 30, 2013. The growth in revenue was attributable to an increase in unit sales of PROPEL and PROPEL mini from 5,600 units to 12,000 units, or 114%, for the three months

ended June 30, 2014, compared to the three months ended June 30, 2013, respectively, and from 9,500 units to 22,800 units, or 140%, for the six months ended June 30, 2014, compared to the six months ended June 30, 2013, respectively. Our average selling price per unit was consistent for all periods presented. The increase in units was driven by an expansion of our sales, marketing and reimbursement organizations. In addition, PROPEL mini had minimal sales during the three and six months ended June 30, 2013, as compared to the three and six months ended June 30, 2014, as we continued its commercial introduction.

Cost of Sales and Gross Margin

Cost of sales increased $0.1 million, or 5%, to $2.3 million during the three months ended June 30, 2014, compared to $2.2 million during the three months ended June 30, 2013. Cost of sales increased $0.5 million, or 13%, to $4.7 million during the six months ended June 30, 2014, compared to $4.2 million during the six months ended June 30, 2013. The increase in cost of sales was primarily attributable to the growth in the number of PROPEL and PROPEL mini units sold, partially offset by the higher unit sales which allowed us to spread the fixed portion of our manufacturing overhead costs over more production units. In addition, the three and six months ended June 30, 2013, included a charge of $0.5 million related to a packaging issue and $0.1 million and $0.8 million, respectively, for expenses associated with establishing and qualifying our new manufacturing facility in Menlo Park, California. After qualification of the Menlo Park facility in June 2013, we closed our facility in Palo Alto, California.

Gross margin for the three months ended June 30, 2014, increased to 73%, compared to 44% for the three months ended June 30, 2013. Gross margin for the six months ended June 30, 2014, increased to 71%, compared to 38% for the six months ended June 30, 2013. The increase in gross margin was primarily due to the growth in unit sales which allowed us to spread the fixed portion of our manufacturing overhead costs over more production units, the impact of the qualification of our new facility and the charge related to the packaging issue. The fixed portion of our manufacturing overhead allows our costs of sales to grow at a slower rate than our revenue.

Selling, General and Administrative Expenses

SG&A expenses increased $4.2 million, or 103%, to $8.3 million during the three months ended June 30, 2014, compared to $4.1 million during the three months ended June 30, 2013. SG&A expenses increased $7.5 million, or 101%, to $14.9 million during the six months ended June 30, 2014, compared to $7.4 million during the six months ended June 30, 2013. The increase in SG&A expenses was primarily due to the build out of our infrastructure to support the commercialization of PROPEL and PROPEL mini. The primary driver of this increase was employee-related expenses of our sales, marketing and reimbursement organizations which increased $3.5 million for the three months ended June 30, 2014, compared to the three months ended June 30, 2013, and $6.4 million for the six months ended June 30, 2014, compared to the six months ended June 30, 2013, as we increased headcount to 72 as of June 30, 2014, compared to 34 at June 30, 2013. In addition, other SG&A expenses increased $0.7 million for the three months ended June 30, 2014, compared to the three months ended June 30, 2013, and $1.1 million for the six months ended June 30, 2014, compared to the six months ended June 30, 2013, primarily due to an increase in headcount and consulting fees.

Research and Development Expenses

R&D expenses were consistent at $2.4 million during both the three months ended June 30, 2014 and 2013. R&D expenses increased $0.3 million, or 6%, to $5.0 million during the six months ended June 30, 2014, compared to $4.7 million during the six months ended June 30, 2013. The increase in R&D expenses for the six month period was primarily due to an increase in clinical trial costs for the evaluation of our steroid-eluting implant for refractory disease for use in the physician office setting.

Other Income (Expense), Net

Other income (expense), net, increased $0.2 million to an income of $0.1 million during the three months ended June 30, 2014, compared to an expense of $0.1 million during the three months ended June 30, 2013. Other income (expense), net, decreased $0.2 million to an expense of $0.3 million during the six months ended June 30, 2014, compared to an expense of $0.1 million during the six months ended June 30, 2013. The changes in other income (expense), net was primarily attributable to fair value adjustment of the convertible preferred stock financing option in connection with our Series D convertible preferred stock financing and the fair value adjustment of the preferred stock warrants, which were accounted for as liabilities and marked-to-market at each reporting period.

Liquidity and Capital Resources

Overview

As of June 30, 2014, we had cash and cash equivalents of $2.7 million and an accumulated deficit of $87.1 million, compared to cash and cash equivalents of $12.3 million and an accumulated deficit of $78.3 million as of December 31, 2013. Our primary sources of capital prior to our IPO in July 2014 have been from private placements of convertible preferred securities and debt financing. To date, we have raised $91.4 million from private placements of convertible preferred securities from our investors. In August 2013, we entered into a loan and security agreement with Silicon Valley Bank for up to $12.0 million of debt financing consisting of an $8.0 million growth capital facility and a $4.0 million revolving accounts receivable line of credit. As of June 30, 2014, we had no outstanding amounts under the loan and security agreement. We entered into equipment loans totaling $2.1 million, of which $1.1 million was outstanding as of June 30, 2014. In August 2014, we repaid in full the amount outstanding under our $2.0 million equipment loan entered into in September 2012. The amount outstanding under this equipment loan at June 30, 2014 was $1.0 million.

In July 2014, we completed our IPO by issuing 5,750,000 shares of common stock at an offering price of $11.00 per share, for net proceeds of approximately $55.8 million, after deducting underwriting discounts and commissions and offering expenses.

Cash Flows

	Six Months Ended June 30,	
	2014	2013
	(in thousands)	
Net cash (used in) provided by:		
Operating activities	$(9,054)	$(10,443)
Investing activities	(246)	(196)
Financing activities	(249)	20,627
Net (decrease) increase in cash and cash equivalents	$(9,549)	$ 9,988

Net Cash Used in Operating Activities

During the six months ended June 30, 2014, net cash used in operating activities was $9.1 million, consisting primarily of a net loss of $8.8 million and an increase in net operating assets of $1.5 million, partially offset by non-cash charges of $1.2 million. The cash used in operations was primarily due to the ongoing commercialization of PROPEL and PROPEL mini. To support the commercialization of these products, we continued to expand our sales, marketing and reimbursement organizations and manufacturing supply chain. The increase in net operating assets was primarily due to increases in deferred offering costs, and inventory and accounts receivable to support the growth of our operations, partially offset by increases in accounts payable due to offering costs and accrued compensation due to increased headcount. The non-cash charges primarily consisted of stock-based compensation expense and the change in fair value of convertible preferred stock warrants accounted for as liabilities as the underlying value of our company increased with the expansion of our business.

During the six months ended June 30, 2013, net cash used in operating activities was $10.4 million, consisting primarily of a net loss of $9.6 million and an increase in net operating assets of $1.4 million, partially offset by non-cash charges of $0.6 million. The cash used in operations was primarily due to the ongoing commercialization of PROPEL and PROPEL mini. The increase in net operating assets was primarily due to increases in accounts receivable and inventory as we expanded our sales, marketing and reimbursement organizations and manufacturing supply chain and a decrease in accrued compensation as annual bonuses were paid. The non-cash charges primarily consisted of depreciation and amortization and the forgiveness of a related party loan. As of December 31, 2013 and June 30, 2014, 87% and 85%, respectively, of accounts receivable was less than 60 days old.

Net Cash (Used in) Provided by Investing Activities

During each of the six months ended June 30, 2013 and 2014, net cash used in investing activities was $0.2 million, consisting of purchases of property and equipment.

Net Cash (Used in) Provided by Financing Activities

During the six months ended June 30, 2014, net cash used in financing activities was $0.2 million, consisting of repayments related to the equipment financing arrangements. During the six months ended June 30, 2013, net cash provided by financing activities was $20.6 million, consisting primarily of net proceeds from the issuance of Series D convertible preferred stock.

Liquidity

We currently believe that our existing cash and cash equivalents and available debt financing arrangements as of June 30, 2014 together with the net proceeds from our IPO completed in July 2014 will be sufficient to meet our capital requirements and fund our operations for at least the next twelve months. If these sources are insufficient to satisfy our liquidity requirements, we may seek to sell additional equity or debt securities or obtain an additional credit facility. If we raise additional funds by issuing equity securities, our stockholders would experience dilution. Debt financing, if available, may involve covenants restricting our operations or our ability to incur additional debt. Any debt financing or additional equity that we raise may contain terms that are not favorable to us or our stockholders. Additional financing may not be available at all, or in amounts or on terms unacceptable to us. If we are unable to obtain additional financing, we may be required to delay the development, commercialization and marketing of our products.

Off-Balance Sheet Arrangements

As of December 31, 2013, and June 30, 2014, we were not a party to any off-balance sheet arrangements that have, or are reasonably likely to have, a current or future effect on our financial condition, changes in financial condition, revenue or expenses, results of operations, liquidity, capital expenditures or capital resources.

Contractual Obligations

Our future minimum contractual obligations as of December 31, 2013 were $1.8 million as reported in our final prospectus filed with the SEC on July 24, 2014. Our contractual obligations as of June 30, 2014, have not significantly changed from December 31, 2013.

Related Parties

For a description of our related party transactions, see Note 14 of our financial statements.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Risk

The risk associated with fluctuating interest rates is primarily limited to our cash equivalents which are carried at quoted market prices. We do not currently use or plan to use financial derivatives in our investment portfolio.

Credit Risk

As of December 31, 2013, and June 30, 2014, our cash and cash equivalents were maintained with one financial institution in the United States, and our current deposits are likely in excess of insured limits. We have reviewed the financial statements of this institution and believe it has sufficient assets and liquidity to conduct its operations in the ordinary course of business with little or no credit risk to us.

Our accounts receivable primarily relate to revenue from the sale of PROPEL and PROPEL mini to hospitals and ambulatory surgery centers in the United States. No single customer represented more than 10% of our accounts receivable as of December 31, 2013 and June 30, 2014.

Foreign Currency Risk

Our business is conducted in U.S. dollars. Any transactions that may be conducted in foreign currencies are not expected to have a material effect on our results of operations, financial position or cash flows.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Management, with the participation of our Chief Executive Officer and our Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of June 30, 2014. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of June 30, 2014, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the three months ended June 30, 2014 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

We are not currently a party to any material legal proceedings. We may at times be involved in litigation and other legal claims in the ordinary course of business. When appropriate in our estimation, we may record reserves in our financial statements for pending litigation and other claims.

ITEM 1A. RISK FACTORS

Investing in our common stock involves a high degree of risk. If any of the risks discussed in this report actually occur, they may materially harm our business, financial condition, operating results, cash flows or growth prospects. As a result, the market price of our common stock could decline, and you could lose all or part of your investment. Additional risks and uncertainties that are not yet identified or that we think are immaterial may also materially harm our business, financial condition, operating results, cash flows or growth prospects and could result in a complete loss of your investment.

Risks Related to Our Business

We have incurred significant operating losses since inception and may not be able to achieve profitability.

We have incurred net losses since our inception in 2003. For the year ended December 31, 2013, and for the six months ended June 30, 2014, we had net losses of $18.4 million and $8.8 million, respectively. As of June 30, 2014, we had an accumulated deficit of $87.1 million. To date, we have financed our operations primarily through private placements of our equity securities, certain debt-related financing arrangements and from sales of our approved products. We have devoted substantially all of our resources to research and development of our products, sales and marketing activities and clinical and regulatory initiatives to obtain approvals for our products. Our ability to generate sufficient revenue from our existing products or from any of our product candidates in development, and to transition to profitability and generate consistent positive cash flows is uncertain. We expect that our operating expenses will continue to increase as we continue to build our commercial infrastructure, develop, enhance and commercialize new products and incur additional operational and reporting costs associated with being a public company. As a result, we expect to continue to incur operating losses for the foreseeable future and may never achieve profitability.

All of our revenue is generated from our PROPEL and PROPEL mini steroid-eluting implants and we are completely dependent on the success of these products, which have a limited commercial history. If these products fail to gain widespread market acceptance, our business will suffer.

