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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, 2021
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," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	x
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, 2021 were 33,461,658.

INTERSECT ENT, INC.
Form 10-Q – QUARTERLY REPORT
For the Quarter Ended September 30, 2021

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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, 2021	December 31, 2020
	(unaudited)	(1)
Assets		
Current assets:		
Cash and cash equivalents	$ 59,183	$ 13,521
Short-term investments	21,813	74,506
Accounts receivable, net	14,402	14,592
Inventories, net	20,057	12,054
Prepaid expenses and other current assets	4,406	3,494
Total current assets	119,861	118,167
Property and equipment, net	5,416	5,624
Operating lease right-of-use assets	16,038	17,151
Intangible assets, net	18,923	21,193
Goodwill	47,035	46,639
Restricted cash	17,978	17,500
Other non-current assets	2,715	1,107
Total assets	$ 227,966	$ 227,381
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 10,249	$ 6,042
Accrued compensation	14,555	13,559
Deferred acquisition related consideration, current	20,338	21,071
Other current liabilities	5,646	3,575
Total current liabilities	50,788	44,247
Operating lease liabilities	15,101	17,736
Long-term debt	111,661	63,650
Deferred acquisition related consideration, non-current	32,806	33,167
Deferred tax liability	565	1,569
Other non-current liabilities	831	—
Total liabilities	211,752	160,369
Commitments and contingencies (note 10)		
Stockholders' equity:		
Preferred stock, $0.001 par value; Authorized shares: 9,994; Issued and outstanding shares: none	—	—
Series DF-1 convertible preferred stock, $0.001 par value; Authorized shares: 6; Issued and outstanding shares: none	—	—
Common stock, $0.001 par value; Authorized shares: 150,000; Issued and outstanding shares: 33,455 as of September 30, 2021 and 32,936 as of December 31, 2020	33	33
Additional paid-in capital	387,738	370,053
Accumulated other comprehensive income (loss)	(1)	1
Accumulated deficit	(371,556)	(303,075)
Total stockholders' equity	16,214	67,012
Total liabilities and stockholders' equity	$ 227,966	$ 227,381

(1) Amounts have been derived from the December 31, 2020 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,	
	2021	2020	2021	2020
Revenue	$ 24,400	$ 22,720	$ 76,077	$ 52,326
Cost of sales	5,087	7,845	21,874	21,612
Gross profit	19,313	14,875	54,203	30,714
Operating expenses:				
Selling, general and administrative	29,473	21,702	86,281	67,399
Research and development	6,719	4,551	19,449	13,715
Total operating expenses	36,192	26,253	105,730	81,114
Loss from operations	(16,879)	(11,378)	(51,527)	(50,400)
Interest expense	(1,760)	(886)	(4,544)	(1,372)
Other income (expense), net	(13,654)	799	(13,716)	(350)
Loss before income taxes	(32,293)	(11,465)	(69,787)	(52,122)
Provision for income tax (benefit)	(444)	—	(1,306)	—
Net loss	(31,849)	(11,465)	(68,481)	(52,122)
Other comprehensive loss:				
Unrealized loss on short-term investments, net	(6)	(73)	(2)	(31)
Comprehensive loss	$ (31,855)	$ (11,538)	$ (68,483)	$ (52,153)
Net loss per share, basic and diluted	$ (0.95)	$ (0.35)	$ (2.06)	$ (1.60)
Weighted average common shares used to compute net loss per share, basic and diluted	33,352	32,695	33,187	32,552

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 as of December 31, 2020	32,936	$ 33	$ 370,053	$ 1	$ (303,075)	$ 67,012
Issuance of common stock and exercise of stock options	200	—	1,121	—	—	1,121
Stock-based compensation expense	—	—	4,141	—	—	4,141
Unrealized gain on short-term investments	—	—	—	14	—	14
Net loss	—	—	—	—	(20,031)	(20,031)
Balance as of March 31, 2021	33,136	33	375,315	15	(323,106)	52,257
Issuance of common stock and exercise of stock options	125	—	1,390	—	—	1,390
Stock-based compensation expense	—	—	4,595	—	—	4,595
Unrealized loss on short-term investments	—	—	—	(10)	—	(10)
Net loss	—	—	—	—	(16,601)	(16,601)
Balance as of June 30, 2021	33,261	33	381,300	5	(339,707)	41,631
Issuance of common stock and exercise of stock options	194	—	2,469	—	—	2,469
Stock-based compensation expense	—	—	3,969	—	—	3,969
Unrealized loss on short-term investments	—	—	—	(6)	—	(6)
Net loss	—	—	—	—	(31,849)	(31,849)
Balance as of September 30, 2021	33,455	$ 33	$ 387,738	$ (1)	$ (371,556)	$ 16,214

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 as of 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 as of 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 as of 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 as of September 30, 2020	32,716	$ 33	$ 364,201	$ 22	$ (282,878)	$ 81,378

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,	
	2021	**2020**
Operating activities:		
Net loss	$ (68,481)	$ (52,122)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	3,579	1,467
Non-cash lease expense	1,474	1,623
Stock-based compensation expense	12,627	11,642
Amortization of net investment premium	583	71
Amortization of debt transaction costs and accretion of debt discount	689	339
Impairment of property, equipment, and intangible assets	708	—
Interest expense on deferred acquisition related costs	1,548	—
Loss on foreign currency forward contracts	2,484	—
Foreign currency remeasurement gain	(2,219)	—
Change in fair value of embedded derivatives	12,721	795
Provision for income tax (benefit)	(1,306)	—
Changes in operating assets and liabilities:		
Accounts receivable, net	(20)	7,233
Inventories, net	(7,924)	5,568
Prepaid expenses and other assets	(3,478)	(634)
Accounts payable	3,977	555
Accrued compensation	1,029	(1,878)
Other liabilities	(1,745)	287
Net cash used in operating activities	(43,754)	(25,054)
Investing activities:		
Purchases of short-term investments	(3,533)	(108,831)
Maturities of short-term investments	55,642	70,106
Proceeds from sale of short-term investments	—	34,794
Purchases of property and equipment	(1,505)	(722)
Net cash provided by (used in) investing activities	50,604	(4,653)
Financing activities:		
Proceeds from debt financing, net of issuance costs	34,588	61,841
Proceeds from issuance of common stock and exercise of stock options	4,980	4,105
Net cash provided by financing activities	39,568	65,946
Effect of exchange rates on cash, cash equivalents, and restricted cash	(278)	—
Net increase in cash, cash equivalents, and restricted cash	46,140	36,239
Cash, cash equivalents, and restricted cash:		
Beginning of the period	31,021	20,652
End of the period	$ 77,161	$ 56,891
Non-cash investing activities:		
Right-of-use assets obtained in exchange for lease obligations	$ 362	$ —
Property and equipment included in accounts payable	336	82
Lessor funded building improvements	201	—

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 is headquartered in Menlo Park, California. The Company is a global ear, nose and throat ("ENT") medical technology leader dedicated to transforming patient care. The Company's U.S. Food and Drug Administration ("FDA") approved products are steroid releasing implants designed to treat patients suffering from chronic rhinosinusitis ("CRS") 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 conjunction with sinus surgery primarily in hospitals and ambulatory surgery centers ("ASC") and increasingly in the physician office setting of care in conjunction with balloon dilation and following post-surgical debridement. 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 combination products regulated as devices approved under a Premarket Approval ("PMA") and SINUVA is a combination product regulated as a drug that was approved under a New Drug Application ("NDA"). The PROPEL family of products have also received CE Markings, permitting them to be marketed in the European Economic Area.

In October 2020, the Company acquired Fiagon AG Medical Technologies ("Fiagon"), a global leader in electromagnetic surgical navigation solutions with an expansive portfolio of ENT product offerings, including the VenSure sinus dilation balloon ("VenSure"), CUBE Navigation System ("CUBE"), and instruments that complement the Company's PROPEL and SINUVA sinus implants and extend its geographic reach. The VenSure products received 510(k) clearance in August 2020 and the latest version of the CUBE Navigation System received 510(k) clearance in July 2021. In addition, some of the Fiagon products are registered in other countries including in Asia Pacific and South America.

The Company continues to invest in research and development in order to expand its portfolio of products and improve its existing products.

Pending Acquisition

On August 6, 2021 the Company entered into an Agreement and Plan of Merger (the "Merger Agreement") with Medtronic, Inc., a Minnesota corporation and wholly-owned subsidiary of Medtronic public limited company ("Medtronic"), and Project Kraken Merger Sub, Inc., a Delaware corporation and wholly-owned subsidiary of Medtronic ("Merger Sub"), providing for the merger of Merger Sub with and into the Company (the "Merger"), with the Company surviving the Merger as a wholly-owned subsidiary of Medtronic. On October 8, 2021, the Company's stockholders adopted the Merger Agreement at a special meeting of its stockholders.

Under the terms of the Merger Agreement, Medtronic will acquire all outstanding shares of the Company's common stock in exchange for consideration of $28.25 per share in cash. The Merger Agreement contains representations and warranties customary for transactions of this type. The closing of the Merger is subject to the satisfaction or waiver of a number of closing conditions, including approval under the Hart-Scott-Rodino Antitrust Improvements Act of 1976. The Merger Agreement provides Medtronic and the Company with certain termination rights and, under certain circumstances, may require that Medtronic or the Company pay a termination fee.

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 subsidiaries. All intercompany balances and transactions have been eliminated upon consolidation.

The interim financial data as of September 30, 2021 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, 2021 and 2020. 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, 2020 filed with the SEC on March 9, 2021.

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. Due to the COVID-19 pandemic, the Company's business has been and will continue to be impacted by patients' decisions whether or not to undergo sinus surgeries and, as a result, ENT ASC and office procedure volumes may fluctuate. The Company's operations may be further impacted by COVID-19 due to changes in its manufacturing operations as a result of the easing 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 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, inventory, common stock valuation and related stock-based compensation, leases, business combinations, embedded derivatives, as well as certain accrued liabilities. Management bases its estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results could differ from those estimates.

Accounting Pronouncements

Recently Adopted Accounting Standards

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 clarifies and amends existing guidance to improve consistent application. ASU 2019-12 became effective for the Company beginning in 2021. The adoption of the standard did not result in a material impact to the Company's condensed consolidated financial statements.

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 became effective for the Company beginning in 2021. The adoption of the standard had no impact to the Company's condensed consolidated financial statements.

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. The Company early adopted this standard and became effective beginning in 2021. The adoption of the standard had no impact to the Company's condensed consolidated financial statements.

Significant Accounting Policies

There have been no significant changes to the accounting policies during the nine months ended September 30, 2021, 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, 2020, except as follows:

Multiple-Element Arrangements

The Company may, from time to time, enter into lease arrangements with certain qualified customers in connection with commitments to purchase consumable products to accompany the use of the equipment. Leases have terms that generally range from 24 to 48 months and are usually collateralized by a security interest in the underlying assets. For the three and nine months ended September 30, 2021, revenue from these arrangements was not material.

Cost of sales

Cost of sales consists primarily of manufacturing overhead costs, material costs, and direct labor. A significant portion of the Company's cost of sales 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. Cost of sales also includes depreciation expense for production equipment, amortization of intangible assets associated with acquired product technologies and processes, maintenance of operational processes, and certain direct costs such as shipping costs.

Property and Equipment

Property and equipment are stated at cost, less accumulated depreciation and amortization. Depreciation is determined using the straight-line method over the estimated useful lives of the respective assets, generally two to five years. Leasehold improvements are amortized on a straight-line basis over the shorter of their estimated useful lives or the term of the lease. Maintenance and repairs are charged to operations as incurred. During the three and nine months ended September 30, 2021, the Company recognized impairment expense of $0.1 million and $0.5 million related to certain property and equipment, which was recorded in selling, general and administrative expense in the condensed consolidated statements of operations.

3. Composition of Certain Financial Statement Items

Accounts receivable, net (in thousands):

	September 30, 2021	December 31, 2020
Accounts receivable	$ 14,796	$ 15,079
Allowance for doubtful accounts	(394)	(487)
	$ 14,402	$ 14,592

Inventories, net (in thousands):

	September 30, 2021	December 31, 2020
Raw materials	$ 4,307	$ 2,865
Work-in-process	6,205	3,411
Finished goods	9,545	5,778
	$ 20,057	$ 12,054

Capitalized stock-based compensation expense of $0.4 million and $0.3 million was included in inventory as of September 30, 2021 and December 31, 2020, respectively.

Operating lease liabilities (in thousands):

	September 30, 2021	December 31, 2020
Current portion presented in other current liabilities	$ 2,351	$ 762
Non-current portion presented in operating lease liabilities	15,101	17,736
	$ 17,452	$ 18,498

Revenue (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
PROPEL family of products	$ 20,870	$ 21,051	$ 64,371	$ 49,622
SINUVA	1,980	1,669	7,101	2,704
VenSure, CUBE, and accessories	1,550	—	4,605	—
	$ 24,400	$ 22,720	$ 76,077	$ 52,326

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 convertible debt embedded derivatives. 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 marketable securities classified within Level 2 is based upon observable inputs that may include benchmark yields, reported trades, broker/dealer quotes, two-sided markets, benchmark securities, bids, offers and reference data including market research publications.

Cash, Cash Equivalents, Short-term Investments, and Restricted Cash

The following is a summary of cash, cash equivalents, and restricted cash (in thousands):

	September 30, 2021	December 31, 2020	September 30, 2020
Cash and cash equivalents	$ 59,183	$ 13,521	$ 56,891
Restricted cash	17,978	17,500	—
Total cash, cash equivalents, and restricted cash shown in the condensed consolidated statements of cash flows	$ 77,161	$ 31,021	$ 56,891

In association with the acquisition of Fiagon, the Company held $17.9 million and $17.5 million as of September 30, 2021 and December 31, 2020, respectively, with an escrow agent with the seller as beneficiary. These balances are presented as restricted cash on the Company's condensed consolidated balance sheets.

The following is a summary of the Company's unrealized gains and losses related to its short-term investments in marketable securities designated available-for-sale (in thousands):

September 30, 2021	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value	Reported as: Cash and cash equivalents	Reported as: Short-term investments
Level 1:						
Cash	$ 44,143	$ —	$ —	$ 44,143	$ 44,143	$ —
Money market funds	15,040	—	—	15,040	15,040	—
	59,183	—	—	59,183	59,183	—
Level 2:						
U.S. treasury bills	17,282	—	—	17,282	—	17,282
Corporate debt securities	3,532	—	(2)	3,530	—	3,530
U.S. government agency bonds	1,001	—	—	1,001	—	1,001
	21,815	—	(2)	21,813	—	21,813
	$ 80,998	$ —	$ (2)	$ 80,996	$ 59,183	$ 21,813

December 31, 2020	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value	Reported as: Cash and cash equivalents	Reported as: Short-term investments
Level 1:						
Cash	$ 9,755	$ —	$ —	$ 9,755	$ 9,755	$ —
Money market funds	2,762	—	—	2,762	2,762	—
	12,517	—	—	12,517	12,517	—
Level 2:						
U.S. treasury bills	49,698	4	(3)	49,699	1,004	48,695
Corporate debt securities	6,307	—	(2)	6,305	—	6,305
U.S. government agency bonds	19,504	3	(1)	19,506	—	19,506
	75,509	7	(6)	75,510	1,004	74,506
	$ 88,026	$ 7	$ (6)	$ 88,027	$ 13,521	$ 74,506

There were no transfers in and out of Level 1 and Level 2 during the nine months ended September 30, 2021 and year ended December 31, 2020.

