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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 September 30, 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** **(Address of principal executive offices)**	**94025** **(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 x 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 x No ☐

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

Large accelerated filer	x	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 x

Shares of common stock outstanding as of October 26, 2020 were 32,719,014.

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

	September 30, 2020	December 31, 2019
	(unaudited)	(1)
Assets		
Current assets:		
Cash and cash equivalents	$ 56,891	$ 20,652
Short-term investments	73,815	69,986
Accounts receivable, net	11,880	19,113
Inventories, net	11,158	17,000
Prepaid expenses and other current assets	2,921	2,300
Total current assets	156,665	129,051
Property and equipment, net	5,555	6,312
Operating lease right-of-use assets	10,357	11,980
Other non-current assets	560	559
Total assets	$ 173,137	$ 147,902
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 4,589	$ 4,056
Accrued compensation	10,839	12,717
Other current liabilities	4,349	2,163
Total current liabilities	19,777	18,936
Operating lease liabilities	8,985	10,886
Convertible notes, net	62,975	—
Other non-current liabilities	22	22
Total liabilities	91,759	29,844
Commitments and contingencies (note 9)		
Stockholders' equity:		
Preferred stock, $0.001 par value; Authorized shares: 9,994 at September 30, 2020 and 10,000 at December 31, 2019; Issued and outstanding shares: none	—	—
Series DF-1 convertible preferred stock, $0.001 par value; Authorized shares: 6 at September 30, 2020 and none at December 31, 2019; Issued and outstanding shares: none	—	—
Common stock, $0.001 par value; Authorized shares: 150,000; Issued and outstanding shares: 32,716 at September 30, 2020 and 32,235 at December 31, 2019	33	32
Additional paid-in capital	364,201	348,729
Accumulated other comprehensive income	22	53
Accumulated deficit	(282,878)	(230,756)
Total stockholders' equity	81,378	118,058
Total liabilities and stockholders' equity	$ 173,137	$ 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 September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Revenue	$ 22,720	$ 24,056	$ 52,326	$ 77,388
Cost of sales	7,845	4,876	21,612	14,567
Gross profit	14,875	19,180	30,714	62,821
Operating expenses:				
Selling, general and administrative	21,702	26,429	67,399	81,247
Research and development	4,551	6,145	13,715	18,452
Total operating expenses	26,253	32,574	81,114	99,699
Loss from operations	(11,378)	(13,394)	(50,400)	(36,878)
Interest expense	(886)	—	(1,372)	—
Other income (expense), net	799	546	(350)	1,841
Net loss	(11,465)	(12,848)	(52,122)	(35,037)
Other comprehensive income (loss):				
Unrealized gain (loss) on short-term investments, net	(73)	(3)	(31)	135
Comprehensive loss	$ (11,538)	$ (12,851)	$ (52,153)	$ (34,902)
Net loss per share, basic and diluted	$ (0.35)	$ (0.41)	$ (1.60)	$ (1.12)
Weighted average common shares used to compute net loss per share, basic and diluted	32,695	31,483	32,552	31,256

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
Issuance of common stock and exercise of stock options	108	—	728	—	—	728
Stock-based compensation expense	—	—	3,586	—	—	3,586
Unrealized gain on short-term investments	—	—	—	61	—	61
Net loss	—	—	—	—	(23,124)	(23,124)
Balance at June 30, 2020	32,645	33	360,396	95	(271,413)	89,111
Issuance of common stock and exercise of stock options	71	—	276	—	—	276
Stock-based compensation expense	—	—	3,529	—	—	3,529
Unrealized loss on short-term investments	—	—	—	(73)	—	(73)
Net loss	—	—	—	—	(11,465)	(11,465)
Balance at September 30, 2020	32,716	$ 33	$ 364,201	$ 22	$ (282,878)	$ 81,378

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

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2018	30,745	$ 31	$ 308,766	$ (41)	$ (187,762)	$ 120,994
Issuance of common stock and exercise of stock options	417	—	4,467	—	—	4,467
Stock-based compensation expense	—	—	4,014	—	—	4,014
Unrealized gain on short-term investments	—	—	—	77	—	77
Net loss	—	—	—	—	(10,805)	(10,805)
Balance at March 31, 2019	31,162	31	317,247	36	(198,567)	118,747
Issuance of common stock and exercise of stock options	307	—	4,964	—	—	4,964
Stock-based compensation expense	—	—	5,680	—	—	5,680
Unrealized gain on short-term investments	—	—	—	61	—	61
Net loss	—	—	—	—	(11,384)	(11,384)
Balance at June 30, 2019	31,469	31	327,891	97	(209,951)	118,068
Issuance of common stock and exercise of stock options	41	1	407	—	—	408
Stock-based compensation expense	—	—	5,258	—	—	5,258
Unrealized loss on short-term investments	—	—	—	(3)	—	(3)
Net loss	—	—	—	—	(12,848)	(12,848)
Balance at September 30, 2019	31,510	$ 32	$ 333,556	$ 94	$ (222,799)	$ 110,883

See accompanying notes to condensed consolidated financial statements.

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

	Nine Months Ended September 30,	
	2020	**2019**
Operating activities:		
Net loss	$ (52,122)	$ (35,037)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	1,467	1,986
Non-cash lease expense	1,623	853
Stock-based compensation expense	11,642	14,615
Amortization of net investment premium (discount)	71	(1,050)
Amortization of debt transaction costs and accretion of debt discount	339	—
Change in fair value of embedded derivatives	795	—
Changes in operating assets and liabilities:		
Accounts receivable, net	7,233	6,373
Inventories, net	5,568	(4,997)
Prepaid expenses and other assets	(634)	(1,066)
Accounts payable	555	(771)
Accrued compensation	(1,878)	374
Other liabilities	287	(1,238)
Net cash used in operating activities	(25,054)	(19,958)
Investing activities:		
Purchases of short-term investments	(108,831)	(97,863)
Maturities of short-term investments	70,106	111,485
Proceeds from sale of short-term investments	34,794	—
Purchases of property and equipment	(722)	(2,613)
Net cash provided by (used in) investing activities	(4,653)	11,009
Financing activities:		
Proceeds from debt financing, net of issuance costs	61,841	—
Proceeds from issuance of common stock and exercise of stock options	4,105	9,839
Net cash provided by financing activities	65,946	9,839
Net increase in cash and cash equivalents	36,239	890
Cash and cash equivalents:		
Beginning of the period	20,652	9,464
End of the period	$ 56,891	$ 10,354
Non-cash investing activities:		
Right-of-use asset obtained in exchange for lease obligations	$ —	$ 117
Property and equipment included in accounts payable	82	370
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 a 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 September 30, 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 and nine months ended September 30, 2020 and 2019. Certain information and 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.

Reclassifications

Certain prior year amounts associated with finished goods inventory have been reclassified to work-in-process inventory to conform to the current year presentation. These reclassifications had no impact on net earnings or financial position.

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 been and will be impacted by its patients' decisions to undergo sinus surgeries as ENT ASC and office procedure volumes recover, and as the Company resumed its manufacturing operations as a result of the ease of certain restrictions of the shelter-in-place orders issued by local and federal authorities. 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 longer, 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, valuation of embedded derivatives associated with the Company's Convertible Notes (see Note 8) 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 currently 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.

Accounting Pronouncements

Recently Adopted Accounting Standards

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.

Recent Issued Accounting Pronouncements Not Yet Adopted

In December 2019, the FASB issued ASU No. 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes* ("ASU 2019-12"), which is intended to simplify various aspects related to accounting for income taxes. ASU 2019-12 removes certain exceptions to the general principles in Topic 740 and also clarified and amends existing guidance to improve consistent application. ASU 2019-12 is effective for the Company beginning in 2021. Early adoption is permitted. The Company is evaluating the impact of the adoption of ASU 2019-12 on its condensed consolidated financial statements, but does not expect the adoption to have a material impact.

In August 2020, the FASB issued ASU No. 2020-06, *Debt- Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging- Contracts in Entity's Own Equity (Subtopic 815-40)* ("ASU 2020-06"). ASU 2020-06 modifies and simplifies accounting for convertible instruments. The new guidance eliminates certain separation models that require separating embedded conversion features from convertible instruments. ASU 2020-06 also addresses how convertible instruments are accounted for in the diluted earnings per share calculation. ASU 2020-06 will become effective for the Company beginning in 2022. Early adoption is permitted, but no earlier than the beginning of 2021. The Company is evaluating the impact of the adoption of ASU 2020-06 on its condensed consolidated financial statements, but does not expect the adoption to have a material impact.

In October 2020, the FASB issued ASU No. 2020-08, *Codification Improvements to Subtopic 310-20, Receivables- Nonrefundable Fees and Other Costs* ("ASU 2020-08"). ASU 2020-08 clarifies the accounting for the amortization period for certain purchased callable debt securities held at a premium by giving consideration to securities which have multiple call dates. ASU 2020-08 will become effective for the Company beginning in 2021. Early adoption is not permitted. The Company is evaluating the impact of the adoption of ASU 2020-08 on its condensed consolidated financial statements, but does not expect the adoption to have a material impact.

Significant Accounting Policies

There have been no significant changes to the accounting policies during the nine months ended September 30, 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 allocable overhead. During the first half of 2020, as a result of a shut-down in production associated with the COVID-19 pandemic for part of the first quarter and throughout the second quarter, the Company recorded $5.5 million for idle facility expense due to its inability to use its manufacturing facility due to the shelter-in-place orders and the Company's decision to suspend production until the third quarter of 2020. When production resumed, the Company recorded an additional $0.6 million in idle facility expense in the third quarter of 2020 due to subnormal production levels. In periods where the manufacturing is below the Company's normal capacity, the Company will record idle facility charges. 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 first quarter of 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 distribution partners 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 nine months ended September 30, 2020.

Restructuring Activities

During the nine months ended September 30, 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 have been and are expected to be significantly impacted by 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 furloughed 18 employees, or approximately 5% of its workforce, and provided for the cost of certain benefits for those employees while furloughed. The charges related to these actions, including severance benefits for terminated employees and the benefits for furloughed employees, were approximately $0.2 million for the nine months ended September 30, 2020. The restructuring activities are substantially complete and there are no remaining accrued liabilities related to restructuring activities as of September 30, 2020.

Embedded Derivatives Related to Convertible Debt Instruments

Embedded derivatives that are required to be bifurcated from their host contract are evaluated and valued separately from the debt instrument and classified accordingly depending on the specific terms of the agreement. The embedded features are remeasured to fair value at each balance sheet date with a resulting gain or loss related to the change in the fair value being recorded to "Other Income (Expense), net" on the condensed consolidated statements of operations. Changes in the Company's assumptions, such as the estimated probability of triggering events and its stock price, used to value the embedded derivatives could result in material changes in the valuation in future periods.

3. Composition of Certain Financial Statement Items

Accounts receivable, net (in thousands):

	September 30, 2020	December 31, 2019
Accounts receivable	$ 12,093	$ 19,244
Allowance for doubtful accounts	(213)	(131)
	$ 11,880	$ 19,113

Inventories, net (in thousands):

	September 30, 2020	December 31, 2019
Raw materials	$ 1,626	$ 2,830
Work-in-process	4,199	5,878
Finished goods	5,333	8,292
	$ 11,158	$ 17,000

Capitalized stock-based compensation expense of $0.6 million and $0.9 million was included in inventory as of September 30, 2020 and December 31, 2019, respectively.

Operating lease liabilities (in thousands):

	September 30, 2020	December 31, 2019
Current portion presented in other current liabilities	$ 2,493	$ 1,336
Noncurrent portion presented in operating lease liabilities	8,985	10,886
	$ 11,478	$ 12,222

Revenue (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
PROPEL family of products	$ 21,051	$ 22,962	$ 49,622	$ 74,257
SINUVA	1,669	1,094	2,704	3,131
	$ 22,720	$ 24,056	$ 52,326	$ 77,388

4. Fair Value of Financial Instruments

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

The fair value of debt is based on the amount of future cash flows associated with the instrument discounted using the Company's estimated market rate as well as a convertible lattice model for the embedded features. As of September 30, 2020, the fair value of the Company's Convertible Notes (see Note 8) was $78.7 million.

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):

					Reported as:	
	Amortized	Gross Unrealized		Estimated	Cash and cash	Short-term
September 30, 2020	Cost	Gains	Losses	Fair Value	equivalents	investments
Level 1:						
Cash	$ 47,313	$ —	$ —	$ 47,313	$ 47,313	$ —
Money market funds	9,578	—	—	9,578	9,578	—
	56,891	—	—	56,891	56,891	—
Level 2:						
U.S. treasury bills	40,912	7	—	40,919	—	40,919
Corporate debt securities	8,379	4	—	8,383	—	8,383
U.S. government agency bonds	23,007	6	—	23,013	—	23,013
Commercial paper	1,495	5	—	1,500	—	1,500
	73,793	22	—	73,815	—	73,815
	$ 130,684	$ 22	$ —	$ 130,706	$ 56,891	$ 73,815

					Reported as:	
	Amortized	Gross Unrealized		Estimated	Cash and cash	Short-term
December 31, 2019	Cost	Gains	Losses	Fair Value	equivalents	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 nine months ended September 30, 2020 and year ended December 31, 2019.

As of September 30, 2020 and December 31, 2019, the Company had no investments with a remaining 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 nine months ended September 30, 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 September 30, 2020 were not attributed to credit.

Convertible Notes Embedded Derivatives

The Convertible Notes due in 2025 (see Note 8) have embedded features which were required to be bifurcated upon issuance and then periodically remeasured separately as embedded derivatives. These embedded features include additional make-whole interest payments which may become payable to the lender upon certain events, such as a change in control, upon optional redemption by the Company, or a sale of all or substantially all of the Company's assets. The embedded features also include additional shares depending on the time to maturity and the stock price which may be added to an early conversion upon certain events. The Company has utilized a convertible lattice model to determine the fair value of the embedded features, which utilizes inputs including the common stock price, volatility of common stock, credit rating, probability of certain triggering events and time to maturity. The fair value measurements of the embedded derivatives are classified as Level 3 financial instruments. At September 30, 2020, the fair value of the embedded features was $2.6 million and has been presented together with the Convertible Notes host instrument on the condensed consolidated balance sheets. Changes in the fair value of the Company's Level 3 liabilities were as follows:

	September 30, 2020
Balance at December 31, 2019	$ —
Additions	1,800
Fair value adjustment	795
Balance at September 30, 2020	$ 2,595

The change in fair value of embedded derivatives for the three and nine months ended September 30, 2020 was a $1.0 million gain and $0.8 million loss, respectively, which was recorded in "Other Income (Expense), net" on the Company's condensed consolidated statements of operations.

5. Stockholders' Equity

Series DF-1 Convertible Preferred Stock

The Company's board of directors has designated 6,310 shares of the authorized 10,000,000 shares of preferred stock, $0.001 par value per share, as Series DF-1 Convertible Preferred Stock (the "Series DF-1 Preferred Stock"). Each share of Series DF-1 Preferred Stock is non-voting and convertible to 1,000 shares of the Company's Common Stock. There is an aggregate of 6,309,459 shares of common stock issuable upon conversion of the Series DF-1 Preferred Stock. The Series DF-1 Preferred Stock does not have voting rights but is eligible for dividends or distributions on an as-converted basis.

6. Stock-based Compensation Expense

2014 Equity Incentive Plan

In July 2014, the Company's board of directors approved the 2014 Equity Incentive Plan (the "2014 Plan"). 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 September 30, 2020, 3,391,263 shares remained available for issuance.

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

	Nine Months Ended September 30, 2020	
	Options	Weighted Average Exercise Price
Outstanding, beginning of period	3,636	$ 23.71
Granted	895	21.87
Exercised	(208)	16.49
Forfeited	(823)	27.89
Outstanding, end of period	3,500	22.68
Exercisable	1,754	22.17

As of September 30, 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 September 30, 2020, these stock options remain unvested.

The aggregate pre-tax intrinsic value of options outstanding was $2.8 million and options outstanding and exercisable was $2.1 million, the weighted-average remaining contractual term of options outstanding was 7.8 years and options outstanding and exercisable was 6.6 years. The aggregate pre-tax intrinsic value of options exercised was $1.3 million and $8.8 million during the nine months ended September 30, 2020 and 2019, respectively.

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

	Nine Months Ended September 30, 2020	
	RSUs	Weighted Average Fair Value
Outstanding, beginning of period	511	$ 25.62
Awarded	294	24.03
Vested	(202)	24.18
Forfeited	(119)	28.39
Outstanding, end of period	484	24.57

As of September 30, 2020, the aggregate pre-tax intrinsic value of RSUs outstanding was $7.9 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 1.9 years.

The Company also offers Performance Stock Units ("PSUs"), subject to both service and market-based vesting conditions. A summary of the Company's PSU activity and related information (PSUs in thousands):

	Nine Months Ended September 30, 2020	
	PSUs	Weighted Average Fair Value
Outstanding, beginning of period	89	$ 14.22
Awarded	103	17.28
Forfeited	(19)	17.28
Outstanding, end of period	173	15.70

As of September 30, 2020, the aggregate pre-tax intrinsic value of PSUs outstanding was $2.8 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 2.3 years.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Cost of sales	$ 446	$ 354	$ 1,221	$ 836
Selling, general and administrative	2,790	4,021	9,204	11,435
Research and development	417	874	1,217	2,344
	$ 3,653	$ 5,249	$ 11,642	$ 14,615

As of September 30, 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 $28.0 million and the weighted average period over which the unearned stock-based compensation is expected to be recognized was 2.4 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 September 30, 2020, 959,970 shares remained available for issuance and a total of 70,817 shares were issued during the nine months ended September 30, 2020.

7. Net Loss per Share

Basic net loss per share is computed by dividing the net loss by the weighted average number of shares of common stock outstanding during the period. Diluted net loss per share is computed by dividing the net loss by the weighted average number of shares of common stock and 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 September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Common stock options	3,073	3,817	3,073	3,817
Market-based performance stock options	427	427	427	427
Restricted stock units	484	606	484	606
Market-based performance stock units	173	—	173	—
Employee stock purchase plan shares	72	75	72	75
Stock issuable upon conversion of convertible note	6,309	—	6,309	—
	10,538	4,925	10,538	4,925

The Company uses the if-converted method for calculating any potential dilutive effects of the convertible note. The Company did not adjust the net loss for the three and nine months ended September 30, 2020 to eliminate any interest expense related to the Convertible Notes (see Note 8) in the computation of diluted loss per share, or calculate the potential common shares from conversion, as the effects would have been anti-dilutive. The shares presented above represent the maximum number of convertible shares which can be issued subject to the make-whole increase to the conversion rate upon certain events.

8. Convertible Notes

On May 11, 2020, in order to finance the Company's commercial activities as well as for general corporate purposes, the Company entered into a Facility Agreement (the "Facility Agreement") by and among the Company, as borrower, 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 $65.0 million principal amount of the Convertible Notes is not payable until the maturity date of May 9, 2025, unless earlier converted or redeemed. The Convertible Notes are convertible into shares of the Company's common stock, at a conversion rate of 64.3501 shares per $1,000 principal amount of Convertible Notes, which represents an initial conversion price of $15.54. The net proceeds from the sale of the Convertible Notes were approximately $61.8 million after deducting the 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 the principal amount of Convertible Notes if:

- 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;
- the volume weighted average price of the common stock on the last trading day of such period; and
- 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:

- 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;
- the volume weighted average price of the common stock on the last trading day of such period; and
- 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. See Note 5 for discussion on the rights and privileges of Series DF-1 Preferred Stock. 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 or make-whole interest provision.

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.

Certain features in the Convertible Notes are accounted for as embedded derivatives bifurcated from the principal balance of the Convertible Notes. See Note 4 for further discussion on the valuation of the embedded derivatives.

Upon issuance, the fair value of the embedded derivatives was $1.8 million. A corresponding convertible debt discount and transaction costs of $1.8 million and $3.0 million, respectively were recorded on the issuance date and are netted against the principal amount of the convertible notes. During the three months ended September 30, 2020, an additional $0.2 million of transaction costs were recorded and netted against the principal amount of the convertible notes. Transaction costs related to the issuance of the convertible notes primarily comprised of underwriters', legal, accounting and other professional fees.

As of September 30, 2020, the net carrying amount of the convertible notes is as follows:

	September 30, 2020
Outstanding principal amount of convertible notes	$ 65,000
Unamortized debt discount and transaction costs	(4,620)
Fair value of embedded derivatives	2,595
Convertible notes, net	$ 62,975

The convertible debt discount and transaction costs are being amortized to expense over the term of the Notes. For the three and nine months ended September 30, 2020, the accretion of the convertible debt discount and amortization of debt issuance costs was $0.2 million and $0.3 million, respectively, and was included in “Interest expense” in the condensed consolidated statements of operations. The accrued interest on the outstanding principal of $65.0 million as of September 30, 2020 was $0.7 million and was included in “Other current liabilities” on the condensed consolidated balance sheets.

9. Commitments and Contingencies

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 appointed the lead plaintiff and set a schedule for initial motions and pleadings. By order dated June 19, 2020, the Court granted the Company’s motion to dismiss the amended complaint with leave to amend. On July 29, 2020, the plaintiff filed an amended complaint. The Company believes this lawsuit is without merit and intends to vigorously defend against it. As of September 30, 2020, the Company has accrued anticipated settlement costs associated with this lawsuit of $0.4 million which is recorded in "Other current liabilities" on the condensed consolidated balance sheets.

10. Subsequent Events

On October 2, 2020, in accordance with the terms of the sale and purchase agreement (the "Purchase Agreement"), the Company acquired Fiagon AG Medical Technologies ("Fiagon"). Fiagon develops, and commercializes globally, innovative electromagnetic surgical navigation systems and an associated suite of surgical tools targeted to the ENT surgical space. Pursuant to the terms of the Purchase Agreement, the Company indirectly acquired all of the outstanding equity interests of subsidiaries of Fiagon, including Fiagon GmbH and Fiagon NA Corporation (such subsidiaries, together with Fiagon, the "Fiagon Group" and, such acquisition, the "Acquisition").

The aggregate consideration payable in exchange for all of the outstanding equity interests of the Fiagon Group is €60.0 million, subject to adjustments set forth in the Purchase Agreement (the "Cash Consideration"). Under the terms of the Purchase Agreement, the Company made an initial €15.0 million payment at the time of closing of the Acquisition, and the Company committed to make €15.0 million annual payments for each of the subsequent three years.

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 revenue growth as the current crisis subsides. Further, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Quarterly Report on Form 10-Q, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These forward-looking statements and statements regarding our beliefs involve risks and uncertainties that could cause our actual results to differ materially from those expressed or implied in these 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 these 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 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 ("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 ("PMA") and SINUVA is a drug that was approved under a New Drug Application ("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 functional endoscopic sinus surgery ("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 the need for 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 ("CMS"), for a product-specific J code for SINUVA, and in July 2019, the 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. The 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. Subsequently, the CMS approved SINUVA for transitional pass-through payment status for reimbursement under the Hospital Outpatient Prospective Payment System ("OPPS") and ASC Payment System. The new C code described as "C9122 Mometasone furoate, sinus implant, 10 micrograms", took effect on July 1, 2020. Pass-Through status lasts for three years. 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 ("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 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 plan to initiate the pivotal clinical study in 2021.

On October 2, 2020, in accordance with the terms of the sale and purchase agreement (the "Purchase Agreement"), which is filed as an exhibit to this Quarterly Report on Form 10-Q, we acquired Fiagon AG Medical Technologies ("Fiagon"). Fiagon develops, and commercializes globally, innovative electromagnetic surgical navigation systems and an associated suite of surgical tools targeted to the ENT surgical space. In addition, in August 2020, Fiagon received U.S. FDA 510(k) clearance for a navigable sinuplasty balloon. The combination of the Intersect ENT and Fiagon portfolios allows us to deliver more comprehensive surgical solutions across the sinusitis care continuum regardless of site of care. The aggregate consideration payable in exchange for all of the outstanding equity interests of the Fiagon is €60.0 million. Under the terms of the Purchase Agreement, we made an initial €15.0 million ($17.5 million) payment at the time of closing of the acquisition and will make €15.0 million annual payments for each of the subsequent three years. We also placed €15.0 million ($17.5 million) in escrow with the seller as beneficiary. The acquisition is expected to be accretive to revenue growth in the first year post close.