We started selling PROPEL in August 2011 and PROPEL mini in November 2012. We expect that sales of these products will account for substantially all of our revenue for the foreseeable future and therefore our ability to become profitable will depend upon the commercial success of these products. Because of their recent commercial introduction, PROPEL and PROPEL mini have limited product and brand recognition. We market these products primarily to ear, nose and throat, or ENT, physicians and believe they may be slow or fail to adopt our products for a variety of reasons, including, among others:

- lack of experience with our products;
- lack of availability of adequate coverage and reimbursement for hospitals, ambulatory surgery centers and physicians;
- lack of evidence supporting cost benefits or cost effectiveness of our products over existing alternatives;
- lack of clinical data supporting patient benefits beyond six months;
- perception that our products are unproven, investigational or experimental;
- liability risks generally associated with the use of new products and procedures; and
- training required to use new products.

If we are unable to effectively demonstrate to ENT physicians the benefits of our products when used during sinus surgery and our products fail to achieve market acceptance, our future revenue will be adversely impacted. In addition, we believe recommendations and support of our products by influential ENT physicians are essential for market acceptance and adoption. If we do not receive support from these influential ENT physicians, ENT physicians in general may not use our products and our future revenue will be harmed.

Because of the numerous risks and uncertainties associated with our commercialization efforts, we are unable to predict the extent to which we will continue to generate revenue from our products or the timing for when or the extent to which we will become profitable. Even if we do achieve profitability, we may not be able to sustain or increase profitability on an ongoing basis.

Pricing pressure from our hospital and ambulatory surgery center customers due to limited coverage and reimbursement for our products may impact our ability to sell our products at prices necessary to support our current business strategies.

Hospital and other healthcare provider customers, including ambulatory surgery center customers, that purchase our products typically bill various third-party payors to cover all or a portion of the costs and fees associated with the sinus surgery procedures in which our products are used and bill patients for any deductibles or co-payments. Because there is often no separate reimbursement for supplies used in surgical procedures, the additional cost associated with the use of our steroid-eluting implants can impact the profit margin of the hospital or surgery center where the sinus surgery is performed. Some of our target customers may be unwilling to adopt our steroid-eluting implants in light of the additional associated cost. Further, any decline in the amount payors are willing to reimburse our customers for sinus surgery procedures could make it difficult for existing customers to continue using, or adopt, our steroid-eluting implants and could create additional pricing pressure for us. If we are forced to lower the price we charge for our products, our gross margins will decrease, which will adversely affect our ability to invest in and grow our business.

We are actively seeking new billing codes for our products and the procedure associated with their use, including codes that are established by the Centers for Medicare & Medicaid Services, or CMS, and the American Medical Association, or AMA. Our ability to obtain new billing codes will depend, in part, on support from the ENT community and physician acceptance of our technology. Although obtaining billing codes may result in payment amounts that better reflect the costs and resources of our products and related procedure, there is a possibility that they may not do so.

We cannot assure you that we will be successful in garnering the necessary support for new codes from the ENT community or from third-party payors, who are responsible for determining which billing codes are to be used for procedures performed on their insured population. Even if we are able to establish reimbursement codes for our products, we will continue to be subject to significant pricing pressure, which could harm our business, results of operations, financial condition and prospects.

Our future growth depends on physician awareness and adoption of our steroid-eluting implants.

We focus our sales, marketing and education efforts primarily on ENT physicians. We train physicians on the patient population that would benefit from our steroid-eluting implants. This patient population is based on those included in our clinical studies and includes, for example, patients with or without polyps as well as patients undergoing either primary or revision surgery. Some physicians may choose to utilize our products on a subset of their patients such as patients with severe polyp disease that they deem at higher risk for postoperative complications. If we are not able to effectively demonstrate to those physicians that our products are beneficial in a broad range of patients on which they operate, their adoption of our products will be limited.

We train our physician customers on the proper techniques in using our devices to achieve the intended outcome. The successful use of our steroid-eluting implants depends in large part on the physician's adherence to the techniques that they are provided in training by our sales representatives. In the event that physicians do not adhere to these techniques or if they perceive that our products are too cumbersome for them to use, we may have difficulty facilitating adoption. Additionally, physicians may develop their own techniques for use of our products during insertion and during the period in which the drug is delivered and is bioabsorbed. For example, we are aware some physicians are removing our steroid-eluting implants before all of the drug has eluted into the surrounding tissue. While physicians were allowed to remove the implant at any time at their discretion in our clinical studies, early removal could lead to suboptimal outcomes. In addition, if physicians utilize our products in a manner that is inconsistent with how they were studied clinically, their outcomes may not be consistent with the outcomes achieved in our clinical studies, which may impact their perception of patient benefit and limit their adoption of our products.

In addition, the initial point of contact for many patients suffering from chronic sinusitis may be primary care physicians or other referring medical professionals who commonly treat patients experiencing sinus-related symptoms or complications. We believe that we must educate these primary care physicians and other referring medical professionals about our steroid-eluting implants in order to grow the market beyond the over 3.5 million patients with chronic sinusitis who are currently managed by ENT physicians. If we fail to do so, these primary care physicians and other referring medical professionals may not refer patients to an ENT physician who will perform sinus surgery and use our steroid-eluting implants. As a result, those patients may go untreated, attempt to manage their sinusitis through medical management alone or seek alternative surgical procedures. If we are not successful in educating primary care physicians and other referring medical professionals about our steroid-eluting implants, our ability to increase our revenue may be impaired.

We have limited experience marketing and selling our steroid-eluting implants, and if we are unable to expand, manage and maintain our direct sales and marketing organizations we may not be able to generate anticipated revenue.

We started selling our first approved product, PROPEL, on a limited basis in August 2011. We subsequently started selling PROPEL mini in November 2012, and in the first half of 2013 we began to expand and scale our direct sales and marketing organizations in the United States. As a result, we have limited experience marketing and selling our steroid-eluting implants. As of June 30, 2014, our direct sales organization, including marketing, customer service and reimbursement, consisted of 72 employees, having increased from 21 employees as of December 31, 2012. Our operating results are directly dependent upon the sales and marketing efforts of our employees. If our direct sales representatives fail to adequately promote, market and sell our products, our sales may suffer.

In order to generate our anticipated sales, we will need to expand the size and geographic scope of our direct sales organization. As a result, our future success will depend largely on our ability to continue to hire, train, retain and motivate skilled regional sales managers and direct sales representatives with significant technical knowledge of ENT. Because of the competition for their services, we cannot assure you we will be able to hire and retain additional direct sales representatives on favorable or commercially reasonable terms, if at all. Failure to hire or retain qualified sales representatives would prevent us from expanding our business and generating sales. Additionally, new hires require training and take time before they achieve full productivity. If we fail to train new hires adequately, new hires may not become as productive as may be necessary to maintain or increase our sales.

If we are unable to expand our sales and marketing capabilities, we may not be able to effectively commercialize our products, which would adversely affect our business, results of operations and financial condition.

Our clinical studies were designed to demonstrate the safety and efficacy of our steroid-eluting implants based on FDA requirements and may not be seen as compelling to physicians. Any subsequent clinical studies that are conducted and published may not be positive or consistent with our existing data, which would affect the rate of adoption of our products.

Our success depends on the medical community's acceptance of our steroid-eluting implants as tools that are useful to ENT physicians treating patients with chronic sinusitis. We have sponsored three multi-center, prospective studies of over 200 patients to track outcomes of treatment with our steroid-eluting implants, which clinical data has resulted in the highest level of evidence generated for any product used in sinus surgery. The principal safety and efficacy information of our steroid-eluting implants is derived from the ADVANCE II study, a prospective, multicenter, randomized controlled, double-blind, pivotal study that was completed in September 2010. We also sponsored the ADVANCE study, a prospective, multicenter, single-cohort, open-label trial completed in December 2009 and the PROPEL Pilot Study, a prospective, multicenter, randomized, controlled, double-blind feasibility study completed in April 2009. While the results of these three studies collectively indicate a favorable safety and efficacy profile, the study designs and results may not be viewed as compelling to our physician customers. If physicians do not find our data compelling, they may choose not to use our products or limit their use. Our PROPEL Pilot study and ADVANCE II study incorporated an intra-patient control design comparing PROPEL to a non-drug-eluting control version of the implant in order to maintain blinding. Primary efficacy endpoints for these two studies were measured at 30 days after placement as we believe that proper healing in the immediate postoperative period is indicative of long-term outcomes. Additionally, it was important to allow for medical intervention after day 30 given one sinus side of each patient had the control device. Clinical efficacy demonstrated at this short-term endpoint does not guarantee long-term clinical benefits. Our ADVANCE study measured patient symptom improvements out to six months. The long-term effects of sinus surgery in conjunction with our steroid-eluting implants beyond six months are not known. Certain ENT physicians, hospitals and surgery centers may prefer to see longer term efficacy data than we have produced. We cannot assure you that any data that we or others generate will be consistent with that observed in these studies nor that results will be maintained beyond the time points studied. We also cannot assure you that any data that may be collected will be compelling to the medical community because the data may not be scientifically meaningful and may not demonstrate that sinus surgery using our steroid-eluting implants is an attractive procedure when compared against data from alternative treatments.

Each ENT physician's individual experience with our steroid-eluting implants will vary, and we believe that physicians will compare actual long-term outcomes in their own practices using our steroid-eluting implants against sinus surgery used in conjunction with traditional sinus packing techniques. A long-term, adequately-controlled clinical study comparing sinus surgery performed in conjunction with our steroid-eluting implants against sinus surgery performed in conjunction with the variety of traditional sinus packing techniques incorporated by physicians would be expensive and time-consuming and we have not conducted, and are not currently planning to conduct, such a study. If the experience of physicians indicates that the use of our steroid-eluting implants in FESS is not as safe or efficacious as other treatment options or does not provide a lasting solution to patients with chronic sinusitis, adoption of our products may suffer and our business would be harmed.

We utilize third-party, single source suppliers for many of the components and materials used in our steroid-eluting implants, and the loss of any of these suppliers could harm our business.

The active pharmaceutical ingredient, or API, and a number of our critical components used in our steroid-eluting implants are supplied to us from single source suppliers. We rely on single source suppliers for some of our polymer materials, some extrusions and molded components, some off-the-shelf components and for finished goods testing. Our ability to supply our products commercially and to develop our product candidates depends, in part, on our ability to obtain these components in accordance with regulatory requirements and in sufficient quantities for commercialization and clinical testing. We have entered into manufacturing, supply or quality agreements with a number of our single source suppliers pursuant to which they supply the components we need. We are not certain that our single source suppliers will be able to meet our demand for their products, either because of the nature of our agreements with those suppliers, our limited experience with those suppliers or our relative importance as a customer to those suppliers. It may be difficult for us to assess their ability to timely meet our demand in the future based on past performance. While our suppliers have generally met our demand for their products on a timely basis in the past, they may subordinate our needs in the future to their other customers.

Establishing additional or replacement suppliers for the API or any of the components or processes used in our products, if required, may not be accomplished quickly. If we are able to find a replacement supplier, the replacement supplier would need to be qualified and may require additional regulatory authority approval, which could result in further delay. For example, the U.S. Food

and Drug Administration, or FDA, could require additional supplemental data if we rely upon a new supplier for the API used in PROPEL and PROPEL mini. While we seek to maintain adequate inventory of the single source components and materials used in our products, any interruption or delay in the supply of components or materials, or our inability to obtain components or materials from alternate sources at acceptable prices in a timely manner, could impair our ability to meet the demand of our customers and cause them to cancel orders.

If our third-party suppliers fail to deliver the required commercial quantities of materials, on a timely basis and at commercially reasonable prices, and we are unable to find one or more replacement suppliers capable of production at a substantially equivalent cost in substantially equivalent volumes and quality, and on a timely basis, the continued commercialization of our products and the development of our product candidates would be impeded, delayed, limited or prevented, which could harm our business, results of operations, financial condition and prospects.

It is difficult to forecast future performance, which may cause our financial results to fluctuate unpredictably.

