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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, 2020

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 May 4, 2020 were 32,559,239.

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INTERSECT ENT, INC.
Form 10-Q – QUARTERLY REPORT
For the Quarter Ended March 31, 2020

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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, 2020 (unaudited)	December 31, 2019 (1)
Assets		
Current assets:		
Cash and cash equivalents	$ 34,193	$ 20,652
Short-term investments	53,517	69,986
Accounts receivable, net	10,306	19,113
Inventories, net	17,048	17,000
Prepaid expenses and other current assets	2,547	2,300
Total current assets	117,611	129,051
Property and equipment, net	6,165	6,312
Operating lease right-of-use assets	11,442	11,980
Other non-current assets	684	559
Total assets	$ 135,902	$ 147,902
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 4,907	$ 4,056
Accrued compensation	10,390	12,717
Other current liabilities	2,442	2,163
Total current liabilities	17,739	18,936
Operating lease liabilities	10,281	10,886
Other non-current liabilities	22	22
Total liabilities	28,042	29,844
Commitments and contingencies (note 7)		
Stockholders' equity:		
Preferred stock, $0.001 par value;		
Authorized shares: 10,000 at March 31, 2020 and December 31, 2019;		
Issued and outstanding shares: none	—	—
Common stock, $0.001 par value;		
Authorized shares: 150,000 at March 31, 2020 and December 31, 2019;		
Issued and outstanding shares: 32,537 at March 31, 2020 and 32,235 at December 31, 2019	33	32
Additional paid-in capital	356,082	348,729
Accumulated other comprehensive loss	34	53
Accumulated deficit	(248,289)	(230,756)
Total stockholders' equity	107,860	118,058
Total liabilities and stockholders' equity	$ 135,902	$ 147,902

(1) Amounts have been derived from the December 31, 2019 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,	
	2020	2019
Revenue	$ 19,826	$ 26,673
Cost of sales	6,410	4,645
Gross profit	13,416	22,028
Operating expenses:		
Selling, general and administrative	26,200	27,207
Research and development	5,146	6,266
Total operating expenses	31,346	33,473
Loss from operations	(17,930)	(11,445)
Interest income and other, net	397	640
Net loss	(17,533)	(10,805)
Other comprehensive income (loss):		
Unrealized (loss) gain on short-term investments, net	(19)	77
Comprehensive loss	$ (17,552)	$ (10,728)
Net loss per share, basic and diluted	$ (0.54)	$ (0.35)
Weighted average common shares used to compute net loss per share, basic and diluted	32,365	30,918

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, 2019	32,235	$ 32	$348,729	$ 53	$ (230,756)	$ 118,058
Issuance of common stock and exercise of stock options	302	1	3,100	—	—	3,101
Stock-based compensation expense	—	—	4,253	—	—	4,253
Unrealized loss on short-term investments	—	—	—	(19)	—	(19)
Net loss	—	—	—	—	(17,533)	(17,533)
Balance at March 31, 2020	32,537	$ 33	$356,082	$ 34	$ (248,289)	$ 107,860
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

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,	
	2020	2019
Operating activities:		
Net loss	$(17,533)	$(10,805)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	496	588
Amortization of right-of-use assets	538	266
Stock-based compensation expense	4,356	3,869
Amortization of net investment discount	(83)	(377)
Changes in operating assets and liabilities:		
Accounts receivable, net	8,807	2,285
Inventories, net	(151)	(2,184)
Prepaid expenses and other assets	(368)	182
Accounts payable	634	(1,295)
Accrued compensation	(2,327)	899
Other liabilities	(325)	(320)
Net cash used in operating activities	(5,956)	(6,892)
Investing activities:		
Purchases of short-term investments	(7,339)	(42,539)
Maturities of short-term investments	23,872	45,310
Purchases of property and equipment	(137)	(1,217)
Net cash provided by investing activities	16,396	1,554
Financing activities:		
Proceeds from issuance of common stock and exercise of stock options	3,101	4,467
Net cash provided by financing activities	3,101	4,467
Net increase (decrease) in cash and cash equivalents	13,541	(871)
Cash and cash equivalents:		
Beginning of the period	20,652	9,464
End of the period	$ 34,193	$ 8,593
Non-cash investing activities:		
Right-of-use asset obtained in exchange for lease obligations	$ —	$ 117
Property and equipment included in accounts payable	321	346
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 transforming care for patients with ear, nose and throat ("ENT") 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 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 adult patients in conjunction with sinus surgery primarily in hospitals and ambulatory surgery centers ("ASC") and SINUVA is designed to be used in the physician 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, the Company 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 interim financial data as of March 31, 2020, 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, 2020 and 2019. 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, 2019 filed with the SEC on February 27, 2020.

Risks and Uncertainties

The Company is subject to risks and uncertainties resulting from the COVID-19 pandemic. The Company cannot predict the extent or duration of the impact of the COVID-19 pandemic on its financial and operating results, as the information regarding the current environment is evolving rapidly. The Company's business has and will be impacted by its customers continuing to suspend elective procedures, reduced ENT ASC and office procedures, as well as the shelter-in-place order issued by San Mateo County and the State of California, where the Company's manufacturing operations and corporate headquarters are located. Furthermore, the COVID-19 pandemic has led to severe disruption and volatility in global capital markets and increased economic uncertainty and instability. The impact of this on the global economy has been and may continue to be severe.

The magnitude of the impact of the COVID-19 pandemic on the Company's business will depend on a number of factors, including, but not limited to: the duration and severity of the pandemic is unknown and could continue, and be more severe, than the Company currently expects; the duration, extent and re-occurrence of the shelter-in-place orders impacting its manufacturing operations; the unknown state of the U.S. economy following the pandemic; the level of demand for the Company's products as the pandemic subsides; and the time it will take for the economy to recover from the pandemic. As of the date of these condensed consolidated financial statements, the extent to which the COVID-19 pandemic may materially adversely impact the Company's financial results, operating results, or liquidity is uncertain.

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, the allowance for doubtful accounts, inventory, common stock valuation and related stock-based compensation expense, leases 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, including the anticipated impact of the COVID-19 pandemic, 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.

Recent Accounting Pronouncements

Effective January 1, 2020, the Company adopted ASU No. 2016-13, *Measurement of Credit Losses on Financial Instruments* ("ASU 2016-13"). ASU 2016-13 requires that credit losses be presented as an allowance rather than as a write-down for available-for-sale debt securities and allows for the reversal of estimated credit losses in the current period, aligning the income statement recognition of credit losses with the reporting period in which changes occur. ASU 2016-13 also broadens the information an entity must consider in developing its expected credit loss estimate for assets measured at amortized cost. The adoption of the standard did not result in a material impact to the Company's condensed consolidated financial statements.

Significant Accounting Policies

There have been no significant changes to the accounting policies during the three months ended March 31, 2020, 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 on Form 10-K for the year ended December 31, 2019, except as described below:

Inventories

Inventories are valued at the lower of cost, computed on a first-in, first-out basis, or net realizable value. The allocation of production overhead to inventory costs is based on normal production capacity. Abnormal amounts of idle facility expense, freight, handling costs, and consumption are expensed as incurred, and not included in overhead. During the three months ended March 31, 2020, as a result of a shut-down in production associated with the COVID-19 pandemic, the Company recorded $1.1 million for idle facility expense due to its inability to use its manufacturing facility for a part of the quarter due to the shelter-in-place orders. While the manufacturing remains shut-down, the Company will continue to incur idle facility charges in future periods. The Company maintains provisions for excess and obsolete inventory based on its estimates of forecasted demand and, where applicable, product expiration. Due to a decline in projected product sales, the Company also increased its reserve for excess and obsolete inventory by $0.8 million during the three months ended March 31, 2020. The Company will continue to monitor the effect of the COVID-19 pandemic on the business and will continue to reassess the need for inventory reserves in future periods.

Credit Losses

The Company is exposed to credit losses primarily through receivables from customers and collaborators and through its available-for-sale debt securities. The Company's expected loss allowance methodology for the receivables is developed using historical collection experience, current and future economic market conditions, a review of the current aging status, and the financial condition of its customers. Specific allowance amounts are established to record the appropriate allowance for customers that have an identified specific risk of default. General allowance amounts are established based upon the Company's assessment of expected credit losses for its receivables by aging category. Balances are written off when they are ultimately determined to be uncollectible. The Company's expected loss allowance methodology for the debt securities is developed by reviewing the extent of the unrealized loss, the size, term, geographical location, industry of the issuer, the issuers' credit ratings and any changes in those ratings, as well as reviewing current and future economic market conditions and the issuers' current status and financial condition. The Company considered the current and expected future economic and market conditions surrounding the COVID-19 pandemic and increased the overall reserve for credit losses by $0.1 million for the three months ended March 31, 2020.

3. Composition of Certain Financial Statement Items

Accounts Receivable (in thousands):

	March 31, 2020	December 31, 2019
Accounts receivable	$ 10,554	$ 19,244
Allowance for doubtful accounts	(248)	(131)
	$ 10,306	$ 19,113

Inventory (in thousands):

	March 31, 2020	December 31, 2019
Raw materials	$ 1,788	$ 2,830
Work-in-process	340	283
Finished goods	14,920	13,887
	$ 17,048	$ 17,000

Capitalized stock-based compensation expense of $0.8 million and $0.9 million was included in inventory as of March 31, 2020 and December 31, 2019, respectively.

Revenue (in thousands):

	Three Months Ended March 31,	
	2020	2019
PROPEL family of products	$19,090	$25,732
SINUVA	736	941
	$19,826	$26,673

4. 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. 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, by type of instrument measured at fair value on a recurring basis (in thousands):

March 31, 2020	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value	Reported as: Cash and cash equivalents	Reported as: Short-term investments
Level 1:						
Cash	$ 8,630	$ —	$ —	$ 8,630	$ 8,630	$ —
Money market funds	25,563	—	—	25,563	25,563	—
	34,193	—	—	34,193	34,193	—
Level 2:						
Corporate debt securities	39,340	15	(20)	39,335	—	39,335
Commercial paper	14,143	39	—	14,182	—	14,182
	53,483	54	(20)	53,517	—	53,517
	$ 87,676	$ 54	$ (20)	$ 87,710	$ 34,193	$ 53,517

December 31, 2019	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value	Reported as: Cash and cash equivalents	Reported as: Short-term investments
Level 1:						
Cash	$ 11,885	$ —	$ —	$ 11,885	$ 11,885	$ —
Money market funds	8,767	—	—	8,767	8,767	—
	20,652	—	—	20,652	20,652	—
Level 2:						
Corporate debt securities	50,137	33	(1)	50,169	—	50,169
Commercial paper	19,796	21	—	19,817	—	19,817
	69,933	54	(1)	69,986	—	69,986
	$ 90,585	$ 54	$ (1)	$ 90,638	$ 20,652	$ 69,986

There were no transfers in and out of Level 1 and Level 2 during the three months ended March 31, 2020 and year ended December 31, 2019.