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 towards the end of the first quarter and throughout the second quarter as the various COVID-19 restrictions were implemented and remained in effect. However, we began to see meaningful change in the business environment towards the end of May with increased procedure volumes as select areas of the country emerged from shelter-in-place orders and restrictions on elective medical procedures were eased. This trend continued in June and throughout the third quarter as we continued to see improvements in the elective procedure market. Our business has been and will be impacted by our patients' decisions to undergo sinus surgeries as ENT ASC and office procedure volumes begin to recover and we resume our manufacturing operations as a result of the ease of certain restrictions of the shelter-in-place orders issued by local and federal authorities. We continue to remain flexible in our approach to continuing our operations in light of rapidly developing laws and restrictions surrounding the COVID-19 pandemic. While the third quarter did provide an improving business environment, the COVID-19 pandemic may continue to create severe disruptions and volatility in global capital markets and increase 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 where physical presence for manufacturing operations is not required 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 in the first quarter of 2020 to curtail spending and to reduce use of cash as revenues are and will continue to be materially impacted. We have also considered the incremental costs of business operations during the pandemic and expect these costs to remain until the current crisis subsides. The cost reduction actions included 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. In total, these cost reduction activities were expected to yield $40.0 million in cash savings; however, higher revenues and costs associated with those higher revenues are expected to result in lower savings as well as a lower rate of cash use in operations than previously expected.

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 toward the end of the first quarter and throughout the second quarter as the various COVID-19 restrictions were implemented. As office-based procedures began to increase in May, our performance had a positive upward trend toward the end of the second quarter and throughout the third quarter. While our business has been and will be impacted by hospitals suspending elective surgical procedures and reduced ENT office visits, we anticipate revenue growth for the remainder of 2020 based on the increased elective procedure volumes and enrollment trends in the third quarter. 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 and nine months ended September 30, 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. Towards the end of the first quarter and throughout the second quarter, manufacturing costs were negatively impacted by the mandatory shelter-in-place order in effect in San Mateo County, California, which prevented us from using our manufacturing facility and our decision to suspend production until the third quarter of 2020. Production resumed during the third quarter of 2020, but below our normal capacity. Idle facility expenses 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.

Interest Expense

Interest expense consists primarily of the interest expense, accretion expense of debt discounts, and amortization of debt issuance costs associated with our Convertible Notes.

Other Income (Expense), Net

Other income (expense), net consists primarily of interest earned on our cash and cash equivalents, changes in the fair value of embedded derivatives, and the effects of foreign exchange.

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 nine months ended September 30, 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 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 allocable overhead. During the first half of 2020, as a result of a shut-down in production associated with the COVID-19 pandemic for part of the first quarter and throughout the second quarter, we recorded $5.5 million for idle facility expense due to our inability to use our manufacturing facility due to the shelter-in-place orders and our decision to suspend production until the third quarter of 2020. Production resumed in the third quarter and we recorded an additional $0.6 million in idle facility expense in the third quarter of 2020 due to subnormal production levels. In periods where the manufacturing is below normal capacity, we will record idle facility charges. 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 increased our reserve for excess and obsolete inventory by $0.8 million during the first quarter of 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.

Embedded Derivatives Related to Convertible Debt Instruments

The Convertible Notes due in May 2025 have embedded features which were required to be bifurcated upon issuance and then periodically remeasured separately as embedded derivatives. These embedded features include additional make-whole interest payments which may become payable to the lender upon certain events, such as a change in control, upon optional redemption by our company, or a sale of all or substantially all of our assets. The embedded features also include additional shares depending on the time to maturity and the stock price which may be added to an early conversion upon certain events. We have utilized a convertible lattice model to determine the fair value of the embedded features, which utilizes inputs including the common stock price, volatility of common stock, credit rating, probability of certain triggering events and time to maturity. The embedded features will be remeasured to fair value at each balance sheet date with a resulting gain or loss related to the change in the fair value being recorded to "Other Income (Expense), net" on the condensed consolidated statements of operations. Changes in our assumptions, such as the estimated probability of triggering events and our stock price, used to value the embedded derivatives could result in material changes in the valuation in future periods. At September 30, 2020, the fair value of the embedded derivatives was $2.6 million and has been presented together with the Convertible Notes host instrument on the condensed consolidated balance sheets.

Accounting Pronouncements

See Note 2 of the condensed consolidated financial statements under the heading "Accounting Pronouncements" for new accounting pronouncements or changes to the recent accounting pronouncements during the nine months ended September 30, 2020.

Results of Operations

(in thousands, expect percentages)	Three Months Ended September 30, 2020	Three Months Ended September 30, 2019	Nine Months Ended September 30, 2020	Nine Months Ended September 30, 2019
Revenue	$ 22,720	$ 24,056	$ 52,326	$ 77,388
Cost of sales	7,845	4,876	21,612	14,567
Gross profit	14,875	19,180	30,714	62,821
Gross margin	65 %	80 %	59 %	81 %
Operating expenses:				
Selling, general and administrative	21,702	26,429	67,399	81,247
Research and development	4,551	6,145	13,715	18,452
Total operating expenses	26,253	32,574	81,114	99,699
Loss from operations	(11,378)	(13,394)	(50,400)	(36,878)
Interest expense	(886)	—	(1,372)	—
Other income (expense), net	799	546	(350)	1,841
Net loss	$ (11,465)	$ (12,848)	$ (52,122)	$ (35,037)

Comparison of the Three and Nine Months ended September 30, 2020 and 2019

Revenue

(in thousands, except percentages)	Three Months Ended September 30, 2020	Three Months Ended September 30, 2019	Nine Months Ended September 30, 2020	Nine Months Ended September 30, 2019	Three Months Ended Change ($) 2020 to 2019	Three Months Ended Change (%) 2020 to 2019	Nine Months Ended Change ($) 2020 to 2019	Nine Months Ended Change (%) 2020 to 2019
PROPEL family of products	$ 21,051	$ 22,962	$ 49,622	$ 74,257	$ (1,911)	(8)%	$ (24,635)	(33)%
SINUVA	1,669	1,094	2,704	3,131	575	53 %	(427)	(14)%
	$ 22,720	$ 24,056	$ 52,326	$ 77,388	$ (1,336)	(6)%	$ (25,062)	(32)%

Revenue decreased by $1.3 million, or 6%, to $22.7 million during the three months ended September 30, 2020, compared to $24.1 million during the three months ended September 30, 2019. The decrease in revenue for the three months ended September 30, 2020 was due to a 8% decline in PROPEL sales, partially offset by a 53% increase in SINUVA sales. Lower PROPEL revenue for the three months ended September 30, 2020 resulted from a 10% decrease in unit sales, slightly offset by a 2% increase in average selling price. SINUVA unit sales increased by 44% during the three months ended September 30, 2020, along with a 6% increase in net revenue per unit from the three months ended September 30, 2019. The increase in unit sales for SINUVA during the three months ended September 30, 2020 was due to a shift of procedures from hospitals and ASCs to the physician office setting of care, as well as sales under a new distributor agreement entered into during the quarter.

Revenue decreased by $25.1 million, or 32%, to $52.3 million during the nine months ended September 30, 2020, compared to $77.4 million during the nine months ended September 30, 2019. The decrease in revenue for the nine months ended September 30, 2020 was due to a 33% decline in PROPEL sales as well as a 14% decline in SINUVA sales. Lower PROPEL revenue for the nine months ended September 30, 2020 resulted from a 35% decrease in unit sales, slightly offset by a 3% increase in average selling price. The decrease in unit sales for PROPEL was driven by a reduction in demand due to the impact of the COVID-19 pandemic. SINUVA unit sales decreased by 15% during the nine months ended September 30, 2020, partially offset by a 1% increase in net revenue per unit from the nine months ended September 30, 2019. The decrease in unit sales for SINUVA during the nine months ended September 30, 2020 was driven by an overall reduction in demand due to the impact of the COVID-19 pandemic.

Based on current elective procedure volumes and enrollment trends, as well as the acquisition of Fiagon, we expect revenue growth for the remainder 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 that a recovery in procedures will continue, and that most patients will return for treatment.

Cost of Sales and Gross Margin

Cost of sales increased by $3.0 million, or 61%, to $7.8 million during the three months ended September 30, 2020, compared to $4.9 million during the three months ended September 30, 2019, and increased by $7.0 million, or 48%, to $21.6 million during the nine months ended September 30, 2020, compared to $14.6 million during the nine months ended September 30, 2019. The increased cost of sales for the three months ended September 30, 2020 was primarily due to the unfavorable impact of higher per unit manufacturing costs and $0.6 million of idle facility expense as a result of lower production volumes, partially offset by manufacturing charges in the prior period related to a writeoff of a single PROPEL production lot as well as decreases in headcount as a result of cost reduction measures taken in the first quarter of 2020. Also, for the nine months ended September 30, 2020, the increase was attributable to $0.8 million in additional charges related to excess and obsolete inventory in response to the estimated impact of the COVID-19 pandemic. There was no reserve for excess and obsolete inventory recorded in the three months ended September 30, 2020. For both periods, the increases were partially offset by lower PROPEL unit sales.

Gross margin for the three months ended September 30, 2020, decreased to 65%, compared to 80% for the three months ended September 30, 2019, and decreased to 59% compared to 81% for the nine months ended September 30, 2019. While the gross margin for our products through the end of February 2020 was relatively consistent with our expectations, the decrease in gross margin during the second and third quarter of 2020 was attributable to the unfavorable impact of higher per unit manufacturing costs as well as the charges related to the impact of COVID-19. The amount of these charges was approximately $6.9 million, representing an effect on our gross margin of approximately 13% for the nine months ended September 30, 2020. Our gross margin recovered during the third quarter relative to previous quarters as we resumed our production and generated revenue.

As a result of the increase in procedure volumes and enrollments during the third quarter, we anticipate that there will be sequential revenue growth for the remainder of 2020 from current quarter levels. With the expected increase in demand and resumption of our manufacturing activities in the third quarter, we do not expect idle facility expense to be incurred in the remainder of 2020. However, idle facility expense could still be incurred in future periods until the current crisis subsides. We cannot reliably estimate the extent to which the COVID-19 pandemic will impact the cost of sales and gross margin for our products beyond 2020.

Selling, General and Administrative Expenses

SG&A expenses decreased by $4.7 million, or 18%, to $21.7 million during the three months ended September 30, 2020, compared to $26.4 million during the three months ended September 30, 2019, and decreased by $13.8 million, or 17%, to $67.4 million during the nine months ended September 30, 2020, compared to $81.2 million during the nine months ended September 30, 2019. The decreases in SG&A expenses were primarily due to decreases in headcount and related expenses as a result of cost reduction measures taken in the first quarter of 2020, in addition to lower sales commissions from reduced sales, partially offset by an increase in transaction costs associated with the acquisition of Fiagon of $1.5 million and $1.9 million for the three and nine months ended September 30, 2020, respectively, which consisted largely of professional fees.

Our spending in the first quarter of 2020 reflected normal business activities while certain spending decreased in the second and third quarter of 2020 as a result of a reduction in demand and the impact of the cost reduction measures put in place in the first quarter. We expect cost control measures to remain in place until the current crisis subsides. However, we will still continue to support our customers, physicians and patients and will incur additional SG&A expenses as a result of the acquisition of Fiagon.

Research and Development Expenses

R&D expenses decreased by $1.6 million, or 26%, to $4.6 million during the three months ended September 30, 2020, compared to $6.1 million during the three months ended September 30, 2019, and decreased by $4.7 million, or 26%, to $13.7 million during the nine months ended September 30, 2020, compared to $18.5 million during nine months ended September 30, 2019. The decreases in R&D expenses were primarily due to decreases in headcount and related expenses as a result of cost reduction measures taken in the first quarter of 2020, as well as a delay of clinical efforts.

Our cost control measures will stay in effect for the remainder of 2020 as a result of the uncertainty related to the timing of resuming our clinical trials due to the COVID-19 pandemic; however, we will incur additional R&D expenses as a result of the acquisition of Fiagon.

Interest Expense

The increases in interest expense of $0.9 million and $1.4 million, respectively, for the three and nine months ended September 30, 2020 were attributable to convertible notes entered into during the second quarter of 2020.

Other Income (Expense), Net

Other income (expense), net, increased by $0.3 million to $0.8 million during the three months ended September 30, 2020, compared to $0.5 million during the three months ended September 30, 2019, and decreased by $2.2 million to $(0.4) million during the nine months ended September 30, 2020, compared to $1.8 million during the nine months ended September 30, 2019. The increase in other income (expense), net during the three months ended September 30, 2020 was attributable to a $1.0 million decrease in fair value of our embedded derivative liability, partially offset by significantly lower interest rates earned on investments. The decrease in other income (expense), net during the nine months ended September 30, 2020 was attributable to a $0.8 million increase in fair value of our embedded derivative liability as well as significantly lower interest rates earned on investments.

Liquidity and Capital Resources

Overview

As of September 30, 2020, we had cash, cash equivalents and short-term investments of $130.7 million, compared to cash, cash equivalents and short-term investments of $90.6 million as of December 31, 2019.

Cash Flows

	Nine Months Ended September 30,	
	2020	2019
(in thousands)		
Net cash provided by (used in):		
Operating activities	$ (25,054)	$ (19,958)
Investing activities	(4,653)	11,009
Financing activities	65,946	9,839
Net increase in cash and cash equivalents	$ 36,239	$ 890

Net Cash Used in Operating Activities

During the nine months ended September 30, 2020, net cash used in operating activities was $25.1 million, consisting primarily of a net loss of $52.1 million, offset by a decrease in net operating assets of $11.1 million and non-cash charges of $15.9 million. The net loss is primarily attributable to the ongoing funding of our sales, marketing and product development activities in order to attain future growth. The non-cash charges primarily consisted of stock-based compensation expense, change in fair value of embedded derivatives, and depreciation and amortization expense. The decrease in net operating assets is primarily attributable to a decrease in accounts receivable due to collections and a decrease in inventory due to the temporary suspension of our manufacturing activities. The decrease was partially offset by a decrease in accrued compensation due to the payout of annual corporate bonuses.

During the nine months ended September 30, 2019, net cash used in operating activities was $20.0 million, consisting primarily of a net loss of $35.0 million and an increase in net operating assets of $1.3 million, partially offset by non-cash charges of $16.3 million. The cash used in operations was primarily due 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 and depreciation and amortization. The contribution to operating cash flow from the change in net operating assets is primarily due to a reduction of accounts receivable, partially offset by an increase in inventory, prepaid expenses and other assets, and a decrease in other liabilities and accounts payable.

Net Cash Provided by (Used in) Investing Activities

During the nine months ended September 30, 2020, net cash used in investing activities was $4.7 million, consisting of net purchases of short-term investments of $38.7 million and purchases of property and equipment of $0.7 million, partially offset by proceeds from the sale of short-term investments of $34.7 million.

During the nine months ended September 30, 2019, net cash provided by investing activities was $11.0 million, consisting of net maturities of short-term investments, of $13.6 million, partially offset by purchases of property and equipment of $2.6 million.

Net Cash Provided by Financing Activities

During the nine months ended September 30, 2020, net cash provided by financing activities was $65.9 million, consisting of net proceeds from the issuance of convertible debt of $61.8 million and $4.1 million of net proceeds from common stock upon exercises of employee stock options and purchases under our employee stock purchase plan.

During the nine months ended September 30, 2019, net cash provided by financing activities was $9.8 million, consisting of net proceeds from the issuance of common stock upon exercises of employee stock options and purchases under our employee stock purchase plan.

Liquidity

We believe that our existing cash, cash equivalents and short-term investments as of September 30, 2020, will be sufficient to fund our working capital needs, capital expenditures, payments associated with the Fiagon acquisition, interest payments on long-term debt and lease arrangements through 2022. However, as a result of the COVID-19 pandemic, our rate of cash consumption compared to the prior year has increased as a result of decreased revenues, and may continue to do so. Also, in response to the COVID-19 pandemic, we took pre-emptive actions to curtail spending and to reduce the use of cash as revenues are and will continue to be materially impacted. These cost reduction actions included a) furloughing and reducing our workforce by approximately 25%, b) substantially reducing new hiring, c) suspending near-term production in the second quarter of 2020, d) reducing discretionary operating expenses and capital expenditures, and e) delaying clinical research projects. In total, these cost reduction activities were expected to yield $40.0 million in cash savings; however, higher revenues and costs associated with those higher revenues are expected to result in lower savings as well as a lower rate of cash use in operations than previously expected. In addition, during the second quarter of 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 in 2025. The net proceeds from the offering were $61.8 million after deducting the issuance costs payable by us. Through the third quarter, we have realized substantial savings and revenues have grown at a higher rate than was expected when the cost reduction actions were taken. As a result, cash was used in operations during the second and third quarters at a lower rate than expected and is expected to remain at a reduced level for the remainder of the year, including impacts from the acquisition of Fiagon.

Under the terms of the Purchase Agreement for the acquisition of Fiagon, we made an initial €15.0 million ($17.5 million) payment upon closing in October 2020 and will make €15.0 million annual payments for each of the subsequent three years. We also placed €15.0 million ($17.5 million) in escrow with the seller as beneficiary.

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. 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 September 30, 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

On May 11, 2020, we entered into a facility agreement with Deerfield Partners L.P. (“Deerfield”) providing for the issuance and sale by our company to Deerfield of $65.0 million of principal amount of 4.0% unsecured senior convertible notes

(the “Convertible Notes”). The Convertible Notes will mature on May 9, 2025 unless earlier converted or redeemed and are convertible into shares or our company’s common stock. 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. Apart from this transaction, our contractual obligations as of September 30, 2020, have not materially changed outside the ordinary course of business from December 31, 2019.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our exposure to market risk as of September 30, 2020, has not materially changed from the disclosures included in our Annual Report on Form 10-K for the year ended December 31, 2019, except as follows:

Interest Rate Risk

We are exposed to market risk for changes in interest rates applicable to the $65.0 million of principal amount of Convertible Notes, bearing interest at 4.0% per annum with interest payable quarterly. The Convertible Notes will mature on May 9, 2025, unless earlier converted or redeemed in accordance with their terms. As of September 30, 2020, the entire principal amount was outstanding as well as $0.7 million in accrued interest. For our Convertible Notes, any changes in market interest rates will generally affect the fair value of the instrument, but not our earnings or cash flows.

Foreign Currency Risk

The majority of our revenue, expenses, and capital expenditures are transacted in U.S. dollars. However, our operating results are exposed to foreign currency risk, in particular the Euro, due to our acquisition of Fiagon. Furthermore, our financial position and operating results will be exposed to foreign currency risk as a result of consolidating Fiagon's balance sheet and operating results. To mitigate these risks, we may enter into foreign exchange forward contracts or other hedging arrangements to reduce the risk that our earnings and cash flows will be adversely affected by changes in exchange rates.

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 September 30, 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 September 30, 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 September 30, 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

The information included in Note 9 to the condensed consolidated financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q is incorporated herein by reference.

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 suspended performing elective procedures, which is where our products are utilized, although we are experiencing a partial lifting of these suspensions. 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. Although certain measures have been relaxed, increases in the rate of COVID-19 cases may cause a tightening of these restrictions. 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, including the risk of further potential outbreaks of COVID-19 cases. 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.

In addition to the above, the effects of the COVID-19 pandemic may exacerbate the effects of many of the risks discussed below.

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 $52.1 million for the nine months ended September 30, 2020, and $43.0 million and $22.9 million for the years ended December 31, 2019 and 2018, respectively. As of September 30, 2020, we had an accumulated deficit of $282.9 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 CMS assigned upper airway procedures, which includes sinus surgery, to a comprehensive Ambulatory Payment Classification (“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, the 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. The 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. Subsequently, the CMS approved SINUVA for transitional pass-through payment status for reimbursement under the Hospital

Outpatient Prospective Payment System ("OPPS") and ASC Payment System. The new C code described as "C9122 Mometasone furoate, sinus implant, 10 micrograms", took effect on July 1, 2020. Pass-Through status lasts for three years. We have limited experience with these reimbursements and do not know how effective these approaches 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 codes are 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 included in our labeling. 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 our product labeling. 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 functional endoscopic sinus surgery ("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 ("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:

- the effects and duration of the COVID-19 pandemic;
- 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 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 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 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 are planning to conduct our pivotal 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. Under the formal withdrawal arrangements between the UK and the EU, the parties had until June 30, 2020 to agree to extend the Transition Period if required. No such extension was agreed upon prior to such date. No agreement has yet been reached between the UK and the EU and it may be the case that no formal customs and trading agreement will be reached prior to the expiry of the Transition Period on December 31, 2020.

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, such as our acquisition of Fiagon.

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, such as our acquisition of Fiagon, 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.

We may incur losses associated with currency fluctuations and may not be able to effectively hedge our exposure.

Our operating results are subject to volatility due to fluctuations in foreign currency exchange rates. Our primary exposure to fluctuations in foreign currency exchange rates relate to our acquisition of Fiagon. The strengthening of the Euro relative to the U.S. dollar could adversely affect our foreign-currency-denominated purchase obligation. To the extent that transactions by Fiagon are denominated in currencies other than the Euro, we bear the risk that fluctuations in the exchange rates of the Euro in relation to other currencies could decrease our revenue or increase our costs and expenses, therefore having an adverse effect on our future results of operations. We may enter into hedging transactions to reduce the impact of foreign currency fluctuations. If we use hedging transactions to reduce our risks in this area, the availability and effectiveness of these hedging transactions may be limited and we may not be able to successfully hedge our exposure. See “Item 3. Quantitative and Qualitative Disclosures about Market Risk” for additional discussion regarding the impact of foreign currency risk.

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 (“PMA”) and New Drug Application (“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 (“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 the CMS of our current average manufacturer price, ("AMP"), and best price, ("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 the 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 the CMS to terminate our Medicaid drug rebate agreement, pursuant to which we participate in the Medicaid program. In the event that the 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 ("VA"), Federal Supply Schedule ("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 ("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 ("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 ("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 (“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 (“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 the 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:

- imposed an annual excise tax of 2.3% on any entity that manufactures or imports medical devices offered for sale in the United States, which was permanently eliminated, effective January 1, 2020, by the 2020 federal spending package;
- established 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
- implemented 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.

There remain executive, 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 several executive orders and other directives designed to eliminate, circumvent, or loosen certain requirements, or implementation of 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, several bills affecting the implementation of certain taxes under the Affordable Care Act have been signed into law. For example, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the Affordable Care Act's mandated "Cadillac" tax on certain high cost employer-sponsored insurance plans, and effective January 1, 2020, also eliminates the health insurer tax. 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 ("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". Further, on December 14, 2018, a United States District Court Judge in the Northern District of Texas rules that the Affordable Care Act is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Cuts and Jobs Act of 2017. Additionally, on December 18, 2019, the United States Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the Affordable Care Act are invalid as well. On March 2, 2020, the United States Supreme Court granted the petitions for writs of certiorari to review this case. Accordingly, the ultimate content, timing or effect of any healthcare reform legislation on the United States healthcare industry is unclear.

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 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 2030, unless additional congressional action is taken. However, the Medicare sequester reductions under the Budget Control Act of 2011 will be suspended from May 1, 2020 through December 31, 2020 due to the COVID-19 pandemic. 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. Further, it is possible that additional governmental action is taken in response to the COVID-19 pandemic.

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 ("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 (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 ("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, such as our acquisition of Fiagon, 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 fund our working capital needs, capital expenditures, payments associated with the Fiagon acquisition, interest payments on long-term debt and lease arrangements 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:

- the duration and severity of the COVID-19 pandemic;
- 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.