As of September 30, 2021 and December 31, 2020, 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, 2021 and year ended December 31, 2020. 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, 2021 and December 31, 2020, respectively, were not attributed to credit.

Convertible Notes Embedded Derivatives

The Convertible Notes due in 2025 (see Note 9) 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 of 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. As of September 30, 2021, the fair value of the embedded features was $15.8 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, 2021
Balance as of December 31, 2020	$ 3,048
Fair value adjustment	12,721
Balance as of September 30, 2021	$ 15,769

The change in fair value of embedded derivatives for the three and nine months ended September 30, 2021 was a $13.0 million loss and a $12.7 million loss, respectively, compared to a $1.0 million gain and $0.8 million loss for the three and nine months ended September 30, 2020, respectively, which was recorded in other income (expense), net in the Company's condensed consolidated statements of operations. The increase in the fair value of the embedded derivative liability during the three and nine months ended September 30, 2021 was due to the increased probability of triggering events as a result of the pending acquisition with Medtronic.

Derivative Financial Instruments

The Company's deferred purchase consideration related to the Fiagon acquisition exposed it to foreign currency exchange risk between rate fluctuations of the U.S. dollar and the Euro. To manage this risk, the Company entered into a series of foreign currency exchange forward contracts. In general, gains and losses related to these contracts are expected to be substantially offset by corresponding gains and losses on the remeasurement of the deferred purchase consideration each reporting period. The risk of loss in the event of a counterparty default is limited to the amount of any unrealized gains on outstanding contracts (e.g., those contracts that have a positive fair value) at the date of default. The Company does not enter into derivative contracts for trading purposes. During the three months ended September 30, 2021, one of the foreign currency forward contracts was exercised in order to make the first anniversary payment for the Fiagon acquisition.

The derivative instruments the Company uses to economically hedge this exposure are not designated as accounting hedges and, as a result, changes in their fair value are recorded in other income (expense), net in its condensed consolidated statements of operations. The derivative assets and liabilities are measured using Level 2 fair value inputs.

The Company had gross notional amounts (in EUR) on foreign currency exchange contracts not designated as hedging instruments outstanding as of September 30, 2021 and December 31, 2020 as follows (in thousands):

	September 30, 2021	December 31, 2020
Notional amounts:		
Forward contracts	€ 30,000	€ 45,000
Gross fair value recorded in:		
Prepaid expenses and other current assets	$ —	$ 275
Other non-current assets	$ —	$ 558
Other current liabilities	$ 825	$ —
Other non-current liabilities	$ 825	$ —

The following table summarizes the effect of the Company's foreign currency exchange contracts on its condensed consolidated statements of operations recognized in other income (expense), net (in thousands):

	Three Months Ended September 30, 2021	Nine Months Ended September 30, 2021
Recognized losses on foreign currency exchange contracts	$ (608)	$ (2,484)
Foreign exchange gains on remeasurement of deferred acquisition related consideration	$ 1,322	$ 3,035

5. Business Combinations

On October 2, 2020, the Company acquired all of the outstanding equity interests of Fiagon and its subsidiaries. Fiagon develops, and commercializes globally, innovative electromagnetic surgical navigation systems and an associated suite of surgical tools and sinus dilation balloons targeted to the ENT surgical space. The transaction increases the Company's product portfolio as well as its ability to serve customers and patients in the U.S., Europe and elsewhere. Assets and operations acquired included developed technologies, a distribution network, customer relationships, trademarks, certain personnel, and net tangible assets, which collectively met the definition of a business. Under the terms of the Purchase Agreement for the acquisition of Fiagon, the Company made an initial €15.0 million ($17.6 million) payment upon closing in October 2020 and will make €15.0 million annual payments for each of the subsequent three years, plus an approximately €2.5 million working capital purchase price adjustment due in October 2021. The total purchase consideration is denominated in Euros with an equivalent value of $69.3 million which included an upfront cash payment of $17.6 million, and deferred payments of $51.7 million, of which $17.5 million (€15.0 million equivalent) of cash was placed in escrow with the seller as beneficiary. The amount placed in escrow is required to be adjusted to the equivalent of €15.0 million on January 15th and July 15th of each year based on the end of the prior month's five-day trailing exchange rate. The restrictions on cash held in escrow will be released upon payment of the last deferred purchase payment due in October 2023. In addition, the Company entered into agreements to pledge the shares of Fiagon and its intellectual property as security for the deferred payments. The share pledge expires upon payment of the last deferred purchase payment due in October 2023 and the intellectual property pledge expires upon payment of the third installment due in October 2022.

The Company recorded $4.6 million of tangible assets, primarily consisting of $2.2 million of inventory, offset by liabilities assumed of $4.2 million, including deferred tax liabilities of $2.2 million. In addition, the Company recorded $21.9 million of intangible assets and $46.6 million in residual goodwill. Goodwill arising from the business combination consists largely of the synergies and economies of scale expected from combining the operations of the Company and Fiagon, as well as the value of Fiagon's assembled workforce.

Intangible assets included patents and developed technology, a distribution network, customer relationships, and trademarks. The Company's management utilized a specialist to assist in the valuation. Key assumptions included in the valuation were (1) the amount and timing of future revenues, expenses, and other cash flows, and (2) the discount rate used to determine the present value of these cash flows. The goodwill is not amortizable for income tax purposes. During the three months ended June 30, 2021, the Company finalized its purchase accounting and recorded a measurement period adjustment to increase goodwill and purchase consideration by $0.4 million, to $47.0 million upon agreement with the Sellers of the installment payment due in October 2021, and as a result of completing its assessment of tax exposure related to pre-acquisition periods.

During the three months ended March 31, 2021, the Company recognized impairment expense of $0.2 million, related to the remaining trademarks value as a result of a decision to rebrand the associated products, which was recorded in selling, general and administrative expenses in the condensed consolidated statements of operations. In addition, during the three months ended September 30, 2021, the Company completed its annual goodwill impairment test and determined that no impairment existed. As of September 30, 2021, there has been no impairment of goodwill.

6. 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.

7. Stock-based Compensation Expense

2014 Equity Incentive Plan

In July 2014, the Company's Board of Directors approved the 2014 Equity Incentive Plan (the "2014 Plan"). The number of shares of common stock reserved for issuance under the 2014 Plan will automatically increase on January 1 of each year, beginning on January 1, 2015, and continuing through and including January 1, 2024, by 3% of the total number of shares of the Company's capital stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares determined by the Company's Board of Directors. On January 1, 2021, the total number of shares of common stock reserved for

issuance increased by 988,070 shares to 10,922,838 shares reserved since the inception of the 2014 Plan. As of September 30, 2021, 3,435,598 shares remained available for issuance.

The following is a summary of the Company's stock option activity and related information (options in thousands):

	Nine Months Ended September 30, 2021	
	Options	Weighted Average Exercise Price
Outstanding, beginning of period	3,599	$ 22.01
Granted	943	22.52
Exercised	(287)	14.34
Forfeited	(586)	25.32
Outstanding, end of period	3,669	22.21
Exercisable	1,565	23.36

Outstanding options as of September 30, 2021 include 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, 2021, these stock options remain unvested.

As of September 30, 2021, the aggregate pre-tax intrinsic value of options outstanding was $21.3 million and options outstanding and exercisable was $8.3 million, the weighted-average remaining contractual term of options outstanding was 7.8 years, and options outstanding and exercisable was 6.5 years. The aggregate pre-tax intrinsic value of options exercised was $2.8 million and $1.3 million during the nine months ended September 30, 2021 and 2020, respectively.

The following is a summary of the Company's RSU activity and related information (RSUs in thousands):

	Nine Months Ended September 30, 2021	
	RSUs	Weighted Average Fair Value
Outstanding, beginning of period	488	$ 23.88
Awarded	331	22.80
Vested	(175)	24.69
Forfeited	(104)	23.33
Outstanding, end of period	540	23.06

As of September 30, 2021, the aggregate pre-tax intrinsic value of RSUs outstanding was $14.7 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 has granted Performance Stock Units ("PSUs") which are subject to service, performance, and market-based vesting conditions. The following is a summary of the Company's PSU activity and related information (PSUs in thousands):

	Nine Months Ended September 30, 2021	
	PSUs	Weighted Average Fair Value
Outstanding, beginning of period	130	$ 15.94
Awarded	187	24.99
Forfeited	(40)	22.07
Outstanding, end of period	277	21.16

As of September 30, 2021, the aggregate pre-tax intrinsic value of PSUs outstanding was $7.5 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 1.7 years.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Cost of sales	$ 421	$ 446	$ 1,142	$ 1,221
Selling, general and administrative	3,093	2,790	10,001	9,204
Research and development	475	417	1,484	1,217
	$ 3,989	$ 3,653	$ 12,627	$ 11,642

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. As of September 30, 2021, 836,075 shares remained available for issuance and 57,754 shares were issued during the nine months ended September 30, 2021. In connection with the proposed transaction with Medtronic, the ESPP will remain in effect until November 15, 2021, which is the final purchase date, subsequent to which the ESPP will no longer be offered.

As of September 30, 2021, the total compensation expense not yet recognized for both the 2014 Plan and 2014 ESPP was $32.2 million and is currently estimated to be expensed through the year 2025. This expense will be amortized on a straight-line basis over a weighted average period of 2.4 years and will be adjusted for subsequent forfeitures.

8. Net Loss per Share

Basic net loss per share is computed by dividing the net loss by the weighted average number of shares of common stock outstanding during the period. Diluted net loss per share is computed by dividing the net loss by the weighted average number of shares of common stock and common stock equivalent shares from dilutive stock options, employee stock purchases and restricted stock units outstanding during the period. Because the Company has reported a net loss for all periods presented, diluted net loss per share is the same as basic net loss per share for those periods as all potentially dilutive securities were antidilutive in those periods.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Common stock options	3,242	3,073	3,242	3,073
Market-based performance stock options	427	427	427	427
Restricted stock units	540	484	540	484
Performance stock units	277	173	277	173
Employee stock purchase plan shares	59	72	59	72
Stock issuable upon conversion of convertible notes	6,309	6,309	6,309	6,309
	10,854	10,538	10,854	10,538

The Company uses the if-converted method for calculating any potentially dilutive effects of the Convertible Notes. The Company did not adjust the net loss for the three and nine months ended September 30, 2021 and 2020 to eliminate any interest expense related to the Convertible Notes (see Note 9) 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.

9. Long-Term Debt

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 $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 6 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 $3.2 million, respectively were recorded on the issuance date and are 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, 2021 and December 31, 2020, the net carrying amount of the Convertible Notes recorded within long-term debt on the condensed consolidated balance sheets was as follows:

	September 30, 2021	December 31, 2020
Outstanding principal amount of convertible notes	$ 65,000	$ 65,000
Unamortized debt discount and transaction costs	(3,720)	(4,398)
Fair value of embedded derivatives	15,769	3,048
Convertible notes, net	$ 77,049	$ 63,650

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, 2021, the accretion of the convertible debt discount and amortization of debt issuance costs was $0.2 million and $0.7 million, respectively, compared to $0.2 million and $0.3 million for the three and nine months ended September 30, 2020, 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 was $0.7 million as of both September 30, 2021 and December 31, 2020, respectively, and was included in other current liabilities on the condensed consolidated balance sheets.

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, 2021, the fair value of the Company's Convertible Notes was $133.7 million.

Deerfield Term Loans

On July 22, 2021, the Company entered into an additional agreement with Deerfield, providing for the issuance and sale by the Company to Deerfield of senior secured loans of an aggregate principal of up to $60.0 million (the "Deerfield Loans"). The Deerfield Loans will mature on July 22, 2026, unless earlier repaid or accelerated. The agreement provides for the disbursement of the Deerfield Loans in three tranches of $20.0 million, with the initial tranche disbursed on the Closing Date, the second tranche to be disbursed at the option of the Company on the earlier of the date of any prepayment of the remaining

Fiagon acquisition payments and September 15, 2022, and the third tranche to be disbursed at the option of the Company on the earlier of the date of any prepayment of the remaining Fiagon acquisition payments and September 15, 2023.

The Deerfield Loans bear interest at 7.5% per annum, payable quarterly in arrears on October 15, January 15, April 15, and July 15 of each year, commencing October 15, 2021. The Company's obligations under the Deerfield Loans are required to be guaranteed by all of its existing and future subsidiaries (other than certain excluded and immaterial subsidiaries). The Company's and each subsidiary guarantor's obligations under the Deerfield Loans and agreement are secured by substantially all of the Company's and each subsidiary guarantor's assets, which includes springing control of the Company's primary deposit and security accounts pursuant to a Deposit Account Control Agreement and Security Account Control Agreement. Deerfield has the ability to exercise exclusive control of these accounts by providing a Notice of Exclusive Control in response to an event of default. As of September 30, 2021, no such notice has been received as the Company was in full compliance with the terms of the Deerfield Loans. The Deerfield Loans will not be permitted to be prepaid prior to 30 months after the Closing Date (the "No Call Date"), except in connection with a change of control.

The Company will have the right, but not the obligation, to prepay the Deerfield Loans at any time after the No Call Date, together with accrued and unpaid interest on the principal amount prepaid, plus an exit fee equal to 1.75% of the principal amount of the Deerfield Loans to be prepaid, plus a prepayment premium equal to (a) 0.75% of the principal amount of the Deerfield Loans to be prepaid, if such prepayment occurs after the No Call Date but on or prior to the fourth anniversary of the Closing Date and (b) 0.50% of the principal amount of the Deerfield Loans to be prepaid, if such prepayment occurs after the fourth anniversary of the Closing Date but prior to the fifth anniversary of the Closing Date; provided that upon any prepayment in connection with a change of control, in lieu of such prepayment premium and the exit fee, the Company will be required to pay a prepayment premium equal to 9.75% of the principal amount being prepaid and the principal amount of any prepayments made within three months of such change of control (the "Change of Control/Acceleration Premium"). The Change of Control/Acceleration Premium is also payable upon any acceleration of the Deerfield Loans upon an event of default. In addition, if a change of control occurs, the Company enters into any definitive agreement the consummation of which would result in a change of control of the Company or announces any prospective change of control, in each case within three months of any prepayment or prepayment in full of the Deerfield Loans prior to the maturity date, then, upon the consummation of such change of control, the Company will be required to pay an additional amount equal to the Change of Control/Acceleration Premium applicable to the principal amount of Deerfield Loans prepaid within three months of such change of control, less any prepayment premiums and exit fees paid in connection with such prior prepayments.

The Company is subject to a number of affirmative and restrictive covenants pursuant to the agreement, including covenants regarding minimum cash and minimum revenue, compliance with applicable laws and regulations, maintenance of property, payment of taxes, maintenance of insurance, business combinations, incurrence of additional indebtedness, prepayments of other 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. The Deerfield Loans contain certain specified events of default, the occurrence of which would entitle the holders of the Deerfield Loans to immediately demand repayment of all outstanding principal and accrued interest on the Loans, together with a prepayment premium equal to 9.75% of the outstanding principal amount of the Deerfield Loans to be prepaid. Such events of default include, among others, failure to make any payment under the Loans 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, a material default by the Company under other indebtedness, and the occurrence of a change of control.