As of March 31, 2020 and December 31, 2019, 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, 2020 and year ended December 31, 2019. 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. The Company concluded that any unrealized losses on investments as of March 31, 2020 were not attributed to credit.

5. 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, 2020, the total number of shares of common stock reserved for issuance increased by 967,064 shares to 9,934,768 shares reserved since the inception of the 2014 Plan. At March 31, 2020, 3,070,479 shares remained available for issuance.

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

	Three Months Ended March 31, 2020	
	Options	Weighted Average Exercise Price
Outstanding, beginning of period	3,636	$ 23.71
Granted	559	25.88
Exercised	(179)	17.30
Forfeited	(217)	27.51
Outstanding, end of period	3,799	24.11
Exercisable	1,725	22.47

As of March 31, 2020, included in the outstanding options was an option subject to both service and market-based vesting conditions to purchase 427,147 shares of the Company's common stock with an exercise price of $20.44. As of March 31, 2020, these stock options remain unvested.

The aggregate pre-tax intrinsic value of options outstanding was $0.7 million and options outstanding and exercisable was $0.7 million, the weighted-average remaining contractual term of options outstanding was 8.1 years and options outstanding and exercisable was 6.9 years. The aggregate pre-tax intrinsic value of options exercised was $1.2 million and $5.1 million during the three months ended March 31, 2020 and 2019, respectively.

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

	Three Months Ended March 31, 2020	
	RSUs	Weighted Average Fair Value
Outstanding, beginning of period	511	$ 25.62
Awarded	248	26.18
Vested	(123)	26.89
Forfeited	(40)	28.97
Outstanding, end of period	596	25.36

As of March 31, 2020, the aggregate pre-tax intrinsic value of RSUs outstanding was $7.0 million, calculated based on the closing price of the Company's common stock at the end of the period, and the weighted-average remaining vesting term of RSUs outstanding was 2.4 years.

A summary of the Company's Performance Stock Unit (PSU) activity and related information (PSUs in thousands):

	Three Months Ended March 31, 2020	
	PSUs	Weighted Average Fair Value
Outstanding, beginning of period	89	$ 14.22
Awarded	103	17.28
Vested	—	—
Forfeited	—	—
Outstanding, end of period	192	15.86

As of March 31, 2020, the aggregate pre-tax intrinsic value of PSUs outstanding was $2.3 million, calculated based on the closing price of the Company's common stock at the end of the period, and the weighted-average remaining vesting term of PSUs outstanding was 2.8 years.

Total stock-based compensation expense recognized is as follows (in thousands):

	Three Months Ended March 31,	
	2020	2019
Cost of sales	$ 441	$ 236
Selling, general and administrative	3,552	2,974
Research and development	363	659
	$ 4,356	$ 3,869

As of March 31, 2020, the amount of unearned stock-based compensation currently estimated to be expensed through the year 2024 related to unvested employee stock-based awards was $38.9 million and the weighted average period over which the unearned stock-based compensation is expected to be recognized was 2.7 years.

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") since the inception of the 2014 ESPP. At March 31, 2020, 1,030,787 shares remained available for issuance and no shares were issued during the three months ended March 31, 2020.

6. 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,	
	2020	2019
Common stock options	3,372	4,142
Market-based performance stock options	427	—
Restricted stock units	596	408
Market-based performance stock units	192	—
Employee stock purchase plan shares	70	74
	4,657	4,624

7. 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 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.

In May 2019, a purported stockholder of the Company, Avi Yaron, filed a putative class action complaint in the United States District Court for the Northern District of California, entitled *Yaron v. Intersect ENT, Inc., et al.*, Case No. 4:19-cv-02647, against the Company and certain individual officers and directors alleging violations of the Securities Exchange Act of 1934. The complaint alleges that the Company and the individual officers made false and/or misleading statements about the Company's business and seeks unspecified damages and attorney's fees. The Court has appointed the lead plaintiff and has set a schedule for initial motions and pleadings. The Company believes this lawsuit is without merit and intends to vigorously defend against it. As of March 31, 2020, the Company has not recorded a contingent liability associated with this lawsuit, as the Company has not determined that a loss is probable. In addition, any possible loss or range of loss, cannot be reasonably estimated at this time.

8. Subsequent Events

Response to COVID-19

In April 2020, as a response to the COVID-19 pandemic, the Company took pre-emptive actions to curtail spending as its business, revenues and cash flows are expected to be significantly impacted due to the suspension of medical procedures involving its products. These actions included reducing its workforce by 96 employees, or approximately 25% of its workforce. In addition, the Company has furloughed 18 employees, or approximately 5% of its workforce, and will be providing for the cost of certain benefits for those employees while furloughed. The Company is also suspending near-term production, reducing discretionary operating expenses and capital expenditures, and delaying clinical research projects. The charges related to these actions, including severance benefits for terminated employees and the benefits for furloughed employees, are expected to be approximately $0.3 million and the material portion of the incurred expense is expected to be substantially complete by June 30, 2020.

Completion of Private Placement

On May 11, 2020, the Company entered into a Facility Agreement (the "Facility Agreement") by and among the Company, as borrower, certain of the Company's subsidiaries from time to time party thereto as guarantors and Deerfield Partners, L.P. ("Deerfield"), as agent for itself and the lenders, providing for the issuance and sale by the Company to Deerfield of $65.0 million of principal amount of 4.0% unsecured senior convertible notes (the "Convertible Notes") upon the terms and conditions set forth in the Facility Agreement (the "Deerfield Financing"). The Convertible Notes will mature on May 9, 2025, unless earlier converted or redeemed, and are convertible into shares of the Company's common stock, at an initial conversion price of $15.54, representing an approximately 15% premium over the Company's closing stock price of $13.49 per share on May 8, 2020. The Company estimates that the net proceeds from the sale of the Convertible Notes were approximately $62.5 million after deducting the estimated expenses payable by the Company.

The Convertible Notes bear interest at 4.0% per annum, payable quarterly in arrears on July 1, October 1, January 1 and April 1 of each year, commencing July 1, 2020. The Convertible Notes are convertible at any time at the option of the holders thereof, provided that Deerfield is prohibited from converting the Convertible Notes into shares of common stock if, as a result of such conversion, the converting holder (together with certain affiliates and "group" members) would beneficially own more than 4.985% of the total number of shares of common stock then issued and outstanding (the "Beneficial Ownership Cap"). Pursuant to the Convertible Notes, the holders of the Convertible Notes have the option to demand repayment of all outstanding principal, any unpaid interest accrued thereon, and make whole interest, in connection with a Major Transaction (as defined in the Convertible Notes), which shall include, among others, any acquisition or other change of control of the Company; the sale or transfer of assets of the Company equal to more than 50% of the Enterprise Value (as defined in the Convertible Notes) of the Company; a liquidation, bankruptcy or other dissolution of the Company; or if at any time shares of the Company's common stock are not listed on an Eligible Market (as defined in the Convertible Notes). The Facility Agreement contains certain specified events of default, the occurrence of which would entitle the holders of the Convertible Notes to immediately demand repayment of all outstanding principal and accrued interest on the Convertible Notes, together with a make-whole payment as determined pursuant to the Facility Agreement. Such events of default include, among others, failure to make any payment under the Convertible Notes when due, failure to observe or perform any covenant under the Facility Agreement or the other transaction documents related thereto (subject in certain cases to specified cure periods), the failure of the Company to be able to pay debts as they come due, the commencement of bankruptcy or insolvency proceedings against the Company, a material judgment levied against the Company and a material default by the Company under other indebtedness.

On or after the date that is the second anniversary of the issuance date, the Company may redeem up to $32.5 million of principal amount of Convertible Notes if (1) the volume weighted average price of the common stock on each of any twenty (20) trading days during a period of thirty (30) consecutive trading days ending on the date which an optional redemption notice is delivered, (2) the volume weighted average price of the common stock on the last trading day of such period and (3) the closing price of the common stock on the last trading day of such period, in each case, are greater than 150% of the conversion price. On or after the date that is the third anniversary of the issuance date, the Company may redeem up to the entire $65.0 million original principal amount of Convertible Notes if (1) the volume weighted average price of the common stock on each of any twenty (20) trading days during a period of thirty (30) consecutive trading days ending on the date which an optional redemption notice is delivered, (2) the volume weighted average price of the common stock on the last trading day of such period and (3) the closing price of the common stock on the last trading day of such period, in each case, are greater than 200% of the conversion price. The Company is obligated to notify the holders of the Convertible Notes no less than ten trading days nor more than sixty calendar days prior to any such redemption. During the period from the date on which the Company delivers an optional redemption notice until the date the optional redemption price is paid to holders, if a holder elects to convert its Convertible Notes, it will receive the shares otherwise issuable upon conversion of the Convertible Notes, plus an additional number of shares determined in accordance with the Convertible Notes. To the extent the holder would be prohibited due to the Beneficial Ownership Cap to convert its Convertible notes during such period, such holder would be entitled to convert all or any portion of its Convertible Notes into shares of Series DF-1 Preferred Stock of the

Company (such conversion, a “Preferred Stock Conversion”). The number of Series DF-1 Preferred Stock issuable upon a Preferred Stock Conversion shall be determined by dividing the number of shares of common stock of the Company that it would be entitled to receive from such conversion by 1,000. Upon any conversion of the Convertible Notes in connection with a major transaction, redemption of the Convertible Notes in connection with a major transaction or an optional redemption, holders of the Convertible Notes will also be entitled to a make-whole increase to the conversion rate.

The Company is subject to a number of affirmative and restrictive covenants pursuant to the Facility Agreement, including covenants regarding compliance with applicable laws and regulations, maintenance of property, payment of taxes, maintenance of insurance, business combinations, incurrence of additional indebtedness, prepayments of other unsecured indebtedness and transactions with affiliates, among other covenants. The Company is also restricted from paying dividends or making other distributions or payments on its capital stock, subject to limited exceptions.

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. In addition, forward-looking statements include the impact that the COVID-19 pandemic will have on our business, and our belief that we will be able to return to growth as the current crisis subsides. 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: the duration and severity of the COVID-19 pandemic is unknown and could continue, and be more severe than we currently expect; the unknown state of the U.S. economy following the pandemic, the level of demand for our products as the pandemic subsides, and the time it will take for the economy to recover from the pandemic; and 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 27, 2020.