Under legislation enacted in 2017, as modified by legislation enacted in 2020, unused U.S. federal net operating losses ("NOLs") generated in tax years beginning after December 31, 2017, will not expire and may be carried forward indefinitely, but the deductibility of such federal net operating losses in taxable years beginning after December 31, 2020, is limited to 80% of taxable income. In addition, 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. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, including a recent California franchise tax law change limiting the usability of California state NOLs to offset taxable income in tax years beginning after 2019 and before 2023.

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 ("FASB") issues new accounting principles. 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 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:

- the duration and severity of the COVID-19 pandemic;
- 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, resulting 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 (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.

Our certificate of incorporation provides that the Court of Chancery of the State of Delaware and the federal district courts of the United States of America will be the exclusive forums for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, or employees.

Our certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for the following types of actions or proceedings under Delaware statutory or common law:

- any derivative action or proceeding brought on our behalf;
- any action asserting a breach of fiduciary duty;
- any action asserting a claim against us arising under the Delaware General Corporation Law; and
- any action asserting a claim against us that is governed by the internal-affairs doctrine.

This provision would not apply to suits brought to enforce a duty or liability created by the Securities Exchange Act of 1934, as amended. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims.

To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our certificate of incorporation provides that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act of 1933, as amended. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated certificate of incorporation. This may require significant additional costs associated with resolving such action in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions.

These exclusive forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, or other employees, which may discourage lawsuits against us and our directors, officers and other employees. If a court were to find either exclusive-forum provision in our certificate of incorporation to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with resolving the dispute in other jurisdictions, all of which could seriously harm our business.

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	Certificate of Designation of Preferences, Rights and Limitations of Series DF-1 Convertible Preferred Stock	8-K	001-36545	3.1	5/11/2020
3.3	Certificate of Amendment to Amended and Restated Certificate of Incorporation	8-K	001-36545	3.1	6/15/2020
3.4	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 through 3.4				
10.1	Fiagon AG Medical Technologies Sale and Purchase Agreement, dated as of October 2, 2020.				
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).				

* 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: November 2, 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)

Exhibit 10.1

SALE AND PURCHASE AGREEMENT

relating to

the acquisition of all shares in

Fiagon AG Medical Technologies

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Table of Definitions

THIS SALE AND PURCHASE AGREEMENT, is made on September 15, 2020 (the "**Agreement**" by and among

(1) **Dr. Dirk Mucha**,

resident at [____]

(2) **High-Tech Gründerfonds GmbH & Co. KG**,

with seat in Bonn, business address at Schlegelstraße 2, 53113 Bonn, Germany, registered with the commercial register of the local court of Bonn under docket no. HRA 6256

(3) **Prof. Dr. Kai Desinger**,

resident at [____]

(4) **V+ GmbH & Co. Fonds 3 KG**,

with seat in Landshut, business address at Neustadt 444, 84028 Landshut, Germany, registered with the commercial register of the local court of Landshut under docket no. HRA 9976

(5) **Björn Hähnlein**,

resident at [____]

(6) **UNU Gesellschaft für Unternehmensnachfolge und Unternehmensführung GmbH**,

with seat in Berlin, business address at Bischweilerstraße 17, 14163 Berlin, Germany, registered with the commercial register of the local court of Charlottenburg under docket no. HRB 94400 B

(7) **Brandenburg Kapital GmbH**,

with seat in Potsdam, business address at Babelsberger Straße 21, 14473 Potsdam, Germany, registered with the commercial register of the local court of Potsdam under docket no. HRB 14869 P

(8) **Dr. Clemens Scholz**,

resident at [____]

(9) **P&T International Ltd.**,

with business address at Palm Grove House, P.O. Box 438, Road Town, Tortola, British Virgin Islands, registered with Register of Companies of the British Virgin Islands under no. BVI 585457

(10) **Mon Repos Vermögensverwaltung GmbH**,

with seat in Berlin, business address at Waldowallee 74, 10318 Berlin, Germany, registered with the commercial register of the local court of Charlottenburg under docket no. HRB 76906 B

(11) **Unternehmensbeteiligungsgesellschaft der Sparkassen des Landes Brandenburg mbH**,

with seat in Potsdam, business address at Saarmunder Straße 61, 14478 Potsdam, Germany, registered with the commercial register of the local court of Potsdam under docket no. HRB 15574 P

(12) **Dr. Adriaan Hart de Ruijter**,

resident at [____]

(13) **aurea invest holding group ag**,

with business address at Alpenquai 36, CH-6005 Luzern, Switzerland, registered with the commercial register of the canton of Luzern under No. CH-100.3.792.143-5

(14) **Prof. Dr. Marc Bloching**,

resident at [____]

(15) **Manfred Gottlieb**,

resident at [____]

(16) **Dr. Lucyna Dymek**,

resident at [____]

(17) **Alkadaro & Barome LLP**,

with business address at Office 3.11, Nwms Center, 3rd Floor, 31 Southampton Row, London WC1B 5HJ, United Kingdom, registered with the Companies House of England and Wales under registration number OC403466

(18) **Patrick Henkel**,

resident at [____]

(19) **Matt Jones**,

resident at [____]

(20) **Tayfun Sen**,

resident at [____]

(21) **Sino-German Alpha Holding Co. Limited**,

with business address at Sertus Chambers, P.O. Box 2547, Cassia Court, Camana Bay, Grand Cayman, Cayman Islands, registered with the Register of Companies of Cayman Islands under company number 304110

(22) **Dmitry Obynochnyy**,

resident at [____]

(23) **Sergio Mondlak Krajmalnik**,

resident at [____]

(24) **German Startups Group VC GmbH**,

with seat in Frankfurt am Main, business address at Platz der Luftbrücke 4-6, 12101 Berlin, Germany, registered with the commercial register of the local court of Frankfurt am Main under docket no. HRB 119460

(25) **NOS Neuro Orthopaedics Surgeries**,

with seat in Rua Dr. Borman 43, salas 601-604, CEP 24020-320-Centro-Niterói, Rio de Janeiro State, Brazil, CNPJ: 05.827.947.0001/94, Ins. Est. : 77592350

(26) **Dr. Friedrich Jacobi**,

resident at [____]

(27) **Chad Smith**,

resident at [____]

(28) **Nicholas Norman**,

resident at [____]

(29) **Maximilian Snyder**,

resident at [____]

(30) **Martin Back**,

resident at [____]

– the natural and legal persons mentioned above under numbers (1) through (30) are hereinafter collectively also referred to as the "**Sellers**" and each a "**Seller**" –

and

(31) **Fiagon AG Medical Technologies**,

with seat in Hennigsdorf, business address at Neuendorfstraße 23b, 16761 Hennigsdorf, Germany, registered in the commercial register of the local court of Neuruppin under docket no. HRB 10738 NP (the "**Company**" or "**Fiagon AG**") however, only for those sections in which a specific obligation of Fiagon AG is explicitly stated

as well as

(32) **Intersect ENT, Inc.,**

with business address at 1555 Adams Drive, Menlo Park, CA 94025, USA, registered with the Delaware Department of State, Division of Corporations under file number 3712091

– "**Intersect**" or the "**Purchaser**" and the Purchaser together with Fiagon AG and the Sellers, collectively the "**Parties**" and individually a "**Party**" –.

PREAMBLE

(A) Fiagon AG with seat in Hennigsdorf, business address at Neuendorfstraße 23b, 16761 Hennigsdorf, Germany, is a stock corporation (*Aktiengesellschaft*) duly incorporated and existing under the laws of the Federal Republic of Germany. The business of Fiagon AG, directly or through its subsidiaries, is described in section 2 (1) of its articles of association as research, development, industrial production and marketing of navigational systems, robotics and computer based planning and manufacturing processes, including the development of software in fields of medical and dental technology, measurement and control technology and the industrial measurement technology (the "**Business**").

(B) Fiagon AG was founded on September 9, 2013 and is registered, since April 1, 2014, in the commercial register (*Handelsregister*) of the local court (*Amtsgericht*) of Neuruppin under docket no. HRB 10738 NP, having a registered nominal share capital of currently EUR 126,788.00, consisting of 126,788 non-par-value shares (subject to Section 1.4 the "**Shares**"). The Shares are issued as registered shares, the transfer of which generally requires the prior approval by the Company to become legally valid (*vinkulierte Namensaktien*).

(C) Fiagon GmbH is a company with limited liability duly incorporated and existing under the laws of the Federal Republic of Germany ("**Fiagon GmbH**"). Fiagon GmbH is registered with the commercial register of the local court of Neuruppin under HRB 9665NP, having a registered share capital of EUR 85,116.00.

(D) Fiagon NA Corporation is a corporation duly incorporated and existing under the laws of the State of Delaware, USA ("**Fiagon US**", Fiagon GmbH and Fiagon US together the "**Subsidiaries**", and the Subsidiaries together with Fiagon AG the "**Group Companies**").

(E) The Company's registered share capital is currently held by the Sellers as set out in Annex (E)-1, while the Company owns directly all the shares in the Subsidiaries. Annex (E)-2 includes a preliminary schedule, which will be updated by the Sellers, in consultation with the Purchaser, as soon as the Purchas Price has been finally determined in accordance with Section 1.7, detailing how the Purchase Price is to be split among the Sellers, including each payment of the First Instalment, the Second Instalment, the Third Instalment and the Fourth Instalment as well as a percentage for all other payments as possible payment obligations of the Sellers, it being understood that Purchaser fulfills its payment obligations vis-à-vis each Seller by payment into the Sellers' Bank Account according to Section 7.3.2.

(F) Fiagon AG has established an employee stock option program (the "**ESOP**") through which members of the management board and selected employees (the "**ESOP Beneficiaries**") can be granted stock options. As of the date hereof, under the ESOP, 1,141 stock options have been granted to ESOP Beneficiaries and will be settled as provided for in Section 2.3.10 of this Agreement, whereas all unallocated options have been cancelled. Annex (F) sets forth each grant of stock options to the ESOP Beneficiaries, the date of grant, the vesting associated with each such stock option, and the exercise price for each such stock option and the amount to be paid in respect of each such stock option upon the extinguishment thereof in connection with the Transaction (as defined below).

(G) Purchaser wishes to acquire, and Sellers are willing to sell and transfer, all Shares representing 100 % of the registered share capital of the Company for the price, on the terms and subject to the conditions set forth herein (the "**Transaction**").

(H) On or about the date hereof, the Sellers Dr. Dirk Mucha, Prof. Dr. Kai Desinger, Sven Schmöle and Matt Jones have entered into amendment agreements to their service agreements (the "**New Service Amendments**").

NOW, THEREFORE, the Parties hereto agree as follows:

1. SALE AND PURCHASE OF THE SHARES

1.1 Defined Terms. In this Agreement, the following definitions are used:

1.1.1 "**Affiliate**" shall mean, (a) with respect to a corporation or an individual, any Person directly or indirectly controlling, controlled by, or under common control with, such Person; provided that, for the purposes of this definition, "control" (including, with correlative meanings, the terms "controlled by" and "under common control with"), as used with respect to any Person, means the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of such Person, whether through the ownership of voting securities, by contract or otherwise, and (b) with respect to an individual, that individual's spouse or cohabitant, any parent of that individual or of that individual's spouse or cohabitant, any brother or brother-in-law or sister or sister-in-law of that individual or of that individual's spouse or cohabitant, and any child or step-child, natural or adopted, of that individual or of his spouse or cohabitant.

1.1.2 "**Best Knowledge of the Sellers**" shall include all facts and circumstances which Dr. Dirk Mucha, Prof. Dr. Kai Desinger and Matt Jones actually knew (*positive Kenntnis*) as of the date hereof or should have known as director (*Vorstand* or *Geschäftsführer*) of the respective Group Company applying the standard of care owed according to Section 93 of German Stock Corporation Act (*Aktiengesetz* ("**AktG**")) and Section 43 of German Limited Liability Companies Act (*Gesetz betreffend die Gesellschaften mit beschränkter Haftung* ("**GmbHG**")).

1.1.3 "**Business Day**" shall mean a day (other than a Saturday or Sunday) when banks are open for ordinary banking business in Berlin, Germany and San Francisco, California, USA.

1.1.4 "**Agreement**" shall mean this Sale and Purchase Agreement including its annexes.

1.1.5 "**Governmental Entity**" means any legislative, administrative, executive or governmental authority of any nature (including any governmental agency, branch, department, official, or entity and any court or tribunal), judicial unit of any governmental entity (multinational, supranational national, federal, regional, state, provincial, municipal or local), or any department, ministry, undersecretariat, division, commission, court, board, agency, bureau, tribunal, official or other body exercising or entitled to exercise any regulatory, administrative, executive, legislative, police, judicial or taxation authority or power of any nature thereof.

1.1.6 "**Person**" shall mean an individual, a partnership, a joint venture, a joint stock corporation, a limited liability company, a limited liability partnership, a trust, an incorporated organization and a Governmental Entity.

1.2 Approval of Transaction. The Sellers, in their capacity as all shareholders of the Company, approve the sale and transfer of the Shares. Each Seller waives any pre-emptive right, pledge, other encumbrance and any other right relating to the Shares or rights regarding other (new) shares to be issued by the Company which the Seller may have under the shareholders' agreement dated April 27, 2018 (the "**Shareholders' Agreement**"), provided, however, that this waiver does not affect the provisions therein regarding the distribution of the sales proceeds. The Company also approved the sale and transfer of the Shares by way of resolution of its supervisory board, a copy of which is attached as Annex 1.2.

1.3 The Company. Fiagon AG Medical Technologies is a stock corporation (*Aktiengesellschaft*) duly incorporated and existing under the laws of the Federal Republic of Germany, with seat in Hennigsdorf, business address at Neuendorfstraße 23b, 16761 Hennigsdorf, Germany, registered with the commercial register (*Handelsregister*) of the local court (*Amtsgericht*) of Neuruppin under docket no. HRB 10738 NP.

1.4 Registered Share Capital. The registered share capital (*Grundkapital*) of the Company amounts to EUR 126,788.00 and is divided into 126,788 registered shares, which are held as set forth in Annex (E)-1. In this Agreement, all shares, which the Sellers hold in the Company, are collectively

referred to as the Shares, regardless of whether the number, nominal amounts and consecutive numbering of the shares or the registered share capital of the Company corresponds the details in the table above.

1.5 Subsidiaries. The Company holds the entire share capital of the Subsidiaries. The shares or equity interests held by the Company in a Group Company are herein referred to collectively as the "**Subsidiaries Shares**". The Company does not own, directly or indirectly, any other shareholding in any other legal entities or other Person.

1.6 Sale and Transfer of the Shares. Upon the terms of this Agreement each Seller hereby agrees to sell and, subject to the condition precedent of the receipt of the First Instalment on the Sellers' Bank Account as well as the Closing Conditions (as defined below) being either fulfilled or its fulfillment being waived by the Party entitled to such waiver, assign (*tritt ab*) to Purchaser, and upon the terms of this Agreement as well as the Closing Conditions being either fulfilled or its fulfillment being waived by the Party entitled to such waiver, Purchaser hereby agrees to purchase and accept (*nimmt an*) such assignments from the Sellers of the respective Shares. The respective Shares are being sold and transferred together with all rights attaching to them on the Closing Date including the right to receive dividends, distributions or any return of capital declared, made or paid on or after the Closing Date.

1.7 Purchase Price for the Shares.

1.7.1 The aggregate purchase price for the Shares (the "**Purchase Price**") shall be an amount to be calculated and determined as follows on the basis of the Effective Date Financial Statements and to be set forth, together with the Purchase Price resulting therefrom, in the Purchase Price Determination Statement included therein:

(i) A fixed amount of EUR 60,000,000.00 (in words: *Euro sixty million*) (the "**Base Amount**"),

(ii) minus the consolidated Financial Debt of the Group Companies as of the Effective Date (the "**Effective Date Financial Debt**"),

(iii) plus the consolidated Cash of the Group Companies as of the Effective Date (the "**Effective Date Cash**"),

(iv) minus further Company Transaction Expenses as of the Effective Date except those which are paid by the Sellers out of the Purchase Price as listed in Annex 1.7,

(v) minus/plus the amount by which the consolidated Net Working Capital of the Group Companies as of the Effective Date (the "**Effective Date Net Working Capital**") falls short of or exceeds EUR 0 (in words: *Euro zero*) (the "**Effective Date Working Capital Deviation**").

"**Effective Date**" shall mean 11:59 pm German time on the day prior to the Closing Date (German time)

"**Financial Debt**" shall mean, with respect to the Group Companies, the sum of

(a) all debt owed to banks (*Kreditinstitute*) and other third party lenders (including, without limitation, loans, overdrafts, bonds, promissory notes or any other securities, letters of credit, performance bonds, surety bonds, bills of exchange and checks, and interest accrued as of the Effective Date and any costs, prepayment compensation or penalties resulting from the repayment of such debt), including any amounts outstanding under debt subject to the U.S. CARES Act Paycheck Protection Program, but not including debt owing from one Group Company to another Group Company or any of such amounts paid, reimbursed or injected by the Sellers out of the Purchase Price as listed on Annex 1.7,

(b) (to the extent not covered under (a) and except for those which are paid, reimbursed or injected to the Company's free capital reserves (sec. 272 (2) no. 4 German Commercial Code – *Handelsgesetzbuch*, "**HGB**") by the Sellers out of the Purchase Price as listed in Annex 1.7) all

payment obligations to the Sellers, the Sellers' Affiliates, the ESOP Beneficiaries or the employees of the Group Companies, including such obligations becoming payable (whether immediately, in the future or contingent on other factors) subject to the consummation of the Closing (e.g. Closing bonus payments, change of control payments, ESOP payments),

(c) the net present value of all obligations of the Group Companies as lessee under any financial leases that have been or, in accordance with German GAAP, would be required to be reflected as finance lease liabilities in German GAAP-based financial statements,

(d) to the extent that these have not been allocated as accruals within the Net Working Capital, all obligations for deferred purchase price payments or purchase price instalments or earnout or milestone type payment obligations relating to the acquisition of assets (*Anlagevermögen*),

(e) all obligations for purchase price payments relating to the acquisition of any other assets, in each case provided that the payment terms have been extended beyond the payment terms customary in the industry or which in each case have remained outstanding as of the Effective Date for more than 90 days,

(f) to the extent that these are not part of other accruals within the Net Working Capital, the amount of accruals and liabilities for any taxes of the Group Companies (for the avoidance of doubt including any payroll tax and social security contribution liability due to the termination of the ESOP),

(g) any other liabilities comparable with liabilities to banks or other forms of financing, whether or not interest bearing,

(h) any dividends payable to the Sellers or any of the Sellers' Affiliates,

(i) any interest rate, currency or other hedging or derivative instruments,

(j) any other payments by Group Companies to managers/employees/advisors in connection with the transaction except those which are paid by the Sellers out of the Purchase Price as listed in Annex 1.7, and

(k) to the extent that these are not part of other accruals within the Net Working Capital, any accruals for any of the above liabilities;

in each case except for those items of Financial Debt which are paid by the Sellers out of the Purchase Price as listed in Annex 1.7.

(iv) "**Cash**" shall mean cash and cash equivalents (convertible to cash in less than 30 days) within the meaning of Section 266 para. 2 lit. B IV HGB, after taking into account outstanding checks and payments in transit, minus any cash that cannot be readily used by the Group Companies, including as a result of any legal obligations, any exchange control regulations and any limitations under corporate, insolvency and similar laws (trapped cash) (collectively, "**Restricted Cash**").

(v) "**Net Working Capital**" shall mean, with respect to the Group Companies, the sum of

(a) inventories (*Vorräte*; Section 266 para. 2 lit. B I HGB),

(b) trade accounts receivable (*Forderungen aus Lieferungen und Leistungen*; Section 266 para. 2 lit. B II No. 1 HGB),

(c) accounts receivable from the Sellers or the Sellers' Affiliates (*Forderungen gegen verbundene Unternehmen*; Section 266 para. 2 lit. B II No. 2 HGB), to the extent that they relate to the supply of goods and services,

(d) accounts receivable from individual persons or legal entities which hold an interest in the Group Companies or in which the Group Companies hold an interest, other than the Sellers or the

Sellers' Affiliates (*Forderungen gegen Unternehmen, mit denen ein Beteiligungsverhältnis besteht*; Section 266 para. 2 lit. B II No. 3 HGB), to the extent that they relate to the supply of goods and services,

(e) other current assets (*sonstige Vermögensgegenstände*; Section 266 para. 2 lit. B II No. 4 HGB), and

(f) prepaid expenses (*aktive Rechnungsabgrenzungsposten*; Section 266 para. 2 lit. C HGB),

minus

(g) prepayments received (*erhaltene Anzahlungen auf Bestellungen*; Section 266 para. 3 lit. C No. 3 HGB),

(h) trade accounts payable (*Verbindlichkeiten aus Lieferungen und Leistungen*; Section 266 para. 3 lit. C No. 4 HGB),

(i) accounts payable to the Sellers or the Sellers' Affiliates (*Verbindlichkeiten gegenüber verbundenen Unternehmen*; Section 266 para. 3 lit. C No. 6 HGB), to the extent they relate to the supply of goods and services,

(j) accounts payable to individual persons or legal entities which hold an interest in the Group Companies or in which the Group Companies hold an interest, other than the Sellers or the Sellers' Affiliates (*Verbindlichkeiten gegenüber Unternehmen, mit denen ein Beteiligungsverhältnis besteht*; Section 266 para. 3 lit. C No. 7 HGB), to the extent they relate to the supply of goods and services,

(k) the aggregate amount of accruals (*Rückstellungen*; Section 266 para. 3 lit. B HGB),

(l) the aggregate amount of other liabilities (*sonstige Verbindlichkeiten*; Section 266 para. 3 lit. C No. 8 HGB), and

(m) deferred income (*passive Rechnungsabgrenzungsposten*; Section 266 para. 3 lit. D HGB),

in each case unless already part of Financial Debt or Company Transaction Expenses. For the avoidance of doubt, Net Working Capital does not include any Cash or Restricted Cash.

(vi) "**Company Transaction Expenses**" means all fees and expenses incurred or payable by the Company or any Group Company at or prior to the Closing (or payable after the Closing to the extent incurred by the Company or a Group Company pursuant to agreements or contracts made prior to the Closing) in connection with the preparation, negotiation and execution of this Agreement and the other documents referred to herein, and the performance and consummation of the Transaction, in each case, solely to the extent that such fees and expenses remain unpaid as of the Effective Date, including any liabilities of the Sellers (to the extent payable by the Company, or any Group Company to any legal counsel, financial or accounting advisor, broker, finder or investment banker with respect to the Transactions) and also only to the extent such expenses are not already included in the Financial Debt or otherwise accrued for in Net Working Capital.

1.7.2 The Sellers undertake vis-à-vis the Purchaser to pay the items as set forth in Annex 1.7 out of the Purchase Price and, as the case may be, to provide the Company with respective funding, and the Purchaser agrees that the items set forth in Annex 1.7 shall not be deducted, neither directly nor indirectly as part of other items, for the purpose of the calculation and determination of the Purchase Price as set forth in this Agreement. The Sellers will provide the Purchaser with copies of the respective payment instructions demonstrating payment of the items as set forth in Annex 1.7. In the case that items set forth in Annex 1.7 have not been paid by the Sellers, the Sellers shall indemnify and hold harmless the Company on a Euro-for-Euro basis, without regard to any De Minimis Amount, baskets or any other limitations in this Agreement from the consequences of not having paid such items set forth in Annex 1.7. The Purchaser shall be entitled to deduct the full amount of any Seller Receivable (as defined

below) that has not been repaid by the relevant Seller prior to the payment of the Second Instalment from the amount of the Second Instalment otherwise payable to such Seller. Concurrently with the making of such deduction, the relevant Group Company will waive any claim against the relevant Seller for such amount.

1.7.3 All Financial Debt in the form of indebtedness for borrowed money, including debt subject to the U.S. CARES Act Paycheck Protection Program, will be repaid in full by the appropriate Group Company on or prior to the Closing Date. Such repayment shall be made out of the Group Companies Cash on hand at the time of payment. The Effective Date Financial Statements will be prepared reflecting such repayment. To the extent reasonably requested by the Purchaser, the Sellers shall provide the Purchaser with customary payoff letters setting forth the amounts to be paid by the Sellers in respect of amounts owing by the Group Companies for borrowed money as of the time of Closing.