Our limited operating history and commercial experience make it difficult for us to predict future performance. As we gain additional commercial experience, a number of factors over which we have limited control may contribute to fluctuations in our financial results, such as seasonal variations in revenue. In the first quarter, our results can be impacted by adverse weather and by resetting of annual patient healthcare insurance plan deductibles, both of which may cause patients to delay elective procedures such as FESS. In the second quarter, demand may be impacted by the seasonal nature of allergies and the resultant onset of sinus-related symptoms. In the third quarter, the number of FESS procedures nationwide is historically lower than other quarters throughout the year, which we believe is attributable to the summer vacations of ENT physicians and their patients. In the fourth quarter, demand may be impacted by the onset of the cold and flu season and related symptoms, as well as the desire of patients to spend their remaining balances in flexible-spending accounts or because they have met their annual deductibles under their health insurance plans. Other factors that may impact our quarterly results include:

- ENT physician adoption of our steroid-eluting implants;
- unanticipated pricing pressure;
- the hiring, retention and continued productivity of our sales representatives;
- our ability to expand the geographic reach of our sales and marketing efforts;
- our ability to obtain regulatory clearance or approval for our products in development or for our current products outside the United States;
- results of clinical research and trials on our existing products and products in development;
- delays in receipt of anticipated purchase orders;
- timing of new product offerings, acquisitions, licenses or other significant events by us or our competitors;
- delays in, or failure of, component and raw material deliveries by our suppliers; and
- positive or negative coverage in the media or clinical publications of our steroid-eluting implants or products of our competitors or our industry.

In the event our actual revenue and operating results do not meet our forecasts for a particular period, the market price of our common stock may decline substantially.

Our long-term growth depends on our ability to develop and commercialize additional ENT products.

It is important to our business that we continue to build a more complete product offering within the ENT market. We are using our drug-eluting bioabsorbable technology to develop new products for use in the physician office setting. Developing additional products is expensive and time-consuming and could divert management's attention away from our current sinus surgery products and harm our business. Even if we are successful in developing additional products, including those currently in development for use in the physician office setting, the success of any new product offering or enhancement to an existing product will depend on several factors, including our ability to:

- properly identify and anticipate ENT physician and patient needs;
- develop and introduce new products or product enhancements in a timely manner;
- avoid infringing upon the intellectual property rights of third parties;
- demonstrate, if required, the safety and efficacy of new products with data from preclinical studies and clinical trials;
- obtain the necessary regulatory clearances or approvals for new products or product enhancements;
- be fully FDA-compliant with marketing of new devices or modified products;
- provide adequate training to potential users of our products;

- receive adequate coverage and reimbursement for procedures performed with our products; and
- develop an effective and FDA-compliant, dedicated sales and marketing team.

If we are unsuccessful in developing and commercializing additional products in other areas of ENT, our ability to increase our revenue may be impaired.

If clinical studies of our future products do not produce results necessary to support regulatory clearance or approval in the United States or, with respect to our current or future products, elsewhere, we will be unable to commercialize these products.

We will likely need to conduct additional clinical studies in the future to support new product approvals, or for the approval of the use of our products in some foreign countries. Clinical testing takes many years, is expensive and carries uncertain outcomes. The initiation and completion of any of these studies may be prevented, delayed, or halted for numerous reasons, including, but not limited to, the following:

- the FDA, institutional review boards or other regulatory authorities do not approve a clinical study protocol, force us to modify a previously approved protocol, or place a clinical study on hold;
- patients do not enroll in, or enroll at a lower rate than we expect, or do not complete a clinical study;
- patients or investigators do not comply with study protocols;
- patients do not return for post-treatment follow-up at the expected rate;
- patients experience unexpected adverse event or side effects for a variety of reasons that may or may not be related to our products;
- sites participating in an ongoing clinical study withdraw, requiring us to engage new sites;
- difficulties or delays associated with establishing additional clinical sites;
- third-party clinical investigators decline to participate in our clinical studies, do not perform the clinical studies on the anticipated schedule, or are inconsistent with the investigator agreement, clinical study protocol, good clinical practices or other agency requirements;
- third-party organizations do not perform data collection and analysis in a timely or accurate manner;
- regulatory inspections of our clinical studies or manufacturing facilities require us to undertake corrective action or suspend or terminate our clinical studies;
- changes in federal, state, or foreign governmental statutes, regulations or policies;
- interim results are inconclusive or unfavorable as to immediate and long-term safety or efficacy;
- the study design is inadequate to demonstrate safety and efficacy; or
- the study does not meet the statistical endpoints.

Clinical failure can occur at any stage of the testing. Our clinical studies may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical and non-clinical testing in addition to those we have planned. Our failure to adequately demonstrate the safety and efficacy of any of our devices would prevent receipt of regulatory clearance or approval and, ultimately, the commercialization of that device or indication for use. Even if our future products are approved in the United States, commercialization of our products in foreign countries would require approval by regulatory authorities in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials. Any of these occurrences may harm our business, results of operations, financial condition and prospects.

Consolidation in the healthcare industry could lead to demands for price concessions, which may impact our ability to sell our products at prices necessary to support our current business strategies.

Healthcare costs have risen significantly over the past decade, which has driven numerous cost reform initiatives by legislators, regulators and third-party payors. A typical FESS procedure is paid at a Medicare rate of approximately $10,000. Private insurer payment rates average 139 percent of Medicare rates nationally. Cost reform has elicited a consolidation trend in the healthcare industry to aggregate purchasing power, which may create more requests for pricing concessions in the future. Additionally, group purchasing organizations, independent delivery networks and large single accounts may continue to use their market power to consolidate purchasing decisions for hospitals and ambulatory surgery centers. We expect that market demand, government regulation, third-party coverage and reimbursement policies and societal pressures will continue to change the healthcare industry worldwide, resulting in further business consolidations and alliances among our customers, which may exert further downward pressure on the prices of our products and may adversely impact our business, results of operations, financial condition and prospects.

We compete or may compete in the future against other companies, some of which have longer operating histories, more established products and greater resources, which may prevent us from achieving significant market penetration or improved operating results.

Our industry is highly competitive, subject to change and significantly affected by new product introductions and other activities of industry participants. Many of the companies developing or marketing ENT products are publicly traded or are divisions of publicly-traded companies, including the Xomed division of Medtronic, the Gyrus ACMI division of Olympus, the Acclarent division of Johnson & Johnson, Stryker and ArthroCare. These companies enjoy several competitive advantages, including:

- greater financial and human capital resources;
- significantly greater name recognition;
- established relationships with ENT physicians, referring physicians, customers and third-party payors;
- additional lines of products, and the ability to offer rebates or bundle products to offer greater discounts or incentives to gain a competitive advantage; and
- established sales, marketing and worldwide distribution networks.

Because of the size of the market opportunity for the treatment of chronic sinusitis, we believe potential competitors have historically dedicated and will continue to dedicate significant resources to aggressively promote their products or develop new products. New product developments that could compete more effectively with our products are possible because of the prevalence of chronic sinusitis and the extensive research efforts and technological progress that exist within the market. Large medical device companies with ENT divisions, such as Medtronic, also have capability in drug-eluting stents and smaller companies may develop competing products. Though we are not aware of any such products to date, these or other companies may develop drug-eluting products that could compete with our products.

Our commercially available products are designed to be used during sinus surgery. If another company successfully develops an approach for the treatment of chronic sinusitis that would not benefit from the use of our steroid-eluting implants, if another company develops a device to treat the inflammation and scarring associated with sinus surgery that is more efficacious than our steroid-eluting implants, or if a pharmaceutical company successfully develops a drug that addresses chronic sinusitis without the need for surgical intervention, sales of our products would be significantly and adversely affected.

We may be unable to manage our growth effectively.

Our past growth has provided, and our future growth may create, challenges to our organization. From December 31, 2012, to June 30, 2014, the number of our employees increased from 75 to 159. In the future, we expect to hire and train new personnel as we continue to grow and expand our operations. As a public company, we will need to further expand our scientific, sales and marketing, managerial, operational, financial and other resources to support our planned research, development and commercialization activities. This growth may place significant strain on our management, financial and operational resources. Successful growth is also dependent upon our ability to implement appropriate financial and management controls, systems and procedures and securing a sufficient amount of office space for additional personnel. If we fail to manage these challenges effectively, our business could be harmed.

We face the risk of product liability claims that could be expensive, divert management's attention and harm our reputation and business. We may not be able to maintain adequate product liability insurance.

Our business exposes us to the risk of product liability claims that are inherent in the testing, manufacturing and marketing of medical devices and drug products. This risk exists even if a device or product is approved for commercial sale by the FDA and manufactured in facilities licensed and regulated by the FDA, such as the case with PROPEL and PROPEL mini, or an applicable foreign regulatory authority. Our products and product candidates are designed to affect important bodily functions and processes. Any side effects, manufacturing defects, misuse or abuse associated with our products or our product candidates could result in patient injury or death. The medical device industry has historically been subject to extensive litigation over product liability claims, and we cannot offer any assurance that we will not face product liability suits. We may be subject to product liability claims if our steroid-eluting implants cause, or merely appear to have caused, patient injury or death. In addition, an injury that is caused by the activities of our suppliers, such as those who provide us with components and raw materials, may be the basis for a claim against us. Product liability claims may be brought against us by consumers, health care providers or others selling or otherwise coming into contact with our products or product candidates, among others. If we cannot successfully defend ourselves against product liability claims, we will incur substantial liabilities and reputational harm. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- costs of litigation;
- distraction of management's attention from our primary business;
- the inability to commercialize our products or, if approved, our product candidates;
- decreased demand for our products or, if approved, product candidates;

- impairment of our business reputation;
- product recall or withdrawal from the market;
- withdrawal of clinical trial participants;
- substantial monetary awards to patients or other claimants; or
- loss of revenue.

While we may attempt to manage our product liability exposure by proactively recalling or withdrawing from the market any defective products, any recall or market withdrawal of our products may delay the supply of those products to our customers and may impact our reputation. We can provide no assurance that we will be successful in initiating appropriate market recall or market withdrawal efforts that may be required in the future or that these efforts will have the intended effect of preventing product malfunctions and the accompanying product liability that may result. Such recalls and withdrawals may also be used by our competitors to harm our reputation for safety or be perceived by patients as a safety risk when considering the use of our products, either of which could have an adverse effect on our business.

In addition, although we have product liability and clinical study liability insurance that we believe is appropriate, this insurance is subject to deductibles and coverage limitations. Our current product liability insurance may not continue to be available to us on acceptable terms, if at all, and, if available, coverage may not be adequate to protect us against any future product liability claims. If we are unable to obtain insurance at an acceptable cost or on acceptable terms with adequate coverage or otherwise protect against potential product liability claims, we will be exposed to significant liabilities, which may harm our business. A product liability claim, recall or other claim with respect to uninsured liabilities or for amounts in excess of insured liabilities could have a material adverse effect on our business, financial condition and results of operations.

The misuse or off-label use of our products may harm our image in the marketplace, result in injuries that lead to product liability suits or result in costly investigations and sanctions by regulatory bodies if we are deemed to have engaged in the promotion of these uses, any of which could be costly to our business.

The products we currently market have been approved by the FDA for specific treatments. We train our marketing and direct sales force to not promote our products for uses outside of the FDA-approved indications for use, known as “off-label uses.” We cannot, however, prevent a physician from using our products off-label, when in the physician’s independent professional medical judgment he or she deems it appropriate. There may be increased risk of injury to patients if physicians attempt to use our products off-label. Furthermore, the use of our products for indications other than those approved by the FDA or any foreign regulatory body may not effectively treat such conditions, which could harm our reputation in the marketplace among physicians and patients.

Physicians may also misuse our products or use improper techniques if they are not adequately trained, potentially leading to injury and an increased risk of product liability. If our products are misused or used with improper technique, we may become subject to costly litigation by our customers or their patients. Product liability claims could divert management’s attention from our core business, be expensive to defend, and result in sizable damage awards against us that may not be covered by insurance. In addition, if the FDA or any foreign regulatory body determines that our promotional materials or training constitute promotion of an off-label use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fine or criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our business activities to constitute promotion of an off-label use, which could result in significant penalties, including, but not limited to, criminal, civil and administrative penalties, damages, fines, disgorgement, exclusion from participation in government healthcare programs, and the curtailment of our operations. Any of these events could significantly harm our business and results of operations and cause our stock price to decline.