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 transforming care for patients with ear, nose and throat ("ENT") 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 adult patients in conjunction with sinus surgery primarily in hospitals and ambulatory surgery centers ("ASC") and SINUVA is designed to be used in the physician 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. While our primary commercial focus is the U.S. market, both PROPEL and PROPEL Mini received CE Markings, permitting them to be marketed in Europe. Approximately 450,000 and 250,000 FESS procedures are performed annually in the Asia Pacific and European regions, respectively. Our commercialization strategy will consider several factors including regulatory requirements, reimbursement coverage for our products, and key opinion leader support. Our initial focus is on Germany and the United Kingdom, where we are working to build our capabilities and develop the market. Going forward, we will continue to assess our capability to penetrate additional markets in Europe, the Asia Pacific and Japan.

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 1a 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. Approximately 350,000 patients have been treated with PROPEL products to-date.

- 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 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 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 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 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 as well as a 63% reduction in occlusion and 73% reduction in surgical interventions.

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 approximately 90 days. We have studied SINUVA in five 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 a 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 a repeat placement during the interval studied.

Our PROPEL family of products are used almost exclusively in the operating room of a hospital or ASC. 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. SINUVA is a physician administered drug, used almost exclusively in the office setting. We applied to the Centers for Medicare & Medicaid Services, or CMS, for a product-specific J code for SINUVA, and in July 2019, CMS announced their final decision to establish a new J code described as "J7401 Mometasone furoate sinus implant, 10 micrograms." This new J code became effective on October 1, 2019. CMS also made a final decision to eliminate the S1090 code, which was previously assigned to PROPEL, because they view it as duplicative to J7401. Prior to October 1, 2019, reimbursement submissions to cover the cost of SINUVA were reported to payors using the unassigned Healthcare Common Procedure Coding System, or HCPCS, code J3490.

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 was a prospective, randomized, blinded, multi-center trial of 70 patients that assessed the safety and efficacy of our ASCEND product. The ASCEND product was randomized against an uncoated balloon and, similar to clinical studies for our PROPEL family of products, the primary endpoint was evaluated at 30 days. This study assessed the ASCEND product's ability to improve patency rates, as well as a number of other endoscopic parameters. As the first trial of its kind for this product platform, we recognized that the outcomes of the ASCEND trial could require further clinical study to support a PMA approval with the FDA. The trial did not meet its primary endpoint of statistically significant improvement in the frontal sinus patency grade at day 30, as judged by an independent reviewer. The ASCEND study was designed to analyze the secondary endpoints if the primary endpoint passed, to help with the interpretation of the data and for use designing the subsequent pivotal study. The secondary endpoints were analyzed. The ASCEND product showed significant differences in several important secondary endpoints favoring the treatment side including reduction in inflammation and polypoid edema at all timepoints through day 30, as assessed by both the clinical investigators and the independent reviewer. There was also a notable reduction in the need for oral steroid interventions at day 30, as determined by the independent reviewer. There were no adverse events related to the drug component of the ASCEND balloon, and no device-related serious adverse events observed in the study. This study gives us valuable insight into the performance of our novel drug-coated balloon, enabling us to refine our clinical and regulatory pathway. We will continue to analyze the ASCEND study findings to inform our clinical and regulatory strategy.

Impact of the COVID-19 Pandemic

Prior to the COVID-19 pandemic, our efforts to enhance commercial execution and improve market access infrastructure were beginning to yield benefits as sales until the end of February 2020 were consistent with our expectations. However, sales declined throughout March as the various COVID-19 restrictions were implemented. Our business has and will be impacted by hospitals suspending elective surgical procedures and reduced ENT office visits as well as by the shelter-in-place order issued by San Metro County and the State of California, where our manufacturing operations and corporate headquarters are located. Furthermore, the COVID-19 pandemic has led to severe disruption and volatility in global capital markets and increased economic uncertainty and instability. The impact of this on the global economy has been and may continue to be severe.

As a result of the COVID-19 pandemic and the impact of the various restrictions implemented, we have taken the following actions:

- **Protect Health and Safety:** Virtually all roles remain working from home, based on state and county guidelines, and non-essential business travel is limited.
- **Maintain Customer Focus:** All patient-support teams remain available to assist customers and patients, while strictly adhering to applicable restrictions, safety precautions and procedures.
- **Reduce Costs:** In response to the COVID-19 pandemic, we took pre-emptive actions to curtail spending as revenues are and will continue to be materially impacted. These cost reduction actions include a) reducing our workforce by approximately 25% and furloughing an additional 5% of our workforce, b) substantially reducing new hiring, c) suspending near-term production, d) reducing discretionary operating expenses and capital expenditures, and e) delaying clinical research projects. The anticipated cost savings from these actions are expected to be approximately $40.0 million for the remainder of the year and does not include significant non-cash items. The anticipated cost savings will impact all expense categories with a proportionally higher impact on manufacturing operations and research and development expenses, driven by the near-term suspension of production and the delay in clinical research projects. However, in absolute dollars, the largest cost savings will be realized in selling, general and administrative expenses.

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. While performance until the end of February 2020 was relatively consistent with our expectations, our revenue substantially declined throughout March as the various COVID-19 restrictions were implemented. Our business has and will be impacted by hospitals suspending elective surgical procedures and reduced ENT office visits. Under current conditions, we do not expect a meaningful amount of revenue in the second quarter of 2020. Once the disruption from the COVID-19 pandemic subsides, 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 the impact of the COVID-19 pandemic as well as 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. Revenue from SINUVA is recognized net of 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, 2020 and 2019.

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. Once the disruption from the COVID-19 pandemic subsides, we expect cost of sales to increase in absolute dollars again primarily as, and to the extent, our revenue grows, or we make additional investments in our manufacturing capabilities.

Our gross margin has been and will continue to be affected by a variety of factors, including manufacturing costs and average selling prices. In the near-term, manufacturing costs will also be negatively impacted by the mandatory shelter-in-place order in effect in Menlo Park, California, which prevents us from using our manufacturing facility. Idle facility expenses are not capitalized into inventory and are charged to cost of goods sold in the period incurred. Manufacturing cost will change as our production volume and product mix changes. The per unit allocation of our manufacturing overhead costs may increase and our gross margin may decline as, and to the extent, production volume decreases.

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 compliance expenses, insurance costs and general corporate expenses including allocated facilities and information technology expenses.

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.

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 critical accounting policies during the three months ended March 31, 2020, as compared to the critical accounting policies described in our Annual Report on Form 10-K for the year ended December 31, 2019, except as described below:

Inventories

Inventories are valued at the lower of cost, computed on a first-in, first-out basis, or net realizable value. The allocation of production overhead to inventory costs is based on normal production capacity. Abnormal amounts of idle facility expense, freight, handling costs, and consumption are expensed as incurred, and not included in overhead. During the three months ended March 31, 2020, as a result of a shut-down in production associated with the COVID-19 pandemic, we recorded $1.1 million for idle facility expense due to our inability to use our manufacturing facility for a part of the quarter due to the shelter-in-place orders. While the manufacturing remains shut-down, we will continue to incur idle facility charges in future periods. We maintain provisions for excess and obsolete inventory based on our estimates of forecasted demand and, where applicable, product expiration. Due to a decline in projected product sales, we also increased our reserve for excess and obsolete inventory by $0.8 million during the three months ended March 31, 2020. We will continue to monitor the effect of the COVID-19 pandemic on the business and will continue to reassess the need for inventory reserves in future periods.

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, 2020.

Results of Operations

	Three Months Ended March 31,	
(in thousands, except percentages)	**2020**	**2019**
Revenue	$ 19,826	$ 26,673
Cost of sales	6,410	4,645
Gross profit	13,416	22,028
Gross margin	*68%*	*83%*
Operating expenses:		
Selling, general and administrative	26,200	27,207
Research and development	5,146	6,266
Total operating expenses	31,346	33,473
Loss from operations	(17,930)	(11,445)
Interest income and other, net	397	640
Net loss	$ (17,533)	$ (10,805)

Comparison of the Three Months ended March 31, 2020 and 2019

Revenue

(in thousands, except percentages)	Three Months Ended March 31, 2020	2019	Change $ 2020 to 2019	Change % 2020 to 2019
PROPEL family of products	$19,090	$25,732	$ (6,642)	(26)%
SINUVA	736	941	(205)	(22)%
	$19,826	$26,673	$ (6,847)	(26)%

Revenue decreased by $6.8 million, or 26%, to $19.8 million during the three months ended March 31, 2020, compared to $26.7 million during the three months ended March 31, 2019. The decrease in revenue was primarily attributable to a 26% decline in PROPEL sales as well as a 22% decline in SINUVA sales, which represented approximately 4% of our revenue during both the three months ended March 31, 2020 and 2019, respectively. SINUVA unit sales decreased by 20% in the three months ended March 31, 2020 along with a 2% decrease in net revenue per unit from three months ended March 31, 2019. Lower PROPEL revenue for the three months ended March 31, 2020 resulted from a 28% decrease in unit sales, slightly offset by a 4% increase in average selling price. The decrease in unit sales for both PROPEL and SINUVA were driven by significant reduction in demand in the last month of the quarter due to the impact of the COVID-19 pandemic.

As the COVID-19 pandemic is expected to continue and cause strain on hospital resources, coupled with recommended deferrals of elective procedures, we do not expect a meaningful amount of revenue in the second quarter of 2020. While we cannot predict the extent or duration of the impact of the COVID-19 pandemic on our financial and operating results, we believe current government policies, including the suspension of elective procedures worldwide, will substantially impact our revenues in the second quarter of 2020 and potentially longer. However, we also believe, based on survey data with physicians, a recovery in procedures will begin in the second half of 2020, and that most patients will return for treatment.

Cost of Sales and Gross Margin

Cost of sales increased by $1.8 million, or 38%, to $6.4 million during the three months ended March 31, 2020, compared to $4.6 million during the three months ended March 31, 2019. The increased cost of sales was primarily attributable to charges related to our inability to use our manufacturing facility due to the shelter-in-place order and additional charges related to excess and obsolete inventory in response to the estimated impacts of the COVID-19 pandemic, partially offset by lower unit sales.

Gross margin for the three months ended March 31, 2020, decreased to 68%, compared to 83% for the three months ended March 31, 2019. While the gross margin for our products until the end of February 2020 was relatively consistent with our expectations, the decrease in gross margin was primarily attributable to charges related to the impacts of COVID-19. These charges included idle facility expense resulting from our inability to use our manufacturing facility due to the shelter-in-place order as well as additional charges for excess and obsolete inventory as a result of the disruption to our business. The amount of these charges was approximately $1.9 million, representing an effect on our gross margin of approximately 9.6% for the three months ended March 31, 2020.

As a result of the COVID-19 restrictions impacting our operations, including the impact and length of the shelter-in-place order in effect impacting our manufacturing facility, we expect a significant decrease in overall demand in the second quarter of 2020. Considering that the shelter-in-place order is now extended until May 31, 2020, we expect to incur significant idle facility expense in the second quarter 2020. We cannot reliably estimate the extent to which the COVID-19 pandemic will impact the gross margin for our products in the third quarter and beyond.