1.8 Payment of the Purchase Price; Other Rules regarding the Purchase Price. The Purchaser shall pay the Purchase Price in four instalments as forth below:

1.8.1 The amount of EUR 15,000,000.00 (in words: *Euro fifteen million*) of the Purchase Price (the "**First Instalment**") shall be due and payable on the Closing Date, without any deduction (e.g. bank charges, fees etc.) by (or on behalf of) the Purchaser by wire transfer to the Sellers' Bank Account in immediately available funds.

The Purchase Price shall be considered finally determined once the Effective Date Financial Statements have become final and binding upon the Parties (see Section 1.11). If the Purchase Price so determined exceeds the Base Amount, the Purchaser shall pay to the Sellers' Bank Account an amount equal to the excess by adding it to the Second Instalment (as defined below). If the Purchase Price so determined falls short of the Base Amount, the Purchaser shall be entitled to offset such amount equal to the shortfall against the Second Instalment owed to the Sellers (jointly).

1.8.2 The amount of EUR 15,000,000.00 (in words: *Euro fifteen million*) of the Purchase Price (subject to adjustment in accordance with the second paragraph of Section 1.8.1 above) (the "**Second Instalment**") shall be due and payable on the first anniversary of the First Instalment Date (the "**Second Instalment Date**"), without any deduction (e.g. bank charges, fees etc.) by (or on behalf of) the Purchaser by wire transfer to the Sellers' Bank Account or such bank account as the Sellers shall have notified the Purchaser by not less than three Business Days prior written notice in immediately available funds;

1.8.3 The amount of EUR 15,000,000.00 (in words: *Euro fifteen million*) of the Purchase Price (the "**Third Instalment**") shall be due and payable on the second anniversary of the First Instalment Date (the "**Third Instalment Date**") without any deduction (e.g. bank charges, fees etc.) by (or on behalf of) the Purchaser by wire transfer to the Sellers' Bank Account or such bank account as the Sellers shall have notified the Purchaser by not less than three Business Days prior written notice in immediately available funds;

1.8.4 The amount of, EUR 15,000,000.00 (in words: *Euro fifteen million*) of the Purchase Price (the "**Fourth Instalment**") shall be due and payable on the third anniversary of the First Instalment Date (the "**Fourth Instalment Date**") without any deduction (e.g. bank charges, fees etc.) by (or on behalf of) the Purchaser by wire transfer to the Sellers' Bank Account or to such bank account as the Sellers shall have notified the Purchaser by not less than three Business Days prior written notice in immediately available funds. The period between the date hereof and the Fourth Instalment Date shall be the "**Payment Period**".

1.8.5 Subject to Section 1.10, if during the Payment Period, a sale of all or substantially all the assets of Intersect and its subsidiaries taken together or any merger, consolidation or acquisition in which Intersect is a constituent party, except any such merger, consolidation or acquisition involving Intersect in which the current shareholders of Intersect hold directly or indirectly at least 50% of the voting stock capital of Intersect or the combined company

immediately after consummation of the transaction (each a "**Change of Control**") is consummated, the portions of the Purchase Price that are unpaid at that point in time, shall become due and payable within one month after consummation of such Change of Control transaction. Purchaser shall promptly (and in any event within five (5) Business Days) provide notice to Sellers regarding Intersect's execution of definitive agreements contemplating such Change of Control transaction.

1.8.6 Any payment by the Sellers to the Purchaser under this Agreement for damages, indemnification or otherwise shall, to the extent consistent with applicable law, be treated by the Sellers and the Purchaser as a subsequent reduction of the Purchase Price.

1.8.7 The Parties assume that the sale and transfer of the Shares is either not subject to value added tax (*Umsatzsteuer* – "**VAT**") (*nicht steuerbar*) or is exempt from VAT (*nicht steuerpflichtig*). The Parties will treat the transactions accordingly in their VAT returns, if applicable. The Purchase Price is a net amount without VAT. The Sellers must not opt for VAT. If the competent Tax Authority presumes – against the common view of the Parties – on the basis of a tax assessment that the sale and transfer is subject to German VAT and that such transfer (without any Seller having opted for VAT) is not exempt from German VAT, the Purchaser will be required to pay German VAT in addition to the Purchase Price. This Section 1.8.7 applies *mutatis mutandis* to any other similar Taxes (such as sales taxes or transfer taxes) that may be levied on the transfer of the Shares in jurisdictions other than Germany.

1.8.8 If and to the extent that a withholding of income taxes or other Taxes (but excluding withholding of VAT or transfer taxes) is imposed on the Purchaser as a result of any payment made or to be made pursuant to this Section 1, the Purchaser shall make such deductions or withholdings as required. The Parties shall use reasonable efforts and cooperate in good faith to minimize any such taxes or to receive a refund of such taxes.

1.8.9 If and to the extent that any amounts under debt subject to the U.S. CARES Act Paycheck Protection Program that have been deducted from the Purchase Price or repaid at Sellers' expense or by a Group Company prior to, or at, Closing, are, for any reason whatsoever granted forgiveness, or repaid or reimbursed to Fiagon US, such amounts shall be paid to the Sellers with the Second Instalment, the Third Instalment or the Fourth Instalment, as the case may be.

1.9 Purchase Price Security. In order to secure the Sellers' claim for the payment of the Second Instalment, Third Instalment and Fourth Instalment of the Purchase Price during the Payment Period, prior to, or on the Closing Date:

(a) The Purchaser shall pay an amount of EUR 15,000,000.00 (in words: *Euro fifteen million*) in an escrow account (the "**Intersect Escrow Account**") managed by Silicon Valley Bank or one of its Affiliates (the "**Intersect Escrow Agent**"), and Sellers, represented by the Sellers' Representative, as well as Purchaser and the Intersect Escrow Agent shall enter into an escrow agreement, in form and substance reasonably satisfactory to the Purchaser and the Sellers (to be prepared and negotiated between the date hereof and the Closing) (the "**Intersect Escrow Agreement**"), setting forth the terms on which such Intersect Escrow Account will be administered, provided that such amount shall be released to the Sellers in case and to the extent (i) the Purchaser does not fulfill any of its payment obligations (including payments into the Claim Notice Escrow Account) with regard to the Second, Third or Fourth Instalment when those are due, subject to the right to set off and the obligation provided for in Section 1.10 and (ii) further provided, that such amount (or the remainder thereof) shall be released to the Purchaser after full payment of the Fourth Instalment or, at the discretion of the Purchaser, be released to the Sellers as payment on the Fourth Instalment. Intersect shall be responsible for the fees and costs under the Intersect Escrow Agreement;

(b) The Parties shall, subject to Section 4.5, enter into the share pledge agreement on the Closing Date, substantially in the form attached hereto as Annex 1.9(b) (the "**Share Pledge Agreement**"); and

(c) The Parties shall, subject to Section 4.5, enter into the pledge agreement regarding any Owned Intellectual Property Rights (as defined below) of a Group Company on the Closing Date for a period until the receipt of the Second Instalment and substantially in the form attached hereto as Annex 1.9(c) (the "**IP Pledge Agreement**"), provided, however, that if during such period Intersect transfers any Owned Intellectual Property Rights, Intersect shall inform the prospective assignee of such pledge.

1.10 Right to set off. If and to the extent that respective claims of the Purchaser (i) have been expressly acknowledged in writing by the Sellers (*schriftlich anerkannt*), (ii) are undisputed (*unbestritten*) or (iii) or have been awarded to the Purchaser by a competent court without further recourse (*rechtskräftig*) ("**Court Decision**"), the Purchaser shall be entitled to set off (*aufrechnen*) against the Second Instalment, the Third Instalment or the Fourth Instalment an amount of up to the Maximum Amount (as defined below), i.e. EUR 12,000,000.00 (in words: *Euro twelve million*), with

(a) claims of the Purchaser against the Sellers resulting from a breach of any of the Guarantees given by the Sellers pursuant to Section 2.1 to 2.19 in relation with Section 5 (Remedies);

(b) claims of the Purchaser against the Sellers resulting from a claim for indemnification resulting from Section 6 (Tax Indemnity).

If Purchaser at least 5 Business Days prior to the Second Instalment, the Third Instalment or the Fourth Instalment has sent to the Sellers a claim notice ("**Claim Notice**") with which Purchaser alleges to have a claim against the Sellers or an individual Seller, subject to the limitations set forth in Section 5 (Remedies) hereof, (i) only the respective instalment less the Claim Amount shall be paid to the Sellers and (ii) the Claim Amount shall not be paid to the Sellers but into an escrow account maintained by FGS Steuerberatungsgesellschaft mbH, with business address c/o Flick Gocke Schaumburg, Rae, StB, WP Partnerschaft mbB, Unter den Linden 10, 10117 Berlin, Germany (the "**Claim Notice Escrow Account**") under an escrow agreement, substantially in the form attached hereto as Annex 1.10 (the "**Claim Notice Escrow Agreement**"), to be entered at the time of the deposit. The Claim Notice shall describe the claim and state the amount of the claim in a Euro amount (the "**Claim Amount**"), to the extent determinable. If the amount of the claim is not determinable at the time of submission, the Purchaser shall provide its best estimate of the amount of the claim. If and to the extent that respective claims of the Purchaser (i) have been expressly acknowledged in writing by the Sellers (*schriftlich anerkannt*), (ii) are undisputed (*unbestritten*) or (iii) or have been awarded to the Purchaser by Court Decision, the Claim Amount (or the portion of the Claim Amount determined to be due and payable to the Purchaser) shall be released from the Claim Notice Escrow Account to the Purchaser. If and to the extent the Claim Amount does not have to be paid to the Purchaser according to the preceding sentence, the Claim Amount shall be paid to the Sellers if and to the extent (i) Purchaser has expressly acknowledged such release in writing to the Sellers (*schriftlich anerkannt*), or (ii) the Claim Amount has not been awarded to the Purchaser in the Court Decision. The Purchaser shall be responsible for the fees of the Claim Notice Escrow Agent.

1.11 Effective Date Financial Statements.

1.11.1 Preparation by the Purchaser. As soon as reasonably practical after the Closing Date, the Purchaser shall prepare with the assistance of the Company a German GAAP balance sheet for the Group Companies as of the Effective Date, prepared in a manner consistent with past accounting practices, in particular, but not limited to, the exercise of reporting options (*Ausübung von Bilanzierungswahlrechten*) as of the Effective Date (the "**Effective Date Financial Statements**") and containing

(i) a consolidated balance sheet (*Bilanz*) for the Group Effective Date Financial Statements (which consolidated balance sheet shall include a line item setting out all amounts owing from a Seller to a Group Company as of the Closing, other than amounts owing from a Seller to a Group Company pursuant to existing, ordinary course commercial arrangements with a Group Company) (a "**Seller Receivable**"), and,

(ii) a statement (the "**Purchase Price Determination Statement**") setting forth

(a) the Effective Date Financial Debt (noting which portions were paid out of the First Instalment or by the Sellers and which were not),

(b) the Effective Date Cash,

(c) the Effective Date Net Working Capital and the Effective Date Working Capital Deviation,

(d) the Company Transaction Expenses, unless paid by the Sellers out of the Purchase Price as listed in Annex 1.7,

(e) the Purchase Price and the Second Instalment.

1.11.2 Pre-Closing Support of Preparation. In order to support the preparation of the Effective Date Financial Statements and commencing on the date hereof, the Company shall, and shall cause the Group Companies to, grant to the Purchaser and the Purchaser's professional advisors as from the date of this Agreement safe and appropriate access to its premises and employees and to make available to them all documentation and other data reasonably required by the Purchaser to prepare the Effective Date Financial Statements.

1.11.3 Review by the Sellers. Within 90 Business Days following the Closing Date, the Purchaser shall submit the Effective Date Financial Statements to the Sellers for review and shall upon the Sellers request cause the Group Companies to make available to the Sellers and the Sellers' professional advisors all documentation and other data reasonably required by them (not including the work papers of the Purchaser's auditors and other professional advisors) to review the Effective Date Financial Statements.

1.11.4 Objections of the Sellers. Any objections of the Sellers to balance sheet items or entries in the profit and loss statements or the computation of the Purchase Price contained in the Effective Date Financial Statements must be stated within 20 Business Days from receipt of the Effective Date Financial Statements by providing the Purchaser with (i) a written statement of objections, specifying the items or entries that are objectionable, and (ii) a revised version of the Effective Date Financial Statements (the "**Revised Effective Date Financial Statements**") taking such objections into account. If and to the extent that the Sellers do not object to any items or entries during such period in such manner, the Effective Date Financial Statements shall with the expiration of such period be final and binding upon the Parties. The Revised Effective Date Financial Statements shall also specify in reasonable detail the grounds for the objections, but failure to provide such detail shall not affect the validity of the Sellers objections.

1.11.5 Partial Objection to Effective Date Financial Statements. If and to the extent the Sellers object to the Effective Date Financial Statements only in part, a preliminary determination of the Purchase Price shall be made based on the undisputed figures in the Effective Date Financial Statements, and the payment resulting from such preliminary adjustment shall be made in accordance with Section 1.8.1. The final determination and payment shall be made once the Effective Date Financial Statements have become final and binding upon the Parties in their entirety.

1.11.6 Costs. The Purchaser shall bear the costs for the preparation, and the Sellers shall bear the costs for the review, of the Effective Date Financial Statements.

Resolution of Disputes.

1.11.7 Appointment of Neutral Auditor. In the case of any objections of the Sellers against the Effective Date Financial Statements timely stated by the Sellers, the Sellers and the Purchaser shall attempt in good faith to settle the disagreement. If the Sellers and the Purchaser cannot settle the disagreement within 20 Business Days after receipt by the Purchaser of the Sellers statement of objections and the Revised Effective Date Financial Statements, the Sellers or the Purchaser may present the matter to a neutral auditor (the "**Neutral Auditor**") from an auditing firm (the "**Neutral Auditor Firm**") of international recognition, which firm shall be jointly designated by the Sellers and the Purchaser. If the Sellers and the Purchaser cannot agree on the Neutral Auditor Firm within 15 Business Days after the respective request for such designation, the Neutral Auditor Firm and the Neutral Auditor shall be appointed by the German Institute of Chartered Accountants (*Institut der Wirtschaftsprüfer in Deutschland e. V.*) at the request of either Party after consideration of the proposals and comments by the Sellers and the Purchaser; the Neutral Auditor so appointed must satisfy the following criteria: (i) The Neutral Auditor must have five years of professional experience in both the areas of audit and transaction services; (ii) the Neutral Auditor must have been a partner of the Neutral Auditor Firm for a period of at least ten years; (iii) the Neutral Auditor Firm must be an auditing firm of international recognition with at least 30 partners and offices in at least five jurisdictions; and (iv) the Neutral Auditor must confirm that he and his firm are not conflicted from accepting the assignment and have the necessary resources to perform the required services in a timely manner.

1.11.8 The Sellers and the Purchaser shall jointly instruct the Neutral Auditor Firm to decide the issues in dispute in accordance with the provisions of this Section. To that end, the Sellers and the Purchaser agree to use their commercially reasonable efforts to engage the Neutral Auditor Firm as promptly as practicable. Each Party agrees to execute, if requested by the Neutral Auditor Firm, an engagement letter with the Neutral Auditor Firm reflecting the terms of this Agreement and otherwise containing reasonable terms.

1.11.9 Scope of Decisions of Neutral Auditor. Unless instructed otherwise by the Sellers and the Purchaser jointly, the Neutral Auditor shall limit its decisions to the issues in dispute, but shall on the basis of such decisions and the undisputed parts of the Effective Date Financial Statements determine the Effective Date Financial Statements in their entirety. In respect of the issues in dispute the decisions of the Neutral Auditor shall be limited to the positions taken by the Sellers and the Purchaser. To the extent necessary for the decisions, the Neutral Auditor shall also be entitled to decide on the interpretation of this Agreement. The Neutral Auditor shall act as an expert (*Schiedsgutachter*) and not as an arbitrator.

1.11.10 Procedure.

(i) The Sellers and the Purchaser shall make available to the Neutral Auditor the Effective Date Financial Statements, the Revised Effective Date Financial Statements and all other documentation and data reasonably required by the Neutral Auditor to make the required decisions and determination. Otherwise, Sections 427 and 444 of the German Civil Procedure Code (ZPO) shall apply accordingly. The Neutral Auditor shall be entitled to request access to the premises, personnel and information technology and accounting systems and data of the Company and, to the extent relevant in his reasonable view, of the Parties. The Neutral Auditor shall immediately submit copies of all documents and other data made available by the Sellers or the Purchaser to the respective other Party as well. The Parties shall have a right to be present (together with their advisors) at any meeting of the Neutral Auditor with any person and at any visit or review of any of the Parties' or the Company's premises, systems or data. Before making the decisions, the Neutral Auditor shall grant the Sellers and the Purchaser the opportunity to present their positions in writing and at least in one oral hearing in the presence of the Sellers and the Purchaser and their professional advisors.

(ii) The Neutral Auditor shall use best efforts to deliver its written opinion with reasons for the decisions as soon as reasonably practical and shall endeavor to do so not later than 90 days after the issues in dispute have been referred to the Neutral Auditor.

(iii) Subject to Section 319 German Civil Code (BGB), the Neutral Auditor's decisions and the Effective Date Financial Statements as determined by the Neutral Auditor shall be final and binding upon the Parties.

1.11.11 Costs. The costs and expenses of the Neutral Auditor shall be borne by the Sellers and the Purchaser pro-rata in proportion to the amounts by which the Purchase Price, as determined by the Purchaser in the Effective Date Financial Statements and by the Sellers in the Revised Effective Date Financial Statements, deviates from the Purchase Price determined by the Neutral Auditor. The Purchaser shall advance such costs of the Neutral Auditor and shall be entitled to set off such amount owed by the Sellers from the Second Instalment or a later instalment of the Purchase Price.

1.12 Pre-Closing Covenants.

1.12.1 Activities of the Sellers. Until (and including) the Closing Date the Sellers shall not, without the prior written consent of the Purchaser or unless explicitly provided in this Agreement

(i) adopt or permit the adoption of any shareholders' resolution of the Company regarding

(a) any change to the articles of association of the Company,

(b) any transformation of the Company within the scope of the German Transformation Act (UmwG),

(c) the conclusion of any enterprise agreement within the scope of Sections 291, 292 AktG,

(d) the redemption of any Shares,

(e) the liquidation of the Company,

(f) the election of new auditors,

(g) the declaration and/or payment of dividends or other distributions,

(h) the appointment, dismissal, or execution of or changes to the service or employment contracts of, any directors and officers, or

(i) the waiver of any claims of the Company against any current or former directors and officers, exoneration (*Entlastung*) or actions with similar effect;

(ii) sell, transfer, create any encumbrances on, or otherwise dispose of, any Shares, or grant any options, warrants, pre-emptive rights, rights of first refusal or other rights to purchase or obtain any of the Shares; or

(iii) enter into any agreement or make any other transaction with the Group Companies at terms which are not at arm's length.

1.12.2 Activities of the Group Companies. Subject to the following sentence, the Sellers and the Company shall ensure that until (and including) the Closing Date the Group Companies shall at all times conduct their businesses in the ordinary course. The Sellers and the Company shall ensure further that without the prior written consent of the Purchaser (email form being sufficient) or unless explicitly provided in this Agreement, none of the actions set forth in

Section 1.12.1 shall be taken with respect to any Group Company, and that no Group Company shall

(i) enter into any agreement or assume any other obligation directed at any of the actions listed in Section 1.12.1;

(ii) enter into any agreement or pursue any of the other activities of the type set forth in Section 2.11 (Material Agreements);

(iii) sell, transfer, purchase or accept the transfer of any interests in any legal entities or any businesses or business divisions;

(iv) pay or otherwise discharge, or provide security for, any material liabilities (whether matured, unmatured, asserted or unasserted, contingent or otherwise), other than the regular servicing of Financial Debt and the discharge of trade accounts payable, both in the ordinary course of business;

(v) sell, transfer, create any encumbrances on or otherwise dispose of any real estate, IP rights or material assets and inventories;

(vi) adopt or amend any agreement, plan or other instrument for any employee benefits;

(vii) take any action outside the ordinary course of business;

(viii) enter into any transaction which is not at arm's length terms; or

(ix) hire any new employees, enter into, terminate or amend any employment agreement or compensation agreement or grant any other bonus to any employee, director or officer, in each case except as set forth in Annex 1.12.2 (ix) hereto.

Purchaser hereby appoints each of Tom West, Randy Meier and David Lehman as representatives in charge to grant any consent under this Section and, furthermore, undertakes to react upon a request from the management of the Company for a consent within a reasonable time period, not exceeding two full Business Days. Sellers shall not become liable for any damage that occurs because the Purchaser refuses a consent or for damage resulting from a management action that the Purchaser has consented to.

1.12.3 Disclosure of Events. Until (and including) the Closing Date the Sellers and the Company undertake to disclose to the Purchaser in writing (email being sufficient) immediately upon becoming aware of any events which are or may constitute a breach by the Sellers or the Company under this Agreement, which materially adversely affect or are reasonably likely to materially adversely affect any of the Group Companies' assets, business, financial condition, results of operations or prospects.

1.12.4 Insurance and Employee Matters. The Sellers and the Company shall procure that the Group Companies and the Business remain insured until the Closing Date in substantially the same way as they are on the date hereof and that all premiums due for such insurances are duly and timely paid. The Company shall use its best efforts to obtain executed invention assignment agreements, in the form provided by the Purchaser to the Company and compliant with German law, from (i) all of the current German employees of the Group Companies who developed any relevant Intellectual Property Rights (as defined herein) for the Group Companies and (ii) each of Prof. Desinger, Dr Mucha, Mr. Schmöle to the extent they participated in the invention or development of Intellectual Property Rights.

1.12.5 No Leakage.

Sellers' Undertaking. The Sellers undertake to the Purchaser that other than with the prior written consent of the Purchaser (email form being sufficient):

(i) during the period from August 1, 2020 to the date of this Agreement, neither Sellers nor any of the Sellers' Affiliates have received or become entitled to receive Leakage other than any Permitted Leakage; and

(ii) during the period from the date of this Agreement until the Closing Date, neither the Sellers nor any of the Sellers' Affiliates will receive or become entitled to receive any Leakage other than any Permitted Leakage.

"**Leakage**" means any payment or transfer of cash or assets or the assumption of any obligation for any payment or transfer (excluding Permitted Leakage) by or for the account of any Group Company to or for the benefit of the Sellers or any of the Sellers' Affiliates including:

(i) a dividend (whether in cash or in specie) or other distribution or return of capital to the Sellers or any of the Sellers' Affiliates, including (without limitation) a redemption, repurchase or reduction of any share capital;

(ii) a cost or bonus or other form of ex gratia award or payment paid to any director, officer or employee of the Sellers or any of the Sellers' Affiliates in connection with the transaction contemplated hereunder;

(iii) any asset transfer, purchase or disposal between a Group Company and the Sellers or any of the Sellers' Affiliates other than in the ordinary course of a trading activity;

(iv) lending or borrowing between a Group Company and the Sellers or any of the Sellers' Affiliates and any increase or reduction thereof;

(v) the waiver, forgiveness or discount of any amounts due to a Group Company from the Sellers or any of the Sellers' Affiliates; and

(vi) the assumption or fulfilment of any obligation or liability legally or commercially owed by the Sellers or any of the Sellers' Affiliates;

in each case except for those items of Leakage, which are paid by the Sellers out of the Purchase Price as listed in Annex 1.7 or which have otherwise been deducted by the Purchaser form the Purchase Price.

"**Permitted Leakage**" means:

(i) any payment to, or entitlement to receive such payment by, any of the Sellers or any of the Sellers' Affiliates pursuant to any agreement entered into prior to the date of the last financial statements of the Company or thereafter with respect to the supply of products or the provision of services in the ordinary course of business and listed in Annex 1.12.5;

(ii) any payment or bonus paid or payable (for the avoidance of doubt, including deferred salary and bonuses) to any director, officer (including members of the management board (*Vorstand*) and the supervisory board (*Aufsichtsrat*)) or employee of any member of the Sellers or any of the Sellers' Affiliates under existing employment or service agreements or in the ordinary course of business;

in each case by or for the account of any Group Company.