As of September 30, 2021, the net carrying amount of the Deerfield Loans recorded within long-term debt on the condensed consolidated balance sheets was as follows:

	September 30, 2021
Outstanding principal amount of loans	$ 20,000
Unamortized debt discount and transaction costs	(402)
Accrued exit fee	14
Deerfield loans, net	$ 19,612

The debt discount and transaction costs associated with the Deerfield Loans are being amortized to interest expense over the term of the Deerfield Loans. For the three months ended September 30, 2021, the accretion of the debt discount and amortization of debt issuance costs was immaterial. The accrued interest on the outstanding principal of $20.0 million as of September 30, 2021 was $0.3 million and was included in other current liabilities on the condensed consolidated balance sheets. As of September 30, 2021, the fair value of Deerfield Loans approximated its carrying value.

Medtronic Financing

On September 25, 2021, the Company entered into a financing arrangement with Medtronic (the "Medtronic Financing"), providing for unsecured subordinated loans of an aggregate principal amount of up to $75.0 million to the Company upon the terms and conditions of the Medtronic Financing. The Medtronic Financing will mature one hundred eighty (180) days following the earlier of (x) the Maturity Date of the Deerfield Loans and (y) the date on which the Deerfield Loans have been fully paid in cash and are terminated, unless earlier repaid or accelerated. The Medtronic Financing provides for the draw of funds by the Company in up to five tranches of $15.0 million, with a tranche permitted to be drawn each fiscal quarter beginning with the first draw which occurred during the three months ended September 30, 2021.

The Medtronic Financing accrues interest at 5% per annum with accrued interest to be paid at maturity. The Company's obligations under the Medtronic Financing are required to be guaranteed by all of its existing and future subsidiaries (other than certain excluded and immaterial subsidiaries). The Medtronic Financing may be prepaid in part or in full prior to maturity without any penalty or premium. Further, the Medtronic Financing may no longer be due and payable upon a termination in accordance with the Merger Agreement.

The Company is subject to a number of affirmative and restrictive covenants pursuant to the Medtronic Financing, including covenants regarding compliance with applicable laws and regulations, maintenance of property, payment of taxes, maintenance of insurance, business combinations, incurrence of additional indebtedness and prepayments of other 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. The Medtronic Financing contains certain specified events of default, the occurrence of which would entitle Medtronic to immediately demand repayment of all outstanding principal and accrued interest on the Medtronic Financing. Such events of default include, among others, failure to make any payment under the Deerfield Loans when due, failure to observe or perform any covenant under the Medtronic Financing 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, a material default by the Company under other indebtedness, and the occurrence of a change of control.

As of September 30, 2021, the Medtronic Financing net carrying amount of $15.0 million was recorded within long-term debt on the condensed consolidated balance sheets. The fair value of the Medtronic Financing approximates its carrying value as of September 30, 2021.

10. Commitments and Contingencies

Retention Bonus Program

On September 1, 2021, the Compensation Committee of the Company's Board of Directors approved the implementation of a retention program that covers substantially all employees of the Company. The program provides for the payment of up to $15.0 million, payable in cash. The amounts of the payments related to this program will depend on the timing of the anticipated Merger. The Company is currently recognizing program costs in its condensed consolidated financial statements ratably over the period of service from September 1, 2021 through July 31, 2022. During the three months ended September 30, 2021, total costs for the retention plans were $1.9 million. As of September 30, 2021, accrued retention bonuses payable of $1.9 million was presented in accrued compensation on the condensed consolidated balance sheets.

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.

Yaron vs. Intersect ENT, Inc.

On May 15, 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 a second amended complaint. The Company moved to dismiss the second amended complaint on September 18, 2020. By order dated January 22, 2021, the Court granted the Company's motion to dismiss the second amended complaint with leave to amend. Although the Company continues to believe this lawsuit is without merit, on March 4, 2021, the Company agreed with the plaintiff to a settlement-in-principle that, if approved, will resolve the litigation in its entirety. The plaintiff filed its motion for preliminary approval of the proposed settlement on May 14, 2021. On June 22, 2021, the Court granted the plaintiff's motion for preliminary approval and set a final settlement approval hearing for October 22, 2021, which was subsequently rescheduled to November 5, 2021. During the three months ended September 30, 2021, the Company funded an escrow account with its anticipated settlement costs associated with this lawsuit of $0.3 million.

Stockholder Litigation Related to the Merger

Beginning on September 1, 2021, seven civil actions were filed challenging the adequacy of certain public disclosures made by the Company concerning the Merger with Medtronic. On September 1, 2021, Elaine Wang, a purported stockholder of the Company, commenced an action in the United States District Court for the Southern District of New York, captioned *Elaine Wang v. Intersect ENT, Inc., et al.*, Case No. 1:21-cv-7348, against the Company and current members of its Board of Directors (the "Wang Complaint"). On September 9, 2021, Marc Waterman, a purported stockholder of the Company, commenced an action in the United States District Court for the Southern District of New York, captioned *Marc Waterman v. Intersect ENT, Inc., et al.*, Case No. 1:21-cv-7552, against the Company and current members of its Board of Directors (the "Waterman Complaint"). On September 15, 2021, Carla Lawson, a purported stockholder of the Company, commenced an action in the United States District Court for the Northern District of California, captioned *Carla Lawson v. Intersect ENT, Inc., et al.*, Case No. 3:21-cv-7150, against the Company, five members of its current Board of Directors, and one former member of its Board of Directors (the "Lawson Complaint"). On September 22, 2021, Brian Jones, a purported stockholder of the Company, commenced an action in the United States District Court for the District of Delaware, captioned *Brian Jones v. Intersect ENT, Inc., et al.*, Case No. 1:21-cv-1339, against the Company and current members of its Board of Directors (the "Jones Complaint"). On September 23, 2021, two other purported stockholders of the Company filed lawsuits against the Company and current members of its Board of Directors: Richard Lawrence commenced an action in the United States District Court for the Northern District of California, captioned *Richard Lawrence v. Intersect ENT, Inc.*, et al., Case No. 3:21-cv-7405 (the "Lawrence Complaint"); and Alex Ciccotelli commenced an action in the United States District Court for the Eastern District of Pennsylvania, captioned *Alex Ciccotelli v. Intersect ENT, Inc., et al.*, Case 2:21-cv-4202 (the "Ciccotelli Complaint"). On September 29, 2021, Michael Kent, a purported stockholder of the Company, commenced an action in the United States District Court for the Southern District of New York, captioned *Michael Kent v. Intersect ENT, Inc., et al.*, Case No. 1:21-cv-8066, against the Company and current members of its Board of Directors (the "Kent Complaint," collectively with the Wang Complaint, Waterman Complaint, Lawson Complaint, Jones Complaint, Lawrence Complaint, and Ciccotelli Complaint, the "Merger Complaints"). The Merger Complaints assert claims under Sections 14(a) and 20(a) of the Securities Exchange Act of 1934 and seek, among other things, an injunction preventing consummation of the proposed transaction with Medtronic, rescission of the proposed transaction or rescissory damages in the event it is consummated, declaratory relief, an accounting by the defendants for all damages caused to the plaintiffs, and the award of attorneys' fees and expenses.

The Company believes the claims asserted in the Merger Complaints are without merit and denies any wrongdoing in connection with the statements made by the Company concerning the Merger with Medtronic. However, as set forth below, the Merger Complaints have all been dismissed:

- On October 1, 2021, Elaine Wang dismissed the Wang Complaint with prejudice;
- On October 5, 2021, Michael Kent dismissed the Kent Complaint without prejudice;
- On October 7, 2021, Brian Jones dismissed the Jones Complaint without prejudice;
- On October 12, 2021, Marc Waterman dismissed the Waterman Complaint without prejudice, and Alex Ciccotelli dismissed the Ciccotelli Complaint without prejudice; and
- On October 13, 2021, Carla Lawson dismissed the Lawson Complaint without prejudice, and Richard Lawrence dismissed the Lawrence Complaint without prejudice.

Additional lawsuits may be filed against the Company or its directors and offers in connection with the Merger. Defending such lawsuits could require the Company to incur significant costs and divert the attention of management. Such legal proceedings could delay or prevent the closing of the Merger from occurring within the contemplated timeframe. The Company cannot predict the outcome of any lawsuit that might be filed subsequent to the date of filing this Quarterly Report on Form 10-Q and cannot reasonably estimate the possible losses with respect to these matters.

11. Income Taxes

The provision for income taxes in the periods presented is based upon the loss before income taxes (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Provision for income tax (benefit)	$ (444)	$ —	$ (1,306)	$ —

The Company's income tax benefit for the three and nine months ended September 30, 2021 was primarily related to the deferred taxes in foreign jurisdictions.

Due to historical losses, management believes it is more likely than not that the net deferred tax assets are not recognizable and will not be recognizable until the Company has sufficient taxable income. Accordingly, the net deferred tax assets have been fully offset by a valuation allowance. If management's assessment of the deferred tax assets of the corresponding valuation allowance were to change, the Company would record the related adjustment to net loss during the period in which management makes the determination.

As of September 30, 2021, there were no material changes to either the nature or the amounts of the uncertain tax positions previously determined for the year ended December 31, 2020.

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. 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. Any statements contained herein that are not of historical facts may be deemed to be forward-looking statements. You can identify these statements by words such as "anticipate," "assume," "believe," "could," "estimate," "expect," "intend," "may," "plan," "should," "will," "would," and other similar expressions that are predictions of or indicate future events and future trends. These forward-looking statements are based on current expectations, estimates, forecasts, and projections about our business and the industry in which we operate and management's beliefs and assumptions and are not guarantees of future performance or development and involve known and unknown risks, uncertainties, and other factors that are in some cases beyond our control. As a result, any or all of our forward-looking statements may turn out to be inaccurate. Factors that could materially affect our business operations and financial performance and condition include, but are not limited to: 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 those discussed in "Part I — Item 1A. Risk Factors" and "Part IV - Consolidated Financial Statements" of our Annual Report on Form 10-K, or Annual Report, filed with the SEC on March 9, 2021. Unless required by law, 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.

In addition, 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 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 statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements.

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 global ear, nose and throat ("ENT") medical technology leader dedicated to transforming patient care. Our U.S. Food and Drug Administration ("FDA") approved steroid releasing products are designed to provide mechanical spacing and deliver targeted therapy (mometasone furoate) to the site of disease. 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 to reduce inflammation and maintain patency following sinus surgery primarily in hospitals and ambulatory surgery centers ("ASC") and has increasing applications in the physician office setting of care in conjunction with balloon dilation and following post-surgical debridement. SINUVA is a physician administered drug, 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 combination products regulated as devices approved under a Premarket Approval ("PMA") and SINUVA is a combination product regulated as a drug that was approved under a New Drug Application ("NDA"). The PROPEL family of products have also received CE Markings, permitting them to be marketed in the European Economic Area.

In October 2020, we acquired Fiagon AG Medical Technologies ("Fiagon"), a global leader of electromagnetic surgical navigation solutions with an expansive portfolio of ENT product offerings, including the VenSure sinus dilation platform ("VenSure") and CUBE Navigation System ("CUBE"), and instruments that complement our PROPEL and SINUVA sinus implants across all settings of care and extend our geographic reach. The VenSure products received 510(k) clearance in August 2020 and the latest version of the CUBE Navigation System received 510(k) clearance in July 2021. In addition, some of the Fiagon products are registered in other countries including in Asia Pacific and South America.

While our primary commercial focus is the U.S, we are also expanding the global reach of our products. Our commercialization strategy will consider several factors including regulatory requirements, reimbursement coverage for our products, and key opinion leader support. For the PROPEL family of products, 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, Asia Pacific and Japan.

Our PROPEL family of steroid releasing implants are clinically proven to improve outcomes for chronic rhinosinusitis ("CRS") 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 over time. 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 399,000 patients have been treated with PROPEL products through the end of 2020. Our primary PROPEL® products are as follows:

- PROPEL, a self-expanding implant designed to conform to and hold open the surgically enlarged sinus while gradually releasing an anti-inflammatory steroid over a period of approximately 30 days and is absorbed into the body over a period of approximately six weeks.
- PROPEL Mini, a smaller version of PROPEL which is approved for use in both the ethmoid and frontal sinuses. PROPEL Mini is used preferentially by physicians compared with PROPEL when treating smaller anatomies or following less extensive procedures.
- PROPEL Contour, 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 physician 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. PROPEL Contour is approved for use in the frontal and maxillary sinus openings in the U.S. and for use in the frontal sinus opening in the European Union ("EU").

The Straight Delivery System ("SDS") is an extension of the PROPEL family of implants. It is specifically engineered for precise, consistent and easy delivery of the PROPEL Mini Implant into the ethmoid sinus. In February 2021, we announced the U.S. availability of the SDS packaged with the PROPEL Mini after the combined packaging received FDA approval.

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. SINUVA is currently approved for use in the U.S.

Our PROPEL family of products are used primarily 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 physician office setting. VenSure provides for complementary use with PROPEL Contour for dilation and localized drug delivery. The CUBE Navigation System supports surgery and balloon dilation in all settings of care. The Centers for Medicare & Medicaid Services ("CMS") approved SINUVA for transitional pass-through payment status for reimbursement under the Hospital Outpatient Prospective Payment System ("OPPS") and ASC Payment System. Pass-Through status lasts for three years and allows us to place SINUVA in the ASC and hospital settings. We applied to CMS in September 2020 and asked to separate the J7401 code from SINUVA and PROPEL. In January 2021, CMS approved a revised coding application for our PROPEL family of products and established a separate code for PROPEL, S1091 "Stent, non-coronary, temporary, with delivery system (propel)". CMS also made updates to the current SINUVA J-code to J7402 "Mometasone furoate sinus implant, (sinuva), 10 micrograms" and attached an average selling price ("ASP") to the code. The new PROPEL and SINUVA codes took effect April 1, 2021. We are also committed to expanding our market development efforts for PROPEL in the physician office setting of care as well as market access outside of the U.S.

Our VenSure Navigable and Stand-alone balloon offerings are used to access and treat the frontal, sphenoid sinus and maxillary ostia in adults using a trans-nasal approach. The VenSure Navigation balloon is intended for use in conjunction with the CUBE navigation system during sinus procedures when surgical navigation or image-guided surgery may be necessary to locate and displace bone, or cartilaginous tissue surrounding the drainage pathways of the frontal, maxillary, and sphenoid sinuses to facilitate dilation of the sinus ostia.

Our CUBE Navigation System is an innovative virtual guidance platform for high precision ENT and ENT related skull-base surgeries. The system's unique photo registration technology, VirtuEye™, enhances the user's navigation experience and improves pre-surgery efficiency. This novel 3D-imaging technology mitigates common tactile tracing errors by collecting thousands of patient reference points in one camera shot. The entire photo registration process can be achieved in under 30 seconds without touching the patient.

We also continue to perform research and development activities and clinical trials in order to expand our portfolio of products and improve our existing products. In the second quarter of 2021, we initiated the EXPAND study to assess the potential to improve frontal sinus ostia size and other outcomes through localized drug delivery following balloon dilation utilizing PROPEL Contour and the VenSure balloon. In support of our focus on expanding our global reach, we plan to make clinical and regulatory investments in PROPEL in Europe. A PROPEL OPEN registry trial is planned to fulfill EU Medical Device Regulation ("MDR") requirements and collect local data in support of our commercial efforts. Other clinical trials initiated in the past include our investigational ASCEND drug-coated sinus balloon study initiated in December 2018.