Selling, General and Administrative Expenses

SG&A expenses decreased by $1.0 million, or 4%, to $26.2 million during the three months ended March 31, 2020, compared to $27.2 million during the three months ended March 31, 2019. The decrease in SG&A expenses was primarily due to a decrease in sales commissions, offset by increases in professional fees, stock-based compensation, and the ongoing commercialization of our PROPEL family of products and SINUVA.

Our spending in the first quarter of 2020 reflected normal business activities. Certain spending will decrease in the second quarter of 2020 as a result of a reduction in demand and the impact of the cost reduction measures put in place in the current quarter. However, we will still continue to support our customers, physicians and patients.

Research and Development Expenses

R&D expenses decreased by $1.1 million, or 18%, to $5.1 million during the three months ended March 31, 2020, compared to $6.3 million during the three months ended March 31, 2019. The decrease in R&D expenses was primarily due to a decrease in headcount and related expenses, as well as costs incurred during the three months ended March 31, 2019 pertaining to the ASCEND drug-coated balloon clinical trial.

Our spending in the first quarter of 2020 reflected normal business activities. Certain spending will decrease in the second quarter of 2020 as a result of the cost reduction measures put in place in the current quarter.

Interest Income and Other, Net

Interest income and other, net, decreased by $0.2 million to $0.4 million during the three months ended March 31, 2020, compared to $0.6 million during the three months ended March 31, 2019. The decrease in interest income and other, net, during the three months ended March 31, 2020 was primarily attributable to lower interest rates earned on our investments.

Liquidity and Capital Resources

Overview

As of March 31, 2020, we had cash, cash equivalents and short-term investments of $87.7 million, compared to cash, cash equivalents and short-term investments of $90.6 million as of December 31, 2019.

Cash Flows

	Three Months Ended March 31,	
(in thousands)	**2020**	**2019**
Net cash (used in) provided by:		
Operating activities	$ (5,956)	$ (6,892)
Investing activities	16,396	1,554
Financing activities	3,101	4,467
Net increase (decrease) in cash and cash equivalents	$ 13,541	$ (871)

Net Cash Used in Operating Activities

During the three months ended March 31, 2020, net cash used in operating activities was $6.0 million, consisting primarily of a net loss of $17.5 million, offset by a decrease in net operating assets of $6.3 million and non-cash charges of $5.3 million. The non-cash charges primarily consisted of stock-based compensation expense. The decrease in net operating assets is primarily due to a decrease in accounts receivable due to collections and an increase in accounts payable, partially offset by a decrease in accrued compensation due to the payout of annual corporate bonuses.

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.

Net Cash Provided by Investing Activities

During the three months ended March 31, 2020, net cash provided by investing activities was $16.4 million, consisting of net maturities of short-term investments of $16.5 million and purchases of property and equipment of $0.1 million.

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 of $2.8 million and purchases of property and equipment of $1.2 million.

Net Cash Provided by Financing Activities

During the three months ended March 31, 2020, net cash provided by financing activities was $3.1 million, consisting of net proceeds from the issuance of common stock upon exercises of employee stock options.

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.

Liquidity

We currently believe that our existing cash, cash equivalents and short-term investments as of March 31, 2020, 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. However, as a result of the COVID-19 pandemic, we expect to increase our rate of cash consumption as a result of decreased revenues. Also, in response to the COVID-19 pandemic, we took pre-emptive actions to curtail spending as revenues are and will continue to be materially impacted. These cost reduction actions include a) furloughing and reducing our workforce by approximately 25%, b) substantially reducing new hiring, c) suspending near-term production, d) reducing discretionary operating expenses and capital expenditures, and e) delaying clinical research projects. We expect that these actions will result in cost savings of approximately $40.0 million for the remainder of the year. In addition, subsequent to March 31, 2020, we entered into a Facility Agreement, providing for the issuance and sale of a $65.0 million principal amount of 4% Convertible Unsecured Senior Notes due 2025. We estimate that the net proceeds from the offering were approximately $62.5 million after deducting the estimated offering expenses payable by us.

If our current sources of liquidity are insufficient, 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. Additional debt financing, if available, may involve covenants restricting our operations or our ability to incur additional debt. Any additional debt or equity financing 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, 2020 and December 31, 2019, 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, 2020, have not materially changed from December 31, 2019.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our exposure to market risk as of March 31, 2020, has not materially changed from the disclosures included in our Annual Report on Form 10-K for the year ended December 31, 2019.

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, 2020. 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, 2020, 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, 2020, 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

In May 2019, a purported stockholder of our company, Avi Yaron, filed a putative class action complaint in the United States District Court for the Northern District of California, entitled *Yaron v. Intersect ENT, Inc., et al.*, Case No. 4:19-cv-02647, against our company and certain individual officers and directors alleging violations of the Securities Exchange Act of 1934. The complaint alleges that we and the individual officers made false and/or misleading statements about our business and seeks unspecified damages and attorney's fees. The Court has appointed the lead plaintiff and has set a schedule for initial motions and pleadings. We believe this lawsuit is without merit and intend to vigorously defend against it.

ITEM 1A. RISK FACTORS

Before deciding to invest in us or to maintain or increase your investment, you should carefully consider the risks described below, in addition to the other information contained in this Quarterly Report on Form 10-Q and in our other filings with the SEC. 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

The impact of COVID-19, and the various medical, social and economic measures being implemented to combat its proliferation, has had and will continue to have a material adverse effect on our business, financial condition, results of operations, and liquidity.

Our business has been materially and adversely impacted by the Novel Coronavirus Disease 2019 (COVID-19) and we are subject to continuing risks related to the COVID-19 pandemic. COVID-19 continues to spread worldwide and has been declared a pandemic by the World Health Organization. The devastating health impacts of COVID-19 are proliferating at an unprecedented rate and the extent and duration of the pandemic is currently unknown. As a result of the COVID-19 pandemic and the associated medical, social and economic restrictions that have been put in place, our customers have suspended performing elective procedures, which is where our products are utilized. As a result, our sales have been materially and adversely affected. Further, our business has and will be impacted by hospitals continuing to suspend elective surgical procedures and reduced ear, nose and throat ("ENT") Ambulatory Surgery Centers ("ASC") and office procedures. While we have taken several measures in response to COVID-19 and its effects on our employees, customers, their patients and our business, a prolonged duration and the ultimate impact of COVID-19, as well as many of the measures implemented to address the threat posed by COVID-19, has and will continue to materially affect our business.

Our sales are being, and we expect will continue to be, materially adversely impacted by COVID-19.

We are a medical technology company that provides products used primarily for ENT elective procedures. As a result of COVID-19, numerous state and local jurisdictions have imposed shelter-in-place orders, and federal medical, health and safety governmental organizations, like the Centers for Disease Control and the Centers (CDC) for Medicare and Medicaid Services (CMS) have issued guidelines which have led to, among other measures, the severe limitation or curtailment of elective procedures. We cannot predict when federal, state and local governments will lift these restrictions, nor when the

CDC and other federal medical agencies will lift restrictions on elective procedures. These restrictions have caused, and we expect will continue to cause, severe reductions in demand for our products and corresponding sales revenue until the pandemic abates and the shelter-in-place orders are lifted, and perhaps afterwards as people take time to resume normal activities.

A prolonged curtailment of operations related to COVID-19 may materially adversely impact our liquidity.

We have implemented numerous capital preservation initiatives in response to COVID-19, including a reduction in force and the furloughing of other employees throughout our organization. Although we believe that our existing cash, cash equivalents and short-term investments will be sufficient to meet our current capital needs for the foreseeable future, a prolonged duration and resulting impact of COVID-19 could materially adversely alter our current cash position and affect our liquidity.

Our business may continue to be materially adversely impacted after COVID-19 medical, social and economic restrictions are lifted.

Even as shelter-in-place orders and other restrictions are lifted, it is uncertain as to when elective procedures will return to their original levels or if they will return to their original levels at all. Further, some physicians may not feel comfortable performing, and some patients may not feel comfortable undergoing, such procedures. Alternatively, at the point that restrictions are lifted, in whole or in part, there may be an increased demand for our products as delayed procedures are scheduled and performed. As and when we recommence operations and sales functions, we may not be able to restart all such functions in a timely, efficient, or compliant fashion, or have sufficient resources to perform manufacturing and regulatory operations sufficient to meet such demand. As a result of the reduction in force and furloughing of some of our employees, we may face challenges as we restart our manufacturing and distribution operations. We may also experience production challenges as we restart our manufacturing lines, including supply chain issues, due to vendors' potential inabilities to fulfill our orders, which may prevent us from having sufficient product in a timely manner to meet demand.

Our ability to raise capital may be materially adversely impacted by COVID-19.

The COVID-19 pandemic has led to severe disruption and volatility in global capital markets and increased economic uncertainty and instability. The macro economic impact on the global economy has been and may continue to be severe. Any sustained disruption may increase our cost of capital and adversely affect our ability to access the capital markets in the future.

The enrollment of our clinical studies has been and may continue to be materially adversely impacted by COVID-19.

Our future business prospects are highly dependent on generating, collecting and disseminating data pursuant to clinical trials. As a result of the cessation of elective procedures, we have been required to delay the initiation of clinical trials on a global basis. These and other clinical trials may continue to be materially impacted by COVID-19 as hospitals and physicians prioritize treating existing patients and creating capacity. Additionally, patients may be less willing to participate in clinical trials as a result of the COVID-19 pandemic. Delays in the initiation of sites or enrollment of patients in these and other clinical studies, may have a material adverse effect on our results of operations and the timing of the development and commercialization of future products.

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 net losses of $17.5 million for the three months ended March 31, 2020, and $43.0 million and $22.9 million for the years ended December 31, 2019 and 2018, respectively. As of March 31, 2020, we had an accumulated deficit of $248.3 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 costs associated with our growth. 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. In July 2019, we received FDA approval to market our new PROPEL Mini Straight Delivery System, designed to facilitate implant placement in the ethmoid sinus. 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 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;
- new technologies that may be competitive to our products; 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 ASC 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 ASC 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 have been seeking reimbursement for the product using an unassigned J Code. We applied for a product-specific J code in the 2018 process, but it was not granted, and we reapplied in the 2019 process. In July 2019, CMS announced their final decision to establish a new J code described as "J7401 Mometasone furoate, sinus implant, 10 micrograms." This new J code became effective on October 1, 2019. CMS also made a final decision to eliminate the S1090 code, which was previously assigned to PROPEL, because they view it as duplicative to J7401. 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 ASC 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 twelve 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, or design 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;
- unexpected credit losses;
- 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 and the new European Medical Device Regulation (MDR);
- 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 ASC. 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, Lyra Therapeutics 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 such as Regeneron Pharmaceuticals, Inc., who recently received FDA approval to market Dupixent for chronic rhinosinusitis with nasal polyposis.