Remedies. In case of Leakage, those of the Sellers which have received the benefit of such Leakage shall indemnify and hold harmless the Group Companies or, at the Purchaser's election, the Purchaser on a Euro-for-Euro basis from the consequences of such Leakage (including by way of repaying or returning the entire amount or benefit constituting the relevant Leakage).

1.13 Closing Conditions. The obligation of the Parties to take the actions set out in Section 1.14.1 shall be subject to each of the conditions set forth in Sections 1.13.1 through 1.13.3 (each such condition a "**Closing Condition**") being either fulfilled or its fulfillment being waived by the Party entitled to such waiver pursuant to Section 1.13.4:

1.13.1 Positive Closing Conditions of the Purchaser.

(i) The New Service Amendments have been duly executed by and between the designated parties thereto and are still in force and effective and have neither terminated nor rescinded.

(ii) The employees listed on Annex 1.13.1 (ii) have entered into amendment agreements to their service agreements with the Company providing for their continuing employment with the respective Group Company after Closing.

(iii) The unaudited consolidated Financial Statements of the Group Companies for the nine months ending September 30, 2019, in form consistent with the unaudited consolidated Financial Statements of the Group Companies as of December 31, 2019 and for the twelve months then ended shall have been delivered to Purchaser.

(iv) The forms of the Intersect Escrow Agreement and the agreements attached as annexes to this Agreement have been negotiated by the designated parties thereto in good faith and finalized.

1.13.2 Positive Closing Conditions of the Sellers.

(i) The forms of the Intersect Escrow Agreement and the agreements attached as annexes to this Agreement have been negotiated by the designated parties thereto in good faith and finalized.

(ii) The Purchaser has paid an amount of EUR 15,000,000.00 (in words: *Euro fifteen million*) in the Intersect Escrow Account and has provided a respective confirmation by the Intersect Escrow Agent to the Sellers, and the Intersect Escrow Agreement as provided for in Section 1.9(a) has been duly executed by and between the designated parties thereto and is still in force and effective and has neither terminated nor rescinded.

1.13.3 Negative Closing Conditions.

(i) None of the employees of the Group Companies listed in Annex 1.13.1 (ii) has given written notice of termination of employment.

(ii) There is no injunction or other court or governmental order prohibiting the Parties from consummating this Agreement or the transactions contemplated herein.

(iii) The Sellers are not in material breach of any of the covenants pursuant to Section 1.12 and other agreements required to be performed or complied with by the Sellers pursuant to this Agreement on or prior to the Closing Date.

(iv) No legal proceedings relating to the Transaction shall be pending before any Governmental Authority.

(v) No temporary restraining order, preliminary or permanent injunction or other order preventing the consummation of the Transaction shall have been issued by any court of competent jurisdiction and remain in effect, and no material law shall have been enacted since the date of this Agreement that makes consummation of the Transaction illegal or otherwise prevents the consummation of the Transaction.

1.13.4 Waiver of Closing Conditions. The Purchaser may waive the fulfillment of each of the Closing Conditions set forth in Section 1.13.1 and Section 1.13.3 and the Sellers may waive the fulfillment of each of the Closing Conditions set forth in Section 1.13.2. The effect of a waiver shall be limited to eliminating the respective Closing Condition and shall not prejudice any claims either Party may have on the basis of any circumstances relating to the non-fulfillment of such Closing Condition.

1.13.5 Best Efforts to Fulfill Closing Conditions. Each Party shall use best efforts to ensure that those of the Closing Conditions which cannot be waived by such Party will be fulfilled as soon as possible.

1.13.6 Notification. As soon as all Closing Conditions have been either fulfilled or their fulfillment been waived, the Sellers and the Purchaser shall mutually notify each other thereof.

1.13.7 Withdrawal. In the event that any Closing Conditions have not been fulfilled or waived within three months after the date of this Agreement either Party (i.e., the Purchaser or the Sellers) may withdraw from this Agreement, provided, however, that neither Party may exercise such right to withdraw against the principles of good faith (*treuwidrig*) which shall, e. g. be deemed breached if the withdrawing Party delays or otherwise prevents the timely fulfillment of the Closing Conditions. The withdrawal must be stated by written notice to the other Party. Any notice of withdrawal on behalf of the Sellers will delivered by the Sellers' Representative and such notice will be deemed given by all Sellers (that is, no partial notice of withdrawal will be permitted), The effect of a withdrawal shall be the termination of this Agreement, provided that any claims that the withdrawing Party may have on the basis of any circumstances relating to the non-fulfillment of any Closing Condition shall not be affected by the termination.

1.14 Closing.

1.14.1 Closing Events. Provided that all Closing Conditions set forth in Section 1.13 shall have been satisfied or waived in accordance with the terms of this Agreement, on October 2, 2020, with the Parties using their reasonable best efforts to have the Closing occur on such date, or, if such Closing Conditions shall not have been satisfied or waived on or prior to such date, on such other date as mutually agreed upon by the Parties as soon thereafter as practicable, and provided in each case that on such date the other Closing Conditions have been and continue to be fulfilled or waived, the Parties shall meet at 11:00 am at the offices of Morrison & Foerster LLP in Berlin, or at such other location as mutually agreed upon by the Parties, where the following events (the "**Closing Events**" which in their entirety shall constitute the "**Closing**") shall take place simultaneously (*Zug um Zug*):

(i) Delivery by the Sellers of written resignation declarations of the members of the supervisory board (*Aufsichtsrat*) of the Company effective as of Closing Date with full release of the Company from any and all present and future payment and other obligations, except for outstanding remuneration to the members of the Supervisory Board (to the extent fully accrued for in the Financial Statements and to be included in the Effective Date Financial Statements).

(ii) Payment by the Purchaser of the First Instalment.

(iii) Delivery by the Purchaser of the duly executed financing and distribution commitment as attached hereto as Annex 4.4.

(iv) Execution of the IP Pledge Agreement, the Share Pledge Agreement and the Intersect Escrow Agreement by the respective parties thereto.

1.14.2 The date on which all Closing Events have been performed shall be the "**Closing Date**".

1.14.3 Waiver of Closing Events. The Purchaser may waive the Closing Event set forth in Section 1.14.1 (i) by written notice to the Sellers. The effect of a waiver shall be limited to eliminating the need for the respective Closing Event to be performed at the Closing and shall not prejudice any claims the Purchaser may have on the basis of any circumstances relating to the non-performance of such Closing Event.

1.14.4 Closing Confirmation. After all Closing Events have been performed or waived, the Sellers and the Purchaser shall confirm in a written document to be jointly executed by the Sellers and the Purchaser (the "**Closing Confirmation**") that all Closing Events have been performed or waived and that the Closing has occurred. The legal effect of such statement shall be limited to serve as evidence that all Closing Events have been performed or waived and that the Closing has occurred, but shall not limit or prejudice in any manner the rights of the Purchaser arising under this Agreement or under the law.

1.14.5 Withdrawal. In the event that any Closing Event has not been performed or waived within 30 Business Days of the date on which all Closing Conditions have been fulfilled or waived, either the Sellers (collectively as a group, as represented by the Sellers' Representative) or the Purchaser may withdraw from this Agreement by written notice to the respective other Party, unless the non-performance of any Closing Event is within the control of the Party stating the withdrawal, and provided that the withdrawal shall be deemed void and shall not have any effect if at the time when the notice is received by the respective other Party all Closing Events have been performed. The effect of a withdrawal shall be the termination of this Agreement, provided that any claims that the withdrawing Party may have on the basis of any circumstances relating to the non-performance of any Closing Event shall not be affected by the termination.

1.15 Transformation of German GAAP to US GAAP and Preparation of Interim Financial Statements.

On the basis of the Financial Statements of the Group Companies for the financial years 2019 and 2020 delivered by Fiagon AG to the Purchaser, the Purchaser will handle the conversion of such financial statements to US GAAP on its own cost. Fiagon AG shall support such conversion process performed by the Purchaser. In the period between execution of this Agreement and the Closing Date, the Company shall work diligently to prepare unaudited Financial Statements of the Group Companies for the nine months ending September 30, 2019 and 2020, with the understanding that only the Financial Statements of the Group Companies for the nine months ending September 30, 2019 will be a Closing Condition. Such interim Financial Statements will be prepared on a basis consistent with the Financial Statements described in Section 2.5.

1.16 Escrow Solution for Specific Circumstances.

1.16.1 If (i) an accelerated payment of the Purchase Price due to a Change of Control pursuant to Section 1.8.5 occurred or (ii) tax reviews for the Pre-Effective Date Period, although being initiated by Purchaser promptly after the Closing Date, are still pending or have not started as of the date of the Fourth Instalment, the Sellers agree that of the Fourth Instalment

(a) With respect to the circumstances described in (i) an aggregate amount of up to EUR 12,000,000.00 may be paid, in settlement in such amount of the Fourth Instalment, into, and kept in, the Claim Notice Escrow Account in order to secure potential claims of the Purchaser from breaches of the Guarantees and tax indemnification pursuant to Section 6;

(b) With respect to the circumstances described in (ii) and irrespective of a Change of Control but in no case in addition to an amount paid into, and kept in, the Claim Notice Escrow Account pursuant to Section 1.16.1(a), an aggregate amount of up to EUR 2,000,000.00 may be paid into, and kept in, the Claim Notice Escrow Account in order to secure potential claims of the Purchaser from tax indemnification pursuant to Section 6 relating to a tax review within the meaning of Section 1.16.1 until and to the extent any claims resulting from tax indemnification pursuant to Section 6 are

time barred as set forth in Section 6.6.1. An amendment to the Claim Notice Escrow Agreement embodying these terms plus any other terms mutually agreed by the Parties at the time to take into account the specifics of the facts and circumstances at such time will be negotiated and executed by the Parties (the Sellers' Representative executing such amendment on behalf of the Sellers); it being understood that Intersect not be entitled to demand an increase of the amounts that may be paid into, and kept in, the Claim Notice Escrow Account under this Section 1.16.1(b).To the extent that prior the earlier of (i) or (ii), the Purchaser has already set off any claims for breaches of Guarantees against any instalment of the Purchase Price, the amount in Section 1.16.1(a) shall be reduced by such set off amount.

2. GUARANTEES OF THE SELLERS

Subject to such facts, circumstances, exceptions, qualifications and limitations set out in this Agreement or in the Annexes hereto, each of the Sellers represents and warrants to the Purchaser by way of an independent guarantee (*selbständiges Garantieversprechen*) within the meaning of Section 311 para. 1 BGB, that the statements set forth in Sections 2.1 and 2.2 (the "**Fundamental Guarantees**") and the statements set forth in Sections 2.3 through 2.19 (the "**Operational Guarantees**", together with the Fundamental Guarantees the "**Guarantees**"", and each a "**Guarantee**") below are true and correct as of the date hereof and, if explicitly stated, as of the Closing Date.

The Guarantees shall not be qualified and construed as quality guarantees concerning the object of the purchase or agreements as to the quality within the meaning of Sections 443, 444 and 434 para. 1 BGB (*Beschaffenheitsgarantien oder Beschaffenheitsvereinbarungen*). Purchaser undertakes the purchase based upon its own decision, inspection and assessment without reliance upon any express or implied representations, warranties or guarantees of any nature made by the Sellers, except for the guarantees expressly provided by the Sellers under this Agreement.

2.1 Status of the Sellers.

2.1.1 Corporate Status; Due Authorization. Each Seller that is not a natural person has been duly established and is validly existing and in good standing under the laws of its jurisdiction of organization. Each Seller has the unrestricted corporate right, power, authority and capacity to execute and consummate this Agreement and the transactions contemplated herein. All required approvals of any corporate bodies of each Seller that is not a natural person have been given.

2.1.2 No Insolvency. No insolvency or similar proceedings have been, or have been threatened in writing to be, opened or applied for regarding the assets of any Seller, and there are no circumstances, which would be reasonably expected to require or justify the opening of or application for such proceedings. No Seller is illiquid *(zahlungsunfähig)* or over-indebted *(überschuldet)*.

2.1.3 Legal, Valid and Binding Obligation. This Agreement constitutes (and all other documents executed by each of the Sellers under or in connection with this Agreement will, when executed, constitute) legal, valid and binding obligations of the respective Seller, respectively, enforceable in accordance with their terms.

2.1.4 No Violation. The execution and consummation of this Agreement and of the transactions contemplated herein by each of the Sellers does not violate the articles of association, partnership agreement or other corporate documents, as the case may be, or any other legal obligation of the respective Seller and has not been challenged *(Anfechtung)* by any third party, including on the basis of any laws for the protection of creditor rights.

2.1.5 No Interference. There is no action, suit, investigation or other proceeding pending or threatened in writing against a Seller before any Governmental Entity which in any manner challenges or seeks to prevent, enjoin, alter or materially delay the execution or consummation of this Agreement or the transaction contemplated herein.

2.2 Status of Fiagon AG.

2.2.1 Corporate Status of Fiagon AG. The information in Section 1.3 and 1.4 first sentence is correct. Fiagon AG has been duly established and is validly existing and in good standing as a stock corporation (AG) under the laws of Germany. Fiagon AG has the unrestricted right, power, authority and capacity to own its assets and to conduct its business as currently conducted.

2.2.2 No Insolvency of Fiagon AG.

(a) No insolvency proceedings in the sense of Section 27 of the German Insolvency Code (InsO) have been, or have been threatened in writing to be, opened or applied for regarding the assets of the Company.

(b) The Company is not illiquid (*zahlungsunfähig*). The Purchaser acknowledges the fact that the auditor of the Company is not in a position to provide an unqualified audit opinion with regard to the financial statements of the Company for the year ending December 31, 2019 because further financing is required to confirm the status of the Company as a '*going concern'*.

2.2.3 Shares in Fiagon AG. The Shares of each respective Seller have been validly issued in compliance with applicable law. Each Seller holds sole, unrestricted legal and beneficial title *(uneingeschränkte rechtliche und wirtschaftliche Inhaberschaft)* to its Shares as set forth in the Share Register as contained in Annex (E)-1 (the "**Share Register**". Other than set forth in the Shareholders' Agreement or in Annex 2.2.3, the Shares of each respective Seller are not pledged *(verpfändet),* attached *(gepfändet)* or otherwise encumbered *(belastet)* with any third party rights and are not subject to any (i) trust arrangement *(Treuhandverhältnis),* sub-participation *(Unterbeteiligung)* or similar arrangement, (ii) pending transfer or other disposition *(Verfügung),* (iii) sale, contribution or other contractual arrangement creating an obligation to transfer or encumber or (iv) shareholders' resolution on the redemption *(Einziehung)* of shares. The Shares of the respective Seller, together with those of the Shares held by the other Sellers in accordance with the Share Register as contained in Annex (E)-1, constitute the entire share capital of Fiagon AG.

2.3 Other Corporate Matters regarding Fiagon AG and the Subsidiaries.

2.3.1 Contributions. The Shares are fully paid up. All contributions have been made in compliance with applicable law and have not been repaid or returned, in whole or in part, whether open or disguised, directly or indirectly, and there have been no payments or transactions in breach of the German Stock Corporation Act (AktG). There are no obligations to make further contributions *(keine Nachschusspflichten).*

2.3.2 No Other Interests in Fiagon AG. The Shares constitute the entire share capital of the Company. Other than set forth in the Shareholders' Agreement, neither the Sellers, nor to the Best Knowledge of the Sellers, any third party has, with respect to the Shares, any pre-emptive right *(Vorkaufsrecht),* right of first refusal (*Vorerwerbsrecht*), subscription right *(Bezugsrecht),* option right *(Optionsrecht),* conversion right *(Wandlungsrecht)* or similar right, or is party to an agreement that may result in any such rights. There are no agreements, which require the allotment, issue or transfer of, any debentures in, or securities of the Company.

2.3.3 Corporate Status of the Subsidiaries. The information in Section 1.5 is complete and correct. Each Subsidiary has been duly established and is validly existing and in good standing as the type of legal entity stated in preamble (C) through (E), respectively, under the laws of the jurisdiction of its organization. Each Subsidiary has the unrestricted right, power, authority and capacity to own its assets and to conduct its business as currently conducted and to own and operate the properties and assets now owned and being operated by it.

2.3.4 No Insolvency. No insolvency or similar proceedings have been, or have been threatened in writing to be, opened or applied for regarding the assets of a Subsidiary. No Subsidiary is illiquid *(zahlungsunfähig)*. The Purchaser acknowledges the fact that the auditor of the Company is not in a position to provide an unqualified audit opinion with regard to the financial statements of the Fiagon GmbH for the year ending December 31, 2019, until the auditor has received the comfort letter as provided for in Section 4.4.

2.3.5 Group Structure. Fiagon AG is the sole shareholder of the Subsidiaries. Other than that, none of the Group Companies holds any shares, partnership interests or, to the Best Knowledge of the Sellers, any other interests in any legal entity. No Group Company is a party to any enterprise agreement *(Unternehmensvertrag)* within the scope of section 291 et seq. of AktG or any equivalent agreement under the laws of any other applicable jurisdiction.

2.3.6 Corporate Documents. Annex 2.3.6 includes for each Group Company true and complete copies of (i) the current commercial register extract (or, in the case of foreign Group Companies, of an equivalent certificate), (ii) pending register applications (or equivalent documents), if any, (iii) the current version of the articles of association (or equivalent document or agreement), (iv) a list of all members of any supervisory, advisory or administrative board and (v) any pending shareholders' resolution to change such articles or agreement. No resolutions or other statements for the amendment of the articles of association (or equivalent document or agreement) of any Group Company have been made, and no filings to the commercial register (or to an equivalent corporate authority) in respect of any Group Company are pending. No shareholders' resolution of any Group Company is void or has been challenged *(angefochten)* or threatened to be challenged by any shareholder of such Group Company or any other third party.

2.3.7 Shareholders' Agreements. The Shareholders' Agreement is in full force and effect and enforceable against the parties thereto in accordance with their terms. The Sellers and the Company hereby agree that the Shareholders Agreement shall be terminated as a result of the transfer of the Shares as expected to occur on, and with effect as of, the Closing Date.

2.3.8 The Shares in the Subsidiaries. The Subsidiary Shares in Fiagon GmbH and Fiagon US have been validly issued in compliance with applicable law. The Company holds sole, unrestricted legal and beneficial title to the Subsidiaries Shares. The Subsidiaries Shares are not pledged *(verpfändet),* attached *(gepfändet)* or otherwise encumbered *(belastet)* with any third party rights and are not subject to any (i) trust arrangement *(Treuhandverhältnis),* sub-participation *(Unterbeteiligung)* or similar arrangement, (ii) pending transfer or other disposition *(Verfügung),* (iii) sale, contribution or other contractual arrangement creating an obligation to transfer or encumber or (iv) shareholders' resolution on the redemption *(Einziehung)* of shares.

2.3.9 No Other Interests. The Subsidiaries Shares constitute the entire share capital of Fiagon GmbH and Fiagon US. Neither the Sellers, nor any third party has, with respect to shares in any Subsidiary, any pre-emptive right *(Vorkaufsrecht),* right of first refusal (*Vorerwerbsrecht*), subscription right *(Bezugsrecht),* option right *(Optionsrecht),* conversion right *(Wandlungsrecht)* or similar right, or is party to an agreement that may result in any such rights. There are no agreements, which require the allotment, issue or transfer of any debentures in, or securities of, the Subsidiaries.

2.3.10 As a result of the transfer of the Shares as contemplated by this Agreement the ESOP Beneficiaries will have claims according to section 5.2. of the ESOP agreements resulting in actual payment claims in an aggregate amount of not more than EUR 90,329.00 (incl. social security contributions), which are borne by the Sellers as part of the Transaction Costs listed in Annex 1.7 and will not have the right to receive any shares in the Company. All ESOP agreements have the form as attached hereto as Annex 2.3.10 and the supervisory board of the Company has already irrevocably agreed to the settlement in cash for the above ESOP claims.

2.3.11 Contributions. The Subsidiaries Shares are fully paid up. All contributions have been made in compliance with applicable law and have not been repaid or returned, in whole or in part, whether open or disguised, directly or indirectly, and there have been no payments or transactions in breach of section 30 German Limited Liability Companies Act (*Gesetz betreffend die Gesellschaften mit beschränkter Haftung*). There are no obligations to make further contributions *(keine Nachschusspflichten)*.

2.3.12 No Pending Business Transactions. Neither any Group Company nor the Company itself is a party to any agreement relating to the acquisition or sale of, or a similar transaction involving, any shares in other legal entities or any business *(Betrieb)* or parts thereof *(Betriebsteile),* other than agreements which have already been fully performed by all parties thereto.

2.3.13 No Participation or Share-Based Rights. Other than the ESOP, there are no silent partnerships *(stille Beteiligung),* stock-appreciation rights, stock-based performance units, "phantom" stock rights or other agreements, arrangements or commitments of any character (contingent or otherwise) pursuant to which any person is or may be entitled to receive any payment or other value based on the revenues, earnings or financial performance, stock price performance or other similar attribute of the Company or any other Group Companies.

2.4 Compliance with Laws

2.4.1 The business of the Group Companies is conducted, in all material respects, in compliance with applicable laws, as in effect, enforced and interpreted on the date hereof and the Closing Date.

2.4.2 Neither the Group Companies nor the members of its management board have, in connection with the business conducted by the Group Companies, (i) used any corporate or other funds for unlawful contributions or other unlawful expenses, including with respect to political activities; (ii) made, offered, promised, authorized, or accepted, any unlawful payment of any money or other thing of value to, directly or indirectly, or for the benefit of, any officials, agents, representatives, or employees, of any foreign or domestic governmental authorities or to (or for the benefit of) any foreign or domestic political parties or campaigns, any candidate for political office, or any public international organization; or (iii) violated any provision of the U.S. Foreign Corrupt Practices Act of 1977, as amended, or other similar applicable law in other jurisdictions; or (iv) made, offered, promised, authorized, or accepted, any other unlawful payment.

2.5 Financial Statements. The (1) audited financial statements as per 31 December 2018, (2) the unaudited draft financial statements as per 31 December 2019 and (3) the unaudited financial statements for the seven months ending 31 July 2020 of the Company and of Fiagon GmbH (the "**Fiagon Germany Financial Statements**") as attached in Annex 2.5-1 have in all material aspects been prepared in accordance with (i) the requirements of relevant laws and relevant generally accepted accounting principles ("**GAAP**") pursuant to HGB, in force as of the relevant dates and (ii) consistent with past practice except for the net loss being carried forward to new account instead of being balanced by a withdrawal from the capital reserve (*Vortrag des Jahresfehlbetrages auf neue Rechnung anstatt Verrechnung mit bestehenden Kapitalrücklagen*), and have been audited by UHY Deutschland AG Wirtschaftsprüfungsgesellschaft and received an unqualified audit opinion, with the exception of (x) the unaudited draft financial statements as per 31 December 2019 which have not obtained an unqualified opinion due to further financing commitments needed and (y) the financial statements for the seven months ending 31 July 2020 have not been audited and do not contain all of the required footnote disclosures. Subject to the limitations that apply due to the financial statements for the seven months ending 31 July 2020 being management accounts only, the Fiagon Germany Financial Statements present a true and fair view in the meaning of section 264 par. 2 HGB of the assets and liabilities (*Vermögenslage*), financial condition (*Finanzlage*) and results of operations (*Ertragslage*) of the Company and Fiagon GmbH as of their respective accounting date. The audited balance sheets and the related statements of operations, changes in stockholder's deficit and cash flows for Fiagon US as of and for the fiscal year ended December 31, 2019 and the unaudited financial statements for Fiagon US for the seven months ending 31 July 2020 as attached in Annex 2.5-2 (the "**Fiagon US Financial**

Statements", and together with the Fiagon Germany Financial Statements, the "**Financial Statements**") have been prepared in accordance with applicable GAAP and derived from the books, records and files of Fiagon US and fairly present in all material respects the financial condition and results of operations of Fiagon US as of the respective accounting dates. To the Best Knowledge of the Sellers, no circumstances existed as of the relevant time, which renders any item on the Financial Statements materially incorrect or incomplete.