Our ability to maintain our competitive position depends on our ability to attract and retain highly qualified personnel.

We believe that our continued success depends to a significant extent upon the efforts and abilities of our key executives. All of our executive officers and other employees are at-will employees, and therefore may terminate employment with us at any time with no advance notice. The replacement of any of our key personnel likely would involve significant time and costs and may significantly delay or prevent the achievement of our business objectives and would harm our business.

Our future success also depends on our ability to continue to attract and retain our executive officers and other key employees. Many of our employees have become or will soon become vested in a substantial amount of stock or number of stock options. Our employees may be more likely to leave us if the shares they own or the shares underlying their vested options have significantly appreciated in value relative to the original purchase prices of the shares or the exercise prices of the options, or if the exercise prices of the options that they hold are significantly below the market price of our common stock. Further, our employees’ ability to exercise those options and sell their stock in a public market may result in a higher than normal turnover rate. We do not carry any “key person” insurance policies.

If our facilities or the facility of a supplier become inoperable, we will be unable to continue to research, develop, manufacture and commercialize our products and, as a result, our business will be harmed until we are able to secure a new facility.

We do not have redundant facilities. We perform substantially all of our research and development, manufacturing and commercialization activity and maintain all our raw material and finished goods inventory in a single location in Menlo Park, California. Menlo Park is situated on or near earthquake fault lines. Our facility and equipment would be costly to replace and could require substantial lead time to repair or replace. The facility may be harmed or rendered inoperable by natural or man-made disasters, including, but not limited to, earthquakes, flooding, fire and power outages, which may render it difficult or impossible for us to perform our research, development, manufacturing and commercialization activities for some period of time. The inability to perform those activities, combined with our limited inventory of reserve raw materials and finished product, may result in the inability to continue manufacturing our products during such periods and the loss of customers or harm to our reputation. Although we possess insurance for damage to our property and the disruption of our business, this insurance may not be sufficient to cover all of our potential losses and this insurance may not continue to be available to us on acceptable terms, or at all.

We expect to incur significant additional costs as a result of being a public company, which may adversely affect our operating results and financial condition.

We expect to incur costs associated with corporate governance requirements, including requirements under the Sarbanes-Oxley Act, as well as rules implemented by the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, or the Dodd-Frank Act, the Securities and Exchange Commission, or the SEC, and NASDAQ. These rules and regulations are expected to increase our accounting, legal and financial compliance costs and make some activities more time-consuming and costly. In addition, we will incur additional costs associated with our public company reporting requirements and we expect those costs to increase in the future. We also expect these rules and regulations to make it more expensive for us to maintain directors' and officers' liability insurance and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees, or as executive officers. Increases in costs incurred as a result of becoming a publicly traded company may adversely affect our operating results and financial condition.

We estimate the additional annual cost that we will incur as a result of our public company reporting obligations is approximately $3.0 million. However, because these rules and regulations are often subject to varying interpretations, it is difficult to accurately estimate or predict the amount or timing of these additional costs. Further, the lack of specificity of many of the rules and regulations may result in an application in practice that may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

If we experience significant disruptions in our information technology systems, our business may be adversely affected.

We depend on our information technology systems for the efficient functioning of our business, including accounting, data storage, compliance, purchasing and inventory management. Our current systems provide virtual redundancy but are operated from one physical location in Menlo Park. However, we are in the process of upgrading the level of redundancy for our IT systems. We expect these upgrades to take one to two years to complete. While we will attempt to mitigate interruptions, we may experience difficulties in implementing some upgrades which could impact our business operations, or experience difficulties in operating our business during the upgrade, either of which could disrupt our operations, including our ability to timely ship and track product orders, project inventory requirements, manage our supply chain and otherwise adequately service our customers. In the event we experience significant disruptions as a result of the current implementation of our information technology systems, we may not be able to repair our systems in an efficient and timely manner. Accordingly, such events may disrupt or reduce the efficiency of our entire operation and have a material adverse effect on our results of operations and cash flows.

We are increasingly dependent on sophisticated information technology for our infrastructure. Our information systems require an ongoing commitment of significant resources to maintain, protect and enhance existing systems. Failure to maintain or protect our information systems and data integrity effectively could have a materially adverse effect on our business. For example, third parties may attempt to hack into our information systems and may obtain our proprietary information.

Fluctuations in insurance costs and availability could adversely affect our profitability or our risk management profile.

We hold a number of insurance policies, including product liability insurance, directors' and officers' liability insurance, general liability insurance, property insurance and workers' compensation insurance. If the costs of maintaining adequate insurance coverage increase significantly in the future, our operating results could be materially adversely affected. Likewise, if any of our current insurance coverage should become unavailable to us or become economically impractical, we would be required to operate our business without indemnity from commercial insurance providers. If we operate our business without insurance, we could be responsible for paying claims or judgments against us that would have otherwise been covered by insurance, which could adversely affect our results of operations or financial condition.

Risks Relating to Regulatory Matters

The existence of adequate coverage and reimbursement is important for sales of our products. Inadequate coverage and reimbursement policies for procedures using our steroid-eluting implants could affect the adoption of our products and our future revenue.

Successful sales of our steroid-eluting implants depend on the availability of adequate coverage and reimbursement from third-party payors for either the products specifically, the procedures associated with the use of the products, or both. Providers that purchase our products generally rely on third-party payors to reimburse all or part of the costs and fees associated with the procedures performed with these medical devices or the devices themselves. Adequate coverage and reimbursement from third-party payors, including governmental payors, such as Medicare and Medicaid, therefore, is important for obtaining product acceptance and widespread adoption in the marketplace.

In the United States, coverage and reimbursement for medical devices vary among payors. In addition, payors continually review new technologies for possible coverage and can, without notice, deny coverage for these new products and procedures. We estimate that private payors covering a significant number of U.S. covered lives currently have non-coverage policies with respect to PROPEL and PROPEL mini and they consider these products investigational or experimental. Some governmental and private third-party payors do not currently cover or reimburse our products because they have determined insufficient evidence of favorable clinical outcomes is available. Although they consider the steroid-eluting implants investigational or experimental at this time, these payors may in the future determine sufficient evidence has been developed to cover and reimburse our products and related procedures. We are actively working to reverse these non-coverage decisions but cannot provide assurance that we will be successful in these efforts. If we are not successful in reversing existing non-coverage policies, or if other third-party payors issue similar policies, this could have a material adverse effect on our business and operations. Further, third-party payors who currently cover and reimburse customers for procedures using our products may in the future choose to decrease current levels of reimbursement or eliminate reimbursement altogether, either of which will cause our business to suffer.

To contain costs of new technologies, governmental healthcare programs and third-party payors are increasingly scrutinizing new and even existing treatments by requiring extensive evidence of favorable clinical outcomes and cost effectiveness before extending or continuing coverage, respectively. Such evidence generally must be derived from well-designed independent studies and published in peer-reviewed journals. Payors also may be influenced by positive position statements on the value of this technology issued by medical specialty societies. For example, payors may be persuaded to extend coverage by positive clinical data demonstrating the long-term safety and efficacy of FESS performed with our steroid-eluting implants against FESS alone. A long-term clinical study randomizing FESS using our products against FESS alone would require an extremely large patient population to demonstrate these differences, and would be expensive and time-consuming. We have not conducted and are not currently planning to conduct such a study. Further, even positive study results do not guarantee adequate third-party payor coverage and reimbursement. Although the American Rhinologic Society has issued a positive position statement regarding the use of our steroid-eluting implants, if the society changes its position in an unfavorable manner, third-party payors may reverse existing favorable coverage and reimbursement policies or otherwise decline to adopt favorable policies for our products, either of which will cause our business to suffer.

Generally, third-party payors currently reimburse hospitals and ambulatory surgery centers and physicians for the FESS procedures during which our technology is implanted using existing Category I Current Procedure Terminology, or CPT, codes relating to the FESS procedures performed. These CPT codes do not currently distinguish between procedures performed with or without our steroid-eluting implants. The amount of reimbursement received by our customers from third-party payors is dependent generally on fee schedules established by these payors for the existing FESS CPT codes. For governmental payors, such as Medicare and Medicaid, the fee schedule amount is determined by statutory and regulatory formulas. For commercial payors, the reimbursement amount generally is dependent upon the specific contract terms between the provider and payor. We cannot provide assurance that government or private third-party payors will continue to reimburse for FESS with our products using the existing codes, nor can we provide assurance that the payment rates will be adequate. If providers and physicians are unable to obtain reimbursement for FESS with the use of our products at cost-effective levels, this could have a material adverse effect on our business and operations. Hospitals and ambulatory surgery centers are unlikely to purchase our products if they do not receive payment sufficient to cover the cost of our products and related procedures. In addition, in the event that the current coding and/or payment methodology for these procedures changes, this could have a material adverse effect on our business and business operations.

To secure separate payment for our products, whether for our currently marketed products or those under development, a unique billing code is required for either the implant, the procedure associated with use of our products, or both. Although a unique billing code currently exists for our marketed products it is not associated with payment by most payors and is not reportable to many payors, including Medicare. New billing codes, including CPT codes, may be developed which are both reportable and payable. In addition, new billing codes may be developed for the specific procedure performed to implant our products. As of now, it is not possible to assess the full impact of product or procedure-specific codes on our business or results of operations or the likelihood of securing such specific codes. If new product or procedure-specific codes are adopted, and the levels of reimbursement declines significantly below current levels, our business and results of operations would be harmed and our stock price would likely decline.

Healthcare cost containment pressures and legislative or administrative reforms resulting in restrictive reimbursement practices of third-party payors could decrease the demand for our products, the prices that customers are willing to pay and the number of procedures performed using our steroid-eluting implants, which could have an adverse effect on our business.

All third-party payors, whether governmental or commercial, whether inside the United States or outside, are developing increasingly sophisticated methods of controlling healthcare costs. These cost-control methods include prospective payment systems, bundled payment models, capitated arrangements, group purchasing, benefit redesign, pre-authorization processes, and requirements for second opinions prior to major surgery. These cost-control methods also potentially limit the amount that healthcare providers may be willing to pay for medical devices. Therefore, coverage or reimbursement for medical devices may decrease in the future.

Further, from time to time, typically on an annual basis, payment amounts are updated and revised by third-party payors. Because the cost of our products generally is recovered by the healthcare provider as part of the payment for performing a procedure and not separately reimbursed, these updates could directly impact the demand for our products. An example of payment updates is the Medicare program updates to physician payments, which is done on an annual basis using a prescribed statutory formula. In the past, when the application of the formula resulted in lower payment, Congress has passed interim legislation to prevent the reductions. Most recently, the Protecting Access to Medicare Act of 2014, signed into law in April 2014, provided for a 0.5% update from 2013 payment rates under the Medicare Physician Fee Schedule through 2014 and a 0% update from January 1 until April 1, 2015. If Congress fails to intervene to prevent the negative update factor in future years, the resulting decrease in payment may adversely affect our revenue and results of operations. In addition, the Medicare physician fee schedule has been adapted by some private payors into their plan-specific physician payment schedule. We cannot predict how pending and future healthcare legislation will impact our business, and any changes in coverage and reimbursement that further restricts coverage of our products or lowers reimbursement for procedures using our products could materially affect our business.

Reimbursement in international markets may require us to undertake country-specific reimbursement activities, including additional clinical studies, which could be time-consuming and expensive and may not yield acceptable reimbursement rates.

In international markets, market acceptance of our products will likely depend in large part on the availability of reimbursement within prevailing healthcare payment systems. Reimbursement and healthcare payment systems in international markets vary significantly by country, and by region in some countries, and include both government-sponsored healthcare and private insurance. We may not obtain international reimbursement approvals in a timely manner, if at all. In addition, even if we do obtain international reimbursement approvals, the level of reimbursement may not be enough to commercially justify expansion of our business into the approving jurisdiction. To the extent we or our customers are unable to obtain reimbursement for our steroid-eluting implants in major international markets in which we seek to market and sell our products, our international revenue growth would be harmed, and our business and results of operations would be adversely affected.

