Table of Contents

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, 2017

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, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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

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

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

Shares of common stock outstanding as of July 31, 2017 were 29,189,423.

Table of Contents

INTERSECT ENT, INC.
Form 10-Q – QUARTERLY REPORT
For the Quarter Ended June 30, 2017

TABLE OF CONTENTS

Table of Contents

PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

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

	June 30, 2017 (unaudited)	December 31, 2016 (1)
Assets		
Current assets:		
Cash and cash equivalents	$ 14,023	$ 9,859
Short-term investments, available-for-sale	86,010	94,086
Accounts receivable, net	12,253	14,421
Inventory	7,979	5,613
Prepaid expenses and other current assets	1,400	1,313
Total current assets	121,665	125,292
Property and equipment, net	4,237	4,127
Other non-current assets	445	358
Total assets	$ 126,347	$ 129,777
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,525	$ 3,267
Accrued compensation	8,948	10,152
Other current liabilities	934	945
Total current liabilities	12,407	14,364
Deferred rent	831	1,016
Total liabilities	13,238	15,380
Commitments and contingencies (note 8)		
Stockholders' equity:		
Preferred stock, $0.001 par value;		
Authorized shares: 10,000 at June 30, 2017 and December 31, 2016;		
Issued and outstanding shares: none	—	—
Common stock, $0.001 par value;		
Authorized shares: 150,000 at June 30, 2017 and December 31, 2016;		
Issued and outstanding shares: 29,153 at June 30, 2017 and 28,673 at December 31, 2016	29	29
Additional paid-in capital	270,547	262,882
Accumulated other comprehensive loss	(40)	(37)
Accumulated deficit	(157,427)	(148,477)
Total stockholders' equity	113,109	114,397
Total liabilities and stockholders' equity	$ 126,347	$ 129,777

(1) Amounts have been derived from the December 31, 2016 audited financial statements included in the Company's Annual Report on Form 10-K 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,	
	2017	2016	2017	2016
Revenue	$23,985	$19,317	$44,459	$ 36,009
Cost of sales	3,684	3,117	6,568	6,327
Gross profit	20,301	16,200	37,891	29,682
Operating expenses:				
Selling, general and administrative	18,682	17,795	39,001	35,188
Research and development	4,176	4,588	8,396	9,083
Total operating expenses	22,858	22,383	47,397	44,271
Loss from operations	(2,557)	(6,183)	(9,506)	(14,589)
Interest income and other, net	288	224	556	409
Net loss	(2,269)	(5,959)	(8,950)	(14,180)
Other comprehensive (loss) income:				
Unrealized (loss) gain on short-term investments	(8)	36	(3)	133
Comprehensive loss	$ (2,277)	$ (5,923)	$ (8,953)	$(14,047)
Net loss per share, basic and diluted	$ (0.08)	$ (0.21)	$ (0.31)	$ (0.50)
Weighted average common shares used to compute net loss per share, basic and diluted	28,950	28,379	28,830	28,293

See accompanying notes to condensed financial statements.

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

	Six Months Ended June 30,	
	2017	**2016**
Operating activities:		
Net loss	$ (8,950)	$(14,180)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	689	540
Stock-based compensation expense	4,772	3,827
Amortization of net investment (discount) premium	(15)	173
Changes in operating assets and liabilities:		
Accounts receivable, net	2,168	1,490
Inventory	(2,366)	(1,948)
Prepaid expenses and other assets	(90)	237
Accounts payable	(645)	525
Accrued compensation	(1,204)	(2,647)
Other current liabilities and deferred rent	(196)	(516)
Net cash used in operating activities	(5,837)	(12,499)
Investing activities:		
Purchases of short-term investments	(61,592)	(92,669)
Maturities of short-term investments	69,680	84,725
Purchases of property and equipment	(981)	(1,042)
Net cash provided by (used in) investing activities	7,107	(8,986)
Financing activities:		
Proceeds from issuance of common stock	2,894	1,065
Net cash provided by financing activities	2,894	1,065
Net increase (decrease) in cash and cash equivalents	4,164	(20,420)
Cash and cash equivalents:		
Beginning of the period	9,859	34,809
End of the period	$ 14,023	$ 14,389
Non-cash investing activities:		
Property and equipment included in accounts payable	$ 121	$ 154

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 approved and in-development products are steroid releasing implants designed to treat the spectrum of needs among patients who are managed by ear, nose and throat ("ENT") physicians for chronic sinusitis, one of the most prevalent chronic diseases in the United States and one of the most costly conditions for U.S. employers. The Company's current commercial products comprise the PROPEL® family of products, which are PROPEL®, PROPEL® Mini and PROPEL® Contour. The PROPEL family of products are used predominantly in hospitals and ambulatory surgical settings, although they may also be used in the physician office setting of care. In addition to these commercial products, the Company is seeking approval of another steroid releasing implant, SINUVA™, previously known as the RESOLVE product, designed for use in the physician's office for treatment of patients who have had ethmoid sinus surgery yet suffer from recurrent sinus obstruction due to polyps. In May 2017, the U.S. Food and Drug Administration ("FDA") accepted the Company's New Drug Application ("NDA") for SINUVA.

Liquidity and Business Risks

As of June 30, 2017, the Company had cash, cash equivalents and short-term investments of $100.0 million, and an accumulated deficit of $157.4 million. The Company expects its cash, cash equivalents and short-term investments 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, 2017, is unaudited and is not necessarily indicative of the results for the full year. In the opinion of the Company's management, the interim data includes only normal and recurring adjustments necessary for a fair presentation of the Company's financial results for the three and six months ended June 30, 2017 and 2016. Certain information and footnote disclosures normally included in annual financial statements prepared in accordance with U.S. 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 Annual Report on Form 10-K ("Annual Report") for the year ended December 31, 2016 filed with the SEC on February 28, 2017.

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, 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 six months ended June 30, 2017, 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 its Annual Report.

Recent Accounting Pronouncements

There have been no significant changes to the disclosures in the recent accounting pronouncements during the six months ended June 30, 2017, as compared to the recent accounting pronouncements described in Note 2 of the "Notes to Financial Statements" in the Company's audited financial statements included in its Annual Report, except as described below.

In March 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2016-9, *Improvements to Employee Share-Based Payment Accounting* ("ASU 2016-9"). ASU 2016-9 simplifies several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, classification on the statement of cash flows and an entity can now make an entity-wide election to either estimate the

number of awards expected to vest or account for forfeitures when they occur. ASU 2016-9 was effective for annual periods beginning after December 15, 2016 and interim periods within those annual periods. The adoption of ASU 2016-9 did not have a material impact on the Company's financial condition or results of operations.