2.6 Certain Accounting Principles.

Without limiting the generality of Section 2.5, to the Best Knowledge of the Sellers,

2.6.1 the inventories shown in the Financial Statements are valued at the lower of cost or market, taking into account adjustments for obsolete or otherwise not marketable items as allowed by applicable GAAP;

2.6.2 sufficient adjustments *(Abschreibungen, Einzel- und Pauschalwertberichtigungen)* were made in the Financial Statements for doubtful accounts or non-collectible receivables, and given historic experience the accounts receivable are good and collectible in the ordinary course of business without any material withholding rights, rights of set-off or rights of deduction outside the ordinary course of business;

2.6.3 the provisions *(Rückstellungen)* in the Financial Statements cover all risks for which provisions have to be made under applicable GAAP and are in the opinion of the management at the date of establishment sufficient to cover all liabilities relating to any period prior to the effective date of the respective Financial Statements *(Bilanzstichtag)* that are not reflected as liabilities; and

2.6.4 the financial position or earnings of the Group Companies as reflected in the Financial Statements have not been influenced by inconsistencies of accounting practices except for the net loss being carried forward to new account instead of being balanced by a withdrawal from the capital reserve (*Vortrag des Jahresfehlbetrages auf neue Rechnung anstatt Verrechnung mit bestehenden Kapitalrücklagen*), by the inclusion of non-recurring items of income or expenditures or by any other factors rendering such results exceptionally high or low unless required by a change in the applicable accounting principles as requested by the auditor.

2.7 No Undisclosed Liabilities. Except as disclosed in the Financial Statements, no Group Company has any material liabilities or obligations, whether accrued, contingent (*Haftungsverhältnisse* within the scope of section 251 HGB) or otherwise (including pursuant to section 285 nos. 3, 3a HGB), relating to any period prior to the effective date of the respective Financial Statements *(Bilanzstichtag)* that would have been required to be reflected in the Financial Statements pursuant to the relevant GAAP.

2.8 Books and Records. The books and accounting and other records of each Group Company (including tax related documentation), in all material respects, (i) are up to date and contain complete and accurate details of the material business activities of such Group Company and of all matters to be recorded under applicable law or applicable GAAP, (ii) have been maintained in accordance with applicable legal requirements on a proper and consistent basis, and (iii) correctly and completely reflect the assets and liabilities and all material transactions entered into by the respective Group Company. No notice or allegation that any books and records are incorrect or should be corrected has been received by any Group Company.

2.9 Litigation; Disputes

2.9.1 Other than set forth in Annex 2.9.1, no lawsuit or other proceeding is pending against the Company before any state court, arbitrator or Governmental Entity and no such lawsuit or proceeding has been threatened against a Group Company in writing.

2.9.2 The Group Companies are not subject to any decision by a court or Governmental Entity in relation to a proceeding involving any Group Company that imposes an obligation, which has not been fulfilled by any such Group Company.

2.9.3 The Fraunhofer Dispute will not result in further costs for the award/settlement together with associated attorneys' fees and other related costs for the Group Companies of more than EUR 10,000.00.

2.10 Employee and Labor Matters

2.10.1 The Group Companies have in the last three years prior to the date hereof not experienced any disputes with governmental authorities with regard to labor or work environment matters (including with respect to disabled persons, repayment obligations, anti-discrimination or civil rights matters or workers safety issues) or any material individual labor disputes or any strike, labor interruption or disturbance or other collective labor disputes of any material nature.

2.10.2 Annex 2.10.2 sets forth, a true and complete list of all members of the Company's management board (*Vorstand*) and supervisory board (*Aufsichtsrat*) as well as a true and complete but anonymized list of all employees of the Company (the "**Employees**"). Anonymized copies of all contracts between the Company and any Employee, as in effect on the date hereof, have been disclosed to Intersect.

2.10.3 The Company has not made any pension commitment to any of its current or former employees.

2.10.4 No works council (*Betriebsrat*) exists at the Company.

2.10.5 Except for the ESOP, no employee participation programs exist at the Company. Except for the exit bonuses to the management, which are set forth in Annex 1.7 and borne by the Sellers pursuant to Section 1.7.2, and annual bonus payments relating to performance of employees in the ordinary course of business that have been disclosed to the Purchaser, and except as required under applicable German law, the Company is not obliged to render any payments to any of its employees with respect to the transactions contemplated by this Agreement.

2.11 Material Agreements

2.11.1 Except for the agreements listed in Annex 2.11.1 (the "**Material Agreements**"), no Group Company is party to any of the following written agreements with the primary contractual obligations (*primäre Hauptleistungspflichten*) of the Group Company still outstanding:

(a) Agreements relating to the acquisition or sale of interests or shares in other companies, businesses or real estate providing, in each case, for a consideration of EUR 10,000.00 or more;

(b) Joint venture, strategic alliances, joint development of products of technology, partnership or shareholder agreements;

(c) Rental and lease agreements relating to real estate, which, individually, provide for annual payments of EUR 10,000.00 or more;

(d) Loan agreements (other than relating to any intercompany debt between the Group Companies), bonds, notes or any other instruments of debt and involving, individually, an indebtedness of a Group Company;

(e) Guarantees, indemnities, suretyships and comfort letters issued for any debt of any third party;

(f) any agreement imposing any restriction on a Group Company to engage in any line of business or compete with any third party, to acquire or to sell certain products or services or to develop any technology, other than nondisclosure agreements entered into in the ordinary course of business;

(g) any transfer of assets, rights or benefits by a Group Company to the Sellers.

2.11.2 (i) The Material Agreements are in full force and effect and enforceable against the parties thereto in accordance with their terms, (ii) no party to a Material Agreement has given notice of termination, and no circumstances caused by a Group Company exist, which give any party to a Material Agreement the right to terminate or modify such Material Agreement, (iii) no party to a Material Agreement is in material breach of such agreement, and (iv) the execution or consummation of this Agreement or the transactions contemplated herein do not trigger any rights of any party to a Material Agreement that would materially impair a Group Company's position under such Material Agreement.

2.12 Intellectual Property

2.12.1 Annex 2.12.1 contains a list of (a) all inventions, technical and business know-how or trade secrets (encompassing without limitation research materials, test data, product data and safety data that is not readily available to the public), and other intellectual property rights, in particular, but not limited to, patents, utility models and designs, trademarks, works capable of being protected by copyright or ancillary rights, including Software and rights to non-creative databases, and domain names (collectively referred to as "Intellectual Property Rights") owned and registered or applied for registration by a Group Company ("Registered Intellectual Property Rights") and (b) all employee inventions disclosed to and claimed by a Group Company which have not been registered or applied for registration as of the date hereof.

2.12.2 Except as disclosed in Annex 2.12.2, the Registered Intellectual Property Rights are neither subject to any pending proceedings for opposition, cancellation, revocation, reexamination or rectification which may negatively affect the operation of the business of a Group Company.

2.12.3 All fees necessary to maintain Registered Intellectual Property Rights have been paid until the date hereof and the Closing Date, and all necessary renewal applications have been filed and all other material steps necessary for their maintenance have been taken.

2.12.4 With regard to all agreements under which Intellectual Property Rights that are material for the business of the Group Companies are licensed or sublicensed to such Group Companies from a person or entity that is not a Group Company ("**Third Party**") (together the "**Inbound License Agreements**") (a) the Group Company has not received a written notice of termination or breach by any licensor, and (b) the execution and performance of this Agreement does not violate any Inbound License Agreement or trigger a termination right of the contracting Third Party or any obligation of a Group Company to pay additional remuneration.

2.12.5 As to the development, manufacture, sale or use of the Group Companies' navigation system products, no Intellectual Property Rights other than (i) the Registered Intellectual Property Rights, (ii) any other Intellectual Property Rights (including but not limited to the sensor coil manufacturing process) that is purported to be owned by any of the Group Companies (the Registered Intellectual Property Rights and such other Intellectual Property Rights collectively, the "**Owned Intellectual Property Rights**"), and (iii) the Intellectual Property Rights licensed under the Inbound License Agreements are currently used by or necessary for any Group Company to conduct its business as conducted as of the Closing Date, or as mutually anticipated by the Parties to be conducted within 12 months following the Closing Date, in all material respects. To the Best Knowledge of the Sellers, none of the Owned Intellectual Property Rights are materially infringed by Third Parties and the Group Companies have taken appropriate measures to keep them secret to the extent those Owned

Intellectual Property Rights have not been published or disclosed in the ordinary course of business.

2.12.6 Except as disclosed in Annex 2.12.6, no Owned Intellectual Property Right is (a) encumbered with any rights of any Third Party, except for moral rights and other statutory rights of creators or inventors, including without limitation the Sellers, or (b) subject to any non-registered or otherwise pending transfer or other disposition or any sale, contribution or other contractual arrangement creating an obligation to transfer or to create, change or abolish any encumbrances. Except as disclosed in Annex 2.12.6, the Group Companies are free to dispose of the Owned Intellectual Property Rights in any manner, and such dispositions do not violate any legal obligations of any Group Company.

2.12.7 As to the development, manufacture, sale or use of the Group Companies' navigation system products, no Group Company infringes any Intellectual Property Rights of Third Parties to an extent that it would materially affect the business of the Group Companies as conducted as of the Closing Date, or as mutually anticipated by the Parties to be conducted within 12 months following the Closing Date. There is no written claim or demand of any person pertaining to, or any proceedings which are pending or threatened in writing, which alleges that a Group Company infringes any Intellectual Property Rights of Third Parties in connection with the development, manufacture, sale or use of the Group Companies' navigation system products to an extent that it would materially affect the business of the Group Companies as conducted as of the Closing Date, or as mutually anticipated by the Parties to be conducted within 12 months following the Closing Date.

2.12.8 Each Group Company has observed, to the extent applicable, the rules under the German Act on Employee Inventions (*Arbeitnehmererfindungsgesetz – ArbnErfG*) and has, in particular, observed the rules under the ArbnErfG on the claims relating to employees' inventions as embodied by the Owned Intellectual Property Rights. All Group Companies have paid all remuneration to persons entitled to any compensation under the ArbnErfG or agreements with employees entered into under the ArbnErfG.

2.12.9 Annex 2.12.9-1 sets forth a complete and accurate list of the Software (as defined below) that is material to the business of the Group Companies and that has been completely developed by the Group Companies' employees in the course of employment with the respective Group Company ("**Company Software**"). Except as set forth in Annex 2.12.9-2, no source code for any Company Software has been delivered, licensed, disclosed or is subject to any source code escrow obligation by the Group Companies to any Third Party. Except as set forth in Annex 2.12.9-2, none of the Company Software is, in whole or in part, subject to the provision of any written open source agreement or other type of license agreement or distribution model agreement that (a) requires the distribution or making available of the source code for any such Software, (b) prohibits or limits the Group Companies from charging a fee or receiving consideration in connection with sublicensing or distributing any such Software, or (c) except as specifically permitted by mandatory law, grants any right to any person other than the Group Companies or otherwise allows any such person to decompile, disassemble or otherwise reverse-engineer any such Software. "**Software**" means any and all (i) computer programs, systems, applications and code, including any and all software implementations of algorithms, models and methodologies and any and all source code, object code, development and design tools, applets, compilers and assemblers, (ii) databases and compilations, including any and all libraries, data and collections of data, whether machine readable, on paper or otherwise, (iii) descriptions, flow-charts and other work product used to design, plan, organize and develop any of the foregoing, (iv) the technology supporting, and the contents and audiovisual displays of any internet site(s) operated by or on behalf of the Group Companies, and (v) all documentation, other works of authorship and media, including user manuals and training materials, relating to or embodying any of the foregoing or on which any of the foregoing is recorded.

2.12.10 No Software that is the subject of the litigation matter *Fraunhofer Gesellschaft e.V. ./. Fiagon GmbH*, originally filed in 2009, or any other cases related thereto (collectively, the "**Fraunhofer Dispute**", is used in the current products or services of the Group Companies.

2.13 Information Technology. Each Group Company either owns or holds valid leases and/or licenses to all computer hardware, Software, networks and other information technology (collectively "**Information Technology**") which is currently used by or necessary for such Group Company to conduct its business as of the Closing Date, or as mutually anticipated by the Parties to be conducted within 12 months following the Closing Date. To the Best Knowledge of the Sellers, during the last 12 months prior to the date hereof there were no interruptions, malfunctions, data losses or similar incidents attributable to the Information Technology owned or used by such Group Company which had, and there are no viruses or defects in the Information Technology owned or used by such Group Company which have or are likely to have, a material adverse effect on such Group Company's business. The Information Technology owned or used by the Group Companies has the capacity and performance necessary for such Group Company to conduct its business as of the Closing Date, or as mutually anticipated by the Parties to be conducted within 12 months following the Closing Date. Precautions considered customary in the industry have been taken to preserve the security and integrity of the Information Technology owned or used by the Group Companies. In the last 12 months prior to the date hereof there has not been any material, unauthorized modification of any Software or data in the Information Technology or any fraud committed by use or abuse of the Information Technology.

2.14 Data Protection. The Group Companies have complied in all material respects with all relevant legal requirements of each applicable law (whether in Germany, the European Union or any other relevant jurisdiction), binding on the Group Companies concerning the protection and/or processing of personal data, in particular the European General Data Protection Regulation (*Datenschutzgrundverordnung*). No Group Company has, in the last 24 months prior to the date hereof, received any notice or allegation in writing from either a data protection registrar, if any, or a data subject alleging non-compliance with data protection legislation or any of the data protection principles.

2.15 Conduct of Business since January 1, 2020

Except as disclosed in Annex 2.15 and except for any transactions contemplated by, or any facts or events otherwise explicitly disclosed in this Agreement in the period between January 1, 2020 and the Closing Date, the business of the Group Companies has in all material respects been conducted in the ordinary course of business and in consistence with past practice, in particular, there has not been:

(a) any recapitalization or reorganization which materially changed the corporate structure of a Group Company;

(b) any merger or similar business combination between a Group Company and any third party;

(c) any divestiture by a Group Company of a shareholding, business or (outside the ordinary course of business) assets or rights with a value in excess of EUR 10,000.00 each;

(d) any borrowing or any incurrence of loans by a Group Company or any guarantee, suretyship (*Bürgschaft*), letters of comfort (*Patronatserklärung*) by a Group Company for any third party's;

(e) any material change in any method of accounting or accounting practice or policy by a Group Company, except as required due to a concurrent change in generally accepted accounting principles;

(f) any payments to the Sellers on whatever factual or legal basis by a Group Company (except for payments and benefits to Sellers Dr. Dirk Mucha, Prof. Dr. Kai Desinger and Matt Jones under their respective service agreements with the Company as attached hereto as Annex 2.15(f)) and no distributions have been paid out or resolved upon by a

Group Company nor is a Group Company obliged to make any payments to the Sellers after the date hereof;

(g) any payments to any subsidiary of the Company exceeding an amount of EUR 20,000.00;

(h) any agreement for joint venture, strategic alliances, joint development of products of technology;

(i) any agreement imposing any restriction on a Group Company to engage in any line of business or compete with any third party, to acquire or to sell certain products or services or to develop any technology;

(j) any transfer of assets, rights or other advantages or benefits by a Group Company to the Sellers;

(k) any increase or commitment to increase the remuneration of any of the directors and officers, employees, agents or consultants of the Group Companies with the exception of the ordinary performance bonuses relating to the financial year 2019 which become due once the financial statements 2019 are adopted;

(l) terminated or modified, or gave notice to terminate or modify, any Material Agreement;

(m) any hire of any new directors and officers or any new employees with an annual base salary of more than EUR 50,000.00;

(n) any agreement or other transaction with the Sellers, the Sellers' Affiliates, any other Group Company, any third-party owner of any shares or other interests in any Group Company, or any of their related parties;

(o) any circumstance that would require or result in any accrual *(Rückstellung)* pursuant to applicable GAAP outside the ordinary course of business;

(p) any material adverse change to the business operations, assets, financial position or earnings position of the Group Companies other than disclosed to the Purchaser or in relation to the Covid-19 pandemic; or

(q) any agreement outside the ordinary course of business and with a value or involving payments in excess of EUR 20,000.00.

2.16 Insurance Coverage. Annex 2.16 contains a true and complete list of all material insurance policies relating to the assets, the business or the operations of the Group Company. All such policies are in full force and effect.

2.17 Permits; Compliance; Public Subsidies

2.17.1 (i) Each Group Company holds all permits, licenses or public law approvals *(öffentlich-rechtliche Erlaubnisse)* which are necessary to conduct its business as currently conducted (the "**Permits**"), (ii) the Permits are in full force and effect *(bestandskräftig),* are not challenged *(angefochten)* by any third party, and there are no circumstances which would be reasonably expected to justify such a challenge, and (iii) no proceedings regarding a revocation *(Widerruf)* or withdrawal *(Rücknahme)* of any Permit have been initiated or threatened, and there are no circumstances which would reasonable expected to justify the initiation of such proceedings.

2.17.2 Each Group Company is and has been in full compliance with the Permits, including any ancillary provisions (*Nebenbestimmungen*) thereto, and with all applicable laws and regulations of any jurisdiction and all orders, decrees, or rulings of, or restrictions imposed by,

any Governmental Entity (collectively "**Administrative Orders**") in all relevant jurisdictions. No non-compliance with the Permits, with applicable laws and regulations or with any Administrative Order has been alleged in writing and, to the Best Knowledge of the Sellers, there are no circumstances, which would be reasonably expected to justify such allegations.

2.17.3 (i) No Group Company is subject to any administrative proceedings or administrative or criminal investigation, (ii) no such investigation has been threatened, and (iii) there are no circumstances which would be reasonably expected to justify the initiation of such an investigation.

2.17.4 No Group Company is a party to any public law agreements *(öffentlich-rechtliche Verträge)*.

2.17.5 Except as disclosed in Annex 2.17.5, no Group Company has received, applied for or used any public grants *(Zuschüsse),* allowances, aids or other subsidies *(Subventionen)* in whatever form (including, without limitation, loans under the European Recovery Program) (collectively "**Public Subsidies**"). Annex 2.17.5 includes for each Group Company a correct and complete list of the Administrative Orders and all other terms relevant for the Public Subsidies granted to such Group Company. Except as disclosed in Annex 2.17.5, (i) the orders or agreements granting the Public Subsidies are in full force and effect, are not challenged by any third party, and, to the Best Knowledge of the Sellers, there are no circumstances which would justify such a challenge, (ii) no proceedings regarding a revocation or withdrawal of a Public Subsidy have been initiated or threatened, and, to the Best Knowledge of the Sellers, there are no circumstances which would justify such a proceedings, (iii) each Group Company is in full compliance with its obligations under or in connection with the Public Subsidies, including the obligations under any ancillary provisions in the respective orders or agreements thereto, (iv) no Group Company is obliged under the Public Subsidies to maintain a certain level of employees or to make any other investments, (v) no Public Subsidy will have to be repaid in whole or in part due to the execution or consummation of this Agreement or the transactions contemplated therein, and (vi) no Group Company is exposed to any liability with respect to any Public Subsidy granted to the Sellers or affiliates of the Sellers.

2.17.6 Product Quality. There are no product or service liability or similar claims, or product or service warranty claims with an aggregate value of more than EUR 10,000.00 pending against the Group Companies.

2.17.7 Compliance with Mandatory State, Federal and International Reporting Obligations. The Group Companies have complied with all mandatory state, federal, and international reporting obligations regarding transfers of values made to health care professionals.

2.17.8 Compliance with Anti-Corruption and Anti-Bribery Laws and Regulations. The Group Companies have complied with all applicable anti-bribery and anti-corruption laws and regulations.

2.17.9 Compliance with Laws and Regulations Governing Product Communications. The Group Companies have complied with all applicable laws and regulations governing product communications and have not received any notification from any regulatory agency regarding such product communications.

2.18 Tax Guarantees.

2.18.1 All material Tax Returns by or on behalf of the Group Companies were filed when due (taking into account any applicable extension of any filing term).

2.18.2 The Group Companies have (taking into account any permitted extension) timely paid on or prior to the Closing Date all Taxes shown as payable on any valid and enforceable Tax assessment notice issued by any Tax Authority or on any Tax Return filed by them, other than Taxes for which a suspension of enforcement of Tax payment obligation (*Aussetzung der Vollziehung*) has been granted.

The information provided to Intersect, including the advisors of Intersect, in connection with this Agreement and in the virtual data room made available by the Sellers to Intersect prior to the date hereof, (the "**Data Room**") is materially correct and complete, is not misleading and presents a true and fair view of the business, assets and liabilities, financial position and earnings position of each Group Company and the Group Companies taken as a whole. To the Best Knowledge of the Sellers, no information was withheld from the Purchaser of which a reasonable purchaser of any interests in any Group Company should be aware. The Sellers Dr. Dirk Mucha, Prof. Dr. Kai Desinger and Matt Jones are not aware that the execution or consummation of this Agreement or the transactions contemplated herein will have an adverse effect on the relationship of any of the Group Companies with its customers, suppliers, employees or any authorities.

3. GUARANTEES OF THE PURCHASER

Purchaser hereby represents and warrants in the form of an independent guarantee and irrespective of negligence (*selbständiges, verschuldensunabhängiges Garantieversprechen*) pursuant to section 311 BGB that the statements set forth in Section 3.1 through Section 3.8 are true and correct in all material respects.

3.1 Corporate Organization, Due Authorization. The Purchaser is a Delaware corporation duly established and organized, validly existing and in good standing under the laws of the State of Delaware, USA. The Purchaser has the unrestricted right, power, authority and capacity to execute and consummate this Agreement and the transactions contemplated herein. All required approvals of any corporate bodies (including by shareholders, if required) of the Purchaser have been given. The execution and performance of this Agreement by Purchaser and the consummation of the transaction requires no approval or consent by any Governmental Entity and does not violate any law applicable to the Purchaser.

3.2 No Insolvency. No insolvency or similar proceedings have been, or have been threatened to be, opened or applied for regarding the assets of the Purchaser, and there are no circumstances, which would require or justify the opening of or application for such proceedings. The Purchaser is neither illiquid *(zahlungsunfähig)* nor over-indebted *(überschuldet),* nor is an illiquidity impending.

3.3 Legal, Valid and Binding Obligation. This Agreement constitutes (and all other documents executed by Purchaser under or in connection with this Agreement will, when executed, constitute) legal, valid and binding obligations of the Purchaser, respectively, enforceable in accordance with their terms.

3.4 No Violation. The execution and consummation of this Agreement and of the transactions contemplated herein by the Purchaser do not violate the articles of association, partnership agreement or other corporate documents, as the case may be, or any other legal obligation of the Purchaser and is not subject to challenge *(Anfechtung)* by any third party on any legal basis, including on the basis of any laws for the protection of creditor rights.

3.5 No Interference. There is no action, suit, investigation or other proceeding pending or threatened against or affecting the Purchaser before any Governmental Entity which in any manner challenges or seeks to prevent, enjoin, alter or materially delay the execution or consummation of this Agreement or the transaction contemplated herein, and there are no circumstances likely to give rise to any of this.

3.6 Finders' Fees. Purchaser does not have any obligation or liability (whether or not contingent) to pay any fees or commissions to any broker, finder, agent or other Person with respect to the transaction contemplated by this Agreement for which the Sellers or the Company would be or could become liable.

3.7 Financial Capability. Purchaser has or will have sufficient immediately available funds or binding and unconditional financing commitments in the form of finally executed loan agreements to enable it to make all payments required to be made by it under this Agreement when they become due.

3.8 Purchaser for own Investment. Purchaser is acquiring the Shares for its own account and not with a view to or for any ensuing sale or syndication. Purchaser (either alone or together with its advisors) has

sufficient knowledge and experience in financial and business matters to be capable of evaluating the merits and risks of its investment in the Company and is capable of bearing the economic risks of such investment.