Our products are subject to extensive regulation by the FDA, including the requirement to obtain premarket approval and the requirement to report adverse events. If we fail to obtain necessary FDA device or drug approvals for our products, or are subject to regulatory enforcement action as a result of our failure to properly report adverse events or otherwise comply with regulatory requirements, our commercial operations would be harmed.

Our steroid-eluting implants are subject to extensive regulation by the FDA and various other federal, state and foreign governmental authorities. The PMA and New Drug Application, or NDA, approval processes can be expensive and lengthy. Despite the time, effort and cost required to obtain approval, there can be no assurance that any product that we intend to commercialize in the future will be approved by the FDA in a timely fashion, if at all. For example, we do not have any prior experience in obtaining approval of an NDA, and this lack of experience may delay or adversely affect our ability to obtain approval for our steroid-eluting implant for refractory disease treated in the physician office setting, which will require NDA approval prior to commercialization in the United States.

Our marketed products are subject to Medical Device Reporting, or MDR, obligations, which require that we report to the FDA any incident in which our products may have caused or contributed to a death or serious injury, or in which our products malfunctioned and, if the malfunction were to recur, it could likely cause or contribute to a death or serious injury. We take a conservative approach in reporting MDRs and have had eight events occur postoperatively with PROPEL and PROPEL mini that we have reported to FDA as MDRs, six of which were for infections and two of which were for adhesions.

The FDA and state authorities have broad enforcement powers. Our failure to comply with applicable regulatory requirements could result in enforcement action by the FDA or state agencies, which may include any of the following sanctions:

- adverse publicity, warning letters, fines, injunctions, consent decrees and civil penalties;
- repair, replacement, recall or seizure of our products;
- operating restrictions or partial suspension or total shutdown of production;
- delaying or refusing our requests for approval of new products, new intended uses or modifications to our existing products;
- refusal to grant export approval for our products;

- withdrawing PMAs that have already been granted; and
- criminal prosecution.

If any of these enforcement actions were to be taken by the government, our business could be harmed.

If we materially modify our FDA-approved products, we may need to seek and obtain new approvals, which, if not granted, would prevent us from selling our modified products.

A component of our strategy is to continue to modify and upgrade our steroid-eluting implants. Medical devices can be marketed only for the indications for which they are approved. We have received a number of PMA supplement approvals since the original approvals of PROPEL and PROPEL mini. We may not be able to obtain additional regulatory approvals for new products or for modifications to, or additional indications for, our existing product in a timely fashion, or at all. Delays in obtaining future approvals would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our revenue and potential future profitability.

We may fail to obtain foreign regulatory approvals to market our products in other countries.

We do not have any sales outside the United States. Sales of our steroid-eluting implants outside the United States are subject to foreign regulatory requirements that vary widely from country to country. In addition, the FDA regulates exports of medical devices from the United States. Complying with international regulatory requirements can be an expensive and time-consuming process and approval is not certain. The time required to obtain approvals, if required by other countries, may be longer than that required for FDA approvals, and requirements for such approvals may significantly differ from FDA requirements. In certain countries we may rely upon a third-party or third party distributors to obtain all required regulatory approvals, and these distributors may be unable to obtain or maintain such approvals. Our distributors in these countries may also incur significant costs in attempting to obtain and in maintaining foreign regulatory approvals or qualifications, which could increase the difficulty of attracting and retaining qualified distributors. If these distributors experience delays in receiving necessary qualifications, clearances or approvals to market our products outside the United States, or if they fail to receive those qualifications, clearances or approvals, we may be unable to market our products or enhancements in certain international markets effectively, or at all.

If we expand our operations outside the United States, we will need to expand our international marketing. International jurisdictions require separate regulatory approvals and compliance with numerous and varying regulatory requirements. The approval procedures vary among countries and may involve requirements for additional testing, and the time required to obtain approval may differ from country to country and from that required to obtain clearance or approval in the United States.

Approval in the United States does not ensure approval or certification by regulatory authorities in other countries or jurisdictions, and approval or certification by one foreign regulatory authority does not ensure approval or certification by regulatory authorities in other foreign countries or by the FDA. The foreign regulatory approval or certification process may include all of the risks associated with obtaining FDA approval. In addition, some countries only approve or certify a product for a certain period of time, and we are required to re-approve or re-certify our products in a timely manner prior to the expiration of our prior approval or certification. We may not obtain foreign regulatory approvals on a timely basis, if at all. We may not be able to file for regulatory approvals or certifications and may not receive necessary approvals to commercialize our products in any market. If we fail to receive necessary approvals or certifications to commercialize our products in foreign jurisdictions on a timely basis, or at all, or if we fail to have our products re-approved or re-certified, our business, results of operations and financial condition could be adversely affected.

These and other factors may have a material adverse effect on our international operations or on our business, results of operations and financial condition generally.

If we or our suppliers fail to comply with ongoing FDA or foreign regulatory authority requirements, or if we experience unanticipated problems with our products, these products could be subject to restrictions or withdrawal from the market.

Any product for which we obtain approval, and the manufacturing processes, reporting requirements, post-approval clinical data and promotional activities for such product, will be subject to continued regulatory review, oversight and periodic inspections by the FDA and other domestic and foreign regulatory bodies. In particular, we and our third-party suppliers are required to comply with the FDA's current good manufacturing practice. These FDA regulations cover the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, storage and shipping of our products. Compliance with applicable regulatory requirements is subject to continual review and is monitored rigorously through periodic inspections by the FDA. If we, or our manufacturers, fail to adhere to current good manufacturing practice requirements in the United States, this could delay production of our products and lead to fines, difficulties in obtaining regulatory approvals, recalls, enforcement actions, including injunctive relief or consent decrees, or other consequences, which could, in turn, have a material adverse effect on our financial condition or results of operations.

In addition, the FDA audits compliance with the current good manufacturing practice through periodic announced and unannounced inspections of manufacturing and other facilities. The failure by us or one of our suppliers to comply with applicable statutes and regulations administered by the FDA, or the failure to timely and adequately respond to any adverse inspectional observations or product safety issues, could result in any of the following enforcement actions:

- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- unanticipated expenditures to address or defend such actions;
- customer notifications or repair, replacement, refunds, recall, detention or seizure of our products;
- operating restrictions, partial suspension or total shutdown of production;
- refusing or delaying our requests for regulatory approvals of new products or modified products;
- withdrawing PMA approvals that have already been granted;
- refusal to grant export approval for our products; or
- criminal prosecution.

Any of these sanctions could have a material adverse effect on our reputation, business, results of operations and financial condition. Furthermore, our key component suppliers may not currently be or may not continue to be in compliance with all applicable regulatory requirements, which could result in our failure to produce our products on a timely basis and in the required quantities, if at all.

If we expand our operations outside the United States, our products and operations will be required to comply with standards set by foreign regulatory bodies, and those standards, types of evaluation and scope of review differ among foreign regulatory bodies. We intend to comply with the standards enforced by such foreign regulatory bodies as needed to commercialize our products. If we fail to comply with any of these standards adequately, a foreign regulatory body may take adverse actions similar to those within the power of the FDA. For example, if we seek to obtain CE marks permitting us to commercially distribute our products in Europe, we will be subject to a conformity assessment procedure under which a so-called Notified Body, an organization accredited by a member state of the European Economic Area, or EEA, will audit and examine our quality system for the manufacture, design, and release of our products and confirm adherence with applicable regulatory requirements. If we fail to obtain or maintain a CE mark in accordance with these requirements, we would be precluded from selling our products in the EEA. Any such action or circumstance may harm our reputation and business, and could have an adverse effect on our business, results of operations and financial condition.

Our products may in the future be subject to product recalls. A recall of our products, either voluntarily or at the direction of the FDA or another governmental authority, or the discovery of serious safety issues with our products, could have a significant adverse impact on us.

The FDA and similar foreign governmental authorities have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture. In the case of the FDA, the authority to require a recall must be based on an FDA finding that there is reasonable probability that the device would cause serious injury or death. In addition, foreign governmental bodies have the authority to require the recall of our products in their respective jurisdictions in the event of material deficiencies or defects in the design or manufacture of our products. We may, under our own initiative, recall a product if any material deficiency in our steroid-eluting implants is found. The FDA requires that recalls be reported to the FDA within 10 working days after the recall is initiated. A government-mandated or voluntary recall by us or one of our international distributors could occur as a result of an unacceptable risk to health, component failures, malfunctions, manufacturing errors, design or labeling defects or other deficiencies and issues. Recalls of any of our products would divert managerial and financial resources and have an adverse effect on our reputation, results of operations and financial condition, which could impair our ability to produce our products in a cost- effective and timely manner in order to meet our customers' demands. We may also be subject to liability claims, be required to bear other costs, or take other actions that may have a negative impact on our future sales and our ability to generate profits. Companies are required to maintain certain records of recalls, even if they are not reportable to the FDA. We may initiate voluntary recalls involving our products in the future that we determine do not require notification of the FDA. If the FDA disagrees with our determinations, they could require us to report those actions as recalls. A future recall announcement could harm our reputation with customers and negatively affect our sales. In addition, the FDA could take enforcement action for failing to report the recalls when they were conducted.

If the third parties on which we rely to conduct our clinical trials and to assist us with pre-clinical development do not perform as contractually required or expected, we may not be able to obtain regulatory approval for or commercialize our products.

We often must rely on third parties, such as medical institutions, clinical investigators, contract research organizations and contract laboratories to conduct our clinical trials and provide data or prepare deliverables for our PMA or NDA submissions. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if these third parties need to be replaced, or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our pre-clinical development activities or clinical trials may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize, our products on a timely basis, if at all, and our business, operating results and prospects may be adversely affected. Furthermore, our third-party clinical trial investigators may be delayed in conducting our clinical trials for reasons outside of their control.

We may be subject to enforcement action if we engage in improper marketing or promotion of our products.

Our promotional materials and training methods must comply with FDA and other applicable laws and regulations, including the prohibition of the promotion of unapproved, or off-label, use. Physicians may use our products off-label, as the FDA does not restrict or regulate a physician's choice of treatment within the practice of medicine. However, if the FDA determines that our promotional materials or training constitutes promotion of an off-label use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fine or criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our promotional or training materials to constitute promotion of an off-label use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. In that event, our reputation could be damaged and adoption of the products could be impaired. Although our policy is to refrain from statements that could be considered off-label promotion of our products, the FDA or another regulatory agency could disagree and conclude that we have engaged in off-label promotion. In addition, the off-label use of our products may increase the risk of product liability claims. Product liability claims are expensive to defend and could divert our management's attention, result in substantial damage awards against us, and harm our reputation.

If we fail to comply with U.S. federal and state healthcare regulatory laws, we could be subject to penalties, including, but not limited to, administrative, civil and criminal penalties, damages, fines, disgorgement, exclusion from participation in governmental healthcare programs, and the curtailment of our operations, any of which could adversely impact our reputation and business operations.

There are numerous U.S. federal and state healthcare regulatory laws, including, but not limited to, anti-kickback laws, false claims laws, privacy laws, and transparency laws. Our relationships with healthcare providers and entities, including but not limited to, physicians, hospitals, ambulatory surgery centers, group purchasing organizations and our international distributors are subject to scrutiny under these laws. Violations of these laws can subject us to penalties, including, but not limited to, administrative, civil and criminal penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in federal and state healthcare programs, including the Medicare, Medicaid and Veterans Administration health programs, and the curtailment of our operations. Healthcare fraud and abuse regulations are complex, and even minor irregularities can potentially give rise to claims that a statute or prohibition has been violated. The laws that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering, or paying remuneration, directly or indirectly, in cash or in kind, in exchange for or to induce either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service for which payment may be made, in whole or in part, under federal healthcare programs such as Medicare and Medicaid;
- the federal civil False Claims Act, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other third-party payors that are false or fraudulent; knowingly making using, or causing to be made our used, a false record or statement to get a false or fraudulent claim paid or approved by the government; or knowingly making, using, or causing to be made or used, a false record or statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal criminal False Claims Act, which imposes criminal fines or imprisonment against individuals or entities who make or present a claim to the government knowing such claim to be false, fictitious or fraudulent;
- the civil monetary penalties statute, which imposes penalties against any person or entity who, among other things, is determined to have presented or caused to be presented, a claim to a federal healthcare program that the person knows, or should know, is for an item or service that was not provided as claimed or is false or fraudulent;
- the federal Health Insurance Portability and Accountability Act of 1996, as amended, which created federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, which impose requirements on certain covered healthcare providers, health plans and healthcare clearinghouses as well as their business associates that perform services for them that involve individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization, including mandatory contractual terms as well as directly applicable privacy and security standards and requirements;
- the Federal Trade Commission Act and similar laws regulating advertisement and consumer protections;

- the federal Foreign Corrupt Practices Act of 1997, which prohibits corrupt payments, gifts or transfers of value to foreign officials; and
- foreign or U.S. state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers.