Pending Acquisition

On August 6, 2021 we entered into an Agreement and Plan of Merger (the "Merger Agreement") with Medtronic, Inc., a Minnesota Corporation and wholly-owned subsidiary of Medtronic public company limited company ("Medtronic"), and Project Kraken Merger Sub, Inc., a Delaware corporation and wholly-owned subsidiary of Medtronic ("Merger Sub"), providing for the merger of Merger Sub with and into Intersect ENT (the "Merger"), with Intersect ENT surviving the Merger as a wholly-owned subsidiary of Medtronic. On October 8, 2021, our stockholders adopted the Merger Agreement at a special meeting of our stockholders.

Under the terms of the Merger Agreement, Medtronic will acquire all outstanding shares of our common stock in exchange for consideration of $28.25 per share in cash. The Merger Agreement contains representations and warranties customary for transactions of this type. The closing of the Merger is subject to the satisfaction or waiver of a number of closing conditions, including approval under the Hart-Scott-Rodino Antitrust Improvements Act of 1976. The Merger Agreement provides Medtronic and us with certain termination rights and, under certain circumstances, may require that Medtronic or we pay a termination fee.

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 of 2020 and throughout the second quarter as the various COVID-19 restrictions were implemented and remained in effect. We began to see meaningful change in the business environment towards the end of May of 2020 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 remainder of 2020 as well as 2021 to date as we continued to see improvements in the elective procedure market. Our business has been and will be impacted by patients' decisions to undergo sinus surgeries and as ENT ASC and office procedure volumes begin to recover. We continue to remain flexible in our approach to continuing our operations in light of developing laws and restrictions surrounding the COVID-19 pandemic. While the second half of 2020 and first nine months of 2021 have provided 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 and may impact our operations and financial results.

Components of Our Results of Operations

Revenue

We have derived our revenue almost exclusively from the sales of our PROPEL family of products, with limited sales of SINUVA beginning in March 2018, as well as sales of CUBE and VenSure products beginning in the fourth quarter of 2020 with the acquisition of Fiagon. While our business has been and may continue to be impacted by hospitals suspending elective surgical procedures and reduced ENT office visits for an extended period of time, we anticipate continued revenue growth during the remainder of 2021, based on the increased elective procedure volumes and enrollment trends towards the end of 2020 and first nine months of 2021. 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 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. In addition to standalone sales of CUBE and VenSure products, from time to time, we enter into lease arrangements of CUBE navigation equipment with certain qualified customers in connection with commitments to purchase VenSure and other consumable products to accompany the use of the equipment. Leases have terms that generally range from 24 to 48 months and are usually

collateralized by a security interest in the underlying assets. Lease arrangements transfer the ownership or provide the customer with a right to purchase the system leased at the end of the lease term.

We have derived our revenue predominantly 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, 2021 and 2020.

Cost of Sales and Gross Profit

We manufacture our PROPEL family of products and SINUVA in our facility in Menlo Park, California. We manufacture CUBE navigation equipment and instruments in Hennigsdorf, Germany, and procure VenSure sinus dilation balloons from a third-party manufacturer. Cost of sales consists primarily of manufacturing overhead costs, material costs, and direct labor. A significant portion of our cost of sales currently consists of manufacturing overhead costs. These overhead costs include 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. Cost of sales also includes depreciation expense for production equipment, amortization of intangible assets associated with acquired product technologies and processes, maintenance of operational processes, and certain direct costs such as shipping costs. 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 improvements in our manufacturing capabilities.

Our gross margin has been and will continue to be affected by a variety of factors, including manufacturing costs, product mix, and average selling prices. Toward the end of the first quarter and throughout the second quarter of 2020, 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, as well as our decision to suspend production until the third quarter of 2020. Production resumed during the third quarter of 2020, but below normal capacity, and was at normal capacity thereafter. We charge idle facility costs 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 compliance expenses, insurance costs, amortization of intangible assets associated with acquired customer and distributor relationships, 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 debt facilities, as well as imputed interest on the carrying value of deferred acquisition related consideration.

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, transactions costs incurred outside the ordinary course of business related to business combinations and our capital structure, changes in the fair value of foreign currency forward contracts and the effects of foreign exchange, including on the carrying value of our deferred acquisition related consideration.

Provision for Income Tax Benefit

Provision for income tax benefit consists of an estimate of federal, state and foreign income taxes based on enacted federal, state and foreign tax rates, as adjusted for allowable credits, deductions, uncertain tax positions, changes in deferred tax assets and liabilities and changes in tax law. Due to the level of historical losses, we maintain a valuation allowance against U.S. federal and state deferred tax assets as we have concluded it is more likely than not that these deferred tax assets will not be realized.

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 on Form 10-K 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, 2021, as compared to the critical accounting policies described in our Annual Report on Form 10-K for the year ended December 31, 2020.

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, 2021.

Results of Operations

(in thousands, expect percentages)	Three Months Ended September 30, 2021	Three Months Ended September 30, 2020	Nine Months Ended September 30, 2021	Nine Months Ended September 30, 2020
Revenue	$ 24,400	$ 22,720	$ 76,077	$ 52,326
Cost of sales	5,087	7,845	21,874	21,612
Gross profit	19,313	14,875	54,203	30,714
Gross margin	79.2 %	65.5 %	71.2 %	58.7 %
Operating expenses:				
Selling, general and administrative	29,473	21,702	86,281	67,399
Research and development	6,719	4,551	19,449	13,715
Total operating expenses	36,192	26,253	105,730	81,114
Loss from operations	(16,879)	(11,378)	(51,527)	(50,400)
Interest expense	(1,760)	(886)	(4,544)	(1,372)
Other income (expense), net	(13,654)	799	(13,716)	(350)
Loss before income taxes	(32,293)	(11,465)	(69,787)	(52,122)
Provision for income tax (benefit)	(444)	—	(1,306)	—
Net loss	(31,849)	(11,465)	$ (68,481)	$ (52,122)

Comparison of the Three and Nine Months ended September 30, 2021 and 2020

Revenue

(in thousands, except percentages)	Three Months Ended September 30, 2021	Three Months Ended September 30, 2020	Nine Months Ended September 30, 2021	Nine Months Ended September 30, 2020	Three Months Ended Change ($) 2021 to 2020	Three Months Ended Change (%) 2021 to 2020	Nine Months Ended Change ($) 2021 to 2020	Nine Months Ended Change (%) 2021 to 2020
PROPEL family of products	$ 20,870	$ 21,051	$ 64,371	$ 49,622	$ (181)	(1)%	$ 14,749	30 %
SINUVA	1,980	1,669	7,101	2,704	311	19 %	4,397	163 %
VenSure, CUBE, and Accessories	1,550	—	4,605	—	1,550	N/A	4,605	N/A
	$ 24,400	$ 22,720	$ 76,077	$ 52,326	$ 1,680	7 %	$ 23,751	45 %

Revenue increased by $1.7 million, or 7%, to $24.4 million during the three months ended September 30, 2021, compared to $22.7 million during the three months ended September 30, 2020, and increased by $23.8 million, or 45%, to $76.1 million during the nine months ended September 30, 2021, compared to $52.3 million during the nine months ended September 30, 2020. The increase in revenue for the three months ended September 30, 2021 was due to a 19% increase in SINUVA sales, partially offset by a 1% decline in PROPEL sales. The increase in revenue for the nine months ended September 30, 2021 was due to a 30% increase in PROPEL sales and a significant increase in SINUVA sales. PROPEL revenue for the three months ended September 30, 2021 remained fairly consistent with the comparative period. The increase in PROPEL revenue for the nine months ended September 30, 2021 resulted from a 27% increase in unit sales and a 2% increase in average selling price. The increase in unit sales for PROPEL was driven by a recovery in demand from the comparative period due to the impact of the COVID-19 pandemic as certain areas of the United States resumed elective procedures. SINUVA unit sales increased by 13% and 138% during the three and nine months ended September 30, 2021, and average selling price increased 5% and 10% per unit compared to the three and nine months ended September 30, 2020, respectively. The increase in unit sales for SINUVA for both periods was due to the recovery in demand from the comparative period due to the impact of the COVID-19 pandemic, in addition to improvements in reimbursement, continued adoption of the technology, and the ongoing shift of procedures from hospitals and ASC to the physician office setting of care. SINUVA sales also benefited from the expansion of our Market Access infrastructure and the addition and expansion of our distributor relationships during the year ended December 31, 2020. Furthermore, revenue for the three and nine months ended

September 30, 2021 also included $1.6 million and $4.6 million, respectively, of sales from the CUBE navigation equipment, instruments and accessories, and VenSure sinus dilation balloons.

Based on current elective procedure volumes and enrollment trends, as well as the acquisition of Fiagon, we expect revenue growth for the full year 2021 compared to the prior year. 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 decreased by $2.8 million, or 35%, to $5.1 million during the three months ended September 30, 2021, compared to $7.8 million during the three months ended September 30, 2020, and increased by $0.3 million, or 1%, to $21.9 million during the nine months ended September 30, 2021, compared to $21.6 million during the nine months ended September 30, 2020. The decreased cost of sales for the three months ended September 30, 2021 was primarily due to the favorable impact of lower per unit manufacturing costs as a result of higher production volumes due to a recovery in demand as elective surgeries resumed following easing of COVID-19 pandemic restrictions and to build additional safety stock. The decrease was offset by amortization of intangible assets, production and obsolescence related period costs, and project costs. The increase for the nine months ended September 30, 2021 was due to increased product sales resulting from a recovery in demand as elective procedures resumed following easing of COVID-19 pandemic restrictions, amortization of intangible assets, production and obsolescence related period costs, and project costs. The increase was offset by approximately $1.9 million of charges related to the impacts of COVID-19 incurred in the prior period which were not incurred during the current periods as production volumes returned to normal capacity.

Gross margin for the three months ended September 30, 2021, increased to 79.2%, compared to 65.5% for the three months ended September 30, 2020, and increased to 71.2% for the nine months ended September 30, 2021, compared to 58.7% for the nine months ended September 30, 2020. The increases for both periods were attributable to the favorable impact of lower per unit manufacturing costs. In addition, the increase for the nine months ended September 30, 2021 was due to approximately $1.9 million of charges related to the impacts of COVID-19 incurred in the prior period which were not incurred during the current periods as production volumes returned to normal capacity, as well as valuation charges for obsolete inventory. The increases were offset in part by amortization of intangible assets, production and obsolescence related period costs, and project costs, collectively representing approximately 3% of revenues for both the three and nine months ended September 30, 2021, respectively.

Consistent with the expected increase in procedure volumes in 2021, we anticipate that there will be revenue growth for the full year 2021 compared to the prior year. With the expected increase in demand and our operation at full capacity, we do not expect idle facility expense to be incurred in 2021. However, idle facility expense could still be incurred in future periods until the current crisis subsides. In addition, once adequate safety stock levels are established, we expect per unit manufacturing costs and gross margins to normalize. 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 the second quarter of 2022.

Selling, General and Administrative Expenses

SG&A expenses increased by $7.8 million, or 36%, to $29.5 million during the three months ended September 30, 2021, compared to $21.7 million during the three months ended September 30, 2020, and increased by $18.9 million, or 28%, to $86.3 million during the nine months ended September 30, 2021, compared to $67.4 million during the nine months ended September 30, 2020. The increases in SG&A expenses for the three and nine months ended September 30, 2021 were primarily due to increased commissions from increased sales, increases in headcount as compared to the prior period as a result of increased sales and marketing and other activities following the easing of COVID-19 pandemic related restrictions, the accrual of retention bonuses, and incremental SG&A expense as a result of the acquisition of Fiagon. Additionally, for the nine months ended September 30, 2021, the increase was due to $0.7 million of impairment expense related to certain property, equipment, and intangible assets, transaction costs associated with the proposed Merger, as well as costs associated with the ongoing integration of Fiagon of $1.9 million, which consisted largely of professional fees.

We will continue to monitor our SG&A expenses in light of the uncertainties related to the COVID-19 pandemic; however, we will still continue to support our customers, physicians and patients and will continue to incur additional SG&A expenses as a result of the acquisition of Fiagon.

Research and Development Expenses

R&D expenses increased by $2.2 million, or 48%, to $6.7 million during the three months ended September 30, 2021, compared to $4.6 million during the three months ended September 30, 2020, and increased by $5.7 million, or 42%, to $19.4 million during the nine months ended September 30, 2021, compared to $13.7 million during the nine months ended September 30, 2020. The increases in R&D expenses were primarily due to increased headcount and related expenses as a result of the acquisition of Fiagon and compared to the prior periods as a result of cost reduction measures taken in prior periods in response to the pandemic, and the accrual of retention bonuses, as well as professional fees pertaining to R&D projects in the current periods.

We will continue to monitor our R&D expenses in light of the uncertainty related to the COVID-19 pandemic; however, we will continue to incur additional R&D expense as a result of the acquisition of Fiagon and fees pertaining to R&D projects in order to continue to grow our business.

Interest Expense

Interest expense was $1.8 million and $4.5 million for the three and nine months ended September 30, 2021 compared to $0.9 million and $1.4 million for the three and nine months ended September 30, 2020. Interest expense for the three months ended September 30, 2021 was attributable to Convertible Notes interest, imputed interest on deferred payments for the acquisition of Fiagon, as well as Deerfield Term Loans interest, while interest expense during the three and nine months ended September 30, 2020 only pertained to Convertible Notes interest, including a partial quarter of interest expense on the Convertible Notes as they were entered into during May 2020.

Other Income (Expense), Net

Other income (expense), net, decreased by $14.5 million to other expense of $13.7 million during the three months ended September 30, 2021, compared to other income of $0.8 million during the three months ended September 30, 2020, and decreased by $13.4 million to other expense of $13.7 million during the nine months ended September 30, 2021, compared to other expense of $0.4 million during the nine months ended September 30, 2020. The decreases in other income (expense), net during the three and nine months ended September 30, 2021 were primarily attributable to an increase in fair value of our embedded derivative liability as the probability of triggering events increased significantly due to the pending acquisition with Medtronic, as well as the overall effects of foreign exchange remeasurement.

Provision for Income Tax Benefit

Provision for income tax benefit amounts of $0.4 million and $1.3 million for the three and nine months ended September 30, 2021 were attributable to the foreign deferred tax impact associated with foreign operations. There were no similar benefits in the comparative periods.

Liquidity and Capital Resources

Overview

As of September 30, 2021, we had cash, cash equivalents, short-term investments, and restricted cash of $99.0 million, compared to cash, cash equivalents, short-term investments, and restricted cash of $105.5 million as of December 31, 2020.

Cash Flows

	Nine Months Ended September 30,	
(in thousands)	**2021**	**2020**
Net cash provided by (used in):		
Operating activities	$ (43,754)	$ (25,054)
Investing activities	50,604	(4,653)
Financing activities	39,568	65,946
Effect of exchange rate changes on cash, cash equivalents, and restricted cash	(278)	—
Net increase in cash, cash equivalents, and restricted cash	$ 46,140	$ 36,239

Net Cash Used in Operating Activities

During the nine months ended September 30, 2021, net cash used in operating activities was $43.8 million, consisting primarily of a net loss of $68.5 million and an increase in net operating assets of $8.2 million, offset by non-cash charges of $32.9 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, as well as transaction costs principally associated with the Medtronic merger agreement. The non-cash charges primarily consisted of stock-based compensation expense, change in fair value of embedded derivatives, the impacts of foreign exchange, impairment of property, equipment, and intangible assets, as well as depreciation and amortization expense. The increase in net operating assets is primarily attributable to an increase in inventory, prepaid expenses and other assets, accounts receivable as well as a decrease in other liabilities, partially offset by an increase in accounts payable and accrued compensation due to accrual of retention bonuses.

