intersect® ENT

TOTAL COMMITMENT

PROPEL®
MOMETASONE FUROATE SINUS IMPLANTS

SINUVA®
(mometasone furoate) sinus implant

Cube™ 4D
Navigation System

VirtuEye™

VenSure™
Balloon Sinus Dilation System

2020

Dear Shareholders,

What a difference a year makes! We are stronger today than we were a year-ago despite the impact of COVID-19 on the market and our business.

2020 was a year that not only tested the resiliency of our business, but also the resolve of our valued employees. The COVID-19 pandemic presented an unprecedented set of circumstances to Intersect ENT as hospitals suspended elective surgical procedures and ENT office visits were significantly reduced. Reflecting on our achievements today, I am proud of the way our team executed and delivered on our objectives. The year was highlighted by the recovery of our core PROPEL and SINUVA sinus implant platforms, the acquisition of Fiagon AG and its surgical navigation and sinus balloon dilation portfolio, the building of essential new executional capabilities and the assignment and utilization of critically important reimbursement coding changes. We are better positioned today than we were a year-ago to deliver sustainable future growth. In total, we successfully transformed Intersect ENT from a single technology innovator into a diversified, outcomes-based, solutions provider in the large and growing global chronic sinusitis market. We are now not only poised to resume growth in the near-term relative to 2019, but sustain strong revenue growth in the years to come.

COVID-19 RESPONSE AND CORPORATE TRANSFORMATION

One year ago, we were navigating the uncertainties of the global pandemic with the U.S. PROPEL family of sinus implants accounting for the vast majority of our corporate revenues. SINUVA's business model was still largely unproven more than two years after launch, international revenues were minimal and we were faced with pandemic-related challenges of suspended elective sinus procedures.

At the start of the pandemic in the spring of 2020, we focused on protecting the health and safety of our employees, maintaining customer engagement, refining our go-to-market commercial model and preserving our capital and liquidity. From a strategic standpoint, we took decisive actions to restructure and refinance the Company thereby enabling us to manage through the pandemic and reposition Intersect ENT as a more diversified and scalable global leader across the continuum of care in chronic rhinosinusitis.

We managed the significant COVID-related downturn in elective procedures by taking swift action to secure our financial position. We reduced operating expenses and raised $65 million in convertible notes from Deerfield Management Group. We suspended manufacturing and bled down inventory to preserve cash. These actions, when combined with our working capital management improvements and renewed revenue growth, give us adequate capital to operate well into 2022.

On the product side of our business, after the initial impact of the pandemic, PROPEL sales recovered rapidly in hospitals and surgical centers. We fueled incremental PROPEL growth in the office setting and international markets. We are particularly excited about the opportunity for use of PROPEL in the office setting of care in conjunction with balloon sinus dilation. Additionally, we pursued longitudinal, real-world, evidence of PROPEL's clinical and health-economic benefits assessing healthcare utilization 18 months following sinus surgery with and without PROPEL. We are confident this health-economic analysis will demonstrate the benefit to payers of greater physician access to, and coverage for, PROPEL following sinus surgery.

For SINUVA, we established and validated the go-to-market model for initiating drug therapy in the doctor's office with improved reimbursement coding and needed payer coverage to drive sustainable, double-digit, growth. Today, in combination with our patient services HUB and specialty pharmacy channel partners we are enabling streamlined benefit verification, coverage, distribution and payment to physicians using SINUVA in the office. Improved physician access complements existing strong clinical evidence of benefit. Closing 2020 with consecutive quarters of record SINUVA revenue underscores our belief that SINUVA is now positioned to meaningfully contribute to our overall revenue growth.

BROADENING OUR PORTFOLIO WITH THE FIAGON ACQUISITION

Two additional and important components to our growth strategy are geographic expansion and product innovation. To that end, we were excited to acquire Fiagon AG Medical Technologies, which met both key criteria. A leader in electromagnetic surgical navigation solutions, Fiagon immediately gives us entry into the adjacent balloon sinus dilation market with their recently FDA-cleared VENSURE sinus balloon while also adding highly complementary navigation and disposable surgical tools to our core portfolio. These important product portfolio additions expand our value proposition among our existing physician customers and allow for efficient incremental growth on top of anticipated gains in PROPEL and SINUVA. This transaction also enables Intersect ENT to gain scale in key European markets, specifically building upon our existing modest presence in Germany, and extends our footprint in U.S. and European ENT physicians' offices.

The integration of Fiagon has progressed smoothly. With several upcoming product launches, including the planned U.S. launch and deployment of VENSURE Balloon and next generation CUBE Navigation, we expect meaningful contributions from our navigation and sinus balloon products in the second half of 2021 and beyond.

POSITIONING INTERSECT ENT FOR GROWTH

Recently, Centers for Medicare and Medicaid Services (CMS) announced coding changes for both PROPEL and SINUVA that we believe will contribute further to our positive revenue growth momentum. At our request, CMS approved a revised coding application that provides for a single and distinct code for PROPEL and consolidates of the two existing SINUVA codes into a single distinct code for SINUVA. These actions will reduce coding confusion and claims uncertainty and help ENT physicians better understand the amount of implant reimbursement they can expect when using PROPEL or SINUVA regardless of setting of care.