Further, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or, collectively, the Affordable Care Act, among other things, amends the intent requirements of the federal Anti-Kickback Statute and certain criminal statutes governing healthcare fraud. A person or entity can now be found guilty of violating the statute without actual knowledge of the statute or specific intent to violate it. In addition, the Affordable Care Act provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act. Moreover, while we do not submit claims and our customers make the ultimate decision on how to submit claims, from time-to-time, we may provide reimbursement guidance to our customers. If a government authority were to conclude that we provided improper advice to our customers or encouraged the submission of false claims for reimbursement, we could face action against us by government authorities. Any violations of these laws, or any action against us for violation of these laws, even if we successfully defend against it, could result in a material adverse effect on our reputation, business, results of operations and financial condition.

We have entered into consulting agreements with physicians, including some who influence the ordering of and use our products in procedures they perform. While we believe these transactions were structured to comply with all applicable laws, including state and federal anti-kickback laws, to the extent applicable, regulatory agencies may view these transactions as prohibited arrangements that must be restructured, or discontinued, or for which we could be subject to other significant penalties. We could be adversely affected if regulatory agencies interpret our financial relationships with ENT physicians who influence the ordering of and use our products to be in violation of applicable laws. This could subject us to the penalties described above.

Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available under such laws, it is possible that some of our business activities, including our relationships with healthcare providers and entities, including, but not limited to, physicians, hospitals, ambulatory surgery centers, group purchasing organizations and our independent distributors and certain sales and marketing practices, including the provision of certain items and services to our customers, could be subject to challenge under one or more of such laws.

To enforce compliance with the healthcare regulatory laws, federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Responding to investigations can be time-and resource-consuming and can divert management’s attention from the business. Additionally, as a result of these investigations, healthcare providers and entities may have to agree to additional onerous compliance and reporting requirements as part of a consent decree or corporate integrity agreement. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business.

In certain cases, federal and state authorities pursue actions for false claims on the basis that manufacturers and distributors are promoting off-label uses of their products. Pursuant to FDA regulations, we can only market our products for cleared or approved uses. Although physicians are permitted to use medical devices for indications other than those cleared or approved by the FDA in their professional medical judgment, we are prohibited from promoting products for off-label uses. We market our products and provide promotional materials and training programs to physicians regarding the use of our products. If it is determined that our business activities, including our marketing, promotional materials or training programs constitute promotion of unapproved uses, we could be subject to significant fines in addition to regulatory enforcement actions, including the issuance of a warning letter, injunction, seizure and criminal penalty.

In addition, there has been a recent trend of increased federal and state regulation of payments and transfers of value provided to healthcare professionals or entities. On February 8, 2013, the Centers for Medicare & Medicaid Services, or CMS, released its final rule implementing section 6002 of the Affordable Care Act known as the Physician Payment Sunshine Act that imposes new annual reporting requirements on device manufacturers for payments and other transfers of value provided by them, directly or indirectly, to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their family members. A manufacturer’s failure to submit timely, accurately and completely the required information for all payments, transfers of value or ownership or investment interests may result in civil monetary penalties of up to an aggregate of $150,000 per year, and up to an aggregate of $1.0 million per year for “knowing failures.” The period between August 1, 2013, and December 31, 2013 was the first reporting period, for which manufacturers were required to report aggregate payment data to CMS by March 31, 2014. Manufacturers also will be required to report to CMS detailed payment and transfers of value data and submit legal attestation to the accuracy of such data during Phase 2 of the program, which is expected to begin in May 2014 and extends for at least 30 days. Thereafter, manufacturers must submit reports by the 90th day of each subsequent calendar year. Due to the difficulty in complying with the Physician Payment Sunshine Act, we cannot assure you that we will successfully report all payments and transfers of value provided by us, and any failure to comply could result in significant fines and penalties. Some states, such as California and Connecticut, also mandate implementation of commercial compliance programs, and other states, such as Massachusetts and Vermont, impose restrictions on device manufacturer marketing practices and tracking and reporting of gifts, compensation and other remuneration to

healthcare professionals and entities. The shifting commercial compliance environment and the need to build and maintain robust and expandable systems to comply with different compliance and reporting requirements in multiple jurisdictions increase the possibility that a healthcare company may fail to comply fully with one or more of these requirements.

Although compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business.

Most of these laws apply to not only the actions taken by us, but also actions taken by our distributors. We have limited knowledge and control over the business practices of our distributors, and we may face regulatory action against us as a result of their actions which could have a material adverse effect on our reputation, business, results of operations and financial condition.

In addition, the scope and enforcement of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal or state regulatory authorities might challenge our current or future activities under these laws. Any such challenge could have a material adverse effect on our reputation, business, results of operations and financial condition. Any state or federal regulatory review of us, regardless of the outcome, would be costly and time-consuming. Additionally, we cannot predict the impact of any changes in these laws, whether or not retroactive.

Legislative or regulatory healthcare reforms may make it more difficult and costly for us to obtain regulatory approval of our products and to produce, market and distribute our products after approval is obtained.

FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Any new regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of our products. Delays in receipt of, or failure to receive, regulatory approvals for our new products would have a material adverse effect on our business, results of operations and financial condition.

Federal and state governments in the United States have recently enacted legislation to overhaul the nation's healthcare system. While the goal of healthcare reform is to expand coverage to more individuals, it also involves increased government price controls, additional regulatory mandates and other measures designed to constrain medical costs. The Affordable Care Act significantly impacts the medical device industry. Among other things, the Affordable Care Act:

- imposes an annual excise tax of 2.3% on any entity that manufactures or imports medical devices offered for sale in the United States beginning in 2013;
- establishes a new Patient-Centered Outcomes Research Institute to oversee and identify priorities in comparative clinical effectiveness research in an effort to coordinate and develop such research;
- implements payment system reforms including a national pilot program on payment bundling to encourage hospitals, physicians and other providers to improve the coordination, quality and efficiency of certain healthcare services through bundled payment models; and
- creates an independent payment advisory board that will submit recommendations to reduce Medicare spending if projected Medicare spending exceeds a specified growth rate.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. On August 2, 2011, President Obama signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee did not achieve a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, triggering the legislation's automatic reduction to several government programs. This includes reductions to Medicare payments to providers of 2% per fiscal year, which went into effect in April 2013 and will stay in effect through 2024, unless additional congressional action is taken. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, or the ATRA, which, among other things, further reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our products or additional pricing pressure.

Our financial performance may be adversely affected by medical device tax provisions in the healthcare reform laws.

The Affordable Care Act imposes, among other things, an excise tax of 2.3% on any entity that manufactures or imports specified medical devices offered for sale in the United States beginning in 2013. Under these provisions, the Congressional Research Service predicts that the total cost to the medical device industry may be up to $29 billion over the next decade. The Internal Revenue Service issued final regulations implementing the tax in December of 2012 which requires, among other things, bi-monthly payments and quarterly reporting. We anticipate that primarily all sales of our products in the United States will be subject to this 2.3% excise tax. During the year ended December 31, 2013 and the six months ended June 30, 2014, we recognized $0.3 million in tax expense for each period associated with the medical device tax in the United States, which is included in selling, general and administrative expenses.

Our operations involve the use of hazardous and toxic materials, and we must comply with environmental laws and regulations, which can be expensive, and may affect our business and operating results.

We are subject to a variety of federal, state and local regulations relating to the use, handling, storage, disposal and human exposure to hazardous materials. Liability under environmental laws can be joint and several and without regard to comparative fault, and environmental laws could become more stringent over time, imposing greater compliance costs and increasing risks and penalties associated with violations, which could harm our business. Although we believe that our activities conform in all material respects with environmental laws, there can be no assurance that violations of environmental and health and safety laws will not occur in the future as a result of human error, accident, equipment failure or other causes. The failure to comply with past, present or future laws could result in the imposition of fines, third-party property damage and personal injury claims, investigation and remediation costs, the suspension of production, or a cessation of operations. We also expect that our operations will be affected by other new environmental and health and safety laws on an ongoing basis. Although we cannot predict the ultimate impact of any such new laws, they will likely result in additional costs, and may require us to change how we manufacture our products, which could have a material adverse effect on our business.

Failure to comply with the United States Foreign Corrupt Practices Act, or the FCPA, and similar laws associated with any activities outside the United States could subject us to penalties and other adverse consequences.

We are subject to the FCPA and other anti-bribery legislation around the world. The FCPA generally prohibits covered entities and their intermediaries from engaging in bribery or making other prohibited payments, offers or promises to foreign officials for the purpose of obtaining or retaining business or other advantages. In addition, the FCPA imposes recordkeeping and internal controls requirements on publicly traded corporations and their foreign affiliates, which are intended to, among other things, prevent the diversion of corporate funds to the payment of bribes and other improper payments, and to prevent the establishment of “off books” slush funds from which such improper payments can be made. Although we do not currently have any operations outside the United States, in the future we may face significant risks if we fail to comply with the FCPA and other laws that prohibit improper payments, offers or promises of payment to foreign governments and their officials and political parties by us and other business entities for the purpose of obtaining or retaining business or other advantages. In many foreign countries, particularly in countries with developing economies, some of which represent significant markets for us, it may be a local custom that businesses operating in such countries engage in business practices that are prohibited by the FCPA or other laws and regulations. Although we have implemented a company policy requiring our employees and consultants to comply with the FCPA and similar laws, such policy may not be effective at preventing all potential FCPA or other violations. There can be no assurance that none of our employees and agents, or those companies to which we outsource certain of our business operations will not take actions that violate our policies or applicable laws, for which we may be ultimately held responsible. As a result of our focus on managing our growth, our development of infrastructure designed to identify FCPA matters and monitor compliance is at an early stage. Any violation of the FCPA and related policies could result in severe criminal or civil sanctions, which could have a material and adverse effect on our reputation, business, operating results and financial condition.

Risks Relating to Intellectual Property Matters

Intellectual property rights may not provide adequate protection, which may permit third parties to compete against us more effectively.

Our success depends significantly on our ability to protect our proprietary rights to the technologies and inventions used in, or embodied by, our products. To protect our proprietary technology, we rely on patent protection, as well as a combination of copyright, trade secret and trademark laws, as well as nondisclosure, confidentiality and other contractual restrictions in our consulting and employment agreements. However, these legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep any competitive advantage.

Patents

The process of applying for patent protection itself is time consuming and expensive and we cannot assure you that all of our patent applications will issue as patents or that, if issued, they will issue in a form that will be advantageous to us. The rights granted to us under our patents, including prospective rights sought in our pending patent applications, may not be meaningful or provide us with any commercial advantage and they could be opposed, contested or circumvented by our competitors or be declared invalid or unenforceable in judicial or administrative proceedings.

We own numerous issued patents and pending patent applications that relate to the sinus delivery of sustained release therapeutics, sinus delivery of implants, implant designs as well as individual components of our steroid-eluting implants. The API contained in our steroid-eluting implants is generic and is not the subject of independent patent protection. If any of our patents are challenged, invalidated or legally circumvented by third parties, and if we do not own other enforceable patents protecting our products, competitors could market products and use processes that are substantially similar to, or superior to, ours, and our business

will suffer. In addition, the patents we own may not be of sufficient scope or strength to provide us with any meaningful protection or commercial advantage, and competitors may be able to design around our patents or develop products that provide outcomes comparable to ours without infringing on our intellectual property rights.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art, may affect patent litigation, and switch the U.S. patent system from a "first-to-invent" system to a "first-to-file" system. Under a "first-to-file" system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to the patent on an invention regardless of whether another inventor had made the invention earlier. The U.S. Patent and Trademark Office, or USPTO, recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first-to-file provisions, only became effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition. In addition, patent reform legislation may pass in the future that could lead to additional uncertainties and increased costs surrounding the prosecution, enforcement, and defense of our patents and applications.