3.9 Indemnification. If the Purchaser breaches any guarantee pursuant to this Section 3, the Purchaser shall indemnify and hold harmless the Sellers from any damages incurred by the Sellers. The liability of the Purchaser for breaches of guarantees pursuant to this Section 3 shall become time barred after five (5) years and shall be limited to the Purchase Price.

4. ADDITIONAL AGREEMENTS

4.1 Consents and Approvals. Each of the Parties shall (i) take all reasonable actions necessary to comply promptly with all legal and regulatory requirements which may be imposed on any of them with respect to the transactions contemplated by this Agreement and the agreements referred to herein and will promptly cooperate with and furnish information (redacted for confidentiality where necessary) to each other in connection with any such requirements imposed on any of them in connection with the transactions contemplated hereby, and (ii) take all reasonable actions necessary to obtain and shall cooperate with each other in obtaining any consent, authorization, order or approval of, or any exemption by, any Governmental Entity or other public or private third party, required to be obtained by any of the Parties in connection with the Transaction.

4.2 Further Assurances. Subject to the terms and conditions of this Agreement, the Parties shall use all reasonable efforts to take, or cause to be taken, all actions and to do, or to cause to be done, all things necessary, proper or advisable to consummate and make effective the Transaction. From time to time after the date of this Agreement, and at the reasonable request of any Party hereto and without further payment of consideration, any other Party shall execute and deliver to the requesting Party such documents and take such other action as the requesting Party may reasonably request in order to consummate more effectively the Transaction.

4.3 Public Announcements. The Purchaser intends to publicly announce the signing of this Agreement and the execution of the Transaction by means of a press release issued promptly following such signing. Except for such press release and except with the prior consent of the other Parties, no Party to this Agreement shall make or cause to be made any press release or public announcement or otherwise communicate with any news media concerning this Agreement or the Transaction, except as required by applicable law or otherwise necessary to consummate the Transaction.

4.4 Financing and Distribution Commitment by Purchaser. In order to obtain an unqualified audit opinion for the financial statements of the Group Companies for the business year ending December 31, 2019, Fiagon AG requires further financing commitments as well as distribution commitments in order to document its status as a ‘going concern’. For the purposes of securing that the Group Companies may obtain an unqualified audit opinion for its financial statements for the business year ending December 31, 2019, the Purchaser shall on the Closing Date issue to Fiagon AG a letter of comfort (*Patronatserklärung*) in the form as attached hereto as Annex 4.4 providing for (i) financing commitments for a period of three years after the Closing Date and up to a maximum amount of (A) EUR 5,000,000.00 (in words: *Euro five million*) plus (B) the total amount of Financial Debt repaid by the Group Companies on or prior to the Closing Date pursuant to Section 1.7.3, to Fiagon AG and the Group Companies as well as (ii) the commitment and confirmation that the Purchaser will engage in the distribution of the products of the Company Group in the United States of America via the Purchaser's distribution channels. Provided that the foregoing commitments are executed by the Purchaser on the Closing Date, the auditor of the Group Companies has confirmed that the aforementioned unqualified audit opinion is issued by the Group Companies’ auditor within five Business Days of the Closing Date.

4.5 Form of Agreements. Where under this Agreement (i) one or more Parties to this Agreement undertake to, and shall, enter into a further agreement after the date hereof and (ii) such further agreement to be entered into is attached hereto as an annex, the Parties undertake towards each other to negotiate in good faith, and to mutually agree, the finals terms of such further agreement.

4.6 Post-Closing Covenants.

4.6.1 Within two (2) weeks after the later to occur of (i) Closing Date or (ii) the delivery of the unqualified audit opinion referred to in Section 4.4 above, the Purchaser shall assure that the supervisory board of the Company shall adopt the financial statements of the Company and the Group Companies for the business year ending December 31, 2019.

4.6.2 Within four (4) weeks after the Closing Date and provided the unqualified audit opinion referred to in Section 4.4 above shall have been issued, the Purchaser shall (i) adopt a shareholder's resolution of the Company, and cause the Company to adopt respective shareholder's resolutions in the Subsidiaries, voting in favor of an exoneration of the respective current directors, members of the Management Board and the Supervisory Board for the time period until and including the Closing Date and (ii) cause the Company to pay all outstanding remuneration to the members of the Supervisory Board including any remuneration under consultancy agreements.

4.6.3 The Sellers shall procure that a certain exit bonus agreement governing the exit bonus for certain members of the Company's management and providing for a respective protection of the Company by way of a genuine contract in favor of third parties (*Echter Vertrag zugunsten Dritter*) within the meaning of Sec. 328 BGB against potential income tax claims resulting from such exit bonuses has been duly executed by and between the designated parties thereto and is still in force and effective and has neither terminated nor rescinded. The Sellers shall indemnify the Purchaser and the Group Companies for any Losses incurred by such parties as a result of such agreement and arrangement.

4.7 Merger Control and Foreign Direct Investments Filings.

4.7.1 According to the analysis of the Parties, there is no need of a merger control filing with any antitrust authority.

4.7.2 Further, the Parties came to the conclusion that there is no need for a filing of the change in ownership with the German ministry of economics in accordance with the German foreign direct investment regime under the Foreign Trade Act (AWG) and Foreign Trade and Payments Regulation (AWV) (sections 4 para. 1 No. 4, 5 para. 2 AWG, sections 55 to 59 AWV), as they concluded that no filing requirement pursuant sec. 55 para. 4 sentence 1 AWV is triggered and also does not deem it necessary to apply for a certificate of non-objection (*Unbedenklichkeitsbescheinigung*, sec. 58 AWV).

5. REMEDIES

5.1 Indemnification

5.1.1 In the event that any of the Guarantees of the Sellers in Section 2 is incorrect or incomplete (a "**Guarantee Breach**"), the Sellers, or the respective individual Seller with regard to Fundamental Guarantees regarding such Seller's Shares, shall, subject to the provisions and limitations contained in this Section 5, put, within a period of 20 Business Days from the receipt by Sellers of a Breach Notice, the Purchaser, and/or at the Purchaser's election, the respective Group Company in the same position they would be in if the Guarantee had been correct and complete, either by providing for such position in kind *(Naturalrestitution),* or, if the remediation in kind is not possible or has not occurred within the period specified above, indemnify *(freistellen)* and hold harmless *(schadlos stellen)* the Purchaser or, at Purchaser's election, the respective Group Company from and against, all direct damages including, without limitation, loss of profit, diminution in value, interest, fines, penalties, costs (including reasonable legal, accounting and other fees and expenses of professional advisors), costs of settlement or investigation and other similar losses to the extent that these are considered damages typically resulting from a breach of guarantee of such type (*aus der konkreten Garantieverletzung typischerweise resultierende Schäden*) (collectively "**Loss**" or "**Losses**")

which they would not have suffered if the respective representation of the Seller had been correct and complete or the covenant complied with, provided that

(a) claims resulting from a breach of any of the Operational Guarantees or a claim for indemnification according to Section 6 shall exclusively be settled by way of set off against the unpaid Purchase Price up to the Maximum Amount and each Seller hereby individually and irrevocably agrees to such set-off against such Seller's portion of the Purchase Price;

(b) claims resulting from a breach of the Fundamental Guarantees set forth in Section 2.2.1 (Corporate Status of Fiagon AG) and Section 2.2.2 (No Insolvency of Fiagon AG) shall exclusively be settled by (i) way of set off against the unpaid and not otherwise set off Purchase Price and (ii) with respect to any exceeding amounts only individually and limited to such amount, which the respective Seller actually received as cash disbursement as its portion from the Purchase Price. In no event shall a Seller be obliged to repay more than such Seller has actually received.

(c) each Seller shall only be individually liable with regard to claims resulting from a breach of the Fundamental Guarantees set forth in Section 2.1 and Section 2.2.3 with regard to such respective Seller and/or those of the Shares sold by the respective Seller or a covenant breach by the respective Seller to the extent such loss is not already compensated by (a) or (b) above and shall be limited to such amount, which the respective Seller actually received as cash disbursement as its portion from the Purchase Price. In no event shall a Seller be obliged to repay more than such Seller has actually received.

Losses shall not include internal administration and overhead costs or damages and other amounts computed as any "multiple of profits" or "multiple of cash flow" or similar valuation methodology. Any advantages resulting from the breach *(Vorteilsausgleich)* shall be taken into account when calculating any Loss.

5.1.2 In the event that any Seller shall have failed to comply with any covenants to be complied with at or prior to Closing set forth in this Agreement, such Seller shall only be individually liable with regard to claims resulting from a breach of such covenant to the extent such loss is not already compensated by Section 5.1.1 (a) or (b) above and shall be limited to such amount, which the respective Seller actually received as cash disbursement as its portion from the Purchase Price. In no event shall a Seller be obliged to repay more than such Seller has actually received.

5.1.3 Indemnification under this Section 5 shall be the sole and exclusive remedy (*einziger und ausschließlicher Rechtsbehelf*) of the Purchaser for any breach of any Guarantee or covenant of the Sellers or any other provision of this Agreement or otherwise, other than proven claims for intentional and knowing fraud (*Vorsatz oder arglistige Täuschung*).

5.1.4 Section 254 BGB shall apply.

5.2 Losses Reflected in Financial Statements; Offsets

The Sellers shall not be liable to Intersect for any Losses to the extent that:

(a) such Losses are represented by, reflected or accounted for as a write-off, value adjustment, liability or provision, including general adjustments (Pauschalwertberichtigungen) or provisions made for the relevant risk category, in the Financial Statements; or

(b) any damages of Intersect or the Group Companies only to the extent (i) those are covered by enforceable claims against third parties, including, but not limited to,

through existing insurance policies and (ii) actually recovered by Intersect or the Group Companies in cash (after deducting any and all costs incurred in the collection of such amounts);

(c) the alleged Guarantee Breach is based on (i) an amendment of a law, ordinance, statute, international treaty, administrative regulation, judgment, resolution, decision, permit, disposition or any other (administrative) act or other legal provision, or (ii) the increase of a Tax (as defined below), occurring after the Closing Date.

5.3 Disclosed or Known Matters

5.3.1 The Sellers shall not be liable for any Guarantee Breach to the extent the underlying facts of the Guarantee Breach have been truly and fairly disclosed to Purchaser in this Agreement or any Annex hereto to the extent that (a) the exceptions and disclosures are set forth in such Annex corresponding to the particular Section of this Agreement in which such Guarantee appears; or (b) the exceptions or disclosures are explicitly cross-referenced in such Annex by reference to another Annex; or (c) the exception or disclosure is set forth in any other Annex or a part thereof to the extent it is reasonably apparent on its face (without reference to any underlying documents) that such exception or disclosure is intended to qualify such Guarantee.

5.3.2 Section 442 BGB shall apply.

5.3.3 For evidence purposes, the Sellers cause the data-room service provider to provide within five Business Days of the date hereof a write-protected USB-stick containing the documents that have been disclosed in the Data Room (and placed in the Data Room no later than 11:59 pm (German time) on September 13, 2020) for the purpose of the due diligence investigation conducted by Purchaser as well as the respective Q&A due diligence tracker (the "**VDR USB-Stick**") to the legal representatives of each side who shall each (i) keep the VDR USB-stick for the maximum limitation period under this Agreement, and (ii) allow the Sellers and Intersect to make copies thereof at the premises of the legal representatives at their own costs and at usual business hours.

5.4 Thresholds, Aggregate Amounts of Liability, Set Off

5.4.1 The Sellers shall only be liable for any Losses under this Agreement if the Loss with respect to an individual matter (or group of related matters) exceeds an amount of EUR 35,000.00 (in words: *Euro thirty-five thousand*) (the "**De Minimis Amount**") and then only if and to the extent that all indemnifiable Losses for matters with Losses above the De Minimis Amount exceed an aggregate amount of EUR 400,000.00 (in words: *Euro four hundred thousand*) in which case the full amount of the indemnifiable Losses shall be recoverable from Euro one (*Freigrenze*).

5.4.2 The Sellers' liability for claims under this Agreement other than for breaches of Fundamental Guarantees shall in the aggregate be limited to the amount of EUR 12,000,000.00 (in words: *Euro twelve million*) ("**Maximum Amount**") and shall only be remedied by way of set-off as provided for in this Section 5. Any liability of a Seller resulting from a breach of a Fundamental Guarantee shall be limited to such amount, which the respective Seller actually received as cash disbursement as its portion from the Purchase Price. In no event shall a Seller be obliged to repay more than such Seller has actually received.

5.4.3 With respect to claims arising out of, or in connection with, the Fraunhofer Dispute, the Sellers shall only be liable if, and to the extent that, the total cost of the award/settlement together with associated attorneys' fees and other related costs exceed the amount of EUR 10,000.00. Section 5 shall apply *mutatis mutandis* except for Section 5.4.1, which shall not apply to these claims.

5.5 Limitation Periods

5.5.1 Any claim of Intersect under this Section 5 resulting from a breach of any Operational Guarantee as well as other claims under this Agreement not covered by 5.5.2 and 5.5.3 shall become time barred after 21 months.

5.5.2 Tax liabilities according to Section 6 become time barred as set forth in Section 6.6.1 and 6.6.2.

5.5.3 Any claim of Intersect under this Section 5 resulting from a breach of a Fundamental Guarantee or a covenant shall become time barred after four (4) years.

5.5.4 Section 203 through 213 BGB shall apply accordingly.

5.6 Indemnification Procedures

5.6.1 In the event that Intersect becomes aware of any circumstances which indicate that there has been a Guarantee Breach, Intersect shall give the Sellers written notice within twenty (20) Business Days thereof ("**Breach Notice**"). The Breach Notice shall state the nature of the Guarantee Breach and the amount of Losses resulting therefrom if and to the extent such Losses can with reasonable effort be determined at the time the Breach Notice is given. To the extent reasonably required by the Sellers to assess the alleged Guarantee Breach and the resulting Losses, Intersect shall provide, and shall procure that the Group Companies provide, to Sellers and their respective professional advisors access during normal business hours to their relevant books, documents and other records and information, and to relevant and management personnel. The Parties agree that Section 442 para. 1 BGB shall apply whereas Section 377 HGB shall not apply.

5.6.2 In the event that any action, claim, demand or proceeding with respect to which the Sellers may be liable to indemnify Intersect under this Agreement is asserted or announced by any third party (including any Governmental Entity) against Intersect or the Group Companies (the "**Claim Addressee**") (any such claim, a "**Third Party Claim**"), Intersect shall have the right to defend the Claim Addressee against the Third Party Claim and shall have, at any time during the proceedings, the sole power to direct and control such defense, however, at any time taking the interests of the Sellers and the Group Companies into account, in particular views of the Sellers with respect to negotiations. No action by the Purchaser or its representatives in connection with the defense shall be construed as an acknowledgement (whether express or implied) of Sellers' liability under this Agreement or of any underlying facts related to such liability. Notwithstanding anything to the contrary included herein, if Purchaser settles the Third Party Claim without the Sellers' Representative's prior written consent, then such settlement, adjustment or compromise shall not be conclusive evidence of the amount of Losses incurred by the Group Companies or the Purchaser in connection with such claim or legal proceeding.

5.6.3 All costs and expenses incurred by Purchaser in connection with the defense in accordance with Section 5.6.2 shall be borne by the Purchaser, except for any Losses to be indemnified by the Sellers under this Agreement.

5.6.4 With respect to the failure of any Claim Addressee to comply with any of its obligations under Section 5.6.1 and Section 5.6.2, Section 254 BGB shall apply.

5.7. No Additional Rights or Remedies

5.7.1 The Parties agree that the rights and remedies which a Party may have with respect to the breach of a representation, warranty, covenant or agreement or any other provision of this Agreement, and under all indemnities contained herein, are limited to the rights and remedies explicitly contained herein.

5.7.2 Each Party hereby waives any claims under statutory representations and warranties (sections 434 et seqq. BGB), statutory contractual or pre-contractual obligations (*vorvertragliche Pflichten*) (section 280 to 282, 311 BGB) or frustration of contract (*Wegfall der Geschäftsgrundlage*) (section 313 BGB) or tort (sections 823 et seqq. BGB), and no Party shall have any right to rescind, cancel or otherwise terminate this Agreement or exercise any right or remedy which would have a similar effect.

5.7.3 The provisions of this Section 5 shall not affect any rights and remedies of the Parties for intentional and knowing fraud (*Vorsatz oder arglistige Täuschung*).

5.7.4 Without limiting the generality of the foregoing, Intersect acknowledges that the Sellers give no representation, warranty or guarantee with respect to any projections, estimates or budgets delivered or made available to Intersect or its counsel, accountants or other advisors regarding future revenues, earnings, cash flow, the future financial condition or the future business operation of the Group Companies.

5.8 No double counting or double recovery; Exclusion of claims pursuant to Section 2.5 to 2.7. There shall be no double counting or double recovery for any claims (relating to the same subject matter) made by (a) Purchaser for remedies provided by the Sellers or (b) the Sellers for remedies provided by the Purchaser under or in connection with this Agreement. Furthermore, all claims of Intersect pursuant to Section 5 in conjunction with Sections 2.5 to 2.7 relating to the Financial Statements shall be excluded, if and to the extent a specific representation, warranty, covenant or agreement of the Sellers relating to the respective subject matter is included in this Agreement.

5.9 Mutual Understanding of the Parties regarding Tax Losses Carried Forward. For the avoidance of doubt, it is the mutual understanding of the Parties that the Sellers shall not be responsible for a potential forfeiture of tax losses carried forward resulting from the sale and transfer of the Shares under this Agreement.

6. TAX INDEMNITY

6.1 Definitions.

"**Straddle Period**" means any period relevant for Taxes (including Veranlagungs- /Erhebungszeitraum or fiscal year (Wirtschaftsjahr)) starting before and ending after the Effective Date. For purposes of the determination of the Pre-Effective Date Taxes, the Straddle Period will be deemed to be split into (a) a period ending on the Effective Date and (b) a period beginning after the Effective Date.

"**Pre-Effective Date Period**" means any time period ending on or before the Effective Date.

"**Pre-Effective Date Tax**" means any Tax attributable to the Pre-Effective Date Period (including, for the avoidance of doubt, any interest on Pre-Effective Date Taxes even if such interest accrues for periods after the Effective Date).

"**Tax**" and "**Taxes**" shall mean (a) any taxes on income, profits or gains, and all other taxes, including any property, payroll, employment, diverted profits, value added, sales, and transfer taxes, together with all penalties, charges, fees and interest relating to any of the foregoing or to any late or incorrect return in respect of any of them, excluding, for the avoidance of doubt, deferred taxes and/or notional taxes (including reductions of loss carryforwards or future depreciation), (b) social security charges (Sozialversicherungsbeiträge) and other similar or comparable contributions, and (c) any liability in respect of the items described in clause (a) and clause (b) payable by reason of contract, assumption, transferee liability, or operation of law (in particular, but not limited to, secondary liabilities with respect of any of the items described in clause (a) and clause (b) owed by another taxpayer, but excluding the provisions of any commercial agreement or arrangement the primary purpose of which is unrelated to Taxes).

"**Tax Authority**" means any government, state or municipality or any local, state, federal or other fiscal, revenue, customs or excise authority, body or official anywhere in the world, authorised to levy

Tax or responsible for the administration and/or collection of Tax or enforcements of any applicable Law in relation to Taxation.

"**Tax Benefit**" means any Tax Refund and any reduction of Tax liability, for example, due to any item (a) reducing the tax base or (b) relevant for the computation of income, profits or gains for the purposes of any Tax, or any right to or actual payment of or saving of Tax including any fee or interest in respect of Tax (including depreciation allowances, deductions or exemptions in respect of Tax, Tax items that can be carried forward or back, or reductions of taxable income), in each case caused by reciprocal effects (Wechselwirkungen), including resulting from the extension of depreciation periods or higher allowances (Phasenverschiebung) or the transfer of items relevant for Taxes into another year or the transfer of Tax items from one entity to another.

"**Tax Proceeding**" means any administrative and judicial proceeding or action relating to Taxes including preparatory proceedings, Tax assessments, Tax audits, objections, appeals, meetings and correspondence with any Tax authority or court.

"**Tax Refund**" means any payment of any Tax (including by way of set-off, deduction or Tax credit) made by a Tax Authority.

"**Tax Return**" means any return, declaration or similar document relating to any Tax and to be submitted to any Tax Authority, including any Schedule or attachment thereto.

"**Taxation**" means the imposition of any Tax.

6.2 Tax Indemnification.

6.2.1 The Sellers undertake that they will pay to Intersect an amount equal to the sum of

(a) any Pre-Effective Date Taxes imposed on the Group Companies; and

(b) any Tax arising in connection with the termination of the ESOP

to the extent paid or payable after the Effective Date by the Group Companies (any Tax to be indemnified under this Section 6.2 the "**Indemnifiable Tax**").

6.2.2 The indemnity contained in paragraph 6.2.1 shall not encompass any Indemnifiable Tax to the extent that:

(a) the aggregate amount of Indemnifiable Taxes paid or payable by the Group Companies after the Effective Date is less than the aggregate amount of provisions and reserves in respect of Taxes in the Effective Date Financial Statements provided that such provisions and reserves were considered in the calculation of the Purchase Price;

(b) the Indemnifiable Tax arises in connection with the termination of the ESOP and was considered in the calculation of the Purchase Price;

(c) the Indemnifiable Tax has been paid (including by way of a Tax pre-payment (*Steuervorauszahlung*) and/or set-off (*Auf-/Verrechnung*)) or discharged on or before the Effective Date;

(d) the Indemnifiable Tax has been recovered or is recoverable by a claim for repayment, reimbursement or indemnification against a party (e.g. an insurer) other than a Group Company;

(e) the Indemnifiable Tax results from income that could be offset against a Tax loss-carry back or loss carry forward actually available (or that would actually have been available but were forfeited due to a measure taken by the Purchaser or a Group

Company after the Effective Date) at the level of the relevant Group Company and generated in periods or portions thereof ending on or before the Effective Date;

(f) the Indemnifiable Tax has arisen by reason of a change in legislation or regulations, made after the Effective Date (whether relating to Tax or otherwise) or any amendment to;

(g) the Indemnifiable Tax is caused by a retroactive reorganization of the Group Companies or the Intersect or any of its subsidiaries of whatsoever kind (i.e. transformation, merger and spin-offs under the laws of the countries having jurisdiction over the Group Companies as well as disposals of shares or contributions of assets) after the Effective Date which takes effect on Pre- Effective Date Period;

(h) the Indemnifiable Tax or its underlying circumstances have caused a Tax Benefit of the Group Companies; the Tax Benefit shall be calculated for a period of five (5) years starting after the Effective Date and discounted at a rate of 2.00%;

(i) Intersect has recovered any amount under this Agreement in respect of the same loss, damage, deficiency or Indemnifiable Tax;

(j) the Indemnifiable Tax is directly or indirectly caused or triggered by any change in the accounting and Taxation principles or practices of the Group Companies after the Closing Date unless required under mandatory law; or

(k) the Indemnifiable Tax is caused or increased by Intersect or any Affiliate of Intersect due to a breach of any of the Intersect's obligations under this Agreement, including but not limited to any Indemnifiable Tax caused by a non-compliance of Intersect or, after the Closing Date of a Group Company, with the procedures set forth in Section 6.4 (without prejudice with regard to any rights of the Sellers arising out of such breach) or result from, or are increased by, a failure of Intersect or, after the Closing Date, of a Group Company, to mitigate damages pursuant to section 254 German Civil Code (*BGB)*.

6.2.3 Any payment under this Section 6.2 shall only be settled by set off pursuant to Section 1.10 or against the Claim Notice Escrow Account pursuant to Section 1.16; for the avoidance of doubt, the Sellers are not obliged to make any payments under this Section 6.2 if a set off pursuant to Section 1.10 or against the Claim Notice Escrow Account pursuant to Section 1.16 is not possible. The set off shall become effective on the day on which the Sellers receive a written set off declaration (*Aufrechnungserklärung*) which includes (i) information about the payment obligation and the corresponding payment date and all circumstances giving rise to the payment obligation pursuant and in accordance with this Agreement and (ii) a copy of the relevant Tax assessment notice (*Steuerbescheid*) of the competent Tax Authority (or a copy thereof) and a detailed calculation of the Indemnifiable Tax.