In August 2015, the FASB issued ASU No. 2015-14, *Revenue from Contracts with Customers: Deferral of the Effective Date* ("ASU 2015-14"), which defers the effective date of ASU No. 2014-09, *Revenue from Contracts with Customers* ("ASU 2014-09") by one year, and is now effective for all entities for annual reporting periods beginning after December 15, 2017. Early adoption is now permitted only as of annual reporting periods beginning after December 15, 2016. ASU 2014-09, 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 and will replace most existing revenue recognition guidance in U.S. GAAP when it becomes effective. In doing so, companies may need to use more judgment and make more estimates than under current guidance. These 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. The Company plans to adopt ASU 2014-09 on January 1, 2018 using the cumulative effect transition method and has substantially completed its evaluation of the potential impact. Based on the Company's work to-date, the Company does not believe the adoption of ASC 2014-09 will have a material effect on the Company's financial condition or results of operations. The Company will continue to monitor industry activities and any additional guidance provided by regulators, standards setters or the accounting profession and may adjust the Company's assessment and implementation plans accordingly.

3. Composition of Certain Financial Statement Items

Accounts Receivable (in thousands):

	June 30, 2017	December 31, 2016
Accounts receivable	$12,395	$ 14,583
Allowance for doubtful accounts	(142)	(162)
	$12,253	$ 14,421

Inventory (in thousands):

	June 30, 2017	December 31, 2016
Raw materials	$ 1,180	$ 778
Work-in-process	306	247
Finished goods	6,493	4,588
	$ 7,979	$ 5,613

4. Cash, Cash Equivalents and Short-term Investments

The following is a summary of cash, cash equivalents and short-term investments (available-for-sale), by type of instrument (in thousands):

	June 30, 2017				December 31, 2016			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Cash	$ 8,869	$ —	$ —	$ 8,869	$ 5,222	$ —	$ —	$ 5,222
Money market funds	5,154	—	—	5,154	4,637	—	—	4,637
Corporate debt securities	65,393	1	(36)	65,358	51,761	3	(26)	51,738
Commercial paper	20,657	1	(6)	20,652	42,362	6	(20)	42,348
	$100,073	$ 2	$ (42)	$100,033	$103,982	$ 9	$ (46)	$103,945
Reported as:								
Cash and cash equivalents				$ 14,023				$ 9,859
Short-term investments, available-for-sale				86,010				94,086
				$100,033				$103,945

As of June 30, 2017 and December 31, 2016, the Company had no investments with a contractual maturity of greater than one year.

Based on an evaluation of securities that have been in a loss position, the Company did not recognize any other-than-temporary impairment charges during the six months ended June 30, 2017 and year ended December 31, 2016. The Company considered various factors which included a credit and liquidity assessment of the underlying securities and the Company's intent and ability to hold the underlying securities until the estimated date of recovery of its amortized cost.

5. Fair Value of Financial Instruments

The Company measures certain financial assets and liabilities at fair value on a recurring basis, including cash equivalents and short-term investments, available-for-sale. 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 – 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.

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.

Cash, Cash Equivalents and Short-term Investments

The following is a summary of cash, cash equivalents and short-term investments (available-for-sale), by type of instrument measured at fair value on a recurring basis (in thousands):

	June 30, 2017				December 31, 2016			
	Level 1	Level 2	Level 3	Total	Level 1	Level 2	Level 3	Total
Cash	$ 8,869	$ —	$ —	$ 8,869	$5,222	$ —	$ —	$ 5,222
Money market funds	5,154	—	—	5,154	4,637	—	—	4,637
Corporate debt securities	—	65,358	—	65,358	—	51,738	—	51,738
Commercial paper	—	20,652	—	20,652	—	42,348	—	42,348
	$14,023	$86,010	$ —	$100,033	$9,859	$94,086	$ —	$103,945
Reported as:								
Cash and cash equivalents				$ 14,023				$ 9,859
Short-term investments, available-for-sale				86,010				94,086
				$100,033				$103,945

There were no transfers in and out of Level 1 and Level 2 during the six months ended June 30, 2017 and year ended December 31, 2016.

6. Stock-based Compensation Expense

2014 Equity Incentive Plan

In July 2014, the Company's board of directors approved the 2014 Equity Incentive Plan (the "2014 Plan"), which became effective upon the Company's Initial Public Offering ("IPO"). 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 the Company's 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. On January 1, 2017, the total number of shares of common stock reserved for issuance increased by 860,019 shares to 7,156,121 shares. The 2014 Plan allows the Company to 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. In January 2017, the Company began issuing restricted stock units ("RSUs"). The RSUs generally vest annually over three years.

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

	Six Months Ended June 30, 2017	
	Options	Weighted Average Exercise Price
Outstanding, beginning of period	3,585	$ 14.81
Granted	1,078	13.64
Exercised	(406)	5.21
Forfeited	(160)	19.44
Expired	(4)	2.67
Outstanding, end of period	4,093	15.28
Exercisable	1,795	13.74

As of June 30, 2017, the aggregate pre-tax intrinsic value of options outstanding was $51.9 million and options outstanding and exercisable was $25.5 million, the weighted-average remaining contractual term of options outstanding was 8.2 years and options outstanding and exercisable was 7.3 years. The aggregate pre-tax intrinsic value of options exercised was $6.8 million and $3.4 million during the six months ended June 30, 2017 and 2016, respectively.

A summary of the Company's RSU activity and related information (RSUs in thousands):

	Six Months Ended June 30, 2017	
	RSUs	Weighted Average Fair Value
Outstanding, beginning of period	—	$ —
Awarded	288	13.74
Vested	—	—
Forfeited	(3)	13.05
Outstanding, end of period	285	13.75

As of June 30, 2017, the aggregate pre-tax intrinsic value of RSUs outstanding was $8.0 million, calculated based on the closing price of the Company's common stock at the end of the period, and the weighted-average remaining contractual term of RSUs outstanding was 2.4 years.

Total stock-based compensation expense by security type (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Stock options (including ESPP)	$ 2,159	$ 1,940	$4,238	$3,827
RSUs	310	—	534	—
	$ 2,469	$ 1,940	$4,772	$3,827

Total stock-based compensation expense as it related to the Company's condensed statements of operations (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Cost of sales	$ 229	$ 182	$ 448	$ 352
Selling, general and administrative	1,826	1,473	3,524	2,901
Research and development	414	285	800	574
	$ 2,469	$ 1,940	$4,772	$3,827

As of June 30, 2017, the amount of unearned stock-based compensation currently estimated to be expensed from now through the year 2021 related to unvested employee stock-based awards was $21.1 million and the weighted average period over which the unearned stock-based compensation is expected to be recognized was 2.5 years. 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 fair value of options granted to employees and/or directors during the periods presented below were estimated as of the grant date using the Black-Scholes model assuming the following weighted average assumptions:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Expected term (years)	6.0	6.0	6.0	6.0
Expected volatility	45%	44%	45%	44%
Risk-free interest rate	1.9%	1.4%	2.1%	1.6%
Dividend yield	0.0%	0.0%	0.0%	0.0%
Fair value	$ 10.38	$ 6.50	$ 6.14	$ 7.95

The fair value of RSUs is estimated using the Company's stock price on the grant date.

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. During the six months ended June 30, 2017 and 2016, 74,791 and 67,755 shares were issued, respectively.