We may be subject to a third-party preissuance submission of prior art to the USPTO, or become involved in opposition, derivation, reexamination, inter partes review, post-grant review, or other patent office proceedings or litigation, in the United States or elsewhere, challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights.

Moreover, the USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In addition, periodic maintenance fees on issued patents often must be paid to the USPTO and foreign patent agencies over the lifetime of the patent. While an unintentional lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we fail to maintain the patents and patent applications covering our products or procedures, we may not be able to stop a competitor from marketing products that are the same as or similar to our products, which would have a material adverse effect on our business.

Furthermore, we do not have patent rights in certain foreign countries in which a market may exist in the future, and the laws of many foreign countries may not protect our intellectual property rights to the same extent as the laws of the United States. Thus, we may not be able to stop a competitor from marketing and selling in foreign countries products that are the same as or similar to our products.

Trademarks

We rely on our trademarks as one means to distinguish our products from the products of our competitors, and have registered or applied to register many of these trademarks. Our trademark applications may not be approved, however. Third parties may oppose our trademark applications, or otherwise challenge our use of the trademarks. In the event that our trademarks are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing new brands. Our competitors may infringe our trademarks and we may not have adequate resources to enforce our trademarks.

Trade Secrets and Know-How

We may not be able to prevent the unauthorized disclosure or use of our technical knowledge or other trade secrets by consultants, vendors, former employees or current employees, despite the existence generally of confidentiality agreements and other contractual restrictions. Monitoring unauthorized uses and disclosures of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property will be effective.

Moreover, our competitors may independently develop equivalent knowledge, methods and know-how. Competitors could purchase our steroid-eluting implants and attempt to replicate some or all of the competitive advantages we derive from our development efforts, willfully infringe our intellectual property rights, design around our protected technology or develop their own competitive technologies that fall outside of our intellectual property rights. If our intellectual property is not adequately protected so as to protect our market against competitors' products and methods, our competitive position could be adversely affected, as could our business.

We may in the future be a party to patent and other intellectual property litigation and administrative proceedings that could be costly and could interfere with our ability to sell our steroid-eluting implants.

The medical device industry has been characterized by frequent and extensive intellectual property litigation. Additionally, the ENT market is extremely competitive. Our competitors or other patent holders may assert that our steroid-eluting implants and the methods employed in our steroid-eluting implants are covered by their patents. If our steroid-eluting implants or methods are found to infringe, we could be prevented from manufacturing or marketing our steroid-eluting implants. In the event that we become involved in such a dispute, we may incur significant costs and expenses and may need to devote resources to resolving any claims, which would reduce the cash we have available for operations and may be distracting to management. We do not know whether our competitors or potential competitors have applied for, will apply for, or will obtain patents that will prevent, limit or interfere with our ability to make, use, sell, import or export our steroid-eluting implants. Competing products may also be sold in other countries in which our patent coverage might not exist or be as strong. If we lose a foreign patent lawsuit, alleging our infringement of a competitor's patents, we could be prevented from marketing our steroid-eluting implants in one or more foreign countries. We may also initiate litigation against third parties to protect our own intellectual property. Our intellectual property has not been tested in litigation. If we initiate litigation to protect our rights, we run the risk of having our patents invalidated, which would undermine our competitive position.

Litigation related to infringement and other intellectual property claims, with or without merit, is unpredictable, can be expensive and time-consuming and can divert management's attention from our core business. If we lose this kind of litigation, a court could require us to pay substantial damages, treble damages and attorneys' fees, and prohibit us from using technologies essential to our steroid-eluting implants, any of which would have a material adverse effect on our business, results of operations and financial condition. If relevant patents are upheld as valid and enforceable and we are found to infringe, we could be prevented from selling our steroid-eluting implants unless we can obtain licenses to use technology or ideas covered by such patents. We do not know whether any necessary licenses would be available to us on satisfactory terms, if at all. If we cannot obtain these licenses, we could be forced to design around those patents at additional cost or abandon our products altogether. As a result, our ability to grow our business and compete in the market may be harmed.

We may be subject to damages resulting from claims that we or our employees have wrongfully used or disclosed alleged trade secrets of our competitors or are in breach of non-competition or non-solicitation agreements with our competitors.

Many of our employees were previously employed at other medical device companies, including our competitors or potential competitors, in some cases until recently. We could in the future be subject to claims that we or our employees have inadvertently or otherwise used or disclosed alleged trade secrets or other proprietary information of these former employers or competitors. In addition, we have been and may in the future be subject to claims that we caused an employee to breach the terms of his or her non-competition or non-solicitation agreement. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and could be a distraction to management. If our defense to those claims fails, in addition to paying monetary damages, a court could prohibit us from using technologies or features that are essential to our products, if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers. An inability to incorporate technologies or features that are important or essential to our products would have a material adverse effect on our business, and may prevent us from selling our products. In addition, we may lose valuable intellectual property rights or personnel. Any litigation or the threat thereof may adversely affect our ability to hire employees or contract with independent sales representatives. A loss of key personnel or their work product could hamper or prevent our ability to commercialize our products, which could have an adverse effect on our business, results of operations and financial condition.

Risks Relating to Our Capital Requirements and Finances

We may need substantial additional funding and may be unable to raise capital when needed, which would force us to delay, reduce, eliminate or abandon our commercialization efforts or product development programs.

Our ability to continue as a going concern may require us to obtain additional financing to fund our operations. We may need to raise substantial additional capital to:

- expand the commercialization of our products;
- fund our operations and clinical studies;
- continue our research and development activities;
- defend, in litigation or otherwise, any claims that we infringe third-party patents or other intellectual property rights;
- enforce our patent and other intellectual property rights;
- address legal or enforcement actions by the FDA or other governmental agencies and remediate underlying problems;
- commercialize our new products in development, if any such products receive regulatory clearance or approval for commercial sale; and
- acquire companies and in-license products or intellectual property.

We believe that our existing cash and cash equivalents, including from the initial public offering of our common stock in July 2014, revenue, and available debt financing arrangements will be sufficient to meet our capital requirements and fund our operations at least through 2016. However, we have based these estimates on assumptions that may prove to be wrong, and we could spend our available financial resources much faster than we currently expect. Any future funding requirements will depend on many factors, including:

- market acceptance of our products;
- the scope, rate of progress and cost of our clinical studies;
- the cost of our research and development activities;
- the cost of filing and prosecuting patent applications and defending and enforcing our patent or other intellectual property rights;
- the cost of defending, in litigation or otherwise, any claims that we infringe third-party patents or other intellectual property rights;
- the cost and timing of additional regulatory clearances or approvals;
- the cost and timing of establishing additional sales, marketing and distribution capabilities;
- costs associated with any product recall that may occur;
- the effect of competing technological and market developments;
- the extent to which we acquire or invest in products, technologies and businesses, although we currently have no commitments or agreements relating to any of these types of transactions; and
- the costs of operating as a public company.

If we raise additional funds by issuing equity securities, our stockholders may experience dilution. Any future debt financing into which we enter may impose upon us covenants that restrict our operations, including limitations on our ability to incur liens or additional debt, pay dividends, repurchase our stock, make certain investments and engage in certain merger, consolidation or asset sale transactions. Any debt financing or additional equity that we raise may contain terms that are not favorable to us or our stockholders. If we raise additional funds through collaboration and licensing arrangements with third parties, it may be necessary to relinquish some rights to our technologies or our products, or grant licenses on terms that are not favorable to us. If we are unable to raise adequate funds, we may have to liquidate some or all of our assets, or delay, reduce the scope of or eliminate some or all of our development programs.

We cannot be certain that additional funding will be available on acceptable terms, if at all. If we do not have, or are not able to obtain, sufficient funds, we may have to delay development or commercialization of our products or license to third parties the rights to commercialize products or technologies that we would otherwise seek to commercialize. We also may have to reduce marketing, customer support or other resources devoted to our products or cease operations. Any of these factors could harm our operating results.

Our ability to use our net operating losses and research and development credit carryforwards to offset future taxable income may be subject to certain limitations.

In general, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, a corporation that undergoes an "ownership change," generally defined as a greater than 50% change by value in its equity ownership over a three-year period, is subject to limitations on its ability to utilize its pre-change net operating losses, or NOLs, and its research and development credit carryforwards to offset future taxable income. Our existing NOLs and research and development credit carryforwards may be subject to limitations arising from previous ownership changes, and if we undergo an ownership change, our ability to utilize NOLs and research and development credit carryforwards could be further limited by Sections 382 and 383 of the Code. Future changes in our stock ownership, some of which might be beyond our control, could result in an ownership change under Section 382 of the Code. For these reasons, in the event we experience a change of control, we may not be able to utilize a material portion of the NOLs and research and development credit carryforwards, even if we attain profitability.

Risks Related to Our Common Stock

An active trading market may not be sustained.

Prior to our initial public offering of our common stock in July 2014, there was no public market for our common stock. Although our stock is currently traded on the NASDAQ Stock Market, an active trading market may not be sustained. The lack of an active market may impair the value of your shares and your ability to sell your shares at the time you wish to sell them. An inactive market may also impair our ability to both raise capital by selling shares and acquire other complementary products, technologies or businesses by using our shares as consideration.

We expect that the price of our common stock will fluctuate substantially.

The market price of our common stock is likely to be highly volatile and may fluctuate substantially due to many factors, including:

- volume and timing of sales of our steroid-eluting implants;
- the introduction of new products or product enhancements by us or others in our industry;
- disputes or other developments with respect to our or others' intellectual property rights;
- our ability to develop, obtain regulatory clearance or approval for, and market new and enhanced products on a timely basis;
- product liability claims or other litigation;
- quarterly variations in our results of operations or those of others in our industry;
- sales of large blocks of our common stock, including sales by our executive officers and directors;
- media exposure of our steroid-eluting implants or products of others in our industry;
- changes in governmental regulations or in the status of our regulatory approvals or applications;
- changes in earnings estimates or recommendations by securities analysts; and
- general market conditions and other factors, including factors unrelated to our operating performance or the operating performance of our competitors.

In recent years, the stock markets generally have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. Broad market and industry factors may significantly affect the market price of our common stock, regardless of our actual operating performance. These fluctuations may be even more pronounced in the trading market for our common stock.

In addition, in the past, class action litigation has often been instituted against companies whose securities have experienced periods of volatility in market price. Securities litigation brought against us following volatility in our stock price, regardless of the merit or ultimate results of such litigation, could result in substantial costs, which would hurt our financial condition and operating results and divert management's attention and resources from our business.

These and other factors may make the price of our stock volatile and subject to unexpected fluctuation.

Securities analysts may not publish favorable research or reports about our business or may publish no information at all, which could cause our stock price or trading volume to decline.

The trading market for our common stock will be influenced to some extent by the research and reports that industry or financial analysts publish about us and our business. We do not control these analysts. As a newly public company, we may be slow to attract research coverage and the analysts who publish information about our common stock will have had relatively little experience with our company or industry, which could affect their ability to accurately forecast our results and could make it more likely that we fail to meet their estimates. In the event we obtain securities or industry analyst coverage, if any of the analysts who cover us provide inaccurate or unfavorable research or issue an adverse opinion regarding our stock price, our stock price could decline. If one or more of these analysts cease coverage of our company or fail to publish reports covering us regularly, we could lose visibility in the market, which in turn could cause our stock price or trading volume to decline.

We are an "emerging growth company" and we cannot be certain if the reduced disclosure requirements applicable to "emerging growth companies" will make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and we may take advantage of certain exemptions and relief from various reporting requirements that are applicable to other public companies that are not "emerging growth companies." In particular, while we are an "emerging growth company" (1) we will not be required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act, (2) we will be exempt from any rules that may be adopted by the Public Company Accounting Oversight Board requiring mandatory audit firm rotations or a supplement to the auditor's report on financial statements, (3) we will be subject to reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and (4) we will not be required to hold nonbinding advisory votes on executive compensation or stockholder approval of any golden parachute payments not previously approved.