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 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 leadership transition may not go smoothly and could adversely impact our future operations.

In June 2019, we announced Mr. Thomas A. West had been appointed as our new President and Chief Executive Officer effective July 22, 2019, replacing Ms. Lisa D. Earnhardt, who notified us in May 2019 of her resignation as our President and Chief Executive Officer effective June 5, 2019. In addition, we also announced in November 2019 that Mr. Richard A. Meier has been appointed as our new Executive Vice President and Chief Financial Officer, effective November 26, 2019, replacing Ms. Jeryl L. Hilleman, who notified us in June 2019 of her intended resignation as our Chief Financial Officer. A significant leadership change is inherently risky, may cause disruption to our business, may cause concerns from third parties with whom we do business and may increase the likelihood of turnover of other key officers and employees. The loss of services of one or more other members of senior management or the inability to attract qualified permanent replacements could have a material adverse effect on our business. We may be unable to manage these transitions smoothly which could adversely impact our future strategy and ability to function or execute and could materially and adversely affect our business, financial condition and results of operations.

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 executive officers and 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. In October 2019, we announced our ASCEND trial did not meet its primary endpoint of statistically significant improvement in the frontal sinus patency grade at day 30, as judged by an independent reviewer. The ASCEND study was designed to analyze the secondary endpoints if the primary endpoint passed, to help with the interpretation of the data and for use designing the subsequent pivotal study. The secondary endpoints were analyzed. The ASCEND product showed significant differences in several important secondary endpoints favoring the treatment side including reduction in inflammation and polypoid edema at all timepoints through day 30, as assessed by both the clinical investigators and the independent reviewer. There was also a notable reduction in the need for oral steroid interventions at day 30, as determined by the independent reviewer. This study gives us valuable insight into the performance of our novel drug-coated balloon, enabling us to refine our clinical and regulatory pathway. The ASCEND study evaluated a clinical version of our drug-coated balloon and we are making enhancements to the product to support the ultimate commercial design. We anticipate needing to conduct clinical studies utilizing the version of the product we intend on commercializing.

Our failure to adequately demonstrate the safety and efficacy of any of our products would prevent receipt of regulatory clearance or approval and, ultimately, the commercialization of that product 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.

Recently, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products. Many companies in our industry have received a governmental request for documents and information relating to product 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, among other things, 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 coverage or reimbursement of approved products, including by federal health care programs such as Medicare and Medicaid and state health care programs.

In addition, Congress and the current administration each 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 payors. Additionally, individual states in the United States and local governments have also increasingly passed legislation and implemented regulations designed to control product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures. Moreover, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine which products to purchase and which suppliers to include in their programs. 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. However, adoption of price controls and other cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures may prevent or limit our ability to generate revenue and attain profitability.

The UK's withdrawal from the EU, commonly referred to as Brexit, could increase our cost of doing business, reduce our gross margins or otherwise negatively impact our business and our financial results.

On January 31, 2020, the UK withdrew from the EU. The UK's withdrawal from the EU is commonly referred to as Brexit. Under the withdrawal agreement between the UK and the EU, the UK will be subject to a transition period until December 31, 2020 (the "Transition Period") during which EU rules will continue to apply. During the Transition Period, negotiations between the UK and the EU are expected to continue in relation to the future customs and trading relationship between the UK and the EU following the expiration of the Transition Period.

Brexit has created significant uncertainty concerning the future relationship between the UK and the EU. Since a significant portion of the regulatory framework in the UK is derived from EU laws, Brexit could materially impact the regulatory regime with respect to the development, manufacture, importation, approval and commercialization of our products and product candidates in the UK or the EU. Although the UK is currently a very small portion of our business, these regulatory changes, if they occur, could increase our costs and otherwise adversely affect our business. In addition, currency exchange rates for the British Pound and the euro with respect to each other and to the U.S. dollar have already been, and may continue to be, negatively affected by Brexit, which could cause volatility in our quarterly financial results.

In any event, we do not know to what extent, or when, the UK's withdrawal from the EU or any other future changes to its membership in the EU will impact our business, particularly our ability to conduct international business. The UK could lose the benefits of global trade agreements negotiated by the EU on behalf of its members, possibly resulting in increased trade barriers, which could make doing business in the UK and Europe more difficult and/or costly. Moreover, in the U.S., tariffs on certain U.S. imports have recently been imposed, and the EU and other countries have responded with retaliatory tariffs on certain U.S. exports. We cannot predict what effects these and potential additional tariffs will have on our business, including in the context of escalating global trade and political tensions. However, these tariffs and other trade restrictions, whether resulting from the UK's withdrawal from the EU or otherwise, could increase our cost of doing business, reduce our gross margins or otherwise negatively impact our business and our financial results.

If we fail to successfully acquire or integrate new business, products, and technology, we may not realize expected benefits, or our business may be harmed.

We need to grow our businesses in response to changing technologies, customer demands, and competitive pressures. In some circumstances, we may decide to grow our business through the acquisition of complementary businesses, products, or technologies rather than through internal development.

Identifying suitable acquisition candidates can be difficult, time-consuming, and costly, and we may not be able to identify suitable candidates or successfully complete identified acquisitions. In addition, completing an acquisition can divert our management and key personnel from our business operations, which could harm our business and affect our financial results. Even if we complete an acquisition, we may not be able to successfully integrate newly acquired organizations, products, technologies, or employees into our operations or may not fully realize some of the expected synergies. An acquired company may have deficiencies in product quality, regulatory marketing authorizations, or intellectual property protections, which are not detected during due diligence activities or which are unasserted at the time of acquisition. It may be difficult, expensive, and time-consuming for us to re-establish market access, regulatory compliance, or cure such deficiencies in product quality or intellectual property protection in such cases, which may have a material adverse impact on our financial conditions, results of operations, or cash flows.

We expect gross profit margins to vary over time, and changes in our gross profit margins could adversely affect our financial condition or results of operations.

Our gross profit margins have fluctuated from period to period. Our gross profit margins may be adversely affected by numerous factors, including:

- changes in customer, geographic, or product mix;
- introduction of new products, which may have lower margins than our existing products;
- our ability to maintain or reduce production costs;
- changes to our pricing strategy;
- changes in competition;
- changes in production volume driven by demand for our products;
- changes in material, labor, or other manufacturing-related costs;
- changes to U.S. and foreign trade policies, such as the enactment of tariffs on goods imported into the United States;
- manufacturing issues, lot failures, inventory obsolescence and product recall charges; and
- market conditions.

If we are unable to offset the unfavorable impact of the factors noted above by increasing the volume of products shipped, reducing product manufacturing costs, or otherwise, our business, financial condition, results of operations, or cash flows may be materially adversely affected.

Risks Relating to Regulatory Matters

Our products are subject to extensive regulation by the FDA, and other agencies, including the requirement to obtain approval prior to commercializing our products and the requirement to report adverse events and other ongoing reporting requirements. If we fail to obtain necessary FDA or other agency 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 or other agencies 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 and drug products can be marketed only for the indications for which they are approved. We have received a number of PMA and NDA supplement approvals since the original approval of PROPEL and SINUVA, as well as substantial change approvals in the EU. 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 distributor 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, ASC, 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), or localized privacy laws (e.g. the California Consumer Privacy Act of 2018, effective beginning January 2020, mirroring a number of the key provisions in the 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, ASC, 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; and

- 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.

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 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.

In addition, recently, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several U.S. Congressional inquiries, and proposed and enacted federal legislation designed to bring transparency to product pricing and reduce the cost of products and services reimbursed under governmental healthcare programs. Congress and the current administration have each indicated that it will continue to seek new legislative and/or administrative measures to control product costs. Additionally, individual states in the United States have also increasingly passed legislation and implemented regulations designed to control product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures. Adoption of price controls and other cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures may prevent or limit our ability to generate revenue and attain profitability.

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 of this Quarterly Report on Form 10-Q. 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.

Our debt obligations under our facility agreement with Deerfield could impair our financial condition and limit our operating flexibility.

Our indebtedness under our facility agreement with Deerfield could:

- impair our ability to obtain financing or additional debt in the future for working capital, capital expenditures, acquisitions or general corporate purposes;
- impair our ability to access capital and credit markets on terms that are favorable to us;
- have a material adverse effect on us if we fail to comply with financial and affirmative and restrictive covenants and an event of default occurs as a result of a failure that is not cured or waived;
- require us to dedicate a portion of our cash flow for interest payments, thereby reducing the availability of our cash flow to fund working capital and capital expenditures; and
- limit our flexibility in planning for, or reacting to, changes in our business and the industry in which we operate.

There is no guarantee that we will be able to pay the principal and interest under the facility agreement with Deerfield or that future working capital, borrowings or equity financing will be available to repay or refinance any amounts outstanding under the facility agreement with Deerfield. In addition, we may enter into debt agreements in the future that may contain similar or more burdensome terms and covenants, including financial covenants.

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, such as the class action filed against us in May 2019, 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				
10.1†	Supply Agreement between the registrant and Hovione Inter AG., dated as of January 20, 2020.				
10.2	Amended Non-Employee Director Compensation Policy				
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	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data file because its XBRL tags are embedded within the Inline XBRL document.				
101.SCH	Inline XBRL Taxonomy Extension Schema Document.				
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.				
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.				
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.				
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.				
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).				

† 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 11, 2020

Intersect ENT, Inc.
(Registrant)

/s/ Thomas A. West

Thomas A. West
President and Chief Executive Officer
(Duly Authorized Officer)

/s/ Richard A. Meier

Richard A. Meier
Executive Vice President and 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.

SUPPLY AGREEMENT

THIS SUPPLY AGREEMENT (this "Agreement") is made this, 20th day of January, 2020 (the "Effective Date"), by and between **HOVIONE INTER AG,** together with its subsidiaries and affiliates, and organized and existing under the laws of Switzerland and having its registered office at Pilatusstrasse 23, CH-6003, Luzern, Switzerland (hereafter referred to as "HOVIONE"), and **INTERSECT ENT, Inc.** together with its subsidiaries and affiliates, and organized and existing under the laws of Delaware and having its registered office at 1555 Adams Drive, Menlo Park, CA 94025 (hereafter referred to as "INTERSECT"). HOVIONE and INTERSECT are each sometimes referred to herein as a "Party" and together as the "Parties."

WHEREAS, HOVIONE has developed and manufacturers the active pharmaceutical ingredient(s) identified in Exhibit A hereto (the "API"); and

WHEREAS, INTERSECT develops and markets Finished Product based on the API, as defined herein; and

WHEREAS, INTERSECT desires to acquire API from HOVIONE to incorporate into the Finished Product; and

WHEREAS, HOVIONE is willing to supply such API for INTERSECT's use, on the terms and conditions set forth in this Agreement.