The fair value of options granted under the 2014 ESPP to employees was estimated as of the grant date using the Black-Scholes model assuming the following weighted average assumptions:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Expected term (years)	1.3	1.3	1.3	1.3
Expected volatility	44%	49%	44%	49%
Risk-free interest rate	1.2%	0.6%	1.2%	0.6%
Dividend yield	0.0%	0.0%	0.0%	0.0%
Fair value	$ 8.08	$ 4.53	$ 8.08	$ 4.53

7. 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 securities were antidilutive in those periods.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Common stock options	4,093	3,911	4,093	3,911
RSUs	285	—	285	—
ESPP shares	260	274	260	274
	4,638	4,185	4,638	4,185

8. 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 amounts 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.

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. 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 Annual Report on Form 10-K, or Annual Report, filed with the SEC on February 28, 2017.

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. Our approved and in-development products are steroid releasing implants designed to treat the spectrum of needs among patients who are managed by ENT physicians for chronic sinusitis, one of the most prevalent chronic diseases in the United States and one of the most costly conditions for U.S. employers. Our current commercial products comprise the PROPEL® family of products, which are PROPEL®, PROPEL® Mini, and most recently, PROPEL® Contour, for which we received approval to market from the U.S. Food and Drug Administration, or FDA, in February 2017.

Our PROPEL family of steroid releasing implants are the first and only dissolvable steroid releasing implants approved by the FDA for chronic sinusitis sufferers 18 years or older. Clinically proven to improve outcomes for chronic sinusitis patients following sinus surgery, PROPEL implants mechanically prop open the sinuses and release mometasone furoate, an advanced corticosteroid with anti-inflammatory properties which is available generically, directly into the sinus lining, then dissolve. PROPEL's safety and effectiveness is supported by Level 1-A clinical evidence from multiple clinical trials, which demonstrates that PROPEL implants reduce inflammation and scarring after surgery, thereby lessening the need for postoperative oral steroids and repeat surgical interventions. More than 150,000 patients have been treated with PROPEL products to-date. The PROPEL family of products are used today predominantly in hospitals and ambulatory surgical settings, although they may also be used in the physician office setting of care. Our current efforts to build our business focus on marketing the PROPEL family of products and on advancing FDA approval of SINUVA™, previously known as RESOLVE:

- PROPEL has been proven in a meta-analysis of prospective, multicenter, randomized, controlled, double-blind clinical studies to improve surgical outcomes, demonstrating a 35% reduction in the need for postoperative oral steroid and surgical intervention. A physician may treat a patient with PROPEL by inserting it into the ethmoid sinuses. PROPEL is a self-expanding implant designed to conform to and hold open the surgically enlarged sinus while gradually releasing an anti-inflammatory steroid over a period of approximately 30 days before being fully absorbed into the body.
- PROPEL Mini has also been shown by our clinical studies to reduce the need for postoperative interventions, including a reduction in the need for postoperative interventions in the frontal sinus by 38%, compared to surgery alone with standard post-operative care. PROPEL Mini is a smaller version of PROPEL, and is approved for use both in the ethmoid and frontal sinuses. PROPEL Mini is preferentially used by physicians compared with PROPEL when treating smaller anatomies or following less extensive procedures.
- PROPEL Contour is designed to facilitate treatment of the frontal and maxillary sinus ostia, or openings, of the dependent sinuses in procedures performed in both the operating room and in the office setting of care. PROPEL Contour's lower profile, hourglass shape and malleable delivery system are designed for use in narrow hard to access sinus ostia which especially facilitates procedures performed in the office setting of care. In PROPEL Contour's final pivotal clinical study, the product demonstrated a 65% relative reduction in the need for postoperative interventions compared to surgery alone with standard post-operative care.
- SINUVA is designed to provide a less invasive solution for patients that have had ethmoid sinus surgery yet suffer from recurrent sinus obstruction due to polyps. The SINUVA implant is designed to be placed in the ethmoid sinus in a procedure conducted in the physician's office as an alternative to other treatment options such as further medical therapy

or revision surgery. We have completed four studies of SINUVA in a total of 417 patients. In October 2016, we announced the results of RESOLVE II, a phase III trial of 300 patients to assess the safety and efficacy of the product. The RESOLVE II clinical study met both primary efficacy endpoints, reduction in nasal congestion and polyp burden. In May 2017, the FDA accepted our New Drug Application to seek regulatory approval to market SINUVA and set a Prescription Drug User Fee Act target action date, or PDUFA date, in January 2018.

We have expanded our sales organization and we intend to continue to grow our sales force in order to expand our communication of the benefits of our steroid releasing implants to our physician customers. We seek to grow our revenue by increasing the frequency of use of our products among current physician customers and by adding new physician users.

Components of Our Results of Operations

Revenue

All of our revenue is currently derived from sales of our PROPEL family of products. We expect our revenue to increase as we continue to expand our sales, marketing and reimbursement efforts and increase the 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, demand for our products may be impacted by adverse weather and by resetting of annual patient healthcare insurance plan deductibles, both of which may cause patients to delay or decline elective procedures such as functional endoscopic sinus surgery, or FESS. In the second quarter, demand may be impacted by the seasonal nature of allergies, the resultant onset of sinus-related symptoms and the growth of high deductible insurance plans which may cause patients to delay or decline elective surgery until their deductible is met later in the year. 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 higher due to 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 PROPEL family of products are used almost exclusively in the operating room of a hospital or ambulatory surgery center where they are commonly treated as general supplies utilized in sinus surgery and the cost is included in the reimbursement to the facility for the FESS procedure. In the event these procedures are performed in the physician office setting, our PROPEL family of products have been assigned a code under the Healthcare Common Procedure Coding System, S1090, which may be used to submit requests for product cost reimbursement to commercial payors. In addition, several existing procedure codes may apply to describe the procedure associated with implant placement. However, the decision to reimburse by the payor is usually dependent on policies the payor has in place regarding these products. If, as a result of policies the payor has in place regarding these products, hospitals or other service providers are unable to receive adequate reimbursement to support the use of our products, or if we are forced to lower the price we charge for our products, this will negatively impact our revenues and our gross margins will decrease, which will adversely affect our ability to invest in and grow our business.

Our revenue is almost entirely 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, 2017 and 2016.

Cost of Sales and Gross Profit

We manufacture our PROPEL family of products at our facility in Menlo Park, California. Cost of sales consists primarily of manufacturing overhead costs, material costs, direct labor and other direct costs such as shipping costs. 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, information technology, equipment and operations supervision and management. We expect overhead costs as a percentage of revenue to become less significant as our production volume increases. 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, including production volumes, average selling prices, manufacturing costs and product yields, and to a lesser extent the implementation of cost-reduction strategies. We expect our gross margin to fluctuate based on changes in the average selling price and the manufacturing costs of our products. Manufacturing cost will change as our production volume changes. The per unit allocation of our manufacturing overhead costs may decrease as production volume increases until we increase our manufacturing capacity, at which point the per unit allocation of our manufacturing overhead costs may increase due to the additional costs of our increased manufacturing capacity.