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.

Net Cash Provided by (Used in) Investing Activities

During the nine months ended September 30, 2021, net cash provided by investing activities was $50.6 million, consisting of net maturities of short-term investments of $52.1 million, partially offset by purchases of property and equipment of $1.5 million.

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 $34.8 million.

Net Cash Provided by Financing Activities

During the nine months ended September 30, 2021, net cash provided by financing activities was $39.6 million, consisting of net proceeds from debt financing of $34.6 million as well as $5.0 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, 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.

Liquidity

Based on our current expectations of the operating environment in 2021 and 2022, as well as the term loan financing obtained from Deerfield in July 2021 and the Medtronic Financing obtained in September 2021, we believe we have adequate cash and other resources to operate for at least twelve months from the issuance of this Quarterly Report on Form 10-Q, including funding our working capital needs, capital expenditures, payments associated with the Fiagon acquisition, interest payments on long-term debt, and lease payments. However, the extent to which the COVID-19 pandemic may continue to materially adversely impact our liquidity is uncertain.

Our obligations under the Deerfield Loans are secured by substantially all of our assets, which includes springing control of our primary deposit and security accounts pursuant to a Deposit Account Control Agreement and Security Account Control Agreement. Deerfield has the ability to exercise exclusive control of these accounts by providing a Notice of Exclusive Control in response to an event of default. As of September 30, 2021, no such notice has been received as we were in full compliance with the terms of the Deerfield Loans.

Under the terms of the Purchase Agreement for the acquisition of Fiagon totaling €62.5 million, we made an initial €15.0 million ($17.6 million) payment upon closing in October 2020 and will make three annual payments of €15.0 million in each October of the subsequent three years, of which one annual payment of €15.0 million plus an estimated €2.5 million purchase price adjustment was paid in October 2021. In accordance with the terms of the Purchase Agreement, we were required to place

$17.5 million (€15.0 million) in escrow with the seller as beneficiary. The amount placed in escrow is required to be adjusted to the equivalent of €15.0 million on January 15th and July 15th of each year based on the end of the prior month's five-day trailing exchange rate.

If the proposed Merger with Medtronic is not executed and our current sources of liquidity are insufficient, we may seek to raise additional capital. If we raise additional funds by issuing equity securities, our stockholders would experience dilution. Any additional capital 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, 2021 and December 31, 2020, 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 July 22, 2021, we entered into a facility agreement with Deerfield providing for the issuance and sale by our company to Deerfield of senior secured loans (the "Deerfield Loans") of an aggregate principal $60.0 million in three tranches, with the initial tranche disbursed on the initial closing date, the second tranche to be disbursed on the earlier of the date of any prepayment of the remaining Fiagon acquisition payments and September 15, 2022, and the third tranche to be disbursed on the earlier of the date of any prepayment of the remaining Fiagon acquisition payments and September 15, 2023. The Deerfield Loans will mature on July 22, 2026 unless earlier repaid or accelerated, and have an exit amount equal to 1.75% of the principal amount of the Loans. The Deerfield Loans bear interest at 7.5% per annum, payable quarterly in arrears on October 15, January 15, April 15, and July 15 of each year, commencing October 15, 2021.

On September 1, 2021, the Compensation Committee of our Board of Directors approved the implementation of a retention program that covers substantially all of our employees. The program is estimated to cost approximately $15.0 million, payable in cash. The amounts of the payments related to this program will depend on the timing of the anticipated Merger.

On September 25, 2021, we entered into a financing agreement (the "Medtronic Financing") with Medtronic providing for the issuance and sale by our company to Medtronic of unsecured subordinated loans of an aggregate principal amount of up to $75.0 million in up to five tranches of $15.0 million per quarter, with the initial tranche disbursed upon closing. The Medtronic Financing accrues interest at 5% per annum with accrued interest to be paid at maturity.

Apart from the items noted above, our contractual obligations as of September 30, 2021, have not materially changed outside the ordinary course of business from December 31, 2020.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our exposure to market risk as of September 30, 2021, has not materially changed from the disclosures included in our Annual Report on Form 10-K for the year ended December 31, 2020, 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, $60.0 million of principal amount of Deerfield Loans, bearing interest at 7.5% per annum with interest payable quarterly, and $75.0 million of principal amount of Medtronic Financing, bearing interest at 5.0% per annum with interest payable at maturity. The Convertible Notes will mature on May 9, 2025, unless earlier converted or redeemed in accordance with their terms. The Deerfield Loans will mature on July 22, 2026, unless earlier repaid or accelerated, and the Medtronic Financing will mature 180 days following the earlier of (i) the Maturity Date of the Deerfield Loans and (ii) the date on which the Deerfield Loans have been fully paid in cash. As of September 30, 2021, the entire principal amount of the Convertible Notes was outstanding as well as $0.7 million in accrued interest. In addition, $20.0 million of the Deerfield Loans was outstanding with $0.3 million in accrued interest, and $15.0 million of the Medtronic Financing was outstanding. For our various debt instruments, any changes in market interest rates will generally affect the fair value of the instrument, but not our earnings or cash flows.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Management, with the participation of our Chief Executive Officer and our Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2021. 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, 2021, 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, 2021, 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 10 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

Risk Factors Summary

You should carefully consider the information set forth below before deciding whether to invest in our securities. Below is a summary of the principal risks associated with an investment in our securities.

- 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.
- The announcement and pendency of our agreement to be acquired by Medtronic may have an adverse effect on our business, operating results and our stock price, and may result in the loss of employees, customers, suppliers and other business partners.
- While the Merger is pending, we are subject to contractual restrictions that could harm our business, operating results and our stock price.
- The failure to complete the Merger may adversely affect our business and our stock price.
- The Merger Agreement with Medtronic limits our ability to pursue alternative transactions which could deter a third party from proposing an alternative transaction.
- We have incurred significant operating losses since inception and may not be able to achieve profitability.
- Our revenue is primarily generated from our PROPEL® family of products and, to a lesser extent, SINUVA® , VenSure, and CUBE. Our revenue is dependent on the success of these products, and if these products fail to grow or to continue experiencing expanded adoption, our business will suffer.
- A track record of adequate coverage and reimbursement is important for sales of our products in the physician office setting of care. Inadequate coverage and negative reimbursement policies for our products could affect their adoption and our future revenue.
- 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.
- 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.
- Our long-term growth depends on our ability to develop and successfully commercialize additional ENT products.
- 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.
- 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.
- 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.
- As our company diversifies its portfolio of products and expands its international reach, we continue to expand the complexity of our operations. We may encounter difficulties in managing this expansion, which could disrupt our business.
- 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.
- 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.

- 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.
- If we elect to pursue but fail to successfully acquire or effectively and efficiently integrate new third-party businesses, products, and/or technologies, we may not realize expected benefits of the transaction or our existing business may be harmed by the distraction, resource demands or unforeseen consequences of the endeavor.
- 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.
- We may incur losses associated with currency fluctuations and may not be able to effectively hedge our exposure.
- If we experience significant disruptions in our information technology systems, our business may be adversely affected.
- Our products are subject to extensive regulation by the FDA, and other agencies, including the requirement to obtain approval and/or register products prior to commercializing our products, maintaining compliance with Quality System and GMP practices, maintaining product quality, 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 fail to maintain compliance with applicable regulations and standards or are subject to regulatory enforcement action as a result of our failure to properly report adverse events or otherwise comply with regulatory requirements and standards, maintain compliance with Quality System and GMP requirements and product quality, our commercial operations would be harmed.
- We cannot predict whether or when we will obtain regulatory approval to commercialize product candidates or our ability to maintain product approvals/clearances/registrations 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.
- 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 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.
- We may fail to obtain foreign regulatory approvals to market our products in other countries.
- 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.
- 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 may be subject to enforcement action if we engage in improper marketing or promotion of our products.
- 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.
- 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.
- 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.
- Intellectual property rights may not provide adequate protection, which may permit third parties to compete against us more effectively.
- 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 debt obligations under our facility agreements with Deerfield and Medtronic could impair our financial condition and limit our operating flexibility.
- 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.

For a more complete discussion of the material risks that could impact our business, see below.

Risks Related to COVID-19 Pandemic

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. 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 in hospitals, which is where the majority of our products are utilized, and although there has been a partial lifting of these suspensions in some jurisdictions, it is currently unknown when these suspensions will be fully lifted. 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 ("CDC") and the Centers 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, together with our debt agreements with Deerfield, will be sufficient to meet our current capital needs for the next twelve months, 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. We may face challenges as we continue our manufacturing and distribution operations, including the risk of further potential outbreaks of COVID-19 cases.

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

The COVID-19 pandemic has led to increased economic uncertainty and instability. The macroeconomic 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.

Risks Related to the Merger with Medtronic

The announcement and pendency of our agreement to be acquired by Medtronic may have an adverse effect on our business, operating results and our stock price, and may result in the loss of employees, customers, suppliers and other business partners.

On August 6, 2021 we entered into an Agreement and Plan of Merger (the "Merger Agreement") with Medtronic, a Minnesota corporation and wholly-owned subsidiary of Medtronic public limited company ("Medtronic"), and Project Kraken Merger Sub, Inc., a Delaware corporation and wholly-owned subsidiary of Medtronic ("Merger Sub"), providing for the merger of Merger Sub with and into our company (the "Merger"), with our company surviving the Merger as a wholly-owned subsidiary of Medtronic. We are subject to risks in connection with the announcement and pendency of the Merger, including, but not limited to, the following:

- market reaction to the announcement of the Merger;
- changes in our business, operations, financial position and prospects;
- market assessments of the likelihood that the Merger will be consummated;
- the amount of cash offered per share will not be increased to account for positive changes in our business, assets, liabilities, prospects, outlook, financial condition or results of operations during the pendency of the Merger, including any successful execution of our current strategy as an independent company or in the event of any change in the market price of, analyst estimates of, or projections relating to, our common stock;
- potential adverse effects on our relationships with our current customers, suppliers and other business partners, or those with which we are seeking to establish business relationships, due to uncertainties about the Merger;
- we have incurred, and will continue to incur, significant costs, expenses and fees for professional services and other transaction costs in connection with the Merger, and many of these fees and costs are payable by us regardless of whether the Merger is consummated;
- potential adverse effects on our ability to attract, recruit, retain and motivate current and prospective employees who may be uncertain about their future roles and relationships with us following the completion of the Merger, and the possibility that our employees could lose productivity as a result of uncertainty regarding their employment following the Merger;
- the pendency and outcome of the legal proceedings that have been or may be instituted against us, our directors, executive officers and others relating to the transactions contemplated by the Merger Agreement; and
- the possibility of disruption to our business, including increased costs and diversion of management time and resources that could otherwise have been devoted to other opportunities that may have been beneficial to us.

While the Merger is pending, we are subject to contractual restrictions that could harm our business, operating results and our stock price.

The Merger Agreement includes restrictions on the conduct of our business prior to the completion of the Merger, generally requiring us to conduct our businesses in the ordinary course, consistent with past practice, and restricting us from taking certain specified actions absent Medtronic's prior written consent. We may find that these and other obligations in the Merger Agreement may delay or prevent us from or limit our ability to respond effectively to competitive pressures, industry developments and future business opportunities that may arise during such period, even if our management and Board of Directors think they may be advisable. These restrictions could adversely impact our business, operating results and our stock price and our perceived acquisition value, regardless of whether the Merger is completed.

The failure to complete the Merger may adversely affect our business and our stock price.

The Merger with Medtronic is subject to a number of conditions, including, among other things, (i) expiration or termination of any waiting periods applicable to the consummation of the Merger under the Hart-Scott-Rodino Antitrust Improvements Act of 1976 and certain other governmental bodies, (ii) the absence of any "material adverse effect" on us occurring after the date of the Merger Agreement that is continuing, (iii) the absence of any legal restraints prohibiting the

Merger, (iv) the absence of certain legal proceedings brought by a governmental entity relating to the Merger, and (v) subject to certain materiality qualifications, the continued accuracy of our representations and warranties, and our continued compliance with covenants and obligations (to be performed at or prior to the closing of the Merger). There can be no assurance that these conditions to the completion of the Merger will be satisfied, or that the Merger will be completed on the proposed terms, within the expected timeframe or at all. If the Merger is not completed, we may be subject to negative publicity or be negatively perceived by the investment or business communities and our stock price could fall to the extent that our current stock price reflects an assumption that the Merger will be completed. Furthermore, if the Merger is not completed, we may suffer other consequences that could adversely affect our business and results of our operations.

The Merger Agreement with Medtronic limits our ability to pursue alternative transactions which could deter a third party from proposing an alternative transaction.

The Merger Agreement contains provisions that, subject to certain exceptions, limit our ability to initiate, solicit, knowingly encourage, assist, knowingly induce or knowingly facilitate, or participate or engage in any negotiations or discussions regarding, or furnish information in response to inquiries with respect to, an alternative transaction. It is possible that these or other provisions in the Merger Agreement might discourage a potential competing acquirer that might have an interest in acquiring all or a significant part of our outstanding common stock from considering or proposing an acquisition or might result in a potential competing acquirer proposing to pay a lower per share price to acquire our common stock than it might otherwise have proposed to pay.

Financial and Operational Risks

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 $68.5 million for the nine months ended September 30, 2021, and $72.3 million and $43.0 million for the years ended December 31, 2020 and 2019, respectively. As of September 30, 2021, we had an accumulated deficit of $371.6 million. To date, we have financed our operations primarily through sales of our capital stock, certain debt-related financing arrangements, and from sales of our approved products. We have devoted substantially all of our resources to research and development of our products, including clinical and regulatory initiatives to obtain approvals for our products, and sales and marketing activities. Our ability to generate sufficient revenue from our existing products or from any of our product candidates in development, and to transition to profitability and generate consistent positive cash flows is uncertain. We expect that our operating expenses will continue to increase as we continue to build our commercial infrastructure, develop, enhance and commercialize new products and incur additional operational 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 primarily from our PROPEL® family of products and, to a lesser extent, SINUVA®, VenSure, and CUBE. Our revenue is 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 expect that sales of the PROPEL family of products, together with SINUVA, VenSure, and CUBE, will account for a large portion 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 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 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, 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 physician 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 physician office setting of care. CMS approved SINUVA for transitional pass-through payment status for reimbursement under the Hospital Outpatient Prospective Payment System (“OPPS”) and ASC Payment System. Pass-Through status lasts for three years and allows us to place SINUVA in the ASC and hospital settings. We applied to CMS in September 2020 and asked to separate the J7401 code from SINUVA and PROPEL. In January 2021, CMS approved a revised coding application for our PROPEL family of products and established a separate code for PROPEL, S1091 “Stent, non-coronary, temporary, with delivery system (propel)”. CMS also made updates to the current SINUVA J-code to J7402 “Mometasone furoate sinus implant, (sinuva), 10 micrograms” and attached an average selling price (“ASP”) to the code. The new PROPEL and SINUVA codes took effect April 1, 2021. 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 primarily 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. At present, there is very little usage of PROPEL products in the physician 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 physician 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 and other products.