NOW THEREFORE, in consideration of the promises and the mutual covenants set forth herein and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereby agree and covenant as follows:

1. Definitions

1.1. ***"Active Pharmaceutical Ingredient" or "API" shall have the meaning given such term in the preamble hereof.***

1.2. ***"Affiliate" means any entity controlling, controlled by or under common control with either Party hereto. For purpose of this definition, "control" shall mean ownership of over fifty percent (50%) of the equity capital, the outstanding voting securities or other ownership interest of an entity, or the right to receive over fifty percent (50%) of the profits or earnings of an entity. In the case of non-stock organizations, the term "control" shall mean the power to control the distribution of profits.***

1.3. ***"Applicable Law" shall mean the laws, regulations, rules and guidelines pertaining to the development, manufacture, packaging, labeling, storage, import, export, distribution, marketing, sale and/or intended use of the API or the Finished Product.***

1.4. ***"Batch Record" shall mean a batch manufacturing record, prepared according to applicable cGMP guidelines, for every production batch of API.***

1.5. ***"Confidential Information" shall mean all the technical information, whether tangible or intangible, including (without limitation) any and all data, techniques, discoveries, inventions, processes, know-how, patent applications, inventor certificates, trade secrets, methods of production and other proprietary information, that either Party or its Affiliates have ownership rights to (as either owner, licensee or sub-licensee), or may hereafter obtain rights.***

1.6. ***"Current Good Manufacturing Practices" or "cGMP" shall mean current Good Manufacturing Practice as set forth by the US FDA as well as current good manufacturing practices applicable to the API, or the making thereof at HOVIONE's manufacturing facility, set forth by the relevant Regulatory Agency.***

1.7. ***"Defect" with respect to the API shall mean failure of the API to comply with the Product Specifications.***

1.8. ***"FDA shall mean the US Food and Drug Administration, and any successor thereto.***

1.9. ***"Finished Product" shall mean the finished dosage form combination drug and device product that contains the API ready for clinical use or commercial sale.***

1.10. ***"Firm Forecast" shall have the meaning given to such term in Section 3.2 hereof.***

1.11. "Product Specifications" shall have the meaning given to such term in Section 2.2 hereof.

1.12. ***"Quality Agreement" shall mean that certain Quality Assurance Agreement, dated of even date herewith, by and between INTERSECT and HOVIONE, which sets forth (a) the roles and responsibilities of the Parties with respect to the quality assurance for the API and (b) how the Parties' quality operations shall interact with each other in connection with the same.***

1.13. ***"Regulatory Agency" shall mean national, or other government entities regulating or otherwise exercising authority with respect to the API or the Finished Product in the United States including, without limitation, the US FDA***

1.14. ***"Term" shall have the meaning assigned to such term in Section 10.***

2. Manufacture and Sale

2.1. Supply. During the term of this Agreement and subject to the terms and conditions set forth herein, INTERSECT shall purchase [*] of its annual API requirement, from HOVIONE and HOVIONE shall manufacture and supply API to INTERSECT (or a third party designated by INTERSECT) in such quantities as from time to time may be ordered by INTERSECT.

2.2. Product Specifications. The specifications of the API as set out in in Exhibit B to this Agreement (the "Product Specifications"); as such Exhibit may be amended according to the terms of the quality agreement between the parties.

3. Costs. HOVIONE shall be responsible for all costs and expenses related to the maintenance of a US DMF or European CEP for the API. Any additional submissions, technical work, documents, data or materials requested by INTERSECT may be chargeable by HOVIONE.

4. Price, Orders and Terms of Payment

4.1. Pricing. The price for the API shall be as set forth on Exhibit C hereto. All sums shall be expressed in and payable in US Dollars.

4.2. Forecasting. For each calendar year during the term of this Agreement, INTERSECT shall submit a twelve (12) month rolling forecast updated on a quarterly basis, broken down on a quarterly basis covering INTERSECT's anticipated requirements of API, each such forecast to be provided to HOVIONE at least ninety (90) days prior to the start of the relevant twelve (12) month period. The rolling forecast shall be for information purposes only and non- binding so long as the INTERSECT provides a blanket purchase order covering their demand for the next six (6) months. In the case that INTERSECT does not provide a blanket purchase order, the forecast will be considered binding. INTERSECT shall place all purchase orders with HOVIONE at least ninety (90) days in advance of required delivery to INTERSECT. Within five (5) days of receipt of a purchase order, HOVIONE shall notify INTERSECT in writing of its acceptance of the purchase order and confirm the delivery date. If the purchase order exceeds the Firm Forecasted amount, HOVIONE shall use commercially reasonable efforts to fill such order but shall not be in breach of this Agreement if HOVIONE does not supply the excess.

4.3. Delivery Terms. Each purchase order shall specify: (i) an identification of the API ordered; (ii) quantity requested; (iii) the requested delivery date; and (iv) shipping instructions and address. HOVIONE agrees to deliver the API DDP Menlo Park, CA USA (Incoterms 2010).

4.4. Payment Terms. HOVIONE shall invoice INTERSECT upon dispatch of the API. INTERSECT shall pay the price to HOVIONE for API within thirty (30) calendar days of the date of invoice of such API. Payments shall be made to HOVIONE by wire transfer.

4.5. Scope of Agreement. In no event shall any terms or conditions included on any purchase order, invoice or acknowledgement thereof or any other document, whether paper, electronic or otherwise, relating thereto, apply to the relationship between the Parties under this Agreement, unless such terms are expressly agreed to by the Parties in writing. If there is a conflict between the terms of any purchase order or other document and this Agreement, the terms of this agreement shall apply. The Parties further agree that no course of dealing between the Parties shall in any way modify, change or supersede the terms and conditions of this Agreement.

5. Manufacture and Delivery of API.

5.1. Manufacture. The API shall be manufactured by HOVIONE at its facilities in accordance with all relevant current Good Manufacturing Practices ("cGMPs"), the Specifications, and Applicable Laws, and pursuant to HOVIONE's Drug Master File ("DMF"), prepared by HOVIONE and filed with the US FDA. HOVIONE shall advise INTERSECT in writing in advance of making any changes to the Product Specifications or any material changes in the methods, processes or procedures in manufacturing the API that could affect the quality, purity and/or physical properties of the API, any changes will be made according to the terms of the quality agreement between the parties. HOVIONE shall provide sufficient notice of any such change to INTERSECT to allow INTERSECT to make any required notices to and obtain any required approvals from any Regulatory Agency with respect to such change.

5.2. Right of Audit. See Quality Agreement.

5.3. Certificate of Analysis; Product Release. The quality control(s) and the release(s) of API (including documentation) shall be done by HOVIONE in accordance with the Quality Agreement. HOVIONE shall provide certificates of analysis to INTERSECT for each batch of API delivered under this Agreement. API shall have at least [*] remaining on the date of delivery.

5.4. Cooperation. During the term of this Agreement, HOVIONE shall assist and cooperate in a timely manner INTERSECT in its preparation of any documents or other materials which may be required by the US FDA to validate sell and/or distribute the API to be supplied by HOVIONE under this Agreement or the Finished Product. HOVIONE shall file with the US FDA and shall maintain at all times as current, a DMF for the API. HOVIONE shall also provide INTERSECT with a referral letter permitting INTERSECT to use HOVIONE's DMF.

5.5. Required Changes. INTERSECT shall deliver to HOVIONE written notice of any required changes to the Product Specifications requested by the Regulatory Authorities, and HOVIONE shall use its commercially reasonable efforts to make such changes to the Product Specifications. If any change to Product Specifications requested by INTERSECT materially affects HOVIONE's costs of producing the API, then HOVIONE shall promptly so inform INTERSECT in writing and the Parties shall negotiate, in good faith, an adjustment to the pricing paid by INTERSECT for API under this Agreement. If the Parties cannot mutually agree, following good faith negotiations, on an equitable adjustment to pricing, then either HOVIONE or INTERSECT may terminate this Agreement for business reasons on not less than ninety (90) days prior written notice, without any further obligation to the other party; provided, however, that INTERSECT shall remain liable for all sums owed to HOVIONE for orders of API that were placed prior to the date of termination.

5.6. Inspection of API. Within thirty (30) calendar days of the arrival of each lot of API at the manufacturing facility designated by INTERSECT, INTERSECT shall inspect and test each lot of API at its own cost and expense. If, upon inspecting and testing the API, INTERSECT determines that a lot of API does not conform to the Product Specifications, then INTERSECT shall, within such thirty (30) day period, give HOVIONE written notice of such non-conformity (setting forth the details of such non-conformity):Unless HOVIONE objects, within 20 working days from the notice by INTERSECT, to the non-conformity INTERSECT will return the non-conforming API to HOVIONE. Any API rejected by INTERSECT may not be reshipped to INTERSECT except if the API is reprocessed according to the DMF. HOVIONE sole responsibility shall be to replace any non-conforming API within thirty (30) days of receiving the notice of non-conformity. Disputes between the Parties as to whether all or any part of a shipment rejected by INTERSECT materially conforms to the Product Specifications shall be resolved by a mutually acceptable third-party testing laboratory located in a neutral country. HOVIONE shall pay all the fees of the third-party laboratory, unless the third-party testing laboratory determines that the delivered API materially conforms to the Product Specifications, in which case INTERSECT shall pay all the fees of such third-party laboratory and also any additional costs that HOVIONE incurred in providing replacement material.

5.7. Regulatory Communications. During the Term, HOVIONE shall notify INTERSECT after receipt of any communication from any Regulatory Agency in connection or that can affect INTERSECT Marketing Authorization.

5.8. Liability. It is understood that HOVIONE has no control over the ultimate use of the Finished Product once it leaves INTERSECT's manufacturing facility. HOVIONE shall have no liability arising out of or in connection with the sale or use of the API or any product or material made from or incorporating the API, except to the extent that the API was not manufactured in accordance with the Product Specifications, cGMPs or Applicable Law or the liability otherwise arises from a breach of this Agreement by HOVIONE.

5.9. Recall. INTERSECT shall be responsible for conducting any recall of Finished Product, and HOVIONE shall co-operate with and give all reasonable assistance to INTERSECT in conducting any such recall to the extent it relates to the API. HOVIONE shall bear the expense of any recall resulting from a material breach of its obligations hereunder and/or of the Quality Agreement and/or from its gross negligence or willful misconduct subject to the limits set out in 8.4. Otherwise, INTERSECT shall bear such expenses. In the event of such recall or similar action, each Party shall use commercially reasonable efforts to mitigate the costs associated therewith. In the case of a disagreement as to the existence or level of nonconforming API, then the matter shall be referred to an independent third-party laboratory. The decision of the laboratory shall be final and binding on the Parties.