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, finance, reimbursement and post-market studies, business development, legal and human resource functions. Additional SG&A expenses include commissions, training, travel expenses, promotional activities, conferences, trade shows, professional services fees, audit and Sarbanes-Oxley Act of 2002 compliance expenses, insurance costs and general corporate expenses including allocated facilities and information technology expenses. We expect SG&A expenses to continue to increase in absolute dollars for the foreseeable future as we expand our commercial infrastructure to drive and support the anticipated growth in revenue and incur additional legal, accounting, insurance and other professional services fees.

Research and Development Expenses

Research and development, or R&D, expenses consist primarily of product development, clinical and regulatory affairs, consulting services and other costs associated with products and technologies in development. These expenses include employee compensation, stock-based compensation, supplies, quality assurance and related travel and allocated facilities and information technology 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 and commercialize new products as well as to enhance current products. 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. generally accepted accounting principles. 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 significant accounting policies during the six months ended June 30, 2017, as compared to the significant accounting policies described in our Annual Report. We believe that the accounting policies discussed in our Annual Report 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

See Note 2 of the Condensed Financial Statements under the heading "Recent Accounting Pronouncements" for new accounting pronouncements or changes to the recent accounting pronouncements during the six months ended June 30, 2017.

Results of Operations

	Three Months Ended June 30,		Six Months Ended June 30,	
(in thousands, except percentages)	**2017**	**2016**	**2017**	**2016**
Revenue	$23,985	$19,317	$44,459	$ 36,009
Cost of sales	3,684	3,117	6,568	6,327
Gross profit	20,301	16,200	37,891	29,682
Gross margin	85%	84%	85%	82%
Operating expenses:				
Selling, general and administrative	18,682	17,795	39,001	35,188
Research and development	4,176	4,588	8,396	9,083
Total operating expenses	22,858	22,383	47,397	44,271
Loss from operations	(2,557)	(6,183)	(9,506)	(14,589)
Interest income and other, net	288	224	556	409
Net loss	$ (2,269)	$ (5,959)	$ (8,950)	$(14,180)

Comparison of the Three and Six Months Ended June 30, 2017 and 2016

Revenue

Revenue increased $4.7 million, or 24%, to $24.0 million during the three months ended June 30, 2017, compared to $19.3 million during the three months ended June 30, 2016, and increased $8.5 million, or 23%, to $44.5 million during the six months ended June 30, 2017, compared to $36.0 million during the six months ended June 30, 2016. The growth in revenue was attributable to an increase in unit sales of our PROPEL family of products, driven by the initial sales of PROPEL Contour which was approved by the FDA in February 2017, and to a lesser degree, an increase in the average selling price.

Cost of Sales and Gross Margin

Cost of sales increased $0.6 million, or 18%, to $3.7 million during the three months ended June 30, 2017, compared to $3.1 million during the three months ended June 30, 2016, and increased $0.3 million, or 4%, to $6.6 million during the six months ended June 30, 2017, compared to $6.3 million during the six months ended June 30, 2016. The increase in cost of sales was primarily attributable to the growth in the number of units sold.

Gross margin for the three months ended June 30, 2017, increased to 85% compared to 84% for the three months ended June 30, 2016, and increased to 85% compared to 82% for the six months ended June 30, 2016. The increase in gross margin was due to several factors, primarily an increase in our average selling price.

Selling, General and Administrative Expenses

SG&A expenses increased $0.9 million, or 5%, to $18.7 million during the three months ended June 30, 2017, compared to $17.8 million during the three months ended June 30, 2016, and increased $3.8 million, or 11%, to $39.0 million during the six months ended June 30, 2017, compared to $35.2 million during the six months ended June 30, 2016. The increase in SG&A expenses was primarily due to the build out of our infrastructure to support the ongoing commercialization of our PROPEL family of products, including PROPEL Contour which was approved by the FDA in February 2017.

The primary component of this increase was employee-related expenses of our sales, marketing and reimbursement organizations which increased $0.5 million and $3.1 million for the three and six months ended June 30, 2017, compared to the three and six months ended June 30, 2016, respectively, as we increased headcount to 152 as of June 30, 2017, compared to 138 as of June 30, 2016. In addition, other SG&A expenses increased $0.4 million and $0.7 million for the three and six months ended June 30, 2017, compared to the three and six months ended June 30, 2016, respectively, primarily due to an increase in headcount.

Research and Development Expenses

R&D expenses decreased $0.4 million, or 9%, to $4.2 million during the three months ended June 30, 2017, compared to $4.6 million during the three months ended June 30, 2016, and decreased $0.7 million, or 8%, to $8.4 million during the six months ended June 30, 2017, compared to $9.1 million during the six months ended June 30, 2016. The decrease in R&D expenses was due to a decrease in clinical trial costs, partially offset by an increase in personnel costs as we increased headcount.

Interest Income and Other, Net

Interest income and other, net, increased $0.1 million to $0.3 million during the three months ended June 30, 2017, compared to $0.2 million during the three months ended June 30, 2016, and increased $0.2 million to $0.6 million during the six months ended June 30, 2017, compared to $0.4 million during the six months ended June 30, 2016. The increase in interest income and other, net, was primarily attributable to higher interest rates.

Liquidity and Capital Resources

Overview

As of June 30, 2017, we had cash, cash equivalents and short-term investments of $100.0 million and an accumulated deficit of $157.4 million, compared to cash, cash equivalents and short-term investments of $103.9 million and an accumulated deficit of $148.5 million as of December 31, 2016.

Cash Flows

	Six Months Ended June 30,	
(in thousands)	**2017**	**2016**
Net cash (used in) provided by:		
Operating activities	$(5,837)	$(12,499)
Investing activities	7,107	(8,986)
Financing activities	2,894	1,065
Net increase (decrease) in cash and cash equivalents	$ 4,164	$(20,420)

Net Cash Used in Operating Activities

During the six months ended June 30, 2017, net cash used in operating activities was $5.8 million, consisting primarily of a net loss of $9.0 million and an increase in net operating assets of $2.3 million, partially offset by non-cash charges of $5.5 million. The cash used in operations was primarily due to the ongoing commercialization of our PROPEL family of products, including PROPEL

Contour which was approved by the FDA in February 2017. To support the ongoing commercialization of these products, we continued to expand our sales, marketing and reimbursement organizations. The non-cash charges primarily consisted of stock-based compensation expense. The increase in net operating assets is primarily due to an increase in inventory and the payment of accrued year-end bonuses, partially offset by a decrease in accounts receivable.

During the six months ended June 30, 2016, net cash used in operating activities was $12.5 million, consisting primarily of a net loss of $14.2 million and an increase in net operating assets of $2.8 million, partially offset by non-cash charges of $4.5 million. The cash used in operations was primarily due to the ongoing commercialization of PROPEL and PROPEL mini. To support the ongoing commercialization of these products, we continued to expand our sales, marketing and reimbursement organizations. The non-cash charges primarily consisted of stock-based compensation expense. The increase in net operating assets is primarily due to the payment of accrued year-end bonuses and an increase in inventory, partially offset by a decrease in accounts receivable.

Net Cash Provided by (Used in) Investing Activities

During the six months ended June 30, 2017, net cash provided by investing activities was $7.1 million, consisting primarily of net maturities of short-term investments, available-for-sale, of $8.1 million, partially offset by purchases of property and equipment of $1.0 million.