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 and other products 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 rhinosinusitis ("CRS"). 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 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 CRS, adoption of our products may suffer, and our business would be harmed.

We utilize third-party, single source suppliers and service providers for many of the components, materials and services used in the production of our steroid releasing implants, and the loss of, or disruption by, any of these suppliers or service providers could harm our business.

The active pharmaceutical ingredient ("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 products. 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 fail to adequately serve patients, or the agreements are terminated without adequate notice, shipments of SINUVA, and associated revenues, would be adversely affected.

Our long-term growth depends on our ability to develop and successfully 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 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 Group PLC. 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 CRS, such as Regeneron Pharmaceuticals, Inc., who recently received FDA approval to market Dupixent for CRS with nasal polyposis.

If another company successfully develops an approach for the treatment of CRS, 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 Current Procedural Terminology ("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. We entered this market in October 2020 with the acquisition of Fiagon AG Medical Technologies ("Fiagon"). 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 CRS 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/cleared by the FDA and other Agencies and/or registered for specific treatments. We train our marketing and direct sales force to not promote our products for uses outside of the 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.

If we were to lose any of our executive management, it could adversely impact our future operations.

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.

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. In the United States, we perform the majority of our research and development, manufacturing and commercialization activity and maintain most of 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. Outside of the United States, CUBE navigation equipment and instruments are manufactured at a single facility in Hennigsdorf, Germany. Our facilities and equipment would be costly to replace and could require substantial lead time to repair or replace. The facilities 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.

As our company diversifies its portfolio of products and expands its international reach, we continue to expand the complexity of our operations. We may encounter difficulties in managing this expansion, which could disrupt our business.

SINUVA was our first commercially available product that is currently regulated as a drug. To sell this product, we have expanded and continue to expand the scope of our operations to comply with manufacturing and regulatory requirements of a

drug. We have also added a network of specialty pharmacies and specialty distributors to support product access and to provide capabilities to handle new operational requirements. We are relying on one integrated sales force to sell all our products. Furthermore, the acquisition of Fiagon expanded the scope of our products and services, including the sale of capital equipment and maintenance services. 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, 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, 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;
- our company or investigators fail to comply with applicable regulations;
- patients do not enroll in, or enroll at a lower rate than we expect, or do not complete a clinical study;
- patients or investigators do not comply with study protocols;
- patients do not return for post-treatment follow-up at the expected rate;
- patients experience unexpected adverse event or side effects for a variety of reasons that may or may not be related to our products;
- sites participating in an ongoing clinical study withdraw, requiring us to engage new sites;
- difficulties or delays associated with establishing additional clinical sites;
- third-party clinical investigators decline to participate in our clinical studies, do not perform the clinical studies on the anticipated schedule, or are inconsistent with the investigator agreement, clinical study protocol, good clinical practices or other agency requirements;
- third-party organizations do not perform data collection and analysis in a timely or accurate manner;
- regulatory inspections of our clinical studies or manufacturing facilities require us to undertake corrective action or suspend or terminate our clinical studies;
- changes in federal, state, or foreign governmental statutes, regulations or policies;
- interim results are inconclusive or unfavorable as to immediate and long-term safety or efficacy;
- the study design is inadequate to demonstrate safety and efficacy; or
- the study does not meet the primary endpoints.

Clinical failure can occur at any stage of the testing. Our clinical studies may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical and non-clinical testing in addition to those we have planned.

Our failure to adequately demonstrate the safety and efficacy of any of our 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 our 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 United Kingdom (the "UK") withdrew from the European Union (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 was subject to a transition period until December 31, 2020 (the "Transition Period") during which EU rules continued to apply. A trade and cooperation agreement (the "Trade and Cooperation Agreement") that outlines the future trading relationship between the UK and the EU was agreed on in December 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, manufacturing, importation, approval and commercialization of our products and product candidates in the UK or the EU. For example, Great Britain is no longer covered by the centralized procedures for obtaining EU-wide marketing authorization from the EMA, and a separate marketing authorization is required to market products in Great Britain. It is currently unclear whether the Medicine & Healthcare products Regulatory Agency ("MHRA") in the UK is sufficiently prepared to handle the increased volume of marketing authorization applications that it is likely to receive. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, would prevent us from commercializing our products in the UK or the EU. Although the UK is currently a very small portion of our business, these regulatory changes 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.

While the Trade and Cooperation Agreement provides for the tariff-free trade of medicinal products between the UK and the EU, there may be additional non-tariff costs to such trade which did not exist prior to the end of the Transition Period. In any event, we do not know to what extent, or when, the UK's withdrawal from the EU will impact our business, particularly our ability to conduct international business. 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 elect to pursue but fail to successfully acquire or effectively and efficiently integrate new third-party businesses, products, and/or technologies, we may not realize expected benefits of the transaction or our existing business may be harmed by the distraction, resource demands or unforeseen consequences of the endeavor.

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 or license 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, internal controls, 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, internal controls, or intellectual property protection in such cases, which may have a material adverse impact on our financial conditions, results of operations, or cash flows. Further, we may record material intangible assets and goodwill related to such companies we acquire. If we determine that future results of the acquired businesses do not meet our expectations, we may be required to record impairments, which would be material and have an adverse effect on our results of operations.

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 have entered into hedging transactions to reduce the impact of foreign currency fluctuations. The availability and effectiveness of these hedging transactions may be limited and we may not be able to successfully hedge our exposure. See "Item 7A. Quantitative and Qualitative Disclosures about Market Risk" of our Annual Report on Form 10-K for additional discussion regarding the impact of foreign currency risk.

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. We are currently in the process of upgrading our information technology systems, including as a result of our acquisition of Fiagon and the need to integrate our information technology systems with those of Fiagon. While we will attempt to mitigate interruptions in our information technology systems, such as our recent and ongoing upgrades to our enterprise resource planning system ("ERP"), we may experience delays, 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. Further, third parties may attempt to hack into our information systems and may obtain our proprietary information. In the event we experience significant disruptions, whether as a result of unexpected delays or difficulties with the upgrades or integration, or as a result of natural disasters or security breaches, we may not be able to implement or repair our systems in an efficient and timely manner. If any of these events or delays occur, they may disrupt or reduce the efficiency of our entire operation and have a material adverse effect on our results of operations and cash flows. As a result of moving our ERP to a cloud-based platform, a third party houses our data and we no longer own the hardware that holds our data. If the third party's platform is hacked, our data would be at risk of being accessed, which could expose us to liability and harm our business.

Risks Relating to Regulatory Matters

Our products are subject to extensive regulation by the FDA, and other agencies, including the requirement to obtain approval and/or register products prior to commercializing our products, maintaining compliance with Quality System and GMP practices, maintaining product quality, 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 fail to maintain compliance with applicable regulations and standards or are subject to regulatory enforcement action as a result of our failure to properly report adverse events or otherwise comply with regulatory requirements and standards, maintain compliance with Quality System and GMP requirements and product quality, 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 Regulation ("MDR") and drug postmarketing safety reporting obligations, which require that we timely report any incidents to the FDA or other Agencies. In the EU, 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 or our ability to maintain product approvals/clearances/registrations 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 many of our product candidates until the appropriate regulatory authorities, such as the FDA, have reviewed and approved or cleared 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 an 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. For example, any post-clearance modifications to the VenSure devices may require submission of a new 510(k) notification and if we fail to obtain such clearance, we may have to recall any affected devices.

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 CMS to be incomplete or incorrect. Governmental agencies may also make changes in program interpretations, requirements or conditions of participation, some of which may have implications for amounts previously estimated or paid. The Medicaid rebate amount is computed each quarter based on our submission to CMS of our current average manufacturer price ("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 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 ("340B") and under other similar government pricing programs

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

Federal law requires that a company must participate in the U.S. Department of Veterans Affairs ("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, 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, from time to time, will audit and examine our quality system for the manufacture, design, and release of our products and confirm adherence with applicable regulatory requirements. Any identified deficiencies in our policies or processes could result in the Notified Body suspending or removing our CE Marks and preclude us from selling our products in the EEA, which could have an adverse effect on our global market expansion, business, results of operations, ability to access capital markets, 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 significant 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 and their business associates that perform services for them that involve individually identifiable health information as well as their covered subcontractors, 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 EU’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 (“FCPA”) 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 (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) 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. Effective January 1, 2021, applicable manufacturers will also be required to report such information regarding its payments and other transfers of value to physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists and certified nurse midwives during the previous year. Manufacturers are required to report to CMS the detailed payment and transfers of value data and submit legal attestation to the accuracy of such data by the 90th day of each calendar year. Due to the difficulty in complying with the Physician Payments Sunshine Act, we cannot assure you that we will successfully report all payments and transfers of value provided by us, and any failure to comply could result in significant fines and penalties. Some states, such as California and Connecticut, also mandate implementation of commercial compliance programs, and other states, such as Massachusetts, Vermont, Maine, Minnesota and New Jersey, impose restrictions on device and pharmaceutical manufacturer marketing practices and tracking and reporting of gifts, compensation and other remuneration to healthcare professionals and entities. The shifting commercial compliance environment and the need to build and maintain robust and expandable systems to comply with different compliance and reporting requirements in multiple jurisdictions increase the possibility that a healthcare company may fail to comply fully with one or more of these requirements.

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

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

In addition, the scope and enforcement of these laws are uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal or state regulatory authorities might challenge our current or future activities under these laws. Any such challenge could have a material adverse effect on our reputation, business, results of operations and financial condition. Any state or federal regulatory review of us,

regardless of the outcome, would be costly and time-consuming. Additionally, we cannot predict the impact of any changes in these laws, whether or not retroactive.

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

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

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

- 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 have been executive, judicial and congressional challenges to other aspects of the Affordable Care Act. For example, since January 2017, the previous President of the United States 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 considered legislation to 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 eliminated 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 ruled 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. The United States Supreme Court is currently reviewing this case, but it is unknown when a decision will be reached. Although the Supreme Court has not yet ruled on the constitutionality of the Affordable Care Act, on January 28, 2021, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through May 15, 2021 for purposes of obtaining health insurance coverage through the Affordable Care Act marketplace. The executive order also instructs certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the Affordable Care Act. It is unclear how the Supreme Court ruling, other such litigation, and the healthcare reform measures of the Biden administration will impact the Affordable Care Act and our business.

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 are suspended from May 1, 2020 through March 31, 2021 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, review the relationship between pricing and manufacturer patient programs and reduce the cost of products and services reimbursed under governmental healthcare programs. At the federal level, the former Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. However, it is unclear whether the Biden administration will work to reverse these measures or pursue similar policy initiatives. 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, and the new presidential administration, 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 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. 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, including distributors, 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. We also own numerous issued patents and pending patent applications that relate to our navigation systems (e.g., CUBE) and our balloon devices (e.g., VenSure). If any of our patents expire, or are challenged, invalidated or legally circumvented by third parties, and 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. For example, 38 of our patents expire between 2021 and 2026, and if our other patents on our products do not provide sufficient patent protection, companies may be able to design around these patents once they expire. 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.

We may be subject to a third-party pre-issuance submission of prior art to the U.S. Patent and Trademark Office (“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, navigation systems, and/or balloon devices 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, may interfere with our ability to sell our commercial and, if approved, pipeline products, and if we are not successful in defending ourselves, could also cause us to pay substantial damages and prohibit us from selling our products.

There are U.S. and foreign patents issued to third parties that relate to the same field as some of our products. Some of these patents may be broad enough to cover one or more aspects of our present or future technology. We do not know whether any of these patents, if they exist and are challenged, would be held valid, enforceable, and infringed. We have received, and likely will continue to receive, letters from third parties accusing us of infringing and/or inviting us to license their patents. We may be sued by, or become involved in an administrative proceeding with, one or more of these third parties.

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 Group PLC, or other patent holders may assert that one or more of our portfolio of products (e.g., steroid releasing implants, CUBE, VenSure) and the methods employed in the use of our products 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 our technical and management personnel will experience a significant diversion of time and effort defending our company. If third parties in patent administrative proceedings are successful, our patent portfolio may be adversely affected. If we lose a patent lawsuit, alleging our infringement of a competitor's patents, we may be prevented from marketing one or more of our portfolio of products 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.

We cannot assure that a court or administrative body would agree with any arguments or defenses we may have concerning invalidity, unenforceability, or non-infringement of any third-party patent. In addition to the issued patents of which we are aware, other parties may have filed, and in the future are likely to file, patent applications covering products that are similar or identical to ours. We cannot assure that any patents issuing from applications filed by a third party will not cover our products or will not have priority over our patent applications.

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 one or more of our portfolio of products, 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 one or more of our portfolio of products unless we can obtain licenses to use technology covered by such patents. We do not know whether any necessary licenses or related royalties 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 cannot be certain that we will have the financial resources or the substantive arguments to defend our parents from infringement or claims of invalidity or unenforceability, or to defend against allegations of infringement of third-party patents. In addition, any public announcements related to litigation or administrative proceedings initiated by us, or initiated or threatened against us, could cause our stock price to decline.

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.

If the Merger does not close, 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 we have adequate cash and other resources to operate for at least twelve months from the issuance of this Quarterly Report on Form 10-Q, including funding our working capital needs, capital expenditures, payments associated with the Fiagon acquisition, interest payments on long-term debt and lease payments. 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 a "change of control," 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. Furthermore, the NOLs acquired from our acquisition of Fiagon may be subject to certain limitations.

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

Our indebtedness under our facility agreements with Deerfield and Medtronic 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 agreements with Deerfield or Medtronic or that future working capital, borrowings or equity financing will be available to repay or refinance any amounts outstanding under the facility agreements with Deerfield or Medtronic. 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

It is difficult to forecast future performance, which may cause our financial results and stock price 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 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 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.

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 of 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.

General Risk Factors

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.

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.

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
2.1	Agreement and Plan of Merger, dates as of August 6, 2021, by and among Medtronic, Inc., a Minnesota corporation, Project Kraken Merger Sub, Inc., a Delaware corporation and wholly-owned subsidiary of Medtronic, Inc., and Intersect ENT, Inc., a Delaware corporation.	8-K	001-36545	2.1	8/10/2021
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, 3.2, 3.3, and 3.4				
10.1**	Amendment to Offer Letter by and between the registrant and Thomas A. West, effective August 14, 2021				
10.2**	Amendment to Offer Letter by and between the registrant and Richard A. Meier, effective August 13, 2021				
10.3**	Amendment to Offer Letter by and between the registrant and Reyna M. Fernandez, effective August 16, 2021				
10.4**	Amendment to Offer Letter by and between the registrant and Patrick A. Broderick, effective August 14, 2021				
10.5**	Letter from the registrant to Thomas A. West regarding acceleration of certain performance-based awards, dated as of September 7, 2021				
10.6**	Letter from the registrant to Richard A. Meier regarding acceleration of certain performance-based awards, dated as of September 7, 2021				
10.7	Facility Agreement, dated as of July 22, 2021, by and among Intersect ENT, Inc., certain of Intersect ENT's subsidiaries from time to time party thereto as guarantors and Deerfield Partners, L.P.	8-K	001-36545	10.1	7/22/2021
10.8	Facility Agreement, dated as of September 25, 2021, by and among Intersect ENT, Inc., certain of Intersect ENT, Inc.'s subsidiaries from time to time party thereto as guarantors and Medtronic, Inc.	8-K	001-36545	10.1	9/27/2021
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.				

Exhibit	Description	Incorporation By Reference			
		Form	SEC File No.	Exhibit	Filing Date
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.				
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).				