In addition, while we are an "emerging growth company" we will not be required to comply with any new financial accounting standard until such standard is generally applicable to private companies. As a result, our financial statements may not be comparable to companies that are not "emerging growth companies" or elect not to avail themselves of this provision.

We may remain an "emerging growth company" until as late as December 31, 2019, the fiscal year-end following the fifth anniversary of the completion of our initial public offering, though we may cease to be an "emerging growth company" earlier under

certain circumstances, including (1) if the market value of our common stock that is held by nonaffiliates exceeds $700 million as of any June 30, in which case we would cease to be an "emerging growth company" as of the following December 31, or (2) if our gross revenue exceeds $1.0 billion in any fiscal year.

The exact implications of the JOBS Act are still subject to interpretations and guidance by the SEC and other regulatory agencies, and we cannot assure you that we will be able to take advantage of all of the benefits of the JOBS Act. In addition, investors may find our common stock less attractive if we rely on the exemptions and relief granted by the JOBS Act. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may decline or become more volatile.

A significant portion of our total outstanding shares are restricted from immediate resale but may be sold into the market in the near future. This could cause the market price of our common stock to drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell their shares, could result in a decrease in the market price of our common stock. As of July 31, 2014, we had outstanding 23,340,860 shares of common stock, 17,590,859 of which are currently restricted as a result of securities laws or lock-up agreements. Moreover, holders of a substantial number of shares of our common stock (an aggregate of 15,771,742 shares immediately after our initial public offering in July 2014), including shares of our common stock issuable upon the exercise or, in certain cases, net exercise of outstanding warrants, have rights, subject to some conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. We have also registered all shares of common stock that we may issue under our equity compensation plans. These shares can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates and the lock-up agreements described above.

Our directors, officers and principal stockholders have significant voting power and may take actions that may not be in the best interests of our other stockholders.

Our officers, directors and principal stockholders each holding more than 5% of our common stock, collectively, control approximately 65.9% of our outstanding common stock. As a result, these stockholders, if they act together, will be able to control the management and affairs of our company and most matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. This concentration of ownership may have the effect of delaying or preventing a change of control and might adversely affect the market price of our common stock. This concentration of ownership may not be in the best interests of our other stockholders.

If we experience material weaknesses in the future or otherwise fail to maintain an effective system of internal controls in the future, we may not be able to accurately report our financial condition or results of operations which may adversely affect investor confidence in us and, as a result, the value of our common stock.

As a result of being a public company, we will be required, under Section 404 of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting beginning with our Annual Report on Form 10-K for the year ended December 31, 2015. This assessment will need to include disclosure of any material weaknesses identified by our management in our internal control over financial reporting. A material weakness is a deficiency or combination of deficiencies in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of a company's annual and interim financial statements will not be detected or prevented on a timely basis.

We are further enhancing internal controls, processes and related documentation necessary to perform the evaluation needed to comply with Section 404. We may not be able to complete our evaluation, testing and any required remediation in a timely fashion. During the evaluation and testing process, if we identify one or more material weaknesses in our internal control over financial reporting, we will be unable to assert that our internal controls are effective. The effectiveness of our controls and procedures may be limited by a variety of factors, including:

- faulty human judgment and simple errors, omissions or mistakes;
- fraudulent action of an individual or collusion of two or more people;
- inappropriate management override of procedures; and
- the possibility that any enhancements to controls and procedures may still not be adequate to assure timely and accurate financial control.

When we cease to be an "emerging growth company" under the federal securities laws, our auditors will be required to express an opinion on the effectiveness of our internal controls. If we are unable to confirm that our internal control over financial reporting is effective, or if our auditors are unable to express an opinion on the effectiveness of our internal controls, we could lose investor confidence in the accuracy and completeness of our financial reports, which could cause the price of our common stock to decline.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

We are subject to the periodic reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act. We designed our disclosure controls and procedures to provide reasonable assurance that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

Provisions in our corporate charter documents and under Delaware law could make an acquisition of us more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our amended and restated certificate of incorporation and our amended and restated bylaws may discourage, delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable, including transactions in which stockholders might otherwise receive a premium for their shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Because our board of directors is responsible for appointing the members of our management team, these provisions could in turn affect any attempt by our stockholders to replace current members of our management team. Among others, these provisions include that:

- our board of directors has the right to expand the size of our board of directors and to elect directors to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors;
- our stockholders may not act by written consent or call special stockholders' meetings; as a result, a holder, or holders, controlling a majority of our capital stock would not be able to take certain actions other than at annual stockholders' meetings or special stockholders' meetings called by the board of directors, the chairman of the board, the chief executive officer or the president;
- our certificate of incorporation prohibits cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- the affirmative vote of holders of at least 66-2/3% of the voting power of all of the then outstanding shares of voting stock, voting as a single class, will be required (a) to amend certain provisions of our certificate of incorporation, including provisions relating to the size of the board, removal of directors, special meetings, actions by written consent and cumulative voting and (b) to amend or repeal our bylaws, although our bylaws may be amended by a simple majority vote of our board of directors;
- stockholders must provide advance notice and additional disclosures in order to nominate individuals for election to the board of directors or to propose matters that can be acted upon at a stockholders' meeting, which may discourage or deter a potential acquiror from conducting a solicitation of proxies to elect the acquiror's own slate of directors or otherwise attempting to obtain control of our company; and
- our board of directors may issue, without stockholder approval, shares of undesignated preferred stock; the ability to issue undesignated preferred stock makes it possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to acquire us.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

Recent Sales of Unregistered Equity Securities

During the three months ended June 30, 2014, we granted to employees options to purchase an aggregate of 0.4 million shares of common stock under our 2013 Plan, at a weighted average exercise price of $11.12 per share.

During the three months ended June 30, 2014, we issued and sold to employees, consultants and other service providers an aggregate of 0.1 million shares of our common stock upon the exercise of options under the 2013 Plan at a weighted average exercise price of $0.77 per share, for an aggregate exercise price of approximately $0.1 million.

The offers, sales and issuances of the securities described in Item 15(a) were deemed to be exempt from registration under the Securities Act under Rule 701 promulgated under the Securities Act as offers and sale of securities pursuant to certain compensatory benefit plans and contracts relating to compensation in compliance with Rule 701.

Use of Proceeds

In July 2014, we completed our initial public offering of 5,750,000 shares of common stock at an offering price of $11.00 per share, for gross proceeds of $63.3 million, and net proceeds of approximately $55.8 million, after deducting underwriting discounts and commissions of approximately $4.5 million and offering expenses of approximately $3.0 million. Our Registration Statement on Form S-1 (File No. 333-196974) relating to the offering was declared effective by the SEC on July 23, 2014.

The offering commenced on July 23, 2014, closed on July 29, 2014, and did not terminate before all of the shares in the IPO that were registered in the registration statement were sold. J.P. Morgan Securities LLC and Piper Jaffray & Co acted as managing underwriters.

No offering expenses were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning ten percent or more of any class of our equity securities or to any other affiliates.

There has been no material change in the planned use of proceeds from our IPO as described in our final prospectus filed with the SEC pursuant to Rule 424(b) under the Securities Act on July 24, 2014. The net proceeds from the offering have been invested in cash and cash equivalents.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not Applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

See the Exhibit Index following the signature page to this Quarterly Report on Form 10-Q for a list of exhibits filed or furnished with this report, which Exhibit Index is incorporated herein by reference.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Dated: September 4, 2014

Intersect ENT, Inc.
(Registrant)

/s/ Lisa D. Earnhardt
Lisa D. Earnhardt
President and Chief Executive Officer
(Duly Authorized Officer)

/s/ Jeryl L. Hilleman
Jeryl L. Hilleman
Chief Financial Officer
(Principal Financial and Accounting Officer)

EXHIBIT INDEX

Exhibit No.	Description
3.1	Amended and Restated Certificate of Incorporation as currently in effect. (Filed with the SEC as Exhibit 3.1 to the Company's current report on Form 8-K, filed with the SEC on July 30, 2014, SEC File No. 000-36545, and incorporated by reference).
3.2	Bylaws, as currently in effect. (Filed with the SEC as Exhibit 3.4 to Amendment No. 1 to the Company's Registration Statement on Form S-1, filed with the SEC on July 9, 2014, SEC File No. 333-196974, and incorporated by reference).
4.1	Form of Common Stock Certificate of the Company (Filed with the SEC as Exhibit 4.1 to the Company's Amendment No. 2 to Registration Statement on Form S-1, filed with the SEC on July 14, 2014, SEC File No. 333-196974, and incorporated by reference).
4.2	Reference is made to Exhibits 3.1 and 3.2.
4.3	Third Amended and Restated Investor Rights Agreement, dated as of February 15, 2013, by and among the Company and certain of its stockholders. (Filed with the SEC as Exhibit 10.6 to the Company's Registration Statement on Form S-1, filed with the SEC on June 23, 2014, SEC File No. 333-196974, and incorporated by reference).
10.1	Offer Letter by and between the registrant and Jeryl L. Hilleman, dated as of May 15, 2014 (Filed with the SEC as Exhibit 10.10 to the Company's Registration Statement on Form S-1, filed with the SEC on June 23, 2014, SEC File No. 333-196974, and incorporated by reference).
10.2#	Supply Agreement by and between the registrant and HOVIONE Inter Ltd, dated as of April 14, 2014 (Filed with the SEC as Exhibit 10.16 to Amendment No. 1 to the Company's Registration Statement on Form S-1, filed with the SEC on July 9, 2014, SEC File No. 333-196974, and incorporated by reference).
10.3#	Master Services Agreement by and between the registrant and Polymer Solutions Corporation, dated as of April 9, 2014 (Filed with the SEC as Exhibit 10.20 to the Company's Registration Statement on Form S-1, filed with the SEC on June 23, 2014, SEC File No. 333-196974, and incorporated by reference).
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document.
101.SCH	XBRL Taxonomy Extension Schema Document.
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.

* Exhibit 32.1 is being furnished and shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liability of that section, nor shall such exhibit be deemed to be incorporated by reference in any registration statement or other document filed under the Securities Act of 1933, as amended, or the Exchange Act, except as otherwise specifically stated in such filing.

\# Confidential treatment has been granted for certain portions of this exhibit.

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF
THE SARBANES-OXLEY ACT OF 2002

I, Lisa D. Earnhardt, certify that:

1. I have reviewed this Form 10-Q of Intersect ENT, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a–15(e) and 15d–15(e)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

September 4, 2014

/s/ Lisa D. Earnhardt
Lisa D. Earnhardt
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER
PURSUANT TO SECTION 302 OF
THE SARBANES-OXLEY ACT OF 2002

I, Jeryl L. Hilleman, certify that:

1. I have reviewed this Form 10-Q of Intersect ENT, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a–15(e) and 15d–15(e)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

September 4, 2014

/s/ Jeryl L. Hilleman
Jeryl L. Hilleman
Chief Financial Officer
(Principal Accounting and Financial Officer)

Exhibit 32.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
AND PRINCIPAL FINANCIAL OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO SECTION 906
OF THE SARBANES-OXLEY ACT OF 2002

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Lisa D. Earnhardt, President and Chief Executive Officer of Intersect ENT, Inc. (the "Company") and Jeryl L. Hilleman, Chief Financial Officer of the Company, each hereby certify that, to the best of his knowledge:

1. The Company's Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2014, to which this Certification is attached as Exhibit 32.1 (the "Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act, and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

September 4, 2014

/s/ Lisa D. Earnhardt
Lisa D. Earnhardt
President and Chief Executive Officer
(Principal Executive Officer)

/s/ Jeryl L. Hilleman
Jeryl L. Hilleman
Chief Financial Officer
(Principal Accounting and Financial Officer)

A signed original of this written statement required by Rule 13a-14(b) of the Securities Exchange Act of 1934 and 18 U.S.C. Section 1350 has been provided to the Registrant and will be retained by the Registrant and furnished to the Securities and Exchange Commission or its staff upon request.

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Registrant under the Securities Act of 1933 or the Securities Exchange Act of 1934 (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.