During the six months ended June 30, 2016, net cash used in investing activities was $9.0 million, consisting primarily of net purchases of short-term investments, available-for-sale, of 8.0 million and purchases of property and equipment of $1.0 million.

Net Cash Provided by Financing Activities

During the six months ended June 30, 2017, net cash provided by financing activities was $2.9 million, consisting of net proceeds from the issuance of common stock upon exercises of employee stock options.

During the six months ended June 30, 2016, net cash provided by financing activities was $1.1 million, consisting of net proceeds from the issuance of common stock upon exercises of employee stock options.

Liquidity

We currently believe that our existing cash, cash equivalents and short-term investments as of June 30, 2017, 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 credit facilities. 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 June 30, 2017 and December 31, 2016, 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, 2016, were $7.4 million, as reported in our Annual Report. Our contractual obligations as of June 30, 2017, have not significantly changed from December 31, 2016.

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 and short-term investments which are carried at fair market value. We do not currently use or plan to use financial derivatives in our investment portfolio.

As of June 30, 2017, we had cash, cash equivalents and short-term investments of $100.0 million. Cash equivalents and short-term investments are composed of money market funds, corporate debt securities and commercial paper. Our investment policy requires investments to be of high credit quality and generally limits the amount of credit exposure to any single issuer or group of issuers. Our objective is the preservation of capital and to maintain proper liquidity to meet our operating requirements while at the same time maximizing the income we receive from our financial instruments without significantly increasing risk. Because our short-term investments have a weighted average maturity of not more than one year, we believe the impact of a hypothetical 10% change in market interest rates at June 30, 2017 would not have a material effect on our financial position, results of operations or cash flows.

Credit Risk

As of June 30, 2017, our cash, cash equivalents and short-term investments were maintained with two financial institutions in the United States, and our current deposits are likely in excess of insured limits. We have reviewed the financial statements of these institutions and believe they have sufficient assets and liquidity to conduct their operations in the ordinary course of business with little or no credit risk to us.

Our accounts receivable relate to revenue from the sale of our PROPEL family of products to hospitals and ambulatory surgery centers almost entirely in the United States. No single customer represented more than 10% of our accounts receivable as of June 30, 2017 and December 31, 2016.

Foreign Currency Risk

Our business is almost entirely conducted in U.S. dollars. Transactions conducted in foreign currencies have not had, and 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, 2017. 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, 2017, 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.

Limitations on Effectiveness of Controls and Procedures and Internal Control over Financial Reporting

In designing and evaluating the disclosure controls and procedures and internal control over financial reporting, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures and internal control over financial reporting must reflect the fact that there are resource constraints and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the three months ended June 30, 2017, 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.

ITEM 1A. RISK FACTORS

Investing in our common stock involves a high degree of risk. You should consider carefully the risk factors discussed in this quarterly report on Form 10-Q, and all other information contained in this report, before making an investment decision. 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. The risks facing our business have not changed substantively from those discussed in our Annual Report, except for those risks marked with an asterisk (*).

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. We had a net loss of $9.0 million for the six months ended June 30, 2017, and $25.2 million and $26.6 million for the years ended December 31, 2016 and 2015, respectively. As of June 30, 2017, we had an accumulated deficit of $157.4 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 has been generated from our PROPEL® family of steroid releasing implants. We are completely dependent on the success of these products and if these products fail to continue to experience expanded adoption, our business will suffer.

We started selling PROPEL® in August 2011, PROPEL® Mini in November 2012 and PROPEL® Contour in February 2017. We expect that sales of these products, and potentially, SINUVA™ – if approved by the FDA and introduced by us, will account for substantially all of our revenue for the foreseeable future. Our ability to become profitable will depend upon the commercial success of these products. We market these products primarily to ear, nose and throat, or ENT, physicians who may be slow, or fail to adopt our products or who may use our products in only a small percentage of their patients undergoing sinus surgery for a variety of reasons, including, among others:

- lack of experience with our products;
- lack of availability of adequate coverage and/or 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;
- our inability to obtain reimbursement for our products from payors; and
- liability risks generally associated with the use of new products and procedures.

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.

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, 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 releasing implants, which could have an adverse effect on our business.***

Hospitals and ambulatory surgery centers 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. These healthcare providers bill patients for any related 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 releasing 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 releasing 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 releasing implants and could create additional pricing pressure for us.

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.

Further, from time to time, typically on an annual basis, payment amounts are updated and revised by third-party payors. On April 16, 2015, the Medicare Access and CHIP Reauthorization Act of 2015, or MACRA, was signed into law. MACRA permanently reforms Medicare payment policy for physician services by repealing the previous sustainable growth rate, or SGR, methodology, establishing a period of stable physician fee schedule updates and then linking updates to participation in either a new Merit-based

Incentive Payment System, or MIPS, or based on participation in qualified Alternative Payment Models, or APMs, (collectively referred to as the "Quality Payment Program"). The Centers for Medicare & Medicaid Services, or CMS, finalized MACRA's Quality Payment Program in 2016, though policies may continue to evolve.

At the beginning of 2017, CMS assigned upper airway procedures, which includes sinus surgery, to a comprehensive Ambulatory Payment Classification, or APC, for procedures performed in the hospital outpatient department setting. With this assignment, the reimbursement per case was set at a fixed amount regardless of the number of procedures performed during that encounter. As a result, while payment increased for encounters involving one or two procedures, payment for encounters with three or more procedures, which are commonly associated with the use of our products, declined significantly below the prior average reimbursement amount. Some commercial payors may use Medicare rates as a reference for facility contract negotiations. If, as a result of this CMS ruling, hospitals are unable to receive adequate reimbursement to support the use of our products, or if we are forced to lower the price we charge for our products, this will negatively impact our revenues and our gross margins will decrease, which will adversely affect our ability to invest in and grow our business. We cannot predict how pending and future healthcare legislation and regulations will impact our business and any changes that further restricts coverage of our products or lowers reimbursement for procedures using our products could materially affect our business.

The existence of adequate coverage and reimbursement will be important for sales of our products in the office setting of care. Inadequate coverage and reimbursement policies for our products could affect the adoption of our products and our future revenue.

Successful sales of our steroid releasing implants in the physician's office setting of care 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.

To receive payment for procedural work associated with the placement of our products, physicians may use a variety of existing Current Procedure Terminology, or CPT, codes. CMS has also assigned a Healthcare Common Procedure Coding System, or HCPCS, code of S1090 to seek reimbursement for the PROPEL implant itself. This code applies to the entire PROPEL family of products.

The HCPCS code S1090 cannot be reported to all payors, including Medicare. Separate payment for this code is dependent upon payor coverage. Since PROPEL Contour has clinical applications that include placement in the office setting, the inability to report HCPCS code S1090 to all payors may be a limiting factor to our sales of PROPEL Contour in the office setting. While PROPEL Contour can be reported with an unlisted HCPCS code J3490 to such payors in the office setting, payment for an unlisted code varies by payor and is also dependent upon favorable coverage by the payor. An application has been submitted to CMS to create a J code for the PROPEL family of products. If approved by CMS, this code could expand use of the PROPEL family of products in the office setting. We cannot assure that a J code for the PROPEL family of products will be created by CMS, nor can we assure the impact of this code upon coverage or payment of the PROPEL family of products.

For SINUVA, we expect to apply for a permanent HCPCS J code consistent with CMS timelines and requirements for physician-administered drugs used mostly in the office setting. Upon FDA approval and until such a product-specific code is assigned, we expect providers will be able to submit claims for reimbursement of SINUVA using an unassigned J code such as J3490 since this is the common path for physician-administered drugs and SINUVA is regulated as a drug, not a device. Our ability to obtain new billing codes will depend, in part, on published clinical evidence, support from the ENT community and physician adoption of our technology. Although obtaining permanent billing codes may result in payment amounts that better reflect the costs and resources associated with the use of our products, we cannot ensure we will be successful in obtaining permanent codes, the assigned payment rates will be adequate nor that payors will cover these codes.

We are also seeking to expand the number of payors with positive coverage policies relating to our products. We believe the reimbursement coverage policies established by commercial payors greatly impact expansion of access to our products, especially in the physician office setting. Many commercial payors have "experimental and investigational" policies that relate to our PROPEL family of products, and payors do not typically reimburse for products under such policies. In some cases, payors have included published data for SINUVA in the reference list of these investigational policies. Since devices and drugs are generally reviewed and managed differently by payors, and since the intended use and clinical applications or SINUVA are different from the PROPEL family of products, it is possible these policies will be revised upon FDA approval of SINUVA to appropriately separate SINUVA from policies related to the use of our PROPEL family of products. Nonetheless, inclusion of this data in these policies could impact early coverage and adoption of SINUVA. We cannot assure that we will be successful in reversing these policies, nor can we assure that our product will be fully reimbursed even under favorable policies.

In the United States, coverage and reimbursement for medical devices vary among payors. In addition, payors review coverage policies on an ongoing basis and can, without notice, change or deny coverage for these new products and procedures. We estimate that commercial payors covering a significant number of U.S. covered lives currently have non-coverage policies relating to our PROPEL family of products, designating these products investigational or experimental. Some governmental and commercial payors

do not currently cover or reimburse our products because they have determined insufficient evidence of favorable clinical outcomes is available. Although some consider the steroid releasing 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.

Our future growth depends on physician awareness and adoption of our steroid releasing 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 releasing 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 releasing 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 releasing implants before all of the drug has been released 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.

Our clinical studies were designed to demonstrate the safety and efficacy of our steroid releasing 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 releasing implants as tools that are useful to ENT physicians treating patients with chronic sinusitis. We have sponsored fourteen multicenter, prospective studies of over 900 patients to track outcomes of treatment with our steroid releasing implants across multiple sinuses and settings of care. These clinical data have resulted in the highest level of evidence generated for any medical device used to improve the outcomes of sinus surgery. While the results of these 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. Additionally, the long-term effects of sinus interventions in conjunction with our steroid releasing 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 that any data that we or others generate will be consistent with that observed in these studies or meet the endpoints, nor that the results will be maintained beyond the time points studied. We also cannot assure 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 procedures using our steroid releasing implants are an attractive option when compared against data from alternative treatments.

Each ENT physician's individual experience with our steroid releasing implants will vary, and we believe that physicians will compare actual long-term outcomes in their own practices using our steroid releasing 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 releasing 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 releasing implants in FESS is not as safe or effective 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 and service providers for many of the components, materials and services used in the production of our steroid releasing implants, and the loss of, or disruption by, any of these suppliers or service providers could harm our business.

The active pharmaceutical ingredient, or API, and a number of our critical components used in our steroid releasing 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, and some off-the-shelf components. If a supplier delivers products of insufficient quality, it could lead to lot

issues, failures or recalls. 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 and quality 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 our PROPEL family of products, and SINUVA if approved. 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, demand for our products may be impacted by adverse weather and by resetting of annual patient healthcare insurance plan deductibles, both of which may cause patients to delay or decline elective procedures such as FESS. In the second quarter, demand may be impacted by the seasonal nature of allergies, the resultant onset of sinus-related symptoms and the growth of high deductible insurance plans which may cause patients to delay or decline elective surgery until their deductible is met later in the year. 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 higher due to 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 releasing 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 approval and reimbursement coverage for our products in development or for our current products outside the United States;
- our ability to maintain intellectual property protection for our products and our competitors being granted patents for competing products;
- 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, failure of, or quality issues with, component and raw material deliveries by our suppliers or service providers;
- manufacturing issues or lot failures; and
- positive or negative coverage in the media or clinical publications of our steroid releasing 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 releasing 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;
- receive adequate reimbursement for such products;
- 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; 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.

****We are expanding our operations into the area of drug development and may encounter difficulties in managing this expansion, which could disrupt our business.***

SINUVA, if approved and successfully launched, will be our first commercial product that is regulated as a drug. Beginning with SINUVA, we expect to expand the scope of our operations, particularly in the area of drug development and related regulatory affairs and sales and marketing. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. We may not be able to effectively manage the expected expansion of our operations or recruit and train additional qualified personnel. Moreover, the expected expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

If clinical studies of our future products or product indications 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 or product indication 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 primary 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 several decades, which has driven numerous cost reform initiatives by legislators, regulators and third-party payors. 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 companies, including Medtronic, Olympus, Johnson & Johnson, Stryker, Smith & Nephew and Entellus. Most of 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 which may prevent us from achieving significant market penetration or improved operating results. New product developments that could compete 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 releasing stents and smaller companies may develop competing products. These or other companies may develop drug releasing products that could compete with our products.

If another company successfully develops an approach for the treatment of chronic sinusitis, including alternative device, drug delivery or pharmaceutical agent, our business could be significantly and adversely affected.

If physicians treat more patients in their offices instead of performing surgery in the operating room, our ability to sell our PROPEL family of products may be harmed.

The prevalence of sinus procedures being performed in the office has increased since sinus dilation products for use in the office setting received Category I CPT codes in 2011. As a result, the number of companies selling sinus dilation products has increased and well-known companies such as Medtronic, Entellus and Johnson & Johnson have begun to sell sinus dilation products. This has led to increased marketing investments to sell these sinus dilation products in an attempt to not only grow the overall sinus procedure market but also to shift procedures from the operating room to the office. If more patients are treated for chronic sinusitis in a physician's office with a sinus dilation product rather than through FESS procedures in the operating room, the volume of FESS procedures performed may not grow as anticipated and our ability to sell our products may 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 our PROPEL family of products, 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 releasing 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, healthcare 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 employees. 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 or the turnover of a meaningful number of our employees within a particular function or throughout the company within a given period of time, 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 or customer become inoperable, we will be unable to continue to research, develop, manufacture, commercialize and sell 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 a significant portion of our 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, water shortages 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 raw materials and finished product reserve, 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. In addition, while we have a limited amount of inventory at a third party storage and fulfillment center, that inventory may not be sufficient to continue our operations if our primary facility is damaged. The occurrence of natural disasters or acts of terrorism could also cause delays in our customers' supply chain, causing them to delay their requirements for our products until they resolve shortages from their other suppliers. Any such occurrences of natural disasters or acts of terrorism could have a material adverse effect on our business, our results of operations and our financial condition.

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 physical and virtual redundancy while being operated from our physical location in Menlo Park. While we will attempt to mitigate interruptions in our information technology systems, we may experience events or circumstances 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, such as natural disasters or security breaches, 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.

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 releasing 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.

Risks Relating to Regulatory Matters

Our products are subject to extensive regulation by the FDA, and other agencies, including the requirement to obtain approval prior to commercializing our products 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 releasing implants are subject to extensive regulation by the FDA and various other federal, state and foreign governmental authorities. The Premarket Approval, or 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 prior experience in obtaining approval of an NDA, which could delay or adversely affect our ability to obtain approval for SINUVA.

Our currently 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. In the European Union, our CE Marked products are subject to vigilance reporting.

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 product approvals 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.

****We cannot predict whether or when we will obtain regulatory approval to commercialize SINUVA and we cannot, therefore, predict the timing of any future revenue from SINUVA. Regulatory approval of an NDA is not guaranteed, and the approval process is expensive, uncertain and lengthy.***

We cannot commercialize our product candidates, including SINUVA, until the appropriate regulatory authorities, such as the FDA, have reviewed and approved the product candidate. Regulatory agencies may not complete their review processes in a timely manner, or we may not be able to obtain regulatory approval for SINUVA. Additional delays may result if SINUVA is brought before an FDA advisory committee, which could recommend restrictions on approval or recommend non-approval of SINUVA. In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action, or changes in regulatory agency policy during the period of product development, clinical studies and the review process. As a result, we cannot predict when, if at all, we will receive any future revenue from commercialization of SINUVA. The FDA has substantial discretion in the drug approval process, including the ability to delay, limit or deny approval of a product candidate for many reasons, including the following:

- we may be unable to demonstrate to the satisfaction of regulatory authorities that a product candidate is safe and effective for any indication;
- regulatory authorities may not find the data from clinical studies sufficient or may differ in the interpretation of the data;
- regulatory authorities may require additional clinical studies;

- the FDA or foreign regulatory authority might not approve our manufacturing processes or facilities for clinical or commercial product of SINUVA;
- the FDA or foreign regulatory authority may change its approval policies or adopt new regulations;
- the FDA or foreign regulatory authorities may disagree with the design or implementation of our clinical studies;
- the FDA or foreign regulatory authority may not accept clinical data from studies that are conducted in countries where the standard of care is potentially different from that in the U.S.;
- the results of clinical studies may not meet the level of statistical significance required by the FDA or foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks; and
- the data collection from clinical studies of our product candidates may not be sufficient to support the submission of a NDA or other submission or to obtain regulatory approval in the U.S. or elsewhere.

In addition, events raising questions about the safety of certain marketed products may result in increased caution by the FDA and other regulatory authorities in reviewing new products based on safety, efficacy or other regulatory considerations and may result in significant delays in obtaining regulatory approvals.

If our recently submitted NDA is not approved by the FDA, our business may be harmed.

In May 2017, the FDA accepted our NDA, to seek regulatory approval to market SINUVA and set a Prescription Drug User Fee Act target action date in January 2018. There is a risk that the FDA will not approve the NDA. Any such decision would have a material adverse effect on our ability to generate revenue from sales of SINUVA. An inability to generate such revenue may have a material adverse effect on our business, financial performance and results of operations. In addition, the FDA may suggest that the clinical trials on which we relied were not sufficient and require that we conduct additional trials at significant costs before we seek regulatory approval of our product candidates. Any such requirement for additional trials would most likely result in our inability to commercialize SINUVA in the United States for a significant period of time.

Even if SINUVA is approved by the FDA, this approval may be limited to certain indications, and additional clinical studies and regulatory applications may be required to expand SINUVA indications. We can provide no assurances that such additional clinical studies or regulatory applications will be successful.

We are developing SINUVA for use in the physician's office for treatment of patients who have had sinus surgery but continue to suffer from symptoms of chronic sinusitis. In October 2016, we announced the results of RESOLVE II, a phase III trial of 300 patients to assess the safety and efficacy of the SINUVA product. The RESOLVE II clinical study met both primary efficacy endpoints, reduction in nasal congestion and polyp burden. It is not certain at this time which indications, if any, the FDA will approve based on this data. The issues raised and information requested by the FDA in response to our NDA may be costly and time-consuming to address and generate. As a result of FDA observations, we could decide or be required to seek our initial approval on a narrower indication than expected. Additional clinical studies may be required to support our targeted indications, which will require additional time and expense and may not prove successful. Limitations in our label for SINUVA will reduce the number of patients for whom SINUVA is indicated and could reduce the size of the anticipated market and our financial prospects. Further, there is no guarantee that any efforts that we decide to undertake will meet the FDA's requirements, and we may not receive approval at all for SINUVA, even in a more narrow indication despite such efforts.

If we materially modify our 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 releasing 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 approval of PROPEL. We may not be able to obtain additional regulatory approvals for new products or for modifications to, or additional indications for, our existing products 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 have only had limited sales outside the United States. Sales of our steroid releasing 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.

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, our suppliers or service providers 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, including pre-approval inspections in conjunction with the FDA's review of the SINUVA NDA. If we, or our suppliers, 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, in Europe, we are 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, which 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 maintain CE Markings 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 releasing 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 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 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 clinical trials may be extended, delayed, suspended or terminated, and/or 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. Bioresearch monitoring inspections of our SINUVA clinical investigators may reveal violations of good clinical practice requirements that delay or prevent approval of our NDA.

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 commercial payors that are false or fraudulent; knowingly making, using, or causing to be made or 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, or HIPAA, 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. 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." Manufacturers are required to report to CMS the detailed payment and transfers of value data and submit legal attestation to the accuracy of such data by the 90th day of each 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 to 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 are 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 and pharmaceutical industry, and if SINUVA is approved, we will have to comply with its drug-specific provisions. 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.

The medical device excise tax was recently suspended by the Consolidated Appropriations Act of 2016, or CAA, for calendar years 2016 and 2017. Absent further congressional action the excise tax will be reinstated for medical device sales beginning January 1, 2018. The CAA also temporarily delays implementation of other taxes intended to help fund Affordable Care Act programs. Further, there have been judicial and congressional challenges to other aspects of the Affordable Care Act, and we expect there will be additional challenges and amendments to the Affordable Care Act in the future.

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, following passage of the Bipartisan Budget Act of 2015, will stay in effect through 2025, unless additional congressional action is taken. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012 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.