** Management compensatory contract or arrangement.

* 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, 2021

Intersect ENT, Inc.
(Registrant)

/s/ Thomas A. West

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

/s/ Richard A. Meier

Richard A. Meier
Executive Vice President and Chief Financial Officer
(Principal Accounting and Financial Officer)

Exhibit 10.1

August 13, 2021

Thomas West
VIA EMAIL/DOCUSIGN

Dear Thomas:

As you know, you are a party to an employment agreement with Intersect ENT, Inc. (the "Company") dated June 24, 2019 (the "Agreement"). The Company is hereby amending the Agreement on the terms set forth below. Capitalized terms not defined herein shall have the meaning set forth in the Agreement.

The first sentence of the definition of "Severance Benefits" as set forth in the Agreement is hereby replaced with the following text:

> "Severance Benefits" shall mean (i) payment of eighteen (18) months of your base salary, less all applicable withholdings and deductions, paid over such 18-month period immediately following the Separation from Service, on the schedule described below (the "Salary Continuation"); (ii) a lump sum payment equal to your annual target bonus prorated for the number of days of the then current bonus period worked prior to your Separation from Service; and (iii) if you timely elect continued coverage under COBRA, eighteen (18) months COBRA reimbursement (with such reimbursement to cease if you become eligible for health insurance benefits through a new employer).

The remaining portion of the "Severance Benefits" paragraph shall remain unchanged.

In addition, if it shall be determined that any Payment (as defined below) would be subject to the Excise Tax (as defined below), then you shall be entitled to receive an additional payment (the "Gross-Up Payment") in an amount such that, after payment by you of all taxes (and any interest or penalties imposed with respect to such taxes), including, without limitation, any income taxes (and any interest and penalties imposed with respect thereto) and Excise Tax imposed upon the Gross-Up Payment, but excluding any income taxes and penalties imposed pursuant to Section 409A of the Code, you retain an amount of the Gross-Up Payment equal to the Excise Tax imposed upon the Payments. The Company's obligation to make Gross-Up Payments shall not be conditioned upon your termination of employment.

Subject to the provisions below, all determinations required to be made, including whether and when a Gross-Up Payment is required, the amount of such Gross-Up Payment, and the assumptions to be utilized in arriving at such determination, shall be made by the Company's accounting firm (the "Accounting Firm"). The Accounting Firm shall provide detailed supporting calculations both to you and the Company within 15 business days after receipt of notice from you that there has been a Payment or such earlier time as is requested by the Company. All fees and expenses of the Accounting Firm shall be borne solely by the Company. Any determination by the Accounting Firm shall be binding upon you and the Company.

As a result of the uncertainty in the application of Section 4999 of the Code at the time of the initial determination by the Accounting Firm hereunder, it is possible that Gross-Up Payments that will not have been made by the Company should have been made (the "Underpayment"), consistent with the calculations required to be made hereunder. In the event the Company exhausts its remedies as set forth herein, and you are required to make a payment of any Excise Tax, the Accounting Firm shall determine the amount of the Underpayment that has occurred, and any such Underpayment shall be promptly paid by the Company to or for the benefit of you.

You shall notify the Company in writing of any claim by the Internal Revenue Service that, if successful, would require the payment by the Company of the Gross-Up Payment. Such notification shall be given as

soon as practicable, but no later than 10 business days after you are informed in writing of such claim. You shall apprise the Company of the nature of such claim and the date on which such claim is requested to be paid. You shall not pay such claim prior to the expiration of the 30-day period following the date on which you give such notice to the Company (or such shorter period ending on the date that any payment of taxes with respect to such claim is due). If the Company notifies you in writing prior to the expiration of such period that the Company desires to contest such claim, you shall: (a) give the Company any information reasonably requested by the Company relating to such claim; (b) take such action in connection with contesting such claim as the Company shall reasonably request in writing from time to time, including, without limitation, accepting legal representation with respect to such claim by an attorney reasonably selected by the Company; (c) cooperate with the Company in good faith in order to effectively contest such claim; and (d) permit the Company to participate in any proceedings relating to such claim; provided, however, that the Company shall bear and pay directly all costs and expenses (including additional interest and penalties) incurred in connection with such contest, and shall indemnify and hold you harmless, on an after-tax basis, for any Excise Tax or income tax (including interest and penalties) imposed as a result of such representation and payment of costs and expenses. Without limitation on the foregoing provisions, the Company shall control all proceedings taken in connection with such contest, and, at its sole discretion, may pursue or forgo any and all administrative appeals, proceedings, hearings, and conferences with the applicable taxing authority in respect of such claim and may, at its sole discretion, either pay the tax claimed to the appropriate taxing authority on your behalf and direct you to sue for a refund or to contest the claim in any permissible manner, and you agree to prosecute such contest to a determination before any administrative tribunal, in a court of initial jurisdiction, and in one or more appellate courts, as the Company shall determine; provided, however, that, if the Company pays such claim and directs you to sue for a refund, the Company shall indemnify and hold you harmless, on an after-tax basis, from any Excise Tax or income tax (including interest or penalties) imposed with respect to such payment or with respect to any imputed income in connection with such payment; and provided, further, that any extension of the statute of limitations relating to payment of taxes for the taxable year with respect to which such contested amount is claimed to be due is limited solely to such contested amount. Furthermore, the Company's control of the contest shall be limited to issues with respect to which the Gross-Up Payment would be payable hereunder, and you shall be entitled to settle or contest, as the case may be, any other issue raised by the Internal Revenue Service or any other taxing authority.

If, after your receipt of a Gross-Up Payment or payment by the Company of an amount on your behalf, you become entitled to receive any refund with respect to the Excise Tax to which such Gross-Up Payment relates or with respect to such claim, you shall (subject to the Company's complying with the requirements herein, if applicable) promptly pay to the Company the amount of such refund (together with any interest paid or credited thereon after taxes applicable thereto). If, after payment by the Company of an amount on your behalf, a determination is made that you shall not be entitled to any refund with respect to such claim and the Company does not notify you in writing of its intent to contest such denial of refund prior to the expiration of 30 days after such determination, then the amount of such payment shall offset, to the extent thereof, the amount of Gross-Up Payment required to be paid.

The following terms shall have the following meanings for purposes of this letter amendment:

(a) "Excise Tax" shall mean the excise tax imposed by Section 4999 of the Code, together with any interest or penalties imposed with respect to such excise tax.

(b) The "Parachute Value" of a Payment shall mean the present value as of the date of the change of control for purposes of Section 280G of the Code of the portion of such Payment that constitutes a "parachute payment" under Code Section 280G(b)(2), as determined by the Accounting Firm for purposes of determining whether and to what extent the Excise Tax will apply to such Payment.

(c) A "Payment" shall mean any payment or distribution in the nature of compensation (within the meaning of Section 280G(b)(2) of the Code) to or for the benefit of you, whether paid or payable pursuant to this letter amendment or otherwise, that relates to the transactions described in the Agreement and Plan

of Merger between the Company, Medtronic, Inc., a Minnesota corporation (“Parent”), and Project Kraken Merger Sub, Inc., a Delaware corporation and wholly-owned subsidiary of Parent.

Except as set forth herein, the terms of the Agreement remain in full force and effect.

This amendment sets forth the entire agreement of the parties with respect to the amended terms herein, and supersedes any prior promises or agreements (oral or written) concerning the subject matter hereof. This amendment may only be amended in a written agreement signed by you and a duly authorized member of the Board of Directors.

Please sign below to indicate your acceptance of these terms.

Sincerely,

/s/ Patrick Broderick
Patrick Broderick
Executive Vice President, General Counsel and Corporate Secretary

Understood, accepted and agreed to:

/s/ Thomas West
Thomas West

8/14/2021
Date

Exhibit 10.2

August 13, 2021

Richard A. Meier
VIA EMAIL/DOCUSIGN

Dear Randy:

As you know, you are a party to an employment agreement with Intersect ENT, Inc. (the "Company") dated November 26, 2019 (the "Agreement"). The Company is hereby amending the Agreement on the terms set forth below. Capitalized terms not defined herein shall have the meaning set forth in the Agreement.

If it shall be determined that any Payment (as defined below) would be subject to the Excise Tax (as defined below), then you shall be entitled to receive an additional payment (the "Gross-Up Payment") in an amount such that, after payment by you of all taxes (and any interest or penalties imposed with respect to such taxes), including, without limitation, any income taxes (and any interest and penalties imposed with respect thereto) and Excise Tax imposed upon the Gross-Up Payment, but excluding any income taxes and penalties imposed pursuant to Section 409A of the Code, you retain an amount of the Gross-Up Payment equal to the Excise Tax imposed upon the Payments. The Company's obligation to make Gross-Up Payments shall not be conditioned upon your termination of employment.

Subject to the provisions below, all determinations required to be made, including whether and when a Gross-Up Payment is required, the amount of such Gross-Up Payment, and the assumptions to be utilized in arriving at such determination, shall be made by the Company's accounting firm (the "Accounting Firm"). The Accounting Firm shall provide detailed supporting calculations both to you and the Company within 15 business days after receipt of notice from you that there has been a Payment or such earlier time as is requested by the Company. All fees and expenses of the Accounting Firm shall be borne solely by the Company. Any determination by the Accounting Firm shall be binding upon you and the Company.

As a result of the uncertainty in the application of Section 4999 of the Code at the time of the initial determination by the Accounting Firm hereunder, it is possible that Gross-Up Payments that will not have been made by the Company should have been made (the "Underpayment"), consistent with the calculations required to be made hereunder. In the event the Company exhausts its remedies as set forth herein, and you are required to make a payment of any Excise Tax, the Accounting Firm shall determine the amount of the Underpayment that has occurred and any such Underpayment shall be promptly paid by the Company to or for the benefit of you.

You shall notify the Company in writing of any claim by the Internal Revenue Service that, if successful, would require the payment by the Company of the Gross-Up Payment. Such notification shall be given as soon as practicable, but no later than 10 business days after you are informed in writing of such claim. You shall apprise the Company of the nature of such claim and the date on which such claim is requested to be paid. You shall not pay such claim prior to the expiration of the 30-day period following the date on which you give such notice to the Company (or such shorter period ending on the date that any payment of taxes with respect to such claim is due). If the Company notifies you in writing prior to the expiration of such period that the Company desires to contest such claim, you shall: (a) give the Company any information reasonably requested by the Company relating to such claim; (b) take such action in connection with contesting such claim as the Company shall reasonably request in writing from time to time, including, without limitation, accepting legal representation with respect to such claim by an attorney reasonably selected by the Company; (c) cooperate with the Company in good faith in order to effectively contest such claim; and (d) permit the Company to participate in any proceedings relating to such claim; provided, however, that the Company shall bear and pay directly all costs and expenses (including additional interest and penalties) incurred in connection with such contest, and shall indemnify and hold you harmless, on an after-tax basis, for any Excise Tax or income tax (including interest and penalties) imposed as a result of

such representation and payment of costs and expenses. Without limitation on the foregoing provisions, the Company shall control all proceedings taken in connection with such contest, and, at its sole discretion, may pursue or forgo any and all administrative appeals, proceedings, hearings, and conferences with the applicable taxing authority in respect of such claim and may, at its sole discretion, either pay the tax claimed to the appropriate taxing authority on your behalf and direct you to sue for a refund or to contest the claim in any permissible manner, and you agree to prosecute such contest to a determination before any administrative tribunal, in a court of initial jurisdiction, and in one or more appellate courts, as the Company shall determine; provided, however, that, if the Company pays such claim and directs you to sue for a refund, the Company shall indemnify and hold you harmless, on an after-tax basis, from any Excise Tax or income tax (including interest or penalties) imposed with respect to such payment or with respect to any imputed income in connection with such payment; and provided, further, that any extension of the statute of limitations relating to payment of taxes for the taxable year with respect to which such contested amount is claimed to be due is limited solely to such contested amount. Furthermore, the Company's control of the contest shall be limited to issues with respect to which the Gross-Up Payment would be payable hereunder, and you shall be entitled to settle or contest, as the case may be, any other issue raised by the Internal Revenue Service or any other taxing authority.

If, after your receipt of a Gross-Up Payment or payment by the Company of an amount on your behalf, you become entitled to receive any refund with respect to the Excise Tax to which such Gross-Up Payment relates or with respect to such claim, you shall (subject to the Company's complying with the requirements herein, if applicable) promptly pay to the Company the amount of such refund (together with any interest paid or credited thereon after taxes applicable thereto). If, after payment by the Company of an amount on your behalf, a determination is made that you shall not be entitled to any refund with respect to such claim and the Company does not notify you in writing of its intent to contest such denial of refund prior to the expiration of 30 days after such determination, then the amount of such payment shall offset, to the extent thereof, the amount of Gross-Up Payment required to be paid.

The following terms shall have the following meanings for purposes of this letter amendment:

(a) "Excise Tax" shall mean the excise tax imposed by Section 4999 of the Code, together with any interest or penalties imposed with respect to such excise tax.

(b) The "Parachute Value" of a Payment shall mean the present value as of the date of the change of control for purposes of Section 280G of the Code of the portion of such Payment that constitutes a "parachute payment" under Code Section 280G(b)(2), as determined by the Accounting Firm for purposes of determining whether and to what extent the Excise Tax will apply to such Payment.

(c) A "Payment" shall mean any payment or distribution in the nature of compensation (within the meaning of Section 280G(b)(2) of the Code) to or for the benefit of you, whether paid or payable pursuant to this letter amendment or otherwise, that relates to the transactions described in the Agreement and Plan of Merger between the Company, Medtronic, Inc., a Minnesota corporation ("Parent"), and Project Kraken Merger Sub, Inc., a Delaware corporation and wholly-owned subsidiary of Parent.

Except as set forth herein, the terms of the Agreement remain in full force and effect.

This amendment sets forth the entire agreement of the parties with respect to the amended terms herein, and supersedes any prior promises or agreements (oral or written) concerning the subject matter hereof. This amendment may only be amended in a written agreement signed by you and a duly authorized member of the Board of Directors.

Please sign below to indicate your acceptance of these terms.

Sincerely,

/s/ Thomas A. West
Thomas A. West
President and Chief Executive Officer

Understood, accepted and agreed to:

/s/ Richard A. Meier
Richard A. Meier

8/13/2021
Date

Exhibit 10.3

August 13, 2021

Reyna Fernandez
VIA EMAIL/DOCUSIGN

Dear Reyna:

As you know, you are a party to an employment agreement with Intersect ENT, Inc. (the "Company") dated November 13, 2020 (the "Agreement"). The Company is hereby amending the Agreement on the terms set forth below. Capitalized terms not defined herein shall have the meaning set forth in the Agreement.

If it shall be determined that any Payment (as defined below) would be subject to the Excise Tax (as defined below), then you shall be entitled to receive an additional payment (the "Gross-Up Payment") in an amount such that, after payment by you of all taxes (and any interest or penalties imposed with respect to such taxes), including, without limitation, any income taxes (and any interest and penalties imposed with respect thereto) and Excise Tax imposed upon the Gross-Up Payment, but excluding any income taxes and penalties imposed pursuant to Section 409A of the Code, you retain an amount of the Gross-Up Payment equal to the Excise Tax imposed upon the Payments. The Company's obligation to make Gross-Up Payments shall not be conditioned upon your termination of employment.