6.2.4 If an Indemnifiable Tax case is not finally assessed but Taxes are set-off pursuant to Section 6.2.3, any indemnification pursuant to Section 6.2.3 shall be considered as an advanced payment to Intersect. If subsequently the Tax for which the advanced payment has been made is reduced again by way of Tax assessment or otherwise lowered, the difference between the higher advanced payment and the lower Tax liability shall be paid by the Purchaser to the Sellers including all interest related thereto (including any security payments (*Sicherheitsleistung*) disbursed by the Sellers)

(a) if the respective Tax is reduced by a Tax assessment within the Payment Period, on the date – immediately following the relevant Tax assessment – on which the next the Purchase Price instalment is due and payable, i.e. the Second Instalment Date, the Third Instalment Date or the Fourth Instalment Date, as the case may be;

(b) if the respective Tax was initially set off against the Claim Notice Escrow Account pursuant to Section 1.16 and is therefore reduced by a Tax assessment after the Payment Period, such difference shall be paid into, and kept in, the Claim Notice Escrow Account until the Claim Notice Escrow Account pursuant to Section 1.16.1(b) amounts to EUR 2,000,000 (this maximum amount is to be reduced by any Tax Refunds that reduced an Indemnifiable Tax pursuant to Section 6.3.2 after the Fourth Instalment Date) and beyond that amount such difference shall be paid by the Purchaser to the Sellers including all interest related thereto (including any security payments (*Sicherheitsleistung*) disbursed by the Sellers) without undue delay (*unverzüglich*); and

(c) without undue delay (*unverzüglich*) in all other cases (e.g. if the relevant Tax was initially set off pursuant to Section 1.10 and is reduced by a Tax assessment after the Payment Period).

6.3 Tax Refunds.

6.3.1 Intersect shall pay to the Sellers an amount equal to

(a) any Tax Refund of a Pre-Effective Date Tax received (including by way of set-off, deduction and Tax credit) by the Group Companies after the Closing Date to the extent the aggregate amount of such Tax Refunds exceeds the aggregate amount of Tax claims in the Effective Date Financial Statements and were not considered in the calculation of the Purchase Price; and

(b) Tax accruals or liabilities which were established by the Group Companies in relation to any Pre-Effective Date Period in the Financial Statements and which were considered in the calculation of the Purchase Price, but which are considered as no longer required under the accounting principles applicable to the relevant Group Company provided that such Tax accruals or liabilities have not reduced an Indemnifiable Tax claim pursuant to Section 6.2.2(a).

6.3.2 Any payment under this Section 6.3 shall initially only be recognized as a reduction of any Indemnifiable Tax that would otherwise be set-off pursuant to Section 1.10 or against the Claim Notice Escrow Account pursuant to Section 1.16. Such reduction shall only occur after the Tax Refund has been received (in cash payment set-off or deduction) or, applying generally accepted accounting standards, realized by the recipient. Intersect shall, and shall procure that the Group Companies will, notify the Sellers of the receipt of any Tax Refund or the dissolution of a Tax accrual or liability relating to a Pre-Effective Date Period.

6.3.3 The Purchaser shall pay to the Sellers an amount equal to the aggregate amount of all Tax Refunds under this Section 6.3 of up to EUR 2.000.000 that have not been recognized as a reduction of any Indemnifiable Tax that would otherwise be set-off pursuant to Section 1.10 or against the Intersect Escrow Account pursuant to Section 1.16 in accordance with Section 6.3.2; payment under this Section 6.3.3 is due on the Fourth Instalment Date, or if the Purchaser made any payments to the Claim Notice Escrow Account pursuant to Section 1.16, on the date on which the Purchaser is obligated to fully release the amounts held in the Claim Notice Escrow Account. In no case, the total amount of (i) all Tax Refunds recognized as a reduction of Indemnifiable Tax that would otherwise be set-off under Section 6.3.2 against the Claim Notice Escrow Account pursuant to Section 1.16. and (ii) any Indemnifiable Tax set-off against the Claim Notice Escrow Account pursuant to Section 1.16, may exceed the amount of EUR 2.000.000; any exceeding amount of Tax Refunds up to EUR 2.000.000 shall be paid to the Sellers without undue delay.

6.4 Tax Cooperation.

6.4.1 Intersect undertakes to cooperate, and to cause the Group Companies to cooperate with the Sellers with respect to Tax Returns to be filed for the Pre-Effective Date Period.

6.4.2 Intersect shall provide the Sellers within ten (10) business days upon receipt with copies of any tax assessment notices for the Pre-Effective Date Period.

6.4.3 Subject to assuming all the related costs, the Sellers have the right to guide and participate in any appeals against tax assessment notices of the Group Companies relating to Pre-Effective Date Periods. The Sellers shall decide whether and which objections or appeals with regard to Pre-Effective Date Taxes the Group Companies shall procure to be filed. Intersect hall ensure that neither the Intersect nor any Group Company enters into any agreement relating to any Indemnifiable Tax the Sellers might be liable for or entitled to and relating to the Group Companies with any Tax Authority without the prior written consent of the Sellers.

6.4.4 The Sellers shall be informed of any Tax field audits and conferences with the field auditors that are to be carried out by the Tax Authorities in respect of the Pre-Effective Date Period and the Sellers and their professional advisers shall be given the opportunity to safeguard the Sellers' interests in such audits and comment on the results of these audits and shall be informed in good time to enable them to prepare themselves to take part and have the right to take part in meetings with the field auditors and receive any related information from the Group Companies including sufficient advance notice of meetings with the field auditors.

6.4.5 After the Closing Date, Intersect shall procure that, when due, all Tax Returns relating in whole or in part to the Group Companies for the Pre-Effective Date Period required to be filed on an individual or consolidated basis by or on behalf of the Group Companies that need to be prepared and filed in relation to the Group Companies are prepared and filed, when due, provided, however, that any such Tax Returns shall be subject to the review and prior written consent of the Sellers which shall not unreasonably withheld. Intersect shall ensure that any Tax Return to be reviewed and approved by the Sellers will be furnished to the Sellers not later than thirty (30) days prior to the due date of the relevant Tax Return. This shall not apply to monthly Tax notifications, including but not limited to returns for VAT, wage tax, social security contributions, or other Tax Returns with a filing period of less than thirty (30) days.

6.4.6 Intersect shall cause the Group Companies to file, make or change any Tax election/claim, and to file, make or amend any Tax Return or take any position on any return in respect of the Pre-Effective Date Period as instructed by the Sellers at Sellers' discretion and in accordance with relevant Tax law and past practice.

6.4.7 Intersect shall procure that the Group Companies request within one (1) month after the Closing Date the competent tax office to conduct a tax audit for the Pre-Effective Date Period.

6.5 Reduction/Increase of Purchase Price.

All payments under this Section 6 shall be treated as a reduction or increase of the Purchase Price and, if and to the extent payments are made to any of the Group Companies, such payments shall be construed and deemed as contributions made by Intersect into the relevant Group Company and shall be treated as reduction of the Purchase Price as between the Parties.

6.6 Limitations.

6.6.1 A claim for an Indemnifiable Tax under this Section 6 shall become time-barred six months from the date when the respective Tax assessment notice becomes final and binding (*formell und materiell bestandskräftig*).

6.6.2 A claim for a Tax Refund under this Section 6.3 shall become time-barred six months from the date when Intersect has notified the Sellers in writing about the relevant claim.

6.6.3 Except for Section 5.4.2, no further limitations pursuant to this Agreement shall apply for an Indemnifiable Tax under this Section 6. The limitations pursuant to Section 6.6.1 and Section 6.6.2 shall not prevent (i) a set off pursuant to Section 1.10 or (ii) a set off against the Intersect

Escrow Account pursuant to Section 1.16; however, the limitations pursuant to Section 6.6.1 and Section 6.6.2 shall apply immediately (i.e. prevent the respective set off) after the Fourth Instalment Date if and to the extent the requirements for a set off pursuant to Section 1.10 sentence 1 were fulfilled on or before the Fourth Instalment Date and the Purchaser/or the relevant Group Company had knowledge of the relevant Indemnifiable Tax by that time.

6.7 Miscellaneous.

6.7.1 Whenever in this Section 6 (or elsewhere in this Agreement) a reference is made to a certain legal entity (e.g., Intersect, a Group Company etc.), this reference shall, for the avoidance of doubt, always include any legal successor of the referred entity (e.g., the receiving entity in a merger etc.).

6.7.2 It is understood and agreed between the Parties that claims of either Party with respect to Taxes under or in connection with this Agreement may only be based on the provisions of this Section 6 and/or Section 2.18, excepts as otherwise governed in this Agreement.

7. GENERAL PROVISIONS

7.1 Default Interest. Any failure by a Party to make any payment when due shall result in such Party's immediate default (*Verzug*), without any reminder by the other Party being required. Any cash payments due under this Agreement shall bear interest from and including the respective due date to, but not including, the date of receipt. The applicable interest rate shall be five per cent per annum calculated on the basis of actual days elapsed and a calendar year with 360 days. The foregoing shall not affect the respective Party's right to claim additional damages.

7.2 Amendment and Waiver. No amendment of any provision of this Agreement (including amendments of this provision) shall in any event be effective unless the same shall be in writing and signed by all the Parties hereto, unless applicable mandatory law requires a stricter form (e.g., notarization). Any failure of any Party to comply with any obligation, agreement or condition hereunder may be waived only in writing by the Party or Parties entitled to benefit from such election, agreement or condition, but such waiver shall not operate as a waiver of, or estoppel with respect to, any subsequent or other failure. No failure by any Party to take any action with respect to any breach of this Agreement or default by any other Party shall constitute a waiver of such Party's right to enforce any provision hereof or to take any such action.

7.3 Miscellaneous.

7.3.1 For the purposes of this Agreement and any claims made hereunder or negotiations, settlements, court proceedings, each of the Sellers hereby irrevocably appoints the Seller Dr. Adriaan Hart de Ruijter as exclusive agent and attorney in fact ("**Sellers' Representative**") with the power to give and receive all declarations, notices and communications for and on behalf of each of the Sellers, and the Sellers' Representative accepts such appointment. For the avoidance of doubt, this power of attorney covers any authorising of indemnification claims, settlement agreements, declarations to offset and acceptance of service of process. Where under this Agreement any declaration, notice, communication and/or other action is to be made by or to the Sellers or individual Sellers, such declaration, notice and/or communication will only be made by, and shall be made to, the Sellers' Representative and the Purchaser shall be entitled to rely fully and completely on such authority. All communications and notices to the Purchaser under this Agreement shall be made by the Sellers' Representative and not any individual Seller in its capacity as such.

7.3.2 Any amounts owed by the Purchaser to the Sellers under this Agreement shall be paid into the joint bank account of the Sellers as notified by the Sellers to the Purchaser on the date hereof or into such other bank account as notified by the Sellers to the Purchaser at least five (5) Business Days prior to the date such payment is due (the "**Sellers' Bank Account**").

With payment into the Sellers' Bank Account, Purchaser settles his payment obligations (*mit schuldbefreiender Wirkung*) vis-à-vis the Sellers and each individual Seller. No individual Seller has a right vis-à-vis the Purchaser to demand a payment directly to himself.

Any set off against the Purchase Price permitted under this Agreement shall be a permitted set off against the claims of the Sellers and of each individual Seller.

7.3.3 Any payments under this Agreement shall be made in Euro by irrevocable wire transfer of immediately available funds free of any costs and fees of the remitting bank.

7.3.4 All notices, requests and other communications hereunder shall be in writing in the English language and shall be deemed given if delivered personally, telecopied or sent via electronic facsimile transmission, to the extent that facsimile number has been provided below (in each case if delivery is confirmed), sent via electronic mail (if delivery is confirmed) or mailed by international courier (return receipt requested) to the Parties at the following addresses (or at such other address for a Party as shall be specified by like notice), provided that (i) receipt of a copy of a notice, request or other communication by a Party's advisors shall not constitute or substitute receipt thereof by the respective Party itself, and (ii) any notice, request or other communication shall be deemed received by a Party regardless of whether a copy thereof was sent to or received by an advisor of such Party, regardless of whether the delivery of such copy was mandated by this Agreement:

(a) If to the Sellers:

Dr. Adriaan Hart de Ruijter
Bekestraat 22,
3090 Overijse
Belgium
Email: adriaan@cascaraventures.com

with a copy to (which shall not constitute a notice):

Dr. Dirk Besse
Morrison & Foerster LLP
Potsdamer Platz 1
10785 Berlin
Facsimile: +49 30 726 221 100
Email: DBesse@mofo.com

(b) If to Purchaser, to:

Intersect ENT, Inc.
1555 Adams Drive
Menlo Park, CA 94025
USA
Attn: General Counsel
Email: dlehman@intersectent.com

with a copy to (which shall not constitute a notice):

Dr. Andreas Driver, LL.M.
Fieldfisher (Germany) LLP
Central Tower
Landsberger Str. 110
80339 München
Facsimile: +49 89 620 30 6400

Email: Andreas.Driver@fieldfisher.com

7.3.5 Intersect hereby appoints Jonas Mark, Fieldfisher (Germany) LLP, Central Tower, Landsberger Str. 110, 80339 München, an attorney-at-law admitted to the bar in Germany, as its agent for service of process (*Zustellungsbevollmächtigter*) for all legal proceedings involving Intersect arising out of or in connection with this Agreement. This appointment shall only terminate upon the appointment of another agent for service of process domiciled in Germany, provided that the agent for service of process is an attorney admitted to the German bar (or a German legal entity) and his appointment has been notified to and approved in writing by the Company (the approval shall not be unreasonably withheld), and the new agent has confirmed in writing his willingness to act as agent for service of process and to accept deliveries. Intersect has before the date hereof issued, and shall upon the appointment of any new agent for service of process (as the case may be) issue, to the agent a written power of attorney (*Vollmachtsurkunde*) and has instructed, or in case of the appointment of a new agent shall instruct, irrevocably the agent to submit such deed in connection with any service of process under this Agreement. Prior to the date hereof, the agent has made available a confirmation to the Sellers confirming his willingness to act as agent for service of process and to accept in such capacity deliveries for Intersect.

7.4 Entire Agreement; Assignment; Governing Law. This Agreement, together with the other documents referred to herein:

7.4.1 constitutes the entire agreement, and supersedes all prior agreements and understandings, both written and oral, between the Parties and their Affiliates with respect to the subject matter hereof (including the letter of intent signed between the Company and the Purchaser dated July 12, 2020);

7.4.2 shall not be assigned by any Party (by operation of law or otherwise) without the prior written consent of the other Parties, and any such purported assignment of this Agreement in violation of this provision shall be null, void and of no legal effect whatsoever; and

7.4.3 shall be governed by, and construed in accordance with, the laws of the Federal Republic of Germany, excluding the United Nations Convention on Contracts for International Sale of Goods (CISG).

7.5 Jurisdiction. To the extent legally permissible, any dispute, controversy or claim of whatever nature arising out of or in connection with this Agreement, including the breach, termination or validity thereof shall be finally resolved by the Regional Court (*Landgericht*) of Frankfurt, Germany.

7.6 Parties in Interest. Unless specifically provided otherwise in this Agreement, this Agreement shall be binding upon and inure solely to the benefit of each Party hereto and their respective permitted successors and assigns, and nothing in this Agreement, express or implied, is intended to confer upon any other person any rights or remedies of any nature whatsoever under or by reason of this Agreement (*kein Vertrag mit Schutzwirkung für Dritte*). The liability of each Seller shall only be individually and not jointly, unless specifically provided for otherwise herein.

7.7 Interpretation. In interpreting this Agreement, the following rules of construction shall apply:

7.7.1 the section and other headings contained in this Agreement and the Annexes are for reference purposes only and shall not affect in any way the meaning or interpretation of this Agreement or the Annexes, respectively;

7.7.2 unless specified otherwise (*e.g.,* by reference to a certain act or law), references to Articles, Sections, Schedules and Annexes, are references to articles, sections, schedules and annexes in this Agreement;

7.7.3 general words shall not be given a restrictive meaning because they are followed by words which are particular examples of the acts, matters or things covered by the general words and all uses of the word "including", "includes" and "in particular" and related grammatical forms shall be understood to be without limitation; nouns and pronouns of the masculine or feminine grammatical gender shall be understood as including persons of both sexes as applicable; and nouns and pronouns that are grammatically singular or grammatically plural shall be understood to refer to one or more objects to which such nouns or pronouns apply as may be required by the context;

7.7.4 headings and sub-headings in this Agreement are inserted for convenience only and shall not affect the construction of this Agreement;

7.7.5 references to a "person" includes any individual, partnership, body corporate, corporation sole or aggregate, state or agency of a state, and any unincorporated association or organization, in each case whether or not having separate legal personality;

7.7.6 references to "Euro" or "EUR" are references to the lawful currency of the Federal Republic of Germany on the date of this Agreement;

7.7.7 references to times of the day are to Central European Time unless otherwise stated;

7.7.8 the usage of "or" shall always be inclusive and be construed as "and/or"; the incidental usage of "and/or" shall not be construed as an exception to this rule; and

7.7.9 the Parties recognize that each of them has been represented by counsel in connection with the negotiation of this Agreement, and so the Parties agree that any ambiguities in this Agreement shall be interpreted in the light of the intentions of the Parties at the time this Agreement was made and shall not be interpreted for or against any Party on the basis that such Party was responsible or primarily responsible for the drafting of this Agreement.

7.8 Severability. If any term, provision, covenant or restriction of this Agreement is held by a court of competent jurisdiction to be invalid, void or unenforceable (*nicht vollstreckbar*), the remainder of the terms, provisions, covenants and restrictions of this Agreement shall remain in full force and effect and shall in no way be affected, impaired or invalidated. In such case the invalid, void or unenforceable (*nicht vollstreckbare*) provision shall be deemed to have been replaced by such valid and enforceable (*vollstreckbare*) provision that reflects as closely as possible the commercial intent of the Parties as regards the invalid, void or unenforceable (*nicht vollstreckbare*) provision. The aforesaid shall apply *mutatis mutandis* to any unintended omission in this Agreement. It is the express intent of the Parties that this Section 7.8 shall not be construed as a mere reversal of burden of proof (*Beweislastumkehr*) but as a contractual exclusion of section 139 BGB in its entirety.

7.9 German Terms. Wherever this Agreement includes English terms after which either in the same provision or elsewhere in this Agreement German terms have been inserted in brackets and/or italics, the respective German terms alone and not the English terms shall be authoritative for the interpretation of the respective term throughout this Agreement.

[*Signature pages to follow*]

[*Signature pages*]

Dr. Dirk Mucha

/s/ Dirk Mucha

Prof. Dr. Kai Desinger

/s/ Kai Designer

High-Tech Gründerfonds GmbH & Co. KG

/s/ Dirk Besse

By: *Dr. Dirk Besse*

(Proxy based on power of attorney under exclusion of any personal liability)

V+ GmbH & Co. Fonds 3 KG

/s/ Dirk Besse

By: *Dr. Dirk Besse*

(Proxy based on power of attorney under exclusion of any personal liability

Björn Hähnlein

/s/ Kai Designer

By: *Prof. Dr. Kai Desinger*

(Proxy based on power of attorney under exclusion of any personal liability

UNU Gesellschaft für Unternehmensnachfolge und Unternehmensführung GmbH

/s/ Kai Designer

By: *Prof. Dr. Kai Desinger*

(Proxy based on power of attorney under exclusion of any personal liability

Brandenburg Kapital GmbH

/s/ Dirk Besse

By: *Dr. Dirk Besse*

(Proxy based on power of attorney under exclusion of any personal liability

Dr. Clemens Scholz

/s/ Kai Designer

By: *Prof. Dr. Kai Desinger*

(Proxy based on power of attorney under exclusion of any personal liability

P&T International Ltd.

/s/ Dirk Mucha

By: *Dr. Dirk Mucha*

(Proxy based on power of attorney under exclusion of any personal liability

Mon Repos Vermögensverwaltung GmbH

/s/ Kai Designer

By: *Prof. Dr. Kai Desinger*

(Proxy based on power of attorney under exclusion of any personal liability)

Unternehmensbeteiligungsgesellschaft der Sparkassen des Landes Brandenburg mbH

/s/ Dirk Besse

By: *Dr. Dirk Besse*

(Proxy based on power of attorney under exclusion of any personal liability)

Dr. Adriaan Hart de Ruijter

/s/ Kai Designer

By: *Prof. Dr. Kai Desinger*

(Proxy based on power of attorney under exclusion of any personal liability)

aurea invest holding group ag

/s/ Kai Designer

By: *Prof. Dr. Kai Desinger*

(Proxy based on power of attorney under exclusion of any personal liability)

Prof. Dr. Marc Bloching

/s/ Kai Designer

By: *Prof. Dr. Kai Desinger*

(Proxy based on power of attorney under exclusion of any personal liability)

Manfred Gottlieb

/s/ Kai Designer

By: *Prof. Dr. Kai Desinger*

(Proxy based on power of attorney under exclusion of any personal liability)

Dr. Lucyna Dymek

/s/ Dirk Mucha

By: *Dr. Dirk Mucha*

(Proxy based on power of attorney under exclusion of any personal liability)

Alkadaro & Barome LLP

/s/ Kai Designer

By: *Prof. Dr. Kai Desinger*

(Proxy based on power of attorney under exclusion of any personal liability)

Patrick Henkel

/s/ Kai Designer

By: *Prof. Dr. Kai Desinger*

(Proxy based on power of attorney under exclusion of any personal liability)

Matt Jones

/s/ Kai Designer

By: *Prof. Dr. Kai Desinger*

(Proxy based on power of attorney under exclusion of any personal liability)

Tayfun Sen

/s/ Dirk Mucha

By: *Dr. Dirk Mucha*

(Proxy based on power of attorney under exclusion of any personal liability)

Sino-German Alpha Holding Co. Limited

/s/ Kai Designer

By: *Prof. Dr. Kai Desinger*

(Proxy based on power of attorney under exclusion of any personal liability)

Dmitry Obynochnyy

/s/ Kai Designer

By: *Prof. Dr. Kai Desinger*

(Proxy based on power of attorney under exclusion of any personal liability)

Sergio Mondlak Krajmalnik

/s/ Kai Designer

By: *Prof. Dr. Kai Desinger*

(Proxy based on power of attorney under exclusion of any personal liability

German Startups Group VC GmbH

/s/ Kai Designer

By: *Prof. Dr. Kai Desinger*

(Proxy based on power of attorney under exclusion of any personal liability

NOS Neuro Orthopaedics Surgeries

/s/ Kai Designer

By: *Prof. Dr. Kai Desinger*

(Proxy based on power of attorney under exclusion of any personal liability)

Dr. Friedrich Jacobi

/s/ Dirk Besse

By: *Dr. Dirk Besse*

(Proxy based on power of attorney under exclusion of any personal liability)

Chad Smith

/s/ Kai Designer

By: *Prof. Dr. Kai Desinger*

(Proxy based on power of attorney under exclusion of any personal liability)

Nicholas Norman

/s/ Kai Designer

By: *Prof. Dr. Kai Desinger*

(Proxy based on power of attorney under exclusion of any personal liability)

Maximilian Snyder

/s/ Kai Designer

By: *Prof. Dr. Kai Desinger*

(Proxy based on power of attorney under exclusion of any personal liability)

Martin Back

/s/ Kai Designer

By: *Prof. Dr. Kai Desinger*

(Proxy based on power of attorney under exclusion of any personal liability)

Intersect ENT, Inc.

/s/ Thomas A. West

By: *Thomas A. West*

Title: President and Chief Executive Officer

Fiagon AG Medical Technologies

/s/ Kai Designer

By: *Prof. Dr. Kai Desinger*

Title: CEO

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.

November 2, 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.

November 2, 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 September 30, 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.

November 2, 2020

/s/ Thomas A. West

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

November 2, 2020

/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.