With our sales force working remotely throughout much of 2020, we implemented a rigorous training curriculum designed to strengthen sales force clinical knowledge, selling skills and account management and analysis to allow our team to pivot quickly to maximize interactions with our customers in an increasingly dynamic COVID-influenced environment. Branded "XENT University" we sought to improve knowledge and skills elevating analytic rigor to improve targeting and message tailoring. These new capabilities are aimed at strengthening our commercial execution as markets begin to reopen post-COVID and our portfolio expands.

Finally, on the product pipeline front, in the first quarter of 2021 we initiated a prospective clinical trial with our new VENSURE Balloon followed by a PROPEL Contour implant to establish the benefits of combined use of our PROPEL localized drug delivery following balloon dilation. The current trial, named EXPAND, will recruit approximately 80-100 patients over the course of 2021 with preliminary results reading out in the second half of 2022 and full results with longer-term data in 2023. In addition, our talented R&D team continues work on further applications of core polymer delivery and drug formulation technologies to address unmet needs in chronic sinusitis.

DELIVERING VALUE IN 2021 AND BEYOND

Our team came together under the most challenging of conditions in an unprecedented year that now has Intersect ENT primed to generate long-term sustainable double-digit growth. We have an incredible opportunity to fulfill this objective by further penetrating existing ENT procedures and by increasing our relevance to the physicians we serve across all sites of care. We are investing in our core products and promising pipeline, building and enhancing our skills and capabilities and taking advantage of pent-up elective sinus procedure demand. Supported by our transformation into a diversified business with a broader and complementary chronic rhinosinusitis portfolio, we have multiple "shots on goal" to drive growth, reinforcing our confidence that we can achieve our goals and return maximum value to our shareholders.

In closing, I would like to express my appreciation to our valued employees, the patients we serve, and our shareholders.

Sincerely,

Thomas A. West
President, CEO & Director

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

(Mark One)

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

For the fiscal year ended December 31, 2020

OR

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

For the transition period from to .

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 No.)**
1555 Adams Drive Menlo Park, CA	**94025**
(Address of principal executive offices)	**(zip code)**

Registrant's telephone number, including area code: (650) 641-2100

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

Title of Each Class	Trading Symbol	Name of Exchange on Which Registered
Common Stock, 0.001 par value	**XENT**	**The Nasdaq Global Market**

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

None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☑ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☑

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☑ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted and posted 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 and post such files). Yes ☑ No ☐

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

Large accelerated filer	☐	Accelerated filer	☑
Non-accelerated filer	☐	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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☑

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

As of June 30, 2020, the last business day of the registrant's most recently completed second fiscal quarter, the aggregate market value of the voting common stock held by non-affiliates, was approximately $436,841,000. Shares of common stock held by each officer and director have been excluded in that such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

The number of shares of common stock outstanding as of March 2, 2021 was 33,015,883.

Documents Incorporated by Reference

Portions of the registrant's definitive Proxy Statement for its 2021 Annual Stockholders' Meeting are incorporated by reference into Part III of this Annual Report on Form 10-K, to be filed within 120 days of the registrant's fiscal year ended December 31, 2020.

INTERSECT ENT, INC.

Annual Report on Form 10-K

For the Fiscal Year Ended

December 31, 2020

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CAUTIONARY INFORMATION REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K for the year ended December 31, 2020, or "Form 10-K," contains forward-looking statements concerning our business, operations, and financial performance and condition as well as our plans, objectives, and expectations for business operations and financial performance and condition. All forward-looking statements are based upon our current expectations and various assumptions. In addition, forward-looking statements include the impact that the COVID-19 pandemic will have on our business, and our belief that we will be able to return to revenue growth as the current crisis subsides. 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 in this Form 10-K 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 among others, those risks and uncertainties described herein under "Item 1A — Risk Factors." You are urged to consider these factors carefully in evaluating the forward-looking statements and are cautioned not to place undue reliance on the forward-looking statements. The forward-looking statements are based on information available to us as of the filing date of this Form 10-K. Unless required by law, we do not intend to publicly update or revise any forward-looking statements to reflect new information or future events or otherwise. You should, however, review the factors and risks we describe in the reports we will file from time to time with the Securities and Exchange Commission, or SEC, after the date of this Form 10-K.

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 of the date of this Annual Report on Form 10-K, 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.

RISK FACTORS SUMMARY

You should carefully consider the information set forth below in the section titled "Risk Factors" 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.
- 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 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 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 prior to commercializing our products and the requirement to report adverse events and other ongoing reporting requirements. If we fail to obtain necessary FDA or other agency device or drug approvals for our products or are subject to regulatory enforcement action as a result of our failure to properly report adverse events or otherwise comply with regulatory requirements, our commercial operations would be harmed.
- We cannot predict whether or when we will obtain regulatory approval to commercialize product candidates and we cannot, therefore, predict the timing of any future revenue from product candidates. Regulatory approval of a product candidate is not guaranteed, and the approval process is expensive, uncertain and lengthy.
- 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.
- 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.
- 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 agreement with Deerfield 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.

PART I

Item 1. Business

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"), with 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. 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 the CUBE surgical navigation system and instrumentation ("CUBE"), that complement our PROPEL and SINUVA sinus implants across all settings of care and extend our geographic reach. 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 VENSURE products received 510(k) clearance in August 2020. CUBE and VENSURE are both regulated as medical devices.

Our Strategy

We are focused on becoming a comprehensive provider of ENT outcomes-based solutions and achieving consistent growth by increasing our market share and improving our operating efficiencies through:

