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

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2019

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

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

Title of Each Class:	Trading symbol(s)	Name of Exchange on Which registered:
Common Stock, 0.001 par value	**XENT**	**The Nasdaq Global Market**

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 every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

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

Large accelerated filer	☒	Accelerated filer	☐
Non-accelerated filer	☐	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 April 30, 2019 were 31,246,267.

INTERSECT ENT, INC.
Form 10-Q – QUARTERLY REPORT
For the Quarter Ended March 31, 2019

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PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

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

	March 31, 2019 (unaudited)	December 31, 2018 (1)
Assets		
Current assets:		
Cash and cash equivalents	$ 8,593	$ 9,464
Short-term investments, available-for-sale	88,993	91,309
Accounts receivable, net	17,331	19,616
Inventory	13,916	11,586
Prepaid expenses and other current assets	2,372	2,695
Total current assets	131,205	134,670
Property and equipment, net	5,975	5,878
Other non-current assets	1,861	413
Total assets	$ 139,041	$ 140,961
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 4,240	$ 6,202
Accrued compensation	13,180	12,281
Other current liabilities	2,674	1,250
Total current liabilities	20,094	19,733
Other non-current liabilities	200	234
Total liabilities	20,294	19,967
Commitments and contingencies (note 9)		
Stockholders' equity:		
Preferred stock, $0.001 par value;		
Authorized shares: 10,000 at March 31, 2019 and December 31, 2018; Issued and outstanding shares: none	—	—
Common stock, $0.001 par value;		
Authorized shares: 150,000 at March 31, 2019 and December 31, 2018; Issued and outstanding shares: 31,162 at March 31, 2019 and 30,745 at December 31, 2018	31	31
Additional paid-in capital	317,247	308,766
Accumulated other comprehensive income (loss)	36	(41)
Accumulated deficit	(198,567)	(187,762)
Total stockholders' equity	118,747	120,994
Total liabilities and stockholders' equity	$ 139,041	$ 140,961

(1) Amounts have been derived from the December 31, 2018 audited consolidated 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 consolidated financial statements.

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

	Three Months Ended March 31,	
	2019	2018
Revenue	$ 26,673	$24,723
Cost of sales	4,645	5,482
Gross profit	22,028	19,241
Operating expenses:		
Selling, general and administrative	27,207	21,516
Research and development	6,266	4,273
Total operating expenses	33,473	25,789
Loss from operations	(11,445)	(6,548)
Interest income and other, net	640	412
Net loss	(10,805)	(6,136)
Other comprehensive income (loss):		
Unrealized gain (loss) on short-term investments, net	77	(65)
Comprehensive loss	$(10,728)	$ (6,201)
Net loss per share, basic and diluted	$ (0.35)	$ (0.21)
Weighted average common shares used to compute net loss per share, basic and diluted	30,918	29,878

See accompanying notes to condensed consolidated financial statements.

INTERSECT ENT, INC.
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(in thousands)
(unaudited)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2018	30,745	$ 31	$308,766	$ (41)	$ (187,762)	$ 120,994
Issuance of common stock and exercise of stock options	417	—	4,467	—	—	4,467
Stock-based compensation expense	—	—	4,014	—	—	4,014
Unrealized gain on short-term investments	—	—	—	77	—	77
Net loss	—	—	—	—	(10,805)	(10,805)
Balance at March 31, 2019	31,162	$ 31	$317,247	$ 36	$ (198,567)	$ 118,747
Balance at December 31, 2017	29,678	$ 30	$282,121	$ (92)	$ (164,840)	$ 117,219
Issuance of common stock and exercise of stock options	421	—	4,224	—	—	4,224
Stock-based compensation expense	—	—	3,138	—	—	3,138
Unrealized loss on short-term investments	—	—	—	(65)	—	(65)
Net loss	—	—	—	—	(6,136)	(6,136)
Balance at March 31, 2018	30,099	$ 30	$289,483	$ (157)	$ (170,976)	$ 118,380

See accompanying notes to condensed consolidated financial statements.

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

	Three Months Ended March 31,	
	2019	2018
Operating activities:		
Net loss	$(10,805)	$ (6,136)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	588	414
Amortization of right-of-use assets	266	—
Stock-based compensation expense	3,869	3,138
Amortization of net investment discount	(377)	(83)
Changes in operating assets and liabilities:		
Accounts receivable, net	2,285	2,322
Inventory	(2,184)	(24)
Prepaid expenses and other assets	182	144
Accounts payable	(1,295)	(406)
Accrued compensation	899	(2,983)
Other liabilities	(320)	(6)
Net cash used in operating activities	(6,892)	(3,620)
Investing activities:		
Purchases of short-term investments	(42,539)	(31,502)
Maturities of short-term investments	45,310	21,282
Purchases of property and equipment	(1,217)	(344)
Net cash provided by (used in) investing activities	1,554	(10,564)
Financing activities:		
Proceeds from issuance of common stock and exercise of stock options	4,467	4,873
Net cash provided by financing activities	4,467	4,873
Net decrease in cash and cash equivalents	(871)	(9,311)
Cash and cash equivalents:		
Beginning of the period	9,464	19,837
End of the period	$ 8,593	$ 10,526
Non-cash investing activities:		
Right-of-use asset obtained in exchange for lease obligations	$ 117	$ —
Property and equipment included in accounts payable	346	21
Lessor funded building improvements	152	—

See accompanying notes to condensed consolidated financial statements.

NOTES TO CONDENSED CONSOLIDATED 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 drug delivery company committed to improving the quality of life for patients with ear, nose and throat conditions. The Company's U.S. Food and Drug Administration ("FDA") approved products are steroid releasing implants designed to treat patients suffering from chronic sinusitis who are managed by ear, nose and throat ("ENT") physicians. These products include the PROPEL® family of products (PROPEL®, PROPEL® Mini and PROPEL® Contour) and the SINUVA® (mometasone furoate) Sinus Implant. The PROPEL family of products are used in conjunction with sinus surgery primarily in hospitals and ambulatory surgery centers and SINUVA is designed to be used in the physician's office setting of care to treat patients who have had ethmoid sinus surgery yet suffer from recurrent sinus obstruction due to polyps. The PROPEL family of products are devices approved under the Premarket Approval ("PMA") and SINUVA is a drug that was approved under a New Drug Application ("NDA"). In addition, Intersect ENT continues to invest in research and development of new products and product improvements.

2. Summary of Significant Accounting Policies

Basis of Preparation

The condensed consolidated 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"). These condensed consolidated financial statements include the accounts of the Company and its consolidated subsidiary. All intercompany balances and transactions have been eliminated in consolidation.

The functional currency of the Company's wholly-owned subsidiary Intersect ENT GmbH, which the Company established in June 2018, is the U.S. dollar. Transaction gains and losses are included in interest income and other, net, on the Company's condensed consolidated statements of operations.

The interim financial data as of March 31, 2019, 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 months ended March 31, 2019 and 2018. Certain information and footnote disclosures normally included in the 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 consolidated financial statements should be read in conjunction with the Company's audited consolidated financial statements and notes thereto included in the Company's Annual Report on Form 10-K ("Annual Report") for the year ended December 31, 2018 filed with the SEC on February 28, 2019.

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 revenue related allowances, 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 three months ended March 31, 2019, as compared to the significant accounting policies described in Note 2 of the "Notes to Consolidated Financial Statements" in the Company's audited consolidated financial statements included in its Annual Report, except as described below.

Leases

The Company adopted Accounting Standards Codification, or ASC, Topic 842, *Leases,* on January 1, 2019 using the modified retrospective transition method. In addition, the Company elected certain practical expedients permitted under the transition guidance, which allowed it to carryforward its historical long-term lease classification, its assessment on whether a contract is or contains a lease and the treatment of its initial direct costs for any leases that existed prior to the adoption of Topic 842. In determining the lease term at commencement date, any renewal or termination options are considered if they are reasonably assured of exercise. The Company has elected to exclude from its condensed consolidated balance sheet any leases having a term of 12 months or less. The Company recorded a right-of-use leased asset of approximately $1.6 million and a corresponding lease liability of $2.2 million in its adoption of Topic 842. In addition, as of the adoption date, the Company derecognized a deferred rent obligation of approximately $0.6 million. There was no cumulative effect adjustment upon the adoption of Topic 842.

The results for the three months ended March 31, 2019 are presented under Topic 842. The results for the three months ended March 31, 2018 and other prior period amounts were not adjusted and continue to be reported in accordance with our historical accounting under prior lease guidance, ASC Topic 840: *Leases* ("Topic 840").

For agreements with a term of more than twelve months, the Company determines if an agreement is a lease at inception. Operating lease liabilities represent an obligation to make lease payments arising from the lease agreement. Operating lease liabilities are recognized at the lease commencement date based on the present value of lease payments over the remaining lease term. In determining the present value of lease payments, the Company estimates its incremental borrowing rate as the rate of interest that the Company would have to pay to borrow on a collateralized basis over a similar term, of an amount equal to the lease payments in a similar economic environment. Operating lease liabilities are included in other current and non-current liabilities in our condensed consolidated balance sheet. Right-of-use assets represent our right to use an underlying asset for the lease term and are classified as other non-current assets. Lease expense is recognized on a straight-line basis over the expected lease term.

Recent Accounting Pronouncements

There have been no significant changes to the disclosures in the recent accounting pronouncements during the three months ended March 31, 2019, as compared to the recent accounting pronouncements described in Note 2 of the "Notes to Consolidated Financial Statements" in the Company's audited consolidated financial statements included in its Annual Report.

3. Composition of Certain Financial Statement Items

Accounts Receivable (in thousands):

	March 31, 2019	December 31, 2018
Accounts receivable	$ 17,400	$ 19,696
Allowance for doubtful accounts	(69)	(80)
	$ 17,331	$ 19,616

Inventory (in thousands):

	March 31, 2019	December 31, 2018
Raw materials	$ 2,246	$ 1,872
Work-in-process	68	368
Finished goods	11,602	9,346
	$ 13,916	$ 11,586

Capitalized stock-based compensation expense of $0.7 million and $0.6 million were included in inventory as of March 31, 2019 and December 31, 2018, respectively.

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):

	March 31, 2019				December 31, 2018			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Cash	$ 5,202	$ —	$ —	$ 5,202	$ 4,168	$ —	$ —	$ 4,168
Money market funds	2,139	—	—	2,139	2,308	—	—	2,308
Corporate debt securities	39,595	21	(3)	39,613	45,177	5	(17)	45,165
Commercial paper	50,614	19	(1)	50,632	49,161	—	(29)	49,132
	$ 97,550	$ 40	$ (4)	$ 97,586	$100,814	$ 5	$ (46)	$100,773
Reported as:								
Cash and cash equivalents				$ 8,593				$ 9,464
Short-term investments, available-for-sale				88,993				91,309
				$ 97,586				$100,773

As of March 31, 2019 and December 31, 2018, 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 three months ended March 31, 2019 and year ended December 31, 2018. 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):

	March 31, 2019				December 31, 2018			
	Level 1	Level 2	Level 3	Total	Level 1	Level 2	Level 3	Total
Cash	$5,202	$ —	$ —	$ 5,202	$4,168	$ —	$ —	$ 4,168
Money market funds	2,139	—	—	2,139	2,308	—	—	2,308
Corporate debt securities	—	39,613	—	39,613	—	45,165	—	45,165
Commercial paper	—	50,632	—	50,632	—	49,132	—	49,132
	$7,341	$90,245	$ —	$97,586	$6,476	$94,297	$ —	$100,773
Reported as:								
Cash and cash equivalents				$ 8,593				$ 9,464
Short-term investments, available-for-sale				88,993				91,309
				$97,586				$100,773

There were no transfers in and out of Level 1 and Level 2 during the three months ended March 31, 2019 and year ended December 31, 2018.

6. Leases

The Company's headquarters is leased under an operating lease agreement entered into in March 2012 and expires in May 2020. This lease is for 50,400 square feet and includes a renewal provision allowing the Company to extend this lease for an additional three years at 95% of the then-current fair market rental rate. Exercise of this extension option was not considered reasonably assured nor reasonably certain and has therefore been excluded from the estimated remaining lease term. In March 2019, the Company entered into an additional operating lease agreement for 10,000 square feet of warehouse space which also expires in May 2020. Both operating lease agreements require the Company to pay executory costs such as real estate taxes, insurance and repairs.

Right-of-use assets (in thousands):

	March 31, 2019
Upon the adoption of Topic 842	$ 1,572
Additional warehouse operating lease	117
Less: accumulated amortization	(266)
	$ 1,423

Operating lease liabilities (in thousands):

	March 31, 2019
Current portion included in other current liabilities	$ 1,786
Non-current portion included in other non-current liabilities	156
	$ 1,942

Cash paid for amounts included in the measurement of lease liabilities for the three months ended March 31, 2019 was $0.4 million and was included in net cash used in operating activities in the condensed consolidated statements of cash flows.

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

Fiscal Years Ending December 31,	March 31, 2019
2019 (remaining)	$ 1,247
2020	782
Thereafter	—
Total minimum payments	2,029
Less: present value adjustment	(87)
Total	$ 1,942

As of March 31, 2019, the weighted average remaining lease term is 1.2 years. Rent expense was $0.5 million during each of the three month periods ended March 31, 2019 and 2018.

7. 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"). 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, 2019, the total number of shares of common stock reserved for issuance increased by 920,190 shares to 8,965,704 shares.

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

	Three Months Ended March 31, 2019	
	Options	Weighted Average Exercise Price
Outstanding, beginning of period	3,688	$ 20.84
Granted	815	31.18
Exercised	(284)	15.74
Forfeited	(77)	23.48
Outstanding, end of period	4,142	23.18
Exercisable	1,945	18.87

As of March 31, 2019, the aggregate pre-tax intrinsic value of options outstanding was $40.0 million and options outstanding and exercisable was $26.5 million, the weighted-average remaining contractual term of options outstanding was 7.8 years and options outstanding and exercisable was 6.6 years. The aggregate pre-tax intrinsic value of options exercised was $5.1 million and $7.9 million during the three months ended March 31, 2019 and 2018, respectively.

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

	Three Months Ended March 31, 2019	
	RSUs	Weighted Average Fair Value
Outstanding, beginning of period	350	$ 24.92
Awarded	205	32.42
Vested	(133)	22.07
Forfeited	(14)	25.49
Outstanding, end of period	408	29.60

As of March 31, 2019, the aggregate pre-tax intrinsic value of RSUs outstanding was $13.1 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 recognized is as follows (in thousands):

	Three Months Ended March 31,	
	2019	2018
Cost of sales	$ 236	$ 260
Selling, general and administrative	2,974	2,366
Research and development	659	512
	$ 3,869	$ 3,138

As of March 31, 2019, the amount of unearned stock-based compensation currently estimated to be expensed through the year 2023 related to unvested employee stock-based awards was $37.8 million and the weighted average period over which the unearned stock-based compensation is expected to be recognized was 2.9 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.

2014 Employee Stock Purchase Plan

In July 2014, the Company's board of directors approved the 2014 Employee Stock Purchase Plan ("2014 ESPP"). A total of 496,092 shares were initially reserved for issuance under the 2014 ESPP. In June 2018, the Company's stockholders approved the Amended and Restated 2014 ESPP, increasing the total number of shares of common stock reserved for issuance under the 2014 ESPP by 1,200,000 shares to a total of 1,696,092 shares (the "Amended and Restated 2014 ESPP"). During the three months ended March 31, 2019, no shares were issued.

8. 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 common stock equivalent shares from dilutive stock options, employee stock purchases and restricted stock units 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 March 31,	
	2019	2018
Common stock options	4,142	4,087
Restricted stock units	408	371
Employee stock purchase plan shares	74	190
	4,624	4,648

9. 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 consolidated 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 consolidated 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, 2019.

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 drug delivery company committed to improving the quality of life for patients with ear, nose and throat conditions. Our U.S. Food and Drug Administration, or FDA, approved products are steroid releasing implants designed to treat adult patients suffering from chronic sinusitis, who are managed by ENT physicians. These products include our PROPEL® family of products (PROPEL®, PROPEL® Mini and PROPEL® Contour) and the SINUVA® (mometasone furoate) Sinus Implant. The PROPEL family of products are used in conjunction with sinus surgery primarily in hospitals and ambulatory surgery centers and SINUVA is designed to be used in the physician's office setting of care to treat adult patients who have had ethmoid sinus surgery yet suffer from recurrent sinus obstruction due to polyps. The PROPEL family of products are devices approved under a Premarket Approval, or PMA and SINUVA is a drug that was approved under a New Drug Application, or NDA.

Our PROPEL family of steroid releasing implants are 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, directly into the sinus lining, and 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 reducing the need for postoperative oral steroids and repeat surgical interventions. More than 300,000 patients have been treated with PROPEL products to-date.

- PROPEL clinical outcomes have been reported in a meta-analysis of prospective, multicenter, randomized, controlled, double-blind clinical studies to improve surgical outcomes, demonstrating a 35% relative reduction in the need for postoperative interventions compared to surgery alone. 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 and is absorbed into the body over a period of approximately six weeks.
- PROPEL Mini has also been shown by our clinical studies to reduce the need for postoperative interventions, including a 38% relative reduction in the need for postoperative interventions in the frontal sinus, compared to surgery alone with standard postoperative care. PROPEL Mini is a smaller version of PROPEL and is approved for use in both 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 the narrow and difficult to access sinus ostia. In PROPEL Contour's pivotal clinical study, the product demonstrated a 65% relative reduction in the need for postoperative interventions in the frontal sinus ostia compared to surgery alone with standard postoperative care.

SINUVA, when placed during a routine physician office visit, expands into the sinus cavity and delivers an anti-inflammatory steroid directly to the site of polyp disease for 90 days. We have studied SINUVA in 4 clinical trials in over 400 patients to-date. Results from the pivotal RESOLVE II randomized clinical trial demonstrated a 74% relative reduction in bilateral polyp grade (a measurement of the extent of ethmoid polyp disease) and a 30% relative reduction in nasal obstruction and congestion for patients treated with SINUVA compared to a control group treated with a sham procedure, receiving no implant. Patients in both arms of the

study were required to use an intranasal steroid spray daily. In addition, the study demonstrated a 61% reduction in the proportion of patients indicated for revision surgery at day 90. To supplement clinical trials performed with SINUVA to-date, in which one course of SINUVA treatment was evaluated, we commenced the ENCORE study in November 2017. ENCORE was a 50-patient multicenter, open-label study focused on evaluation of the safety of repeat placement of SINUVA in a population of chronic sinusitis patients with nasal polyps. Study findings showed no serious adverse events related to the implants during the measurement period and no serious adverse events related to repeat placement.

Our PROPEL family of products are used almost exclusively in the operating room of a hospital or ambulatory surgery center. These providers receive a facility fee for the sinus surgery procedure which is intended to pay for supplies used in this procedure, including the PROPEL family of products. Reimbursement submissions to cover the cost of SINUVA may be reported to payors using the unassigned Healthcare Common Procedure Coding System, or HCPCS, code J3490. We applied to the Centers for Medicare & Medicaid Services, or CMS, for a product-specific J code for SINUVA, and on April 26, 2019, CMS announced that they intend to establish a new J code described as "Mometasone furoate, implant, 10 micrograms." CMS has also indicated a preliminary decision to eliminate the S1090 code, which was previously assigned to PROPEL. When CMS issues its final decision in November 2019, we expect they will issue further explanation of their decision to eliminate the S1090 code, which will help us better understand the implications to our business.

We continue to invest in research and development of new products and product improvements. We commenced a clinical trial in December 2018 of a new pipeline product, the investigational ASCEND drug-coated sinus balloon. The ASCEND study is a prospective, randomized, blinded, multi-center trial of 70 patients that will assess the safety and efficacy of our ASCEND product. The ASCEND product will be randomized against an uncoated balloon and, similar to clinical studies for our PROPEL family of products, the primary endpoint will be evaluated at 30 days. This study will assess the ASCEND product's ability to improve patency rates, as well as a number of other endoscopic parameters. If successful, we expect that ASCEND would be submitted to the FDA under the PMA pathway for potential approval. We believe that the ASCEND drug-coated balloon would be complementary to our current commercial products.

We are continuing to grow and develop our sales force in order to expand our communication of the benefits of our commercial products 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

Our revenue has been derived almost exclusively from the sales of our PROPEL family of products, with limited sales of SINUVA beginning in March 2018. We expect our revenue to increase as we continue to expand our sales, marketing and reimbursement efforts in order to increase usage of our products. We also expect revenue from our PROPEL family of products to fluctuate from quarter to quarter due to seasonal variations in the volume of sinus surgery procedures performed, which has been impacted historically by factors including the status of patient healthcare insurance plan deductibles and the seasonal nature of allergies which can impact sinus-related symptoms. In addition, revenue from SINUVA may fluctuate because we recognize estimated product sales discounts, rebates, returns and other allowances as a reduction of revenue in the same period the related revenue is recognized. We will adjust these estimates if actual allowances vary from our estimates, which would affect revenue in the period such variances become known.

Our revenue is almost entirely derived from within the United States and no single customer accounted for more than 10% of our revenue during the three months ended March 31, 2019 and 2018.

Cost of Sales and Gross Profit

We manufacture our PROPEL family of products and SINUVA in 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 compensation, including stock-based compensation and other operating expenses associated with the cost of quality assurance, material procurement, inventory control, facilities, information technology, equipment and operations supervision and manufacturing and warehouse management. We expect cost of sales to increase in absolute dollars primarily as, and to the extent, our revenue grows.

Our gross margin has been and will continue to be affected by a variety of factors, including manufacturing costs and average selling prices, and we expect our gross margin to fluctuate based on changes in these factors. Manufacturing cost will change as our production volume and product mix changes. The per unit allocation of our manufacturing overhead costs may decrease as production volume increases until we increase our manufacturing capacity or introduce additional products, at which point the per unit allocation of our manufacturing overhead costs may increase due to the additional costs of our expanded manufacturing operations.

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, market access, reimbursement, business development, legal and human resource functions as well as costs related to any post-market studies. 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 and administrative 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 compensation for personnel, including stock-based compensation, related to product development, regulatory affairs, clinical and medical affairs, and allocated facilities and information technology expenses. R&D expenses also may include expenses for clinical studies related to clinical trial design, site reimbursement, data management, travel expenses and the cost of manufacturing products for clinical trials. Finally, R&D expenses also include expenses related to the development of products and technologies such as consulting services and supplies. Although R&D expenses have fluctuated, we expect R&D expenses to remain at a relatively consistent level in absolute dollars for the foreseeable future as we continue to seek to develop and commercialize new products and enhance our current products.

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.

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. There have been no significant changes to our significant accounting policies during the three months ended March 31, 2019, as compared to the significant accounting policies described in our Annual Report.

Recent Accounting Pronouncements

See Note 2 of the Condensed Consolidated Financial Statements under the heading "Recent Accounting Pronouncements" for new accounting pronouncements or changes to the recent accounting pronouncements during the three months ended March 31, 2019.

Results of Operations

	Three Months Ended March 31,	
	2019	2018
(in thousands, except percentages)		
Revenue	$ 26,673	$24,723
Cost of sales	4,645	5,482
Gross profit	22,028	19,241
Gross margin	*83%*	*78%*
Operating expenses:		
Selling, general and administrative	27,207	21,516
Research and development	6,266	4,273
Total operating expenses	33,473	25,789
Loss from operations	(11,445)	(6,548)
Interest income and other, net	640	412
Net loss	$(10,805)	$ (6,136)

Comparison of the Three Months ended March 31, 2019 and 2018

Revenue

Revenue increased $2.0 million, or 8%, to $26.7 million during the three months ended March 31, 2019, compared to $24.7 million during the three months ended March 31, 2018. The growth in revenue was attributable to an increase in unit sales and average selling price of our PROPEL family of products and initial sales of SINUVA, which contributed approximately 4% to revenue during the three months ended March 31, 2019.

Cost of Sales and Gross Margin

Cost of sales decreased $0.9 million, or 15%, to $4.6 million during the three months ended March 31, 2019, compared to $5.5 million during the three months ended March 31, 2018. The lower cost of sales was primarily attributable to charges during the three months ended March 31, 2018 related to our decision not to commercialize the initial SINUVA production output and the favorable impact of a lower cost structure during the three months ended March 31, 2019.

Gross margin for the three months ended March 31, 2019, increased to 83%, compared to 78% for the three months ended March 31, 2018. The increase in gross margin was primarily attributable to charges during the three months ended March 31, 2018 related to our decision not to commercialize the initial SINUVA production output, which accounted for approximately 4% of the increase in gross margin, and the favorable impact of a lower cost structure and a higher average selling price for the PROPEL family of products during the three months ended March 31, 2019.

Selling, General and Administrative Expenses

SG&A expenses increased $5.7 million, or 26%, to $27.2 million during the three months ended March 31, 2019, compared to $21.5 million during the three months ended March 31, 2018. The increase in SG&A expenses was primarily due to an increase in headcount and related expenses to support the commercial launch of SINUVA, which was approved by the FDA in December 2017, and the ongoing commercialization of our PROPEL family of products.

Research and Development Expenses

R&D expenses increased $2.0 million, or 47%, to $6.3 million during the three months ended March 31, 2019, compared to $4.3 million during the three months ended March 31, 2018. The increase in R&D expenses was primarily due to an increase in headcount and related expenses, and development of our investigational ASCEND drug-coated sinus balloon.

Interest Income and Other, Net

Interest income and other, net, increased $0.2 million to $0.6 million during the three months ended March 31, 2019, compared to $0.4 million during the three months ended March 31, 2018. The increase in interest income and other, net, was primarily attributable to higher interest rates earned on our investments.

Liquidity and Capital Resources

Overview

As of March 31, 2019, we had cash, cash equivalents and short-term investments of $97.6 million, compared to cash, cash equivalents and short-term investments of $100.8 million as of December 31, 2018.

Cash Flows

	Three Months Ended March 31,	
	2019	2018
(in thousands)		
Net cash (used in) provided by:		
Operating activities	$(6,892)	$ (3,620)
Investing activities	1,554	(10,564)
Financing activities	4,467	4,873
Net decrease in cash and cash equivalents	$ (871)	$ (9,311)

Net Cash Used in Operating Activities

During the three months ended March 31, 2019, net cash used in operating activities was $6.9 million, consisting primarily of a net loss of $10.8 million and an increase in net operating assets of $0.4 million, partially offset by non-cash charges of $4.3 million. The cash used in operations was due primarily to an increase in headcount and related expenses to support the ongoing commercialization of our PROPEL family of products and the launch of SINUVA in March 2018. 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 a decrease in accounts payable, partially offset by a decrease in accounts receivable.

During the three months ended March 31, 2018, net cash used in operating activities was $3.6 million, consisting primarily of a net loss of $6.1 million and an increase in net operating assets of $1.0 million, partially offset by non-cash charges of $3.5 million. The cash used in operations was due primarily to an increase in headcount to support the ongoing commercialization of our PROPEL family of products and to prepare for the launch of SINUVA. The non-cash charges primarily consisted of stock-based compensation expense. The increase in net operating assets is primarily due to a decrease in accrued compensation from the payment of accrued year-end bonuses, partially offset by a decrease in accounts receivable.

Net Cash Provided (Used in) by Investing Activities

During the three months ended March 31, 2019, net cash provided by investing activities was $1.6 million, consisting of net maturities of short-term investments, available-for-sale, of $2.8 million and purchases of property and equipment of $1.2 million.

During the three months ended March 31, 2018, net cash used in investing activities was $10.6 million, consisting of net purchases of short-term investments, available-for-sale, of $10.3 million and purchases of property and equipment of $0.3 million.

Net Cash Provided by Financing Activities

During the three months ended March 31, 2019, net cash provided by financing activities was $4.5 million, consisting of net proceeds from the issuance of common stock upon exercises of employee stock options.

During the three months ended March 31, 2018, net cash provided by financing activities was $4.9 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 March 31, 2019, will be sufficient to meet our capital requirements and fund our operations for at least twelve months after the date these financial statements are issued. Beyond that, 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 March 31, 2019 and December 31, 2018, 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 contractual obligations as of March 31, 2019, have not materially changed from December 31, 2018.

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 March 31, 2019, we had cash, cash equivalents and short-term investments of $97.6 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 March 31, 2019 would not have a material effect on our financial position, results of operations or cash flows.

Credit Risk

As of March 31, 2019, 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 and of SINUVA to specialty pharmacies and specialty distributors in the United States. No single customer represented more than 10% of our accounts receivable as of March 31, 2019 and December 31, 2018.

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 March 31, 2019. 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 March 31, 2019, 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 March 31, 2019, 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.

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 incurred a net loss of $10.8 million for the three months ended March 31, 2019, and $22.9 million and $16.4 million for the years ended December 31, 2018 and 2017, respectively. As of March 31, 2019, we had an accumulated deficit of $198.6 million. To date, we have financed our operations primarily through sales of our capital stock, 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, including clinical and regulatory initiatives to obtain approvals for our products, and sales and marketing activities. 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.

Our revenue is generated from our PROPEL® family of products and, to a lesser extent, SINUVA®. Our revenue is completely dependent on the success of these products, and if these products fail to grow or to continue experiencing expanded adoption, our business will suffer.

We started selling PROPEL® in August 2011, PROPEL® Mini in November 2012 and PROPEL® Contour in February 2017, collectively referred to as our PROPEL family of products. We expect that sales of these products, together with SINUVA, which we started selling in March 2018, will account for all of our revenue for the foreseeable future. In addition, our ability to become profitable will depend upon the commercial success of these products. We market our 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 eligible patients for a variety of reasons, including, among others:

- lack of experience with our products;
- lack of adequate reimbursement or cost to the patient;
- lack of conviction regarding evidence supporting cost benefits or cost effectiveness of our products over existing alternatives;
- lack of clinical data supporting longer-term patient benefits or, in the case of SINUVA, repeated use; and
- liability risks generally associated with the use of new products and procedures.

If we are unable to effectively demonstrate to ENT physicians and patients the benefits of our products or our products fail to achieve growing 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 cost sensitivities resulting from healthcare cost containment pressures and reimbursement changes could decrease demand for our PROPEL family of products, the prices that customers are willing to pay and the frequency of use of our products, which could have an adverse effect on our business.

Hospitals and ambulatory surgery centers that purchase our PROPEL family of products typically bill various third-party payors for a facility fee to cover the costs of supplies, including our PROPEL family of products, used in sinus surgery procedures. 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 or use broadly our steroid releasing implants in light of the additional associated cost. Further, any decline in the amount payors reimburse our customers for sinus surgery procedures could make it difficult for existing customers to continue using, or to adopt, our steroid releasing implants. This 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, value-based payment models, capitated arrangements, group purchasing, benefit redesign, prior 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.

Effective January 1, 2017, the Centers for Medicare & Medicaid Services, or 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, for Medicare patients, 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 peg their rates directly to Medicare rates or use these 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.

A track record of adequate coverage and reimbursement is important for sales of our products in the office setting of care. Inadequate coverage and negative reimbursement policies for our products could affect their adoption and our future revenue.

We are early in our commercialization of SINUVA for use in the office setting of care. SINUVA is designated as a drug by the FDA and as such, providers or specialty pharmacies are seeking reimbursement for the product using an unassigned J Code. We applied for a product-specific J code, and on April 26, 2019, CMS announced that they intend to establish a new J code described as "Mometasone furoate, implant, 10 micrograms." CMS has also indicated a preliminary decision to eliminate the S1090 code, which was previously assigned to PROPEL. When CMS issues its final decision in November 2019, we expect they will issue further explanation of their decision to eliminate the S1090 code, which will help us better understand the implications to our business. We cannot be assured we will be successful in our efforts to secure a product-specific J code. We have limited experience with this reimbursement and do not know how effective this approach will be over time in securing reimbursement from payors to cover the cost of SINUVA or if the level of reimbursement will be sufficient to support usage. While the reimbursement code is used for submission of claims for reimbursement, the payment is determined by and at the discretion of the payor. Reimbursement related factors that will impact adoption of SINUVA, and may change at any time, include:

- payors adoption of positive medical policies covering SINUVA or including SINUVA on their formularies;
- payors providing product reimbursement;
- physicians being able to secure payment for their time through appropriate procedural codes;
- patients' willingness to make any required co-pay or co-insurance payments; and
- physician's willingness to purchase the product directly and seek reimbursement from payors and patient co-pay for that expense, as is required by some payors. Such payments may or may not be received by the physician or may not fully cover the cost of the product.

The degree to which each of these factors is realized will impact SINUVA adoption and our ability to grow revenue.

Our PROPEL family of products are used principally in the operating room setting in hospitals and ASCs where the cost of these products is paid for out of the reimbursed facility fee associated with sinus surgery. Should this fee be reduced by commercial payors or government agencies or should the occurrence of procedures shift significantly to lower cost centers of care with lower reimbursement, our ability to sell our PROPEL family of products may be limited. There is very little usage of PROPEL products in the office setting of care because sinus surgery is more typically performed in the operating room and because there is limited reimbursement for the PROPEL family of products available in the office setting of care. While there are a few payors that may provide such coverage, that can change, and the majority of payors consider this usage experimental and investigational and therefore would not cover reimbursement claims.

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 absorbed. 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 do not know whether the results of SINUVA's use will be consistent with the results from our clinical studies.

While the FDA granted approval of SINUVA based on the data included in its NDA, including data from our completed clinical trials, we do not know whether the results, when a large number of patients are exposed to SINUVA, including results related to safety and efficacy, will be consistent with the results from the clinical trials of SINUVA that served as the basis for the approval of SINUVA. During research and development, SINUVA's use was limited principally to clinical trial patients under controlled conditions and under the care of expert physicians. New data relating to SINUVA, including from adverse event reports, may result in changes to the product label and may adversely affect sales, or result in withdrawal of SINUVA from the market. The FDA and regulatory authorities in other jurisdictions may also consider any new data in connection with further marketing approval applications. In addition, in patients who take multiple medications, drug interactions could occur that can be difficult to predict. If SINUVA or any additional approved products cause serious or unexpected side effects after receiving market approval, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw their approval of SINUVA or impose restrictions on its distribution;
- regulatory authorities may require the addition of labeling statements, such as warnings or contraindications;
- we may be required to change the way SINUVA is promoted or administered, or conduct additional clinical studies;
- we could be sued and held liable for harm caused to patients; or
- our reputation may suffer.

Any of these events could prevent us from maintaining market acceptance of the affected product and could substantially increase the costs of commercializing SINUVA or any additional products.

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 service 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 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. 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 or provide required services, 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.

We rely on specialty pharmacies and specialty distributors for distribution of SINUVA in the United States, and the failure of those specialty pharmacies and specialty distributors to distribute SINUVA effectively would adversely affect sales of SINUVA.

We have historically relied on our internal sales channel to sell our products. However, we rely on specialty pharmacies and specialty distributors for the distribution of SINUVA in the United States. A specialty pharmacy is a pharmacy that specializes in the dispensing, and a specialty distributor that specializes in the distribution, of medications for complex or chronic conditions, which often require a high level of patient education, physician administration and ongoing management. The use of specialty pharmacies and specialty distributors involves certain risks, including, but not limited to, risks that these specialty entities will:

- not provide us accurate or timely information regarding their inventories, the number of patients who are using our products or complaints about our products;
- reduce or discontinue their efforts to sell or support or otherwise not effectively sell or support our products;
- not devote the resources necessary to sell our products in the volumes and within the time frames that we expect;
- engage in unlawful or inappropriate business practices that result in legal or regulatory enforcement activity which could result in liability to the Company or damage its goodwill with customers; or
- be unable to satisfy financial obligations to us or others.

In the event that any of the specialty pharmacies or specialty distributors whom we work with do not fulfill their contractual obligations to us or refuses to or fails to adequately serve patients, or the agreements are terminated without adequate notice, shipments of SINUVA, and associated revenues, would be adversely affected.

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

It is 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. Demand for our products may be impacted adversely by weather and the annual resetting of patient healthcare insurance plan deductibles, both of which may cause patients to delay or decline elective procedures such as FESS and SINUVA implantation. Demand may also be impacted by the seasonal nature of allergies and cold and flu season and the resultant onset of sinus-related symptoms. Other factors that may impact our quarterly results include:

- ENT physician adoption of our steroid releasing implants;
- ENT physician willingness to engage in the buy and bill process for SINUVA implants;
- fluctuations in revenue due to changes in or from estimated gross-to-net deductions, including distributor fees and prompt payment discounts, discounts related to commercial agreements or government mandated programs, returns and replacements and, should we elect to offer such support, patient or payor assistance programs, and other related deductions and adjustments;
- 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, including into the UK and the EU in light of regulatory and geopolitical uncertainties arising from Brexit;
- our ability to obtain or maintain regulatory approval and reimbursement coverage for our products in development or for our current products outside the United States;
- fluctuations in revenue due to changes in third-party payor reimbursement for procedures associated with the use of our products;
- 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, 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 and manufacturing 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.

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 and Smith & Nephew. These companies could develop drug releasing products that could compete with our products and 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.

In addition, there are and have been venture companies seeking to develop competitive products. Companies may also market alternatives to current modes of treatment, such as OptiNose. Finally, there are established pharmaceutical companies evaluating monoclonal antibodies for the treatment of chronic sinusitis.

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, Stryker 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 and SINUVA, 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 centers, 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.

We have expanded the complexity of our operations by adding commercialization of a drug to our underlying device business. We may encounter difficulties in managing this expansion, which could disrupt our business.

SINUVA is our first commercially available product that is regulated as a drug. To sell this product, we are expanding the scope of our operations to comply with manufacturing and regulatory requirements of a drug. We are also adding a network of specialty pharmacies and specialty distributors to support product access, and adding internal or external capabilities to handle new operational requirements. We are relying on one integrated sales force to sell all our products. We will remain subject to ongoing inspection by regulatory agencies and must maintain compliance with both device and drug regulatory requirements for Quality Systems Regulation and Good Manufacturing Practice compliance, respectively.

To manage our anticipated future growth for SINUVA, our PROPEL family of products and our pipeline, 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 conduct additional clinical studies in the future to support new product or product indication approvals, including our investigational ASCEND drug-coated balloon, 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.

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. Securing separate payment for our products may require additional investment in clinical data to satisfy the requirements of health technology assessment organizations in these countries. 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.

Pricing for pharmaceutical products has come under increasing scrutiny by governments, legislative bodies and enforcement agencies. These activities may result in actions that have the effect of reducing our revenue or harming our business or reputation.

Many companies in our industry have received a governmental request for documents and information relating to drug pricing and patient support programs. We could receive a similar request, which would require us to incur significant expense and result in distraction for our management team. Additionally, to the extent there are findings, or even allegations, of improper conduct on the part of the company, such findings could further harm our business, reputation and/or prospects. It is possible that such inquiries could result in: negative publicity or other negative actions that could harm our reputation; changes in our product pricing and distribution strategies; reduced demand for our approved products; and/or reduced reimbursement of approved products, including by federal health care programs such as Medicare and Medicaid and state health care programs.

In addition, the current administration has indicated interest in taking regulatory and other policy actions pertaining to drug pricing, including potential proposals relating to Medicare price negotiations, importation of drugs from other countries and facilitating value-based arrangements between manufacturers and payers. At this time, it is unclear whether any of these proposals will be pursued and how they would impact our products or our future product candidates.

State and local governments continue to consider prescription drug pricing transparency proposals. In October 2017, California enacted legislation requiring pharmaceutical manufacturers to disclose and provide justification for certain price increases; however, the regulations under which we will have to operate have not yet been promulgated. While we have taken and will continue to take appropriate actions to ensure compliance with this new law, without knowing the final regulations applicable to us, we cannot comprehensively assess the potential impact on our business. Additional legislation or ballot initiatives may be proposed by various states and municipalities in the future, and we cannot predict the outcome of any future proposals, the market's perception of them or their potential impact on us.

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 and other ongoing reporting requirements. 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.

Our currently marketed products are subject to Medical Device Reporting, or MDR, and drug postmarketing safety reporting obligations, which require that we timely report any incidents to the FDA. 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 product candidates and we cannot, therefore, predict the timing of any future revenue from product candidates. Regulatory approval of a product candidate is not guaranteed, and the approval process is expensive, uncertain and lengthy.

We cannot commercialize our product candidates 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 product candidates. Additional delays may result if product candidates are brought before an FDA advisory committee, which could recommend restrictions on approval or recommend non-approval. 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 product candidates. 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 production;
- 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 United States;
- 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 United States 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 we participate in but fail to comply with our reporting and payment obligations under the Medicaid Drug Rebate Program, or other governmental pricing programs, we could be subject to additional reimbursement requirements, penalties, sanctions and fines which could have a material adverse effect on our business, financial condition and results of operations.

If we participate in the Medicaid Drug Rebate Program, and other governmental pricing programs, we will be obligated to pay certain specified rebates and report pricing information with respect to SINUVA. Pricing and rebate calculations are complex and are often subject to interpretation by us, governmental or regulatory agencies and the courts. We cannot assure you that our submissions will not be found by the CMS to be incomplete or incorrect. Governmental agencies may also make changes in program interpretations, requirements or conditions of participation, some of which may have implications for amounts previously estimated or paid. The Medicaid rebate amount is computed each quarter based on our submission to CMS of our current average manufacturer

price, or AMP, and best price, or BP, for the quarter. If we become aware that our reporting for a prior quarter was incorrect or has changed as a result of recalculation of the pricing data, we are obligated to resubmit the corrected data for a period not to exceed twelve quarters from the quarter in which the data originally were due, and CMS may request or require restatements for earlier periods as well. Such restatements and recalculations increase our costs for complying with the laws and regulations governing the Medicaid Drug Rebate Program. Any corrections to our rebate calculations could result in an overage or underage in our rebate liability for past quarters, depending on the nature of the correction. Price recalculations also may affect the ceiling price at which we are required to offer our products to certain covered entities, such as safety-net providers, under the Public Health Service's 340B drug pricing program, or 340B, and under other similar government pricing programs.

We will also be liable for errors associated with our submission of pricing data. In addition to retroactive rebates and the potential for 340B refunds, if we are found to have knowingly submitted false AMP or BP information to the government, we may be liable for civil monetary penalties. If we are found to have made a misrepresentation in the reporting of our AMP, we may be liable for civil monetary penalties as well. Our failure to submit monthly or quarterly AMP and BP data on a timely basis could result in a civil monetary penalty for each day the information is late beyond the due date. Such failure also could be grounds for CMS to terminate our Medicaid drug rebate agreement, pursuant to which we participate in the Medicaid program. In the event that CMS terminates our rebate agreement, federal payments may not be available under Medicaid for SINUVA. A final regulation imposes a civil monetary penalty for each instance of knowingly and intentionally charging a 340B covered entity more than the 340B ceiling price.

Federal law requires that a company must participate in the U.S. Department of Veterans Affairs, or VA, Federal Supply Schedule, or FSS, pricing program to be eligible to have its products paid for with federal funds. As part of this program, we are obligated to make SINUVA available for procurement on an FSS contract under which we must comply with standard government terms and conditions and charge a price that is no higher than the statutory Federal Ceiling Price, or FCP, to several federal agencies including the VA, the U.S. Department of Defense, the Public Health Service and the U.S. Coast Guard. The FCP is based on the Non-Federal Average Manufacturer Price, or Non-FAMP, which we calculate and report to the VA on a quarterly and annual basis. If we overcharge the government in connection with our FSS contract or Section 703 Agreement, whether due to a misstated FCP or otherwise, we are required to refund the difference to the government. Failure to make necessary disclosures and/or to identify contract overcharges can result in allegations against us under the U.S. civil False Claims Act and other laws and regulations. Unexpected refunds to the government, and responding to a government investigation or enforcement action, would be expensive and time consuming, and could have a material adverse effect on our business, financial condition and results of operations.

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 practices and Quality Systems regulation. These FDA regulations cover the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, storage and shipping of our products. Compliance with applicable regulatory requirements is subject to continual review and is monitored rigorously through periodic inspections by the FDA. If we, or our 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 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 or NDA 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.

As 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. In addition, corrective action to a recall may require regulatory approvals for product or manufacturing changes, which may take time to accomplish and may impact product availability in the marketplace. 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 such product candidates.

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, including supplements thereto. 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.

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 and applicable international 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 independent 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, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, 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 federal health care programs, such as Medicare and Medicaid 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, as well as comparable international privacy laws (e.g. the European Union's General Data Protection Regulation, or GDPR);
- 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 Payments Sunshine Act that imposes annual reporting requirements on device and pharmaceutical 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. 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 Payments 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, Vermont, Maine, Minnesota and New Jersey, impose restrictions on device and pharmaceutical 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 new 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 and pharmaceutical industries. 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. In January 2018, the medical device excise tax suspension was extended for calendar years 2018 and 2019. Absent further congressional action the excise tax will be reinstated for medical device sales beginning January 1, 2020. 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. For example, since January 2017, our current President of the United States has signed two executive orders and other directives designed to delay, circumvent, or loosen certain requirements mandated by the Affordable Care Act. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the Affordable Care Act. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the Affordable Care Act have been signed into law. The recent resolution on appropriations for fiscal year 2018 that extended the suspension of the medical device excise tax also delayed the implementation of the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, as well as the annual fee imposed on certain health insurance providers based on market share. Additionally, the Tax Cuts and Jobs Act of 2017 includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the Affordable Care Act on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate". Further, the Bipartisan Budget Act of 2018, or the BBA, among other things, amends the Affordable Care Act, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole". 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 subsequent legislative amendments to the statute, including the BBA, will stay in effect through 2027, 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.

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 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 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.

Changes in funding for the FDA, the SEC and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept payment of user fees, and statutory, regulatory and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including most recently in December 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

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 pre-issuance 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 commercial and, if approved, pipeline products.

The industries in which we operate in have 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, and Smith & Nephew, 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 for at least twelve months after the date the financial statements are issued. However, we have based these estimates on assumptions that may prove to be wrong, and we could spend our available financial resources much faster than we currently expect. Any future funding requirements will depend on many factors, including:

- market acceptance of our products, including access to adequate reimbursement;
- the cost of our research and development activities, including clinical studies;

- 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 growing sales, marketing and distribution capabilities;
- costs associated with any product recall that may occur;
- the effect of competing technological and market developments;
- the extent to which we acquire or invest in products, technologies and businesses, although we currently have no commitments or agreements relating to any of these types of transactions; and
- the costs of operating as a public company.

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

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

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

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

Changes in generally accepted accounting principles may materially adversely affect our reported results of operation or financial condition.

From time to time, the Financial Accounting Standards Board, or FASB, issues new accounting principles. For example, in May 2014, the FASB issued Accounting Standards Update No. 2014-09, *Revenue from Contracts with Customers*, with amendments in 2015 and 2016, which created a new Accounting Standards Codification Topic 606, or Topic 606, that replaced most existing revenue recognition guidance in U.S. generally accepted accounting principles, or GAAP, when it became effective for us on January 1, 2018. Under Topic 606, more judgment and estimates are required within the revenue recognition process than were previously required under GAAP. Changes to existing rules, or changes to interpretations of existing rules, could lead to changes in our accounting policies and systems. Such changes could materially adversely affect our reported financial results and stock price.

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. 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 or otherwise fail to maintain an effective system of internal controls, 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

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†	Processing Agreement by and between the registrant and Isomedix Operations Inc., dated as of February 1, 2019				
10.2	Amendment to Offer Letter by and between the registrant and Robert H. Binney, Jr., dated as of January 17, 2019				
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.				

† Certain confidential information contained in this document, marked by brackets, is omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

* 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.

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: May 7, 2019

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)

[*] = Certain confidential information contained in this document, marked by brackets, is omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

Exhibit 10.1

PROCESSING AGREEMENT

THIS PROCESSING AGREEMENT ("Agreement") is made on January 1, 2019 (the "Effective Date") between Isomedix Operations Inc., including its affiliates, Isomedix Corporation, STERIS Isomedix Puerto Rico, Inc., and Synergy Health AST, LLC ("STERIS"), with headquarters at 5960 Heisley Road, Mentor, Ohio 44060, and Intersect ENT, Inc. ("Customer"), having a principal place of business at 1555 Adams Drive, Menlo Park, California 94025.

WHEREAS, Customer seeks to have certain of its ear, nose, and throat devices (Customer's "Product" or "Products"), processed with radiation and STERIS is in the business of operating various radiation processing facilities (the "Facilities"); and

WHEREAS, the Food and Drug Administration ("FDA") has recognized that it is a common industry practice to manufacture and/or assemble, package and fully label a device as sterile at one establishment and then ship such device in interstate commerce to another establishment or to a contract sterilizer for processing; and

WHEREAS, the FDA will institute no regulatory action against the device as misbranded or adulterated during such shipment when the device is labeled sterile, provided the requirements of 21 C.F.R. § 801.150 are met.

NOW THEREFORE, in consideration of the agreements hereinafter set forth, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereby agree as follows:

1. **INTENT OF THE PARTIES.** It is the intention of the parties hereto to adhere to all of the requirements of the FDA, including 21 C.F.R. § 801.150.

2. **PRODUCT HANDLING.**

(a) Both Customer and STERIS acknowledge that Products transported from Customer to STERIS pursuant to this Agreement are non-sterile and are being shipped for further processing by STERIS.

(b) All Products shipped by Customer to STERIS shall be conspicuously marked "Non-Sterile – Shipped for Further Processing" or the equivalent and shall not be identified as sterile until the Products are established as sterile after treatment by methods specified by the Customer. The provisions of this paragraph shall apply during all times when the Product is introduced into or moving in intrastate or interstate commerce, during processing, and when held in quarantine.

(c) Each shipment of the Product for processing will be accompanied by documents (packing list and/or bill of lading) stating the number of cartons or other designated units in the shipment listed by manufacturer's lot and code number and the non-sterile nature of the Product. Upon receipt and prior to processing, STERIS will record on its receiving documents the number of cartons or other designated units by manufacturer's lot and code number received from Customer. STERIS will notify Customer of all count discrepancies and the parties shall ensure that all such discrepancies are reconciled before processing.

(d) STERIS will segregate unprocessed Products and Products designated as nonconforming or processed incorrectly (i.e., those processed not in accordance to specifications such as Product that received incorrect sterilization dose) from processed Products, to prevent accidental mixing of Products. STERIS will also segregate Customer's Products from all other products stored at the STERIS Facility.

(e) After completion of processing and until released by the Customer, the Product will be conspicuously marked by STERIS in the following way: each pallet, carton or other designated unit will show that the Product is "Processed" or the equivalent. Labels with such markings will be provided by STERIS.

(f) After radiation processing, STERIS will return all cartons or other designated units to the Customer's address or to a controlled destination point selected by the Customer.

(g) Except as otherwise agreed by STERIS and Customer, Products will be shipped in the same manner as received.

3. **PROCESSING.**

(a) All Product processing will occur in accordance with a set of processing specifications ("Procedures"). Customer will develop Procedures, which shall be in writing and shall clearly state minimum and maximum dose limitations, instructions regarding product counts, and handling, shipping, receiving, and special processing requirements. STERIS may accept or reject the Procedures, but no processing will occur until STERIS and Customer agree in writing to the applicable Procedures. STERIS's approval of the Procedures is limited to confirmation of its ability to process to the specifications and is not an approval or determination of the efficacy of the dose which is solely the responsibility of Customer.

(b) Customer shall provide and STERIS shall process Products in volumes summarized in Appendix A, "Processing Volumes," which is hereby incorporated into this Agreement. If, at any time, STERIS determines that the demand for certain processing exceeds the supply, then STERIS shall [*].

(c) Customer shall bear sole responsibility for determining the compatibility of Products and packages with the radiation process and for determining the radiation dosage(s). The Customer shall ship Product to STERIS in containers that are the same dimensions, weight, and internal packing configuration as qualified by STERIS. The Customer shall notify STERIS of any changes to the Product, its materials, packaging or configuration. STERIS will not be responsible for non-sterile or damaged Product because of changes made to Products. All tests related to the processing of the Products are the responsibility of Customer.

[*] = Certain confidential information contained in this document, marked by brackets, is omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

(d) After STERIS receives all required Products and documentation, STERIS will complete processing within such time frame as agreed by the parties.

(e) STERIS will inform the Customer, in writing, of any changes or modifications to the processing equipment which may impact routine processing or validation. STERIS will notify the Customer of deviations from the Procedures and the Customer will direct STERIS as to the disposition or reprocessing of those affected Products.

(f) All tests related to assessing the final sterility assurance of the Products are solely the responsibility of the Customer. Release of the sterilized Product to the market is the sole responsibility of the Customer. Customer shall develop appropriate procedures for approving the sterilized Products for release into the stream of commerce. Such procedures shall be designed to prevent the release of any Product for commercial distribution until Customer's designated representative shall properly approve the Product's release. Customer bears ultimate and full responsibility for Products released into commercial distribution, including labeling of Products as sterile.

(g) Except for Products sent to STERIS for test purposes (which shall be clearly labeled "FOR TESTING PURPOSES ONLY"), the Customer warrants to STERIS that Products sent for services can be processed without violating any government regulations.

4. **TITLE TO PRODUCTS.** Customer shall retain title to the Products at all times.

5. **AUDITS.** STERIS will allow the Customer access to the Facilities, upon reasonable notice and subject to STERIS's restrictions of confidentiality, during normal business hours, for the purpose of conducting GMP/ISO/EN audits related to the processing of the Products. STERIS will also make training records available to Customer during such audits, provided Customer requests such records reasonably in advance of the audit. STERIS will conduct periodic internal audits according to STERIS's QSM/QA Manual. STERIS will retain confirmation that it performed these internal audits, and Customer may review the confirmation upon reasonable prior notice. Customer shall keep confidential all information revealed to it during its audit of STERIS. The parties agree that notified bodies of the Customer are permitted to perform unannounced audits when necessary.

6. **TERM AND TERMINATION.** The initial term of this Agreement shall be for a period of three (3) years from the date of execution by both parties (the "Initial Term"). Thereafter, the Agreement shall automatically renew for one (1) year periods. Either party may, in its sole discretion, prevent the automatic renewal of this Agreement by giving a written notice of termination to the other party no less than [*] prior to the expiration of the Initial Term or the then applicable renewal period. Either party shall have the right to terminate this Agreement at any time upon [*] written notice if the other party is materially in default with respect to any of its obligations hereunder, and such default is not cured within [*] of notice to the defaulting party.

7. **RIGHT OF FIRST REFUSAL.** Intentionally Omitted.

8. **REQUIREMENTS.** Customer agrees that STERIS will perform 100% of the volume outlined in Appendix A pursuant to this Agreement, of Customer's radiation sterilization processing requirements during the term of the Agreement. Customer will use its best efforts to ensure that such processing will be requested of STERIS at a uniform monthly rate.

[*] = Certain confidential information contained in this document, marked by brackets, is omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

9. **REMOVAL AND STORAGE; SHIPPING.**

(a) STERIS shall provide, at no extra charge to Customer, sufficient storage space for all processed Product for not more than [*] from completion of processing. Thereafter, STERIS shall have the option of removing Customer's Product via common carrier or other means to an alternate facility designated by Customer, or of charging Customer for storage for each day in excess of the aforementioned [*].

(b) The Customer shall pay all shipping costs. STERIS will not be responsible for any shipping damage or delay.

10. **CHARGES AND TERMS OF PAYMENT.**

(a) The charges for the processing of Customer's Products pursuant to the Procedures are set forth in Appendix B, "Processing Charges." Customer shall have full and sole responsibility for all charges. Invoices will be rendered upon shipments made against a blanket order issued to STERIS by the Customer. Taxes, if applicable, are not included in the prices and shall be paid by the Customer.

(b) Payments shall be due [*] from the date of invoice. All payments shall be made in United States dollars. Any amount not paid when due shall bear interest at [*] or the highest lawful rate, if less, from the date due until paid.

11. **NOTICES**. All communications related to the terms of this Agreement or communication seeking approval for changes in any procedures covered thereby shall be in writing and shall be personally delivered or sent by registered or certified mail, postage prepaid, to the address indicated below, or to such other address as to the addressee shall have designated by notice given to the other party hereto, and shall be effective when received.

If to STERIS:

Manager, Plant Operations
Isomedix Operations Inc.
3200 Lakeville Highway
Petaluma, California 94954

cc: Kenneth E. Kohler
Vice President and General Manager
STERIS Applied Sterilization Technologies
5960 Heisley Road
Mentor, Ohio 44060

Manager, Plant Operations
Isomedix Operations Inc.
9020 Activity Road, Suite D
San Diego, California 92126

If to Customer:

Elaine Lindsay
Intersect ENT
1555 Adams Drive
Menlo Park, California 94025

[*] = Certain confidential information contained in this document, marked by brackets, is omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

12. **CONFIDENTIALITY; OWNERSHIP OF INTELLECTUAL PROPERTY.**

(a) The parties acknowledge and agree that in connection with the services provided under this Agreement valuable technical or marketing information of a confidential nature may be exchanged by the parties; that such information will be retained by the receiving party in confidence; that the transmittal of such information by a disclosing party is upon the condition that the information is to be used solely for the purpose of effectuating the Agreement; and that the receiving party shall not, either during the term of the Agreement or after its termination, use, publish, or disclose any technical or marketing information supplied by the disclosing party. This restriction on disclosure and use shall not apply to any information which the receiving party can show by written evidence was known to it through proper means at the time of receipt thereof from the disclosing party, or which may subsequently be obtained from sources other than the disclosing party who are not bound by a confidentiality agreement with Customer or STERIS.

(b) The parties acknowledge and stipulate that the covenants and agreements contained herein are of a special nature and that any breach, violation, or evasion by it of the restrictions of disclosure and use contained in this Agreement (i) may result in damages to the disclosing party in amounts difficult to ascertain; and (ii) may give rise to irreparable injury to the disclosing party. Accordingly, the parties agree that the disclosing party has a right to sue and is entitled to equitable relief, including, without limitation, injunctive relief and specific performance, without the necessity of proof of actual damage, against the actual or threatened breach, violation, or evasion of the Agreement by the receiving party in any proceeding that the disclosing party may bring to enforce any provision of this Agreement, in addition to any other legal remedies that may be available. In the event of any breach, violation, or evasion of the restriction on disclosure and use contained in this Agreement, the disclosing party shall be entitled to recover reasonable legal fees and all costs and expenses associated with the enforcement of any provision hereof or of the Agreement.

(c) STERIS shall retain all trademark, copyright, trade secret, and patent rights which it may have with respect to the processing. Customer shall retain all trademark, copyright, trade secret, and patent rights it may have with respect to the Products. Neither party shall use the trademark or tradename of the other party or its parents or affiliates in its company name or for otherwise conducting business with its customers.

13. **WARRANTY; LIMITATION OF LIABILITY; INSURANCE.**

(a) STERIS warrants only that Products shall be processed in accordance with Customer specifications, as accepted by STERIS. [*] EXCEPT AS SET FORTH ABOVE, STERIS MAKES NO REPRESENTATION OR WARRANTY OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

(b) STERIS SHALL NOT BE RESPONSIBLE FOR LOSS OF USE, LOSS OF INCOME OR PROFITS, COST OR RENTAL OF A SIMILAR PRODUCT, OR ANY OTHER CONSEQUENTIAL OR INCIDENTAL DAMAGES OF ANY KIND WHATSOEVER, WHETHER DUE TO BREACH OF CONTRACT OR WARRANTY OR TORT, INCLUDING NEGLIGENCE OF STERIS OR STRICT LIABILITY, OR ANY OTHER CAUSE. In the event STERIS fails to process any Products as agreed, or any Products are damaged or destroyed due to the fault of STERIS, [*]. However, if the Products [*] prior to processing and [*] related to such Products shall be [*]. Notwithstanding the foregoing, the parties acknowledge and agree that [*] any loss or damage to Products that is caused by [*] and [*].

[*] = Certain confidential information contained in this document, marked by brackets, is omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

(c) Customer shall carry an occurrence basis liability insurance policy with respect to the processed Products.

14. **INDEMNITY.** Customer agrees to defend, indemnify, and hold harmless STERIS for any and all claims, liability, damages or expenses due to personal injuries, including death, to employees of Customer, STERIS and to third parties, and for property damage, including damage to Customer Products, arising from Customer's negligence, willful misconduct or breach of contract, except to the extent caused by STERIS's negligence or breach of contract. Subject to the Limitations of Liability set forth above, STERIS agrees to defend, indemnify, and hold harmless Customer for any and all claims, liability, damages or expenses due to personal injuries, including death, to employees of Customer, STERIS and to third parties, and for property damage, including damage to Customer Products, arising from STERIS's negligence or breach of contract, except to the extent caused by Customer's negligence or breach of contract.

15. **MISCELLANEOUS.**

(a) If any provision of this Agreement shall be held invalid by a court of competent jurisdiction, such invalidity shall not affect any other provision which can be given effect without the invalid provision.

(b) The delay or failure of either party to require performance by the other party, or the waiver of a breach of any provision of this Agreement by either party, will not affect such party's right to subsequently require performance of any provision of this Agreement.

(c) The headings are inserted in the Agreement only as a matter of convenience and for reference and are not intended to define, limit, or describe the scope of the Agreement nor the intent of any of its provisions.

(d) The Agreement represents the complete agreement, understanding and obligation between the parties concerning its subject matter and supersedes all previous negotiations, representations, commitments and agreements, whether written, oral or implied, relating to its subject matter. No change, amendment or modification of this Agreement shall be effective unless made in writing and signed by both parties. Any terms in Customer's purchase order or any other document of order or acceptance which are different from or additional to this Agreement shall be of no force and effect. No course of dealing, or custom or usage, which is contrary to this Agreement shall serve to modify the terms of this Agreement.

(e) Neither party shall be liable for either its failure to perform or its delays in performance hereunder arising out of or resulting from causes beyond its control. Such causes include but are not restricted to acts of God, acts of Government or the public enemy, fires, floods, epidemics, power disruptions, equipment failure, quarantine restrictions, strikes, freight embargoes, unusually severe weather or default of suppliers due to any such causes.

[*] = Certain confidential information contained in this document, marked by brackets, is omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

(f) The relationship between the parties is that of vendor and independent contractor. Neither the Customer nor any of its officers, directors, agents, or employees shall be considered as an agent or employee of STERIS. In performing obligations and accepting benefits under this Agreement, Customer acts on its own account and has no authority or power to bind or to create any express or implied obligation on STERIS's behalf.

(g) Neither party shall assign this Agreement, or any of the rights or privileges contained in this Agreement, to any third party without the written consent of the other party which shall not be unreasonably withheld; provided, however, a party hereto may assign all or a portion of its rights and delegate all or a portion of its duties under this Agreement in connection with a merger, acquisition, or a sale of all or substantially all of its assets to which this Agreement pertains. STERIS may assign its rights and duties hereunder to an affiliate of STERIS.

(h) The Agreement and the relationship between the parties shall be governed by and interpreted in accordance with the laws of the State of Delaware without regard to its conflicts-of-law principles.

IN WITNESS WHEREOF, the parties have caused this Agreement to be executed by their duly authorized representatives.

Isomedix Operations Inc.

By: /s/ Kenneth E. Kohler
(Signature)
Kenneth E. Kohler
(Print Name)
Title: VP and General Manager, STERIS Applied Sterilization Technologies

Date: 02/01/2019

Intersect ENT, Inc.

By: /s/ Lisa Earnhardt
(Signature)
Lisa Earnhardt
(Print Name)
Title: President and CEO

Date: 1/14/19

[*] = Certain confidential information contained in this document, marked by brackets, is omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

APPENDIX A
PROCESSING VOLUMES

Customer Requirements

- [*]
- [*]

[*] = Certain confidential information contained in this document, marked by brackets, is omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

APPENDIX B
PROCESSING CHARGES

Electron Radiation Processing

Electron Radiation Processing – Petaluma and San Diego Facility

- [*]

Radiation Processing, Reference Mapping, Dose Validation and Dose Audit Charges

- Pricing available upon request from the STERIS Radiation Tech Center.

Processing Optional Services and other Ancillary Charges

- These prices are available upon request.

On the first anniversary date of this Agreement, and on each anniversary date thereafter, STERIS shall have the right to increase the processing charges [*].

Pricing is dependent on the processing parameters set forth above and the anticipated volumes set forth in Appendix A. In the event the processing parameters change or volumes are not consistent with Appendix A, STERIS may request a price adjustment, which shall not be unreasonably withheld.

[*] = Certain confidential information contained in this document, marked by brackets, is omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

Exhibit 10.2

January 16, 2019

Robert Binney

Re: Amended and Restated Employment Terms

Dear Rob:

Intersect ENT, Inc. (the "Company") is pleased to offer you the position of Chief Commercial Officer on the following terms. These terms shall supersede and replace, in their entirety, the terms set forth in your most recent offer letter from the Company (which was effective June 23, 2011, as amended November 18, 2013, January 26, 2015, May 1, 2017, and April 2, 2018) (referred to herein as your "Offer Letter").

You will be responsible for the management and oversight of all aspects of the Company's operations and personnel related to global sales and marketing. You will continue to report directly to me, as the Company's CEO, and you will continue to be based in Atlanta, Georgia. Of course, subject to your Good Reason rights described below, the Company may change your position, duties, and work location from time to time in its discretion.

Effective as of January 16, 2019 your base salary will be $345,000 per year, less payroll deductions and all required withholdings. You will be paid every other Friday and you will be eligible for the Company's standard benefits, including: health, dental, and vision insurance, paid time off, and holidays (subject to the terms and conditions of such plans). Details about all our benefit plans are available for your review.

In addition, you will also be eligible for an annual bonus of up to 40% of your eligible annual earnings (base salary paid during the calendar year), less deductions and required withholdings. Your annual bonus will be determined in the sole discretion of the Company based upon an evaluation of both your performance and the Company's performance, and such other criteria that the Company deems relevant. Bonuses are earned upon payment. Thus, in order to earn any such bonus, you must remain employed through the time when bonuses are paid in the first quarter after the end of the fiscal year to which the bonus applies. The Company may change compensation and benefits from time to time in its discretion. As an exempt salaried employee, you will not be eligible for overtime pay.

You have previously been granted various equity interests in the Company. Except as set forth herein, all such interests shall continue to be governed in all respects by the terms of the applicable plan documents and option and restricted stock unit agreements.

As originally agreed in your Offer Letter, if you are a full-time employee at the time of the closing of a Change in Control (as defined below), 50% of the then unvested shares subject to all Company stock options and restricted stock units held by you shall be fully vested. Notwithstanding the foregoing, as a pre-condition of the accelerated vesting referenced in the immediately preceding sentence, you will be required to timely sign, date and return to the Company (or its successor), and to not subsequently revoke, a general release of all known and unknown claims in the form provided to you by the Company.