Subject to the provisions below, all determinations required to be made, including whether and when a Gross-Up Payment is required, the amount of such Gross-Up Payment, and the assumptions to be utilized in arriving at such determination, shall be made by the Company's accounting firm (the "Accounting Firm"). The Accounting Firm shall provide detailed supporting calculations both to you and the Company within 15 business days after receipt of notice from you that there has been a Payment or such earlier time as is requested by the Company. All fees and expenses of the Accounting Firm shall be borne solely by the Company. Any determination by the Accounting Firm shall be binding upon you and the Company.

As a result of the uncertainty in the application of Section 4999 of the Code at the time of the initial determination by the Accounting Firm hereunder, it is possible that Gross-Up Payments that will not have been made by the Company should have been made (the "Underpayment"), consistent with the calculations required to be made hereunder. In the event the Company exhausts its remedies as set forth herein, and you are required to make a payment of any Excise Tax, the Accounting Firm shall determine the amount of the Underpayment that has occurred and any such Underpayment shall be promptly paid by the Company to or for the benefit of you.

You shall notify the Company in writing of any claim by the Internal Revenue Service that, if successful, would require the payment by the Company of the Gross-Up Payment. Such notification shall be given as soon as practicable, but no later than 10 business days after you are informed in writing of such claim. You shall apprise the Company of the nature of such claim and the date on which such claim is requested to be paid. You shall not pay such claim prior to the expiration of the 30-day period following the date on which you give such notice to the Company (or such shorter period ending on the date that any payment of taxes with respect to such claim is due). If the Company notifies you in writing prior to the expiration of such period that the Company desires to contest such claim, you shall: (a) give the Company any information reasonably requested by the Company relating to such claim; (b) take such action in connection with contesting such claim as the Company shall reasonably request in writing from time to time, including, without limitation, accepting legal representation with respect to such claim by an attorney reasonably selected by the Company; (c) cooperate with the Company in good faith in order to effectively contest such claim; and (d) permit the Company to participate in any proceedings relating to such claim; provided, however, that the Company shall bear and pay directly all costs and expenses (including additional interest and penalties) incurred in connection with such contest, and shall indemnify and hold you harmless, on an after-tax basis, for any Excise Tax or income tax (including interest and penalties) imposed as a result of

such representation and payment of costs and expenses. Without limitation on the foregoing provisions, the Company shall control all proceedings taken in connection with such contest, and, at its sole discretion, may pursue or forgo any and all administrative appeals, proceedings, hearings, and conferences with the applicable taxing authority in respect of such claim and may, at its sole discretion, either pay the tax claimed to the appropriate taxing authority on your behalf and direct you to sue for a refund or to contest the claim in any permissible manner, and you agree to prosecute such contest to a determination before any administrative tribunal, in a court of initial jurisdiction, and in one or more appellate courts, as the Company shall determine; provided, however, that, if the Company pays such claim and directs you to sue for a refund, the Company shall indemnify and hold you harmless, on an after-tax basis, from any Excise Tax or income tax (including interest or penalties) imposed with respect to such payment or with respect to any imputed income in connection with such payment; and provided, further, that any extension of the statute of limitations relating to payment of taxes for the taxable year with respect to which such contested amount is claimed to be due is limited solely to such contested amount. Furthermore, the Company's control of the contest shall be limited to issues with respect to which the Gross-Up Payment would be payable hereunder, and you shall be entitled to settle or contest, as the case may be, any other issue raised by the Internal Revenue Service or any other taxing authority.

If, after your receipt of a Gross-Up Payment or payment by the Company of an amount on your behalf, you become entitled to receive any refund with respect to the Excise Tax to which such Gross-Up Payment relates or with respect to such claim, you shall (subject to the Company's complying with the requirements herein, if applicable) promptly pay to the Company the amount of such refund (together with any interest paid or credited thereon after taxes applicable thereto). If, after payment by the Company of an amount on your behalf, a determination is made that you shall not be entitled to any refund with respect to such claim and the Company does not notify you in writing of its intent to contest such denial of refund prior to the expiration of 30 days after such determination, then the amount of such payment shall offset, to the extent thereof, the amount of Gross-Up Payment required to be paid.

The following terms shall have the following meanings for purposes of this letter amendment:

(a) "Excise Tax" shall mean the excise tax imposed by Section 4999 of the Code, together with any interest or penalties imposed with respect to such excise tax.

(b) The "Parachute Value" of a Payment shall mean the present value as of the date of the change of control for purposes of Section 280G of the Code of the portion of such Payment that constitutes a "parachute payment" under Code Section 280G(b)(2), as determined by the Accounting Firm for purposes of determining whether and to what extent the Excise Tax will apply to such Payment.

(c) A "Payment" shall mean any payment or distribution in the nature of compensation (within the meaning of Section 280G(b)(2) of the Code) to or for the benefit of you, whether paid or payable pursuant to this letter amendment or otherwise, that relates to the transactions described in the Agreement and Plan of Merger between the Company, Medtronic, Inc., a Minnesota corporation ("Parent"), and Project Kraken Merger Sub, Inc., a Delaware corporation and wholly-owned subsidiary of Parent.

Except as set forth herein, the terms of the Agreement remain in full force and effect.

This amendment sets forth the entire agreement of the parties with respect to the amended terms herein, and supersedes any prior promises or agreements (oral or written) concerning the subject matter hereof. This amendment may only be amended in a written agreement signed by you and a duly authorized member of the Board of Directors.

Please sign below to indicate your acceptance of these terms.

Sincerely,

/s/ Thomas A. West
Thomas A. West
President and Chief Executive Officer

Understood, accepted and agreed to:

/s/ Reyna Fernandez
Reyna Fernandez

8/16/2021
Date

Exhibit 10.4

August 13, 2021

Patrick Broderick
VIA EMAIL/DOCUSIGN

Dear Patrick:

As you know, you are a party to an employment agreement with Intersect ENT, Inc. (the "Company") dated November 12, 2020 (the "Agreement"). The Company is hereby amending the Agreement on the terms set forth below. Capitalized terms not defined herein shall have the meaning set forth in the Agreement.

If it shall be determined that any Payment (as defined below) would be subject to the Excise Tax (as defined below), then you shall be entitled to receive an additional payment (the "Gross-Up Payment") in an amount such that, after payment by you of all taxes (and any interest or penalties imposed with respect to such taxes), including, without limitation, any income taxes (and any interest and penalties imposed with respect thereto) and Excise Tax imposed upon the Gross-Up Payment, but excluding any income taxes and penalties imposed pursuant to Section 409A of the Code, you retain an amount of the Gross-Up Payment equal to the Excise Tax imposed upon the Payments. The Company's obligation to make Gross-Up Payments shall not be conditioned upon your termination of employment.

Subject to the provisions below, all determinations required to be made, including whether and when a Gross-Up Payment is required, the amount of such Gross-Up Payment, and the assumptions to be utilized in arriving at such determination, shall be made by the Company's accounting firm (the "Accounting Firm"). The Accounting Firm shall provide detailed supporting calculations both to you and the Company within 15 business days after receipt of notice from you that there has been a Payment or such earlier time as is requested by the Company. All fees and expenses of the Accounting Firm shall be borne solely by the Company. Any determination by the Accounting Firm shall be binding upon you and the Company.

As a result of the uncertainty in the application of Section 4999 of the Code at the time of the initial determination by the Accounting Firm hereunder, it is possible that Gross-Up Payments that will not have been made by the Company should have been made (the "Underpayment"), consistent with the calculations required to be made hereunder. In the event the Company exhausts its remedies as set forth herein, and you are required to make a payment of any Excise Tax, the Accounting Firm shall determine the amount of the Underpayment that has occurred and any such Underpayment shall be promptly paid by the Company to or for the benefit of you. You shall notify the Company in writing of any claim by the Internal Revenue Service that, if successful, would require the payment by the Company of the Gross-Up Payment. Such notification shall be given as soon as practicable, but no later than 10 business days after you are informed in writing of such claim. You shall apprise the Company of the nature of such claim and the date on which such claim is requested to be paid. You shall not pay such claim prior to the expiration of the 30-day period following the date on which you give such notice to the Company (or such shorter period ending on the date that any payment of taxes with respect to such claim is due). If the Company notifies you in writing prior to the expiration of such period that the Company desires to contest such claim, you shall: (a) give the Company any information reasonably requested by the Company relating to such claim; (b) take such action in connection with contesting such claim as the Company shall reasonably request in writing from time to time, including, without limitation, accepting legal representation with respect to such claim by an attorney reasonably selected by the Company; (c) cooperate with the Company in good faith in order to effectively contest such claim; and (d) permit the Company to participate in any proceedings relating to such claim; provided, however, that the Company shall bear and pay directly all costs and expenses (including additional interest and penalties) incurred in connection with such contest, and shall indemnify and hold you harmless, on an after-tax basis, for any Excise Tax or income tax (including interest and penalties) imposed as a result of such representation and payment of costs and expenses. Without limitation on the foregoing provisions, the Company shall control all proceedings taken in connection with such

contest, and, at its sole discretion, may pursue or forgo any and all administrative appeals, proceedings, hearings, and conferences with the applicable taxing authority in respect of such claim and may, at its sole discretion, either pay the tax claimed to the appropriate taxing authority on your behalf and direct you to sue for a refund or to contest the claim in any permissible manner, and you agree to prosecute such contest to a determination before any administrative tribunal, in a court of initial jurisdiction, and in one or more appellate courts, as the Company shall determine; provided, however, that, if the Company pays such claim and directs you to sue for a refund, the Company shall indemnify and hold you harmless, on an after-tax basis, from any Excise Tax or income tax (including interest or penalties) imposed with respect to such payment or with respect to any imputed income in connection with such payment; and provided, further, that any extension of the statute of limitations relating to payment of taxes for the taxable year with respect to which such contested amount is claimed to be due is limited solely to such contested amount. Furthermore, the Company's control of the contest shall be limited to issues with respect to which the Gross-Up Payment would be payable hereunder, and you shall be entitled to settle or contest, as the case may be, any other issue raised by the Internal Revenue Service or any other taxing authority.

If, after your receipt of a Gross-Up Payment or payment by the Company of an amount on your behalf, you become entitled to receive any refund with respect to the Excise Tax to which such Gross-Up Payment relates or with respect to such claim, you shall (subject to the Company's complying with the requirements herein, if applicable) promptly pay to the Company the amount of such refund (together with any interest paid or credited thereon after taxes applicable thereto). If, after payment by the Company of an amount on your behalf, a determination is made that you shall not be entitled to any refund with respect to such claim and the Company does not notify you in writing of its intent to contest such denial of refund prior to the expiration of 30 days after such determination, then the amount of such payment shall offset, to the extent thereof, the amount of Gross-Up Payment required to be paid.

The following terms shall have the following meanings for purposes of this letter amendment:

(a) "Excise Tax" shall mean the excise tax imposed by Section 4999 of the Code, together with any interest or penalties imposed with respect to such excise tax.

(b) The "Parachute Value" of a Payment shall mean the present value as of the date of the change of control for purposes of Section 280G of the Code of the portion of such Payment that constitutes a "parachute payment" under Code Section 280G(b)(2), as determined by the Accounting Firm for purposes of determining whether and to what extent the Excise Tax will apply to such Payment.

(c) A "Payment" shall mean any payment or distribution in the nature of compensation (within the meaning of Section 280G(b)(2) of the Code) to or for the benefit of you, whether paid or payable pursuant to this letter amendment or otherwise, that relates to the transactions described in the Agreement and Plan of Merger between the Company, Medtronic, Inc., a Minnesota corporation ("Parent"), and Project Kraken Merger Sub, Inc., a Delaware corporation and wholly-owned subsidiary of Parent.

Except as set forth herein, the terms of the Agreement remain in full force and effect.

This amendment sets forth the entire agreement of the parties with respect to the amended terms herein, and supersedes any prior promises or agreements (oral or written) concerning the subject matter hereof. This amendment may only be amended in a written agreement signed by you and a duly authorized member of the Board of Directors.

Please sign below to indicate your acceptance of these terms.

Sincerely,

/s/ Thomas A. West
Thomas A. West
President and Chief Executive Officer

Understood, accepted and agreed to:

/s/ Patrick Broderick
Patrick Broderick

8/14/2021
Date

Exhibit 10.5

Date: September 7, 2021

To: Thomas A. West

Subject: Equity Acceleration

We are pleased to share with you that the Board of Directors of Intersect ENT, Inc. (the "***Company***") have granted you certain equity acceleration benefits, as described below. This letter will serve as an amendment to certain vesting acceleration provisions included in your performance-based vesting equity awards, as described below.

Equity Acceleration: You have been granted a performance-based vesting stock option award granted on July 22, 2019 that vests based on achievement of 30-day average share price targets (the "***CEO PSO***"), and a performance-based vesting stock unit award granted on February 3, 2020 that vests based on achievement of average share price targets (the "***CEO PSU***"). The Company's Board of Directors have amended the CEO PSO and CEO PSU to provide that such awards will be fully vested and, if applicable, exercisable immediately prior to and contingent upon the merger transaction described in the Agreement and Plan of Merger dated August 6, 2021, by and among Medtronic, Inc., a Minnesota corporation ("***Parent***"), Project Kraken Merger Sub, Inc., a Delaware corporation and wholly-owned subsidiary of Parent and the Company (the "***Merger***").

Except as noted above, this letter does not amend or modify the terms of the CEO PSO or CEO PSU, nor does it amend or modify the Company's rights or obligations under either the CEO PSO or CEO PSU. Rather, this letter supplements the CEO PSO and CEO PSU by establishing that such awards will accelerate in the event of the Merger. This letter is part of CEO PSO and CEO PSU and should be kept with those documents for your recordkeeping.

Sincerely,

/s/ Patrick Broderick
Patrick Broderick
EVP, General Counsel & Corporate Secretary
Intersect ENT, Inc.

Exhibit 10.6

Date: September 7, 2021

To: Richard A. Meier

Subject: Equity Acceleration

We are pleased to share with you that the Board of Directors of Intersect ENT, Inc. (the "***Company***") have granted you certain equity acceleration benefits, as described below. This letter will serve as an amendment to certain vesting acceleration provisions included in your performance-based vesting equity award, as described below.

Equity Acceleration: You have been granted a performance-based vesting stock unit award granted on November 26, 2019 that vests based on achievement of average share price targets (the "***CFO PSU***"). The Company's Board of Directors have amended the CFO PSU to provide that such award will be fully vested immediately prior to and contingent upon the merger transaction described in the Agreement and Plan of Merger dated August 6, 2021, by and among Medtronic, Inc., a Minnesota corporation ("Parent"), Project Kraken Merger Sub, Inc., a Delaware corporation and wholly-owned subsidiary of Parent and the Company (the "***Merger***").

Except as noted above, this letter does not amend or modify the terms of the CFO PSU, nor does it amend or modify the Company's rights or obligations under the CFO PSU. Rather, this letter supplements the CFO PSU by establishing that the CFO PSU will accelerate in the event of the Merger. This letter is part of CFO PSU and should be kept with it for your recordkeeping.

Sincerely,

/s/ Patrick Broderick
Patrick Broderick
EVP, General Counsel & Corporate Secretary
Intersect ENT, Inc.

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, 2021

/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, 2021

/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 their knowledge:

1. The Company's Quarterly Report on Form 10-Q for the period ended September 30, 2021, 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, 2021

/s/ Thomas A. West

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

November 2, 2021

/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.