In January 2017, Congress voted to adopt a budget resolution for fiscal year 2017, or the Budget Resolution, that authorizes the implementation of legislation that would repeal portions of the Affordable Care Act. The Budget Resolution is not a law; however, it is widely viewed as the first step toward the passage of legislation that would repeal certain aspects of the Affordable Care Act. Further, on January 20, 2017, the President of the United States signed an Executive Order directing federal agencies with authorities and responsibilities under the Affordable Care Act to waive, defer, grant exemptions from, or delay the implementation of any provision of the Affordable Care Act that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. Congress also could consider subsequent legislation to replace elements of the Affordable Care Act that are repealed.

Given the current political environment, 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. Sales of our products in the United States have been subject to this 2.3% excise tax. During the year ended December 31, 2015, we recognized $1.1 million in tax expense associated with the medical device tax in the United States which is included in selling, general and administrative expenses. The excise tax has been suspended for calendar years 2016 and 2017, and under current law will be reinstated for calendar year 2018. We cannot predict whether this tax will be reinstated or what effect the excise tax may have on our financial performance in future years if the tax is reinstated as planned.

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 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 currently have very little commercial activity 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 may represent attractive 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 portions 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 releasing systems. The API contained in our steroid releasing 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 may 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 may 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 may increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which may have a material adverse effect on our business and financial condition. In addition, patent reform legislation may pass in the future that may 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. An adverse determination in any such submission, proceeding or litigation may 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 may have a material adverse effect on our business.

Competing products may also be sold in other countries in which our patent coverage might not exist or be as strong. 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 may be forced to rebrand our products, which may result in loss of brand recognition and may 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 releasing 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 may be adversely affected, as may our business.

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

The medical device industry has been characterized by frequent and extensive intellectual property litigation. Additionally, the ENT market is extremely competitive. Our competitors, such as Medtronic, Olympus, Johnson & Johnson, Stryker, Smith & Nephew and Entellus, or other patent holders may assert that our steroid releasing implants and the methods employed in our steroid releasing implants are covered by their patents. If our steroid releasing implants or methods are found to infringe, we may be prevented from

manufacturing or marketing our steroid releasing implants. In the event that we become involved in such a dispute, we may incur significant costs and expenses, may be prevented from marketing our products 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. If we lose a patent lawsuit, alleging our infringement of a competitor's patents, we may be prevented from marketing our steroid releasing implants in one or more 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 may undermine our competitive position.

Litigation related to infringement and other intellectual property claims, with or without merit, is unpredictable, may be expensive and time-consuming and may divert management's attention from our core business. If we lose this kind of litigation, a court may require us to pay substantial damages, treble damages and attorneys' fees, and prohibit us from using technologies essential to our steroid releasing implants, any of which may 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 may be prevented from selling our steroid releasing implants unless we can obtain licenses to use technology 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 may 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 may 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 may result in substantial costs and may be a distraction to management. If our defense to those claims fails, in addition to paying monetary damages, a court may 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 may 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 may hamper or prevent our ability to commercialize our products, which may 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, cash equivalents and short-term investments, revenue and available debt financing arrangements will be sufficient to meet our capital requirements and fund our operations at least through the next twelve months. 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:

- successful regulatory approval of our NDA;

- market acceptance of our products, including access to adequate reimbursement;
- 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 including, but not limited to, preparations for a potential commercial launch of SINUVA;
- 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

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

The market price of our common stock has been, and is likely to continue to be, highly volatile. The stock market in general and the market for medical device companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may experience losses on their investment in our common stock. The market price of our common stock may be influenced by many factors, including:

- volume and timing of sales of our steroid releasing implants;
- changes in reimbursement or in coverage by commercial payors related to our products;
- changes in governmental regulations or in the status of our regulatory approvals or applications;
- 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 releasing implants or products of others in our industry;
- 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.

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.

We are required, under Section 404 of the Sarbanes-Oxley Act to furnish a report by management on the effectiveness of our internal control over financial reporting, and our auditors are required to express an opinion on the effectiveness of our internal controls. This resulted in increased compliance fees. Our management assessment needs 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.

Though we have enhanced our internal controls, processes and related documentation necessary to perform the evaluation needed to comply with Section 404, future evaluations and tests may reveal material weaknesses. If during the evaluation and testing process, 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.

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

None.

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: August 4, 2017

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	Description	Incorporation By Reference			
		Form	SEC File No.	Exhibit	Filing Date
3.1	Amended and Restated Certificate of Incorporation.	8-K	001-36545	3.1	7/30/2014
3.2	Amended and Restated Bylaws.	S-1	333-196974	3.4	7/9/2014
4.1	Form of Common Stock Certificate of the Registrant.	S-1	333-196974	4.1	7/14/2014
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 Registrant and certain of its stockholders.	S-1	333-196974	10.6	6/23/2014
10.1	Amendment to Offer Letter by and between the registrant and Richard E. Kaufman, dated as of May 8, 2017.				
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.

Exhibit 10.1

VIA HAND DELIVERY

May 8, 2017

Richard Kaufman
Intersect ENT, Inc.
1555 Adams Drive
Menlo Park, CA 94025

Re: Amended Separation Benefits

Dear Richard:

This letter agreement sets out an amendment (the ***"Amendment"*** to the terms of your employment offer letter with Intersect ENT, Inc. (the ***"Company"*)** dated December 6, 2006, as amended November 18,2013 and January 26, 2015 (collectively, the ***"Offer Letter").*** The terms set forth in this Amendment replace and supersede the terms with respect to such matters set forth in the Offer Letter. This Amendment is effective as of the date of your signature below.

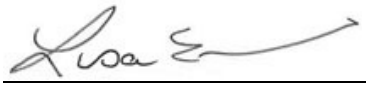
Amendment of Section 2: Severance Upon Termination or in Connection with Change in Control:

The second full paragraph under section number 2 of your Offer Letter, entitled, *Severance Upon Termination in Connection with a Change in Control,* is hereby deleted and replaced with the following paragraph:

> If, in connection with or within twelve (12) months after a Change of Control Transaction, a Separation from Service occurs, you shall be entitled to (i) payment of twelve (12) months of your base salary, less all applicable withholdings and deductions, paid over such 12-month period immediately following the Separation from Service, on the schedule described below, (ii) a lump sum payment equal to your annual target bonus prorated for the number of days of the then current bonus period worked prior to your Separation from Service, (iii) twelve (12) months COBRA reimbursement and (iv) vesting of all outstanding stock options held by you such that all unvested shares subject to your outstanding options shall be fully vested, but only if the event constituting Good Reason upon which your resignation is based occurs in connection with or subsequent to and as a result of such Change of Control Transaction.

Except as modified herein, all other terms of your Offer Letter shall remain in full force and effect. Any conflict between the terms of your Offer Letter and this Amendment shall be determined in favor of this Amendment.

Please sign below if the terms of this Amendment are acceptable to you, and return the fully signed letter to me.

By: 

Lisa D. Earnhardt
President and Chief Executive Officer
Intersect ENT, Inc.

Understood and Agreed to by:

Richard Kaufman
SVP and Chief Operating Officer
Date: 5/8/17

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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

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

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

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

August 4, 2017

/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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

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

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

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

August 4, 2017

/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 her knowledge:

1. The Company's Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2017, 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.

August 4, 2017

/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 Company and will be retained by the Company 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 Company 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.