If within one month before or within 12 months after the closing of a Change in Control (as defined below), your employment is either (A) terminated by the Company or a successor entity without Cause (defined below)(and not in connection with death or disability), or (B) terminated by you due to your resignation for Good Reason (defined below), provided that such termination constitutes a "separation from service" (as defined under Treasury Regulation Section 1.409A-1(h), without regard to any alternative definition thereunder, a "Separation from Service"), then 100% of the then unvested shares subject to all Company stock options and restricted stock units held by you shall be fully vested. Notwithstanding the foregoing, as a pre-condition of the accelerated vesting referenced in the immediately preceding sentence, you will be required to timely sign, date and return to the Company (or its successor), and to not subsequently revoke, a general release of all known and unknown claims in the form provided to you by the Company.

In addition, you shall receive the Severance Benefits (as defined below) if at any time your employment is either (i) terminated by the Company or a successor entity without Cause (defined below) (and not in connection with death or disability), or (ii) terminated by you due to your resignation for Good Reason (defined below), provided that such termination constitutes a Separation from Service" (as defined above).

For purposes of this letter agreement, the following definitions shall apply:

(1) Change in Control. "Change in Control" shall mean the following: (i) any consolidation or merger of the Company with or into any other corporation or other entity or person, or any other corporate reorganization, other than any such consolidation, merger or reorganization in which the stockholders of the Company immediately prior to such consolidation, merger or reorganization, continue to hold a majority of the voting power of the surviving entity (or, if the surviving entity is a wholly owned subsidiary, its parent) immediately after such consolidation, merger or reorganization; (ii) any transaction or series of related transactions to which the Company is a party in which in excess of fifty percent (50%) of the Company's voting power is transferred; provided that the foregoing shall not include any transaction or series of transactions principally for bona fide equity financing purposes in which cash is received by the Company or indebtedness of the Company is cancelled or converted or a combination thereof; or (iii) a sale, lease, exclusive license or other disposition of all or substantially all of the assets of the Company.

(2) Cause. "Cause" shall mean any of the following conduct by you: (i) embezzlement, misappropriation of corporate funds, or other material acts of dishonesty; (ii) commission or conviction of any felony, or of any misdemeanor involving moral turpitude, or entry of a plea of guilty or nolo contendere to any felony or misdemeanor; (iii) engagement in any activity that you know or should know could materially harm the business or reputation of the Company; (iv) material failure to adhere to the Company's corporate codes, policies or procedures as in effect from time to time; (v) material violation of any statutory, contractual, or common law duty or obligation to the Company, including, without limitation, the duty of loyalty; (vi) repeated failure, in the reasonable judgment of the Board, to substantially perform your assigned duties or responsibilities after written notice from the Board describing the failure(s) in reasonable detail and your failure to cure such failure(s) within thirty (30) days of receiving such written notice; or (vii) material breach of the Company's Employee Confidential Information and Inventions Agreement executed by you ("Confidential Information Agreement").

(3) Good Reason. "Good Reason" shall mean any of the following which occurs without your written consent: (i) a relocation of the office where you are required to work to a location more than thirty-five (35) miles from the office where you previously were required to work; (ii) a material decrease in your base salary (except for salary decreases generally applicable to the Company's other executive employees); or (iii) a material reduction in the scope of your duties or responsibilities, provided, however, that to resign for Good Reason, you must (1) provide written notice to the Company's Chief Executive Officer within 30 days after the first occurrence of the event giving rise to Good Reason setting forth the basis for your resignation, (2) allow the Company at least 30 days from receipt of such written notice to cure such event, and (3) if such event is not reasonably cured within such period, your resignation from all positions you then hold with the Company is effective not later than 90 days after the expiration of the cure period.

(4) Severance Benefits. "Severance Benefits" shall mean (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 (the "Salary Continuation"); (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; and (iii) if you timely elect continued coverage under COBRA, twelve (12) months COBRA reimbursement (with such reimbursement to cease if you become eligible for health insurance benefits through a new employer). Such Severance Benefits are conditional upon (a) your continuing to comply with your obligations under your Confidential Information Agreement during the period of time in which you are receiving the Severance Benefits; and (b) your delivering to the Company an effective, general release of claims in favor of the Company in a form acceptable to the Company within 60 days following your Separation from Service. The Salary Continuation will be paid in equal installments on the Company's regular payroll schedule and will be subject to applicable tax withholdings over the period outlined above following the date of your Separation from Service; provided, however, that no payments will be made prior to the 60th day following your Separation from Service. On the 60th day following your Separation from Service, the Company will pay you in a lump sum the Salary Continuation and the pro-rated target bonus payment that you would have received on or prior to such date under the original schedule but for the delay while waiting for the 60th day in compliance with Section 409A of the Internal Revenue Code of 1986, as amended ("Code Section 409A") and the effectiveness of the release, with the balance of the Salary Continuation being paid as originally scheduled.

As a condition of your employment, you are required to abide by the Company's policies and procedures. You also agree to read, sign and comply with the Confidential Information Agreement.

In your work for the Company, you will be expected not to make unauthorized use or disclosure of any confidential information or materials, including trade secrets, of any former employer or other third party to whom you have an obligation of confidentiality. Rather, you will be expected to use only that information generally known and used by persons with training and experience comparable to your own, which is common knowledge in the industry or otherwise legally in the public domain, or which is otherwise provided or developed by the Company. By accepting employment with the Company, you are representing to us that you will be able to perform your duties within the guidelines described in this paragraph. You represent further that you have disclosed to the Company any contract you have signed that may restrict your activities on behalf of the Company in any manner.

Your employment relationship is at-will. Accordingly, you may terminate your employment with the Company at any time and for any reason whatsoever simply by notifying the Company. Likewise, the Company may terminate your employment at any time, with or without cause or advance notice.

It is intended that all of the benefits and payments under this letter satisfy, to the greatest extent possible, the exemptions from the application of Code Section 409A provided under Treasury Regulations 1.409A 1(b)(4), 1.409A 1(b)(5) and 1.409A 1(b)(9), and this letter will be construed to the greatest extent possible as consistent with those provisions. If not so exempt, this letter (and any definitions hereunder) will be construed in a manner that complies with Code Section 409A, and incorporates by reference all required definitions and payment terms. For purposes of Code Section 409A (including, without limitation, for purposes of Treasury Regulation Section 1.409A 2(b)(2)(iii)), your right to receive any installment payments under this letter (whether severance payments, reimbursements or otherwise) will be treated as a right to receive a series of separate payments and, accordingly, each installment payment hereunder will at all times be considered a separate and distinct payment. Notwithstanding any provision to the contrary in this letter, if you are deemed by the Company at the time of your Separation from Service to be a "specified employee" for purposes of Code Section 409A(a)(2)(B)(i), and if any of the payments upon your Termination of Services set forth herein and/or under any other agreement with the Company are deemed to be "deferred compensation", then if delayed commencement of any portion of such payments is required to avoid a prohibited distribution under Code Section 409A(a)(2)(B)(i) and the related adverse taxation under Code Section 409A, the timing of the payments upon your Separation from Service will be delayed as follows: on the earlier to occur of (i) the date that is six months and one day after the effective date of your Termination of Services, and (ii) the date of the your death (such earlier date, the "Delayed Initial Payment Date"), the Company will (A) pay to you a lump sum amount equal to the sum of the payments upon your Separation from Service that you would otherwise have received through the Delayed Initial Payment Date if the commencement of the payments had not been delayed pursuant to this paragraph, and (B) commence paying the balance of the payments in accordance with the applicable payment schedules set forth above.

This letter, together with your Confidential Information Agreement, forms the complete and exclusive statement of your agreement with the Company concerning the subject matter hereof. The terms in this letter supersede any other representations or agreements made to you by any party, whether oral or written, including without limitation, all of your previous offer letters and agreements describing the terms of your employment with the Company, including your Offer Letter. The terms of this agreement cannot be changed (except with respect to those changes expressly reserved to the Company's discretion in this letter) without a written agreement signed by you and a duly authorized officer of the Company. This agreement is to be governed by the laws of the state of California without reference to conflicts of law principles. Any action brought by either party under or in relation to this agreement, including without limitation to interpret or enforce any provision of this agreement, shall be brought in, and each party agrees to and does hereby submit to the jurisdiction and venue of, any state or federal court located in the County of San Mateo, California. In case any provision contained in this agreement shall, for any reason, be held invalid or unenforceable in any respect, such invalidity or unenforceability shall not affect the other provisions of this agreement, and such provision will be construed and enforced so as to render it valid and enforceable consistent with the general intent of the parties insofar as possible under applicable law. With respect to the enforcement of this agreement, no waiver of any right hereunder shall be effective unless it is in writing. For purposes of construction of this agreement, any ambiguity shall not be construed against either party as the drafter. This agreement may be executed in more than one counterpart, and signatures transmitted via facsimile shall be deemed equivalent to originals. As required by law, this offer is subject to satisfactory proof of your identity and right to work in the United States.

You agree that you have been provided with an opportunity to consult with you own counsel with respect to this agreement.

If you wish to accept the revised employment terms described above, please sign and date this letter. The offer represented hereby shall be valid until January 31, 2019 and upon your acceptance shall be effective as of January 16, 2019 ("Commencement Date").

Congratulations on this new role at the Company. We look forward to continuing our work together.

Sincerely,

/s/ Lisa Earnhardt
Lisa Earnhardt
Chief Executive Officer

Understood and Accepted:

/s/ Robert Binney
Robert Binney Date 1-17-19

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.

May 7, 2019

/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.

May 7, 2019

/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 period ended March 31, 2019, to which this Certification is attached as Exhibit 32.1 (the "Periodic 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 Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

May 7, 2019

/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, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.