5.10. Retention of Documentation. All documentation related to the manufacturing of the API shall be archived with HOVIONE after manufacturing in accordance with HOVIONE's document retention policies.

5.11. Safety of API. Each Party shall immediately notify the other Party of any unusual health or environmental occurrence relating to API. Each Party shall advise the other Party immediately of any safety or toxicity problems of which it becomes aware regarding API.

6. Warranties.

6.1. HOVIONE's Warranties. HOVIONE represents and warrants to INTERSECT that:

(a) It has full right and power to enter into this Agreement and perform its obligations hereunder in accordance with its terms;

(b) The API and all components and ingredients thereof shall be manufactured and delivered in strict compliance with: (i) the Product Specifications; (ii) the methods processes and procedures, including the site manufacture, set forth in the DMF, together with all applicable regulatory requirements relating to the manufacture of the API

(c) the plant(s) for manufacture of the API is and shall be in compliance with all applicable cGMPs and that such plant(s) is and shall continue to be available for inspection if and when the Regulatory Authorities so requests;

6.2. INTERSECT's Warranties. INTERSECT represents and warrants to HOVIONE that:

(a) It has the full right and power to enter into this Agreement and perform its obligations hereunder in accordance with its terms; and

(b) That it will purchase the API in strict compliance with the terms of this agreement. as set forth under Section 2.1 and 2.1.

6.3. DISCLAIMER. EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATION OR EXTENDS ANY WARRANTY OF ANY KIND, EITHER EXPRESS OR IMPLIED INCLUDING, BUT NOT LIMITED TO, WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR NON-INFRINGEMENT.

6.4. Mutual Warranties. Each party represents and warrants to the other party that it holds all necessary and required permits and authorizations, including, but not limited to, those required by the FDA, and shall undertake throughout the term of this Agreement to maintain the same in full force and effect. Each party further covenants that it shall use commercially reasonable efforts to obtain all such other permits and authorizations as may be reasonably required from time to time in either case to operate their respective facilities and/or businesses in order to manufacture, provide, distribute and/or sell API hereunder.

7. Confidentiality.

7.1. Confidentiality. Each party agrees to retain in confidence all Confidential Information disclosed to it pursuant to this Agreement, whether such disclosure occurred before or after the date hereof. Disclosed information shall not be deemed Confidential Information hereunder if: (a) it is now or later becomes publicly known, other than through the fault of the receiving party; (b) it is lawfully known without restriction to the receiving party at the time of disclosure as evidenced by written documentation; (c) it is rightfully obtained by the receiving party from a third party without restriction and without breach of this Agreement or any similar agreement; and/or (d) it is independently developed by the receiving party without access to the disclosing party's information, as evidenced by written documentation. If either Party is required under Applicable Law to disclose Confidential Information by any court or to any Regulatory Agency, the Party required disclosing the Confidential Information shall, prior to such disclosure, notifying the other Party of such requirement and all particulars related to such requirement. The notified Party shall have the right, at its expense, to object to such disclosure and to seek confidential treatment of any Confidential Information to be so disclosed on such terms as it shall determine, and the other Party shall fully cooperate with the notified Party in this regard. The confidentiality of disclosed Confidential Information and the obligation of confidentiality hereunder shall survive any expiration or termination of this Agreement for a period of ten years. The Parties specifically agree that all terms of this Agreement, all sales and API requirements and costs and all purchase orders shall be deemed to be confidential.

7.2. Separate Confidentiality Agreement. If the Parties entered into one or more separate confidentiality agreements or non-disclosure agreements (each, a "Confidentiality Agreement"), such Confidentiality Agreement(s) shall be and remain in full force and effect as provided therein. In the event of any conflict between the terms of this Agreement and the terms of any such Confidentiality Agreement, the terms of such Confidentiality Agreement shall control.

7.3. Public Announcements. During the term of this Agreement, no party hereto shall issue or release, directly or indirectly, any press release, marketing material or other communication to or for the media or the public that pertains to this Agreement, the API, the Finished Product or the transactions contemplated hereby (collectively, a "Press Release") unless the content of such Press Release has been approved by the other party hereto, such approval not to be unreasonably withheld or delayed; provided, however, that nothing contained in this Agreement shall prevent or preclude any party from making such disclosures as may be required by applicable law, including, but not limited to, any disclosures required applicable securities laws.

8. Indemnification.

8.1. INTERSECT shall indemnify, defend and hold HOVIONE and its officers, directors, affiliates, agents and employees harmless from and against any and all claims, demands, costs, expenses, losses, liabilities and/or damages (including, but not limited to, reasonable attorneys' fees) of every kind and nature caused by, arising out of or resulting from INTERSECT's negligence relating to, or breach of, this Agreement, and any claim for personal or bodily injury arising from the use of the Finished Product or any substance, dosage composition or compound manufactured therefrom; provided, however, that in no event shall this Section apply to any claim covered by Section 8.2 below.

8.2. HOVIONE shall indemnify, defend and hold INTERSECT and its officers, directors, affiliates, agents and employees harmless from and against any and all claims, demands, costs, expenses, losses, liabilities and/or damages (including, but not limited to, reasonable attorneys' fees and court costs) of every kind and nature caused by, arising out of or resulting from HOVIONE's negligence relating to, or breach of, this Agreement and any claim for personal or bodily injury arising from the manufacture and/or distribution of API by HOVIONE. This indemnification obligation does not apply to any claim for personal or bodily injury arising from the use or administration of the API except to the extent such injury is attributable to a Defect in the API arising out of HOVIONE's gross negligence, willful misconduct, or failure to manufacture and deliver the API in accordance with the Product Specifications and all Applicable Law.

8.3. Each party will promptly notify the other of any actual or threatened judicial or other proceedings which could involve either or both parties. Each party reserves the right to defend itself in any such proceedings; provided, however, that, if indemnity is sought, then the party from whom indemnity is sought shall have the right to control the defense of the claim, and the indemnified party may participate with counsel of its choice at its own expense. The Parties shall cooperate with each other to the extent reasonably necessary in the defense of all actual or potential liability claims and in any other litigation relating to the API supplied pursuant to this Agreement. Each party will supply information to the other relevant to any product liability claims and litigation affecting the API and/or the Finished Product, as the case may be.

8.4. NOTWITHSTANDING ANYTHING IN THIS AGREEMENT TO THE CONTRARY, IN NO EVENT WILL EITHER PARTY BE LIABLE FOR ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL OR INDIRECT DAMAGES ARISING OUT OF THIS AGREEMENT, HOWEVER CAUSED AND ON ANY THEORY OF LIABILITY. THIS LIMITATION WILL APPLY EVEN IF THE OTHER PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGE; PROVIDED, HOWEVER, THAT THIS LIMITATION WILL NOT APPLY TO DAMAGES RESULTING FROM BREACHES BY A PARTY OF ITS DUTY OF CONFIDENTIALITY AND NON-USE IMPOSED UNDER THIS AGREEMENT OR THE CONFIDENTIALITY AGREEMENT OR SUCH PARTY'S INDEMNIFICATION OBLIGATIONS STATED ABOVE. FURTHER AND NOTWITHSTANDING ANYTHING TO THE CONTRARY IN THIS AGREEMENT, THE TOTAL LIABILITY PER YEAR OF HOVIONE SHALL BE LIMITED TO THE VALUE OF THE REVENUES COLLECTED IN THE PREVIOUS CONTRACTUAL YEAR.

9. Insurance. Unless the Parties otherwise agree in writing, the following terms shall apply:

9.1. During the term of this Agreement and for a period [*] after any expiration or termination of this Agreement, each of INTERSECT and HOVIONE shall maintain in full force and effect a comprehensive general liability insurance policy, including Products Liability coverage, with minimum limits of [*] for bodily injury including death.

10. Term and Termination.

10.1. Term.

Unless terminated in accordance with the provisions of Section 10.2 below, the term of this Agreement shall commence on the Effective Date and shall continue in effect for a FIVE (5) year period.

10.2. Grounds for Termination.

(a) Either party shall have the right to terminate this Agreement upon the occurrence of any of the following events: (i) the failure of the other party to comply with any of the terms of this Agreement or otherwise discharge its duties hereunder in any material respect, or the breach by the other party of any of its representations or warranties herein in any material respect, if such failure or breach is not cured within ninety (90) days of such breaching party's receipt of written notice specifying the nature of such failure or breach with particularity; or (ii) the making by the other party of an assignment for the benefit of its creditors, or the filing by or against such other party of any petition under any federal, state or local bankruptcy, insolvency or similar laws, if such filing has not been stayed or dismissed within sixty (60) days after the date thereof.

10.3. INTERSECT shall also have the right to suspend further performance under this Agreement and/or terminate this agreement in its entirety, without liability except for unpaid previously delivered API that conforms with the terms hereof, if: (i) HOVIONE loses any approval(s) from the US FDA required to perform its obligations under this Agreement or if HOVIONE is involved in felonious or fraudulent activities.

10.4. HOVIONE shall also have the right to suspend further performance under this Agreement, terminate this Agreement and demand compensation if INTERSECT fails to comply with any of the terms and conditions of this Agreement; provided, however, that if any such failure is disputed by INTERSECT in good faith, HOVIONE shall not have the right to terminate this Agreement with respect to such dispute until such dispute is adjudicated in favor of HOVIONE in accordance with Section 14.6.

10.5. Obligations on Termination:

10.5.1. Of HOVIONE. Upon termination of this Agreement pursuant to this Section 10, HOVIONE will not perform any further work, except the following:

10.5.1.1. perform only those services and other activities mutually agreed upon by INTERSECT and HOVIONE as being necessary or advisable to comply with issued and paid for purchase orders;

10.5.1.2. promptly return all Confidential Information of INTERSECT that it has received pursuant to this Agreement.

10.5.2. Of INTERSECT. Upon termination of this Agreement pursuant to this Section 10, COMPANY will:

10.5.2.1. promptly pay HOVIONE any monies due and owing HOVIONE, up to the time of termination, for API actually manufactured, all authorized expenses actually incurred and any uncancellable commitments made by HOVIONE in connection with the scope of this Agreement; and

10.5.2.2. promptly return all Confidential Information of HOVIONE that it has received pursuant to this Agreement.

11. Continuing Obligations; Survival. In no event shall any termination or expiration of this Agreement excuse either party from any breach or violation of this Agreement and full legal and equitable remedies shall remain available therefore, nor shall it excuse either party from making any payment due under this Agreement with respect to any period prior to the date of expiration or termination.

12. Agreement to Consummate; Further Assurances. Subject to the terms and conditions of this Agreement, each of the Parties hereto agrees to use commercially reasonable efforts to do all things necessary, proper or advisable under this Agreement, applicable laws and regulations to consummate and make effective the transactions contemplated hereby. If, at any time after the date hereof, any further action is necessary, proper or advisable to carry out the purposes of this Agreement, then, as soon as is reasonably practicable, each party to this Agreement shall take, or cause its proper officers to take, such action.

13. Force Majeure. Any delay in the performance of any of the duties or obligations of either party hereto (except for the payment of money) caused by an event outside the affected party's reasonable control shall not be considered a breach of this Agreement and the time required for performance shall be extended for a period equal to the period of such delay. Such events shall include, but will not be limited to, acts of God, acts of a public enemy, acts of terrorism, insurrections, riots, injunctions, embargoes, fires, explosions, floods, or other unforeseeable causes beyond the reasonable control and without the fault or negligence of the Party so affected. The Party so affected shall give prompt written notice to the other party of such event. The suspension of performance shall be of no greater scope and no longer duration than is reasonably required and the nonperforming Party shall use its commercially reasonable efforts to remedy its inability to perform; provided, however, that in the event the suspension of performance continues for sixty (60) days after the date of the occurrence, and such failure to perform would constitute a material breach of this Agreement in the absence of such force majeure event, the no affected Party may terminate this Agreement immediately by written notice to the affected Party.

14. General Provisions.

14.1. Assignment. Neither this Agreement nor any interest herein may be assigned, in whole or in part, by either party without the prior written consent of the other, which consent shall not be unreasonably withheld or delayed, except that either party may assign its rights and obligations under this Agreement: (a) to an affiliate, division or subsidiary of such party; and/or (b) to any third party that acquires all or substantially all of the stock or assets of such party, whether by asset sale, stock sale, merger or otherwise, and, in any such event such assignee shall assume the transferring party's obligations hereunder. However, notwithstanding any such assignment, in the case of an assignment to an affiliate, division or subsidiary, the transferring party shall remain liable under this Agreement (in addition to the transferee) unless such liability is specifically waived in writing by the other party hereto. Subject to the foregoing, this Agreement shall be binding upon and inure to the benefit of the Parties hereto, and their respective successors and permitted assigns.

(a) Buyout. In the case that either company is acquired by, or merges with, another company which has reason to not wish to continue the relationship, that company may make a contract buyout payment [*] for the [*], with a [*] buyout payment amount of [*].

14.2. Notice. Any notice or request required or permitted to be given under or in connection with this Agreement shall be deemed to have been sufficiently given if in writing and sent by: (a) personal delivery against a signed receipt therefore, (b) certified mail, return receipt requested, first class postage prepaid, (c) nationally recognized overnight delivery service (signature required), (d) confirmed facsimile transmission, or (e) electronic mail (with any notices to send by facsimile transmission or electronic mail to also be sent by one of the other methods set forth in this Section), addressed as follows:

If to HOVIONE, then to:

Hovione FarmaCiencia SA
Attention: General Counsel Estrada do
Paco do Lumiar
Campus do Lumiar, Edificio R
1649-038 Lisboa, Portugal

With a copy, sent as provided herein, to:

gc@hovione.com

If to INTERSECT, then to:

1555 Adams Dr., Menlo Park, CA 94025
Attn: Chief Operations Officer
email: purchasing@intersectent.com

Any party may alter the address to which communications are to be sent by giving notice of such change of address in conformity with the provisions of this Section providing for the giving of notice. Notice shall be deemed to be effective, if personally delivered, when delivered; if mailed, at midnight on the third business day after being sent by certified mail; if sent by nationally recognized overnight delivery service, on the next business day following delivery to such delivery service; and if sent by confirmed facsimile transmission or electronic mail, on the next business day following transmission (so long as any notices sent by facsimile transmission or electronic mail are also sent by one of the other methods set forth in this Section).

14.3. Entire Agreement. This Agreement sets forth the entire agreement and understanding between the Parties as to the subject matter hereof and merges all prior discussions and negotiations between them, and neither party shall be bound by any conditions, definitions, warranties, understandings or representations with respect to such subject matter other than as expressly provided herein or as duly set forth on or subsequent to the date hereof in writing and signed by a proper and duly authorized officer or representative of the Parties to be bound thereby, except that this Agreement shall not supersede any separate confidentiality or non-disclosure agreement that may have been, or that may be, entered into by the Parties. To the extent that any conflict arises among the documents that comprise this Agreement (including any schedules or exhibits), the terms and conditions of this Agreement shall govern. The terms and conditions of this Agreement shall control over and supersede any contrary term in any purchase order,

14.4. Amendment and Modification. This Agreement may be amended, modified and supplemented only by written agreement duly executed and delivered by each of the Parties hereto.

14.5. Waiver. The failure of any party to exercise any right or to demand the performance by the other party of duties required hereunder shall not constitute a waiver of any rights or obligations of the Parties under this Agreement. A waiver by any party of a breach of any of the terms of this Agreement by any other party shall not be deemed a waiver of any subsequent breach of the terms of this Agreement.

14.6. Governing Law. This Agreement is to be governed by and construed in accordance with the laws of the State of New York, United States, notwithstanding any conflict of law provisions to the contrary. The United Nations Convention on Contracts for the International Sale of Goods shall not apply to this Agreement. Any action which in any way involves the rights, duties and obligations of either party hereto under this Agreement shall be brought in the courts of Geneva and the Parties to this Agreement hereby submit to the personal jurisdiction of any such court. The Parties waive any and all rights to have any dispute, claim or controversy arising out of or relating to this Agreement tried before a jury.

14.7. Severability. Whenever possible, each provision of this Agreement shall be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Agreement is held to be invalid, illegal or unenforceable in any respect under any applicable law or rule in any jurisdiction, such invalidity, illegality or unenforceability shall not affect any other provision of this Agreement or any action in any other jurisdiction, but this Agreement shall be reformed, construed and enforced in such jurisdiction as if such invalid, illegal or unenforceable provision had not been contained herein.

14.8. Construction. The Parties have participated jointly in the negotiation and drafting of this Agreement. In the event of any ambiguity or question of intent or interpretation arises, this Agreement shall be construed as if drafted jointly by the Parties and no presumption or burden of proof shall arise favoring or disfavoring any party by virtue of the authorship of any of the provisions of this Agreement. As used in this Agreement, the singular shall include the plural and vice versa, and the terms “include” and “including” shall be deemed to be immediately followed by the phrase “but not limited to.” The terms “herein” and “hereunder” and similar terms shall be interpreted to refer to this entire Agreement, including any schedules attached hereto.

14.9. Parties/Relationship. Neither party shall hold itself out to third parties as possessing any power or authority to enter into any contract or commitment on behalf of any other party. This Agreement is not intended to, and shall not; create any agency, partnership or joint venture relationship between or among the Parties. Each Party is an independent contractor with respect to the others. No Party is granted any right or authority to assume or create any obligation or responsibility, express or implied, on behalf of, or in the name of any other Party hereto, or to bind any other party hereto in any manner or with respect to anything, whatsoever.

14.10. Captions. The captions and headings in this Agreement are inserted for convenience and reference only and in no way define or limit the scope or content of this Agreement and shall not affect the interpretation of its provisions.

14.11. Counterparts. This Agreement may be executed in multiple counterparts, each of which shall be deemed an original and all of which together shall constitute one and the same instrument.

14.12. Subcontractors. Any work that is to be done by any Party under this Agreement may be subcontracted to a third party in accordance with the approved Marketing Authorisation, cGMPs and any applicable PMDA guidelines which relate to the work to be performed under the direction and supervision of such party, as the case may be; provided, however, that the subcontracting party exercises reasonable diligence in selecting such subcontractor and, as between the parties hereto, the subcontracting party shall be and remain responsible for all acts and omissions of any such subcontractor.

14.13. Schedules and Exhibits. All Schedules and Exhibits referenced in this Agreement, if any, are hereby incorporated by reference into, and made a part of, this Agreement.

14.14. Currency. All sums set forth in this Agreement and ay appendices, exhibits or schedules hereto are, and are intended to be, expressed in US dollars.

IN WITNESS WHEREOF, the parties have executed the Agreement as of the date first above written.

HOVIONE INTER AG:

By: /s/ Frederic Kahn
Name: Frederic Kahn
Its: VP Marketing and Sales

INTERSECT ENT, INC.:

By: /s/ Thomas A. West
Name: Thomas A. West
Its: CEO

AMENDED NON-EMPLOYEE DIRECTOR COMPENSATION POLICY

Our non-employee directors receive an annual retainer of $40,000. Our Board Chairman receives an additional retainer of $40,000. In addition, all non-employee directors who serve on one or more committees will receive the following annual committee fees:

Committee	Chair	Member
Audit	$20,000	$10,000
Compensation	15,000	7,500
Nominating and Corporate Governance	10,000	5,000

Other than the annual retainers and committee fees described above, non-employee directors are not entitled to receive any cash fees in connection with their service on our Board. Each non-employee director is granted an equity grant for a fair value of $120,000, consisting of an equal amount of stock options and RSUs, at each annual stockholders' meeting, provided the non-employee director has served since March 1st of the year the annual meeting was held and continued to serve. The stock option grants have an exercise price equal to the fair market value of our common stock on the date of grant and vest monthly over one year from the date of grant. The RSU awards cliff vest 100%, one year from the date of grant. New non-employee directors receive an initial stock option grant for a fair value of $180,000. The initial grants have an exercise price equal to the fair market value of our common stock on the date of grant and vest 25% in one year and monthly thereafter over the next three years, provided the non-employee director continues to serve. All of the Board stock options and RSUs described in this paragraph become fully vested upon a change in control.

Prior to the beginning of each year, each non-employee director may elect to receive their annual retainer for the following year in the form of a stock option that vests monthly over one year from the beginning of the year. The option is granted at the first Board or Compensation Committee meeting of the year for a fair value equivalent to their annual retainer with an exercise price equal to the fair market value of our common stock on the date of grant. These options are not subject to vesting acceleration upon a change in control.

We have a policy of reimbursing our directors for their reasonable out-of-pocket expenses in connection with attending Board of Directors and committee meetings.

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF

THE SARBANES-OXLEY ACT OF 2002

I, Thomas A. West, 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 11, 2020

/s/ Thomas A. West
Thomas A. West
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, Richard A. Meier, 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 11, 2020

/s/ Richard A. Meier
Richard A. Meier
Executive Vice President and 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), Thomas A. West, President and Chief Executive Officer of Intersect ENT, Inc. (the "Company") and Richard A. Meier, Executive Vice President and 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, 2020, 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 11, 2020

/s/ Thomas A. West
Thomas A. West
President and Chief Executive Officer
(Principal Executive Officer)

/s/ Richard A. Meier
Richard A. Meier
Executive Vice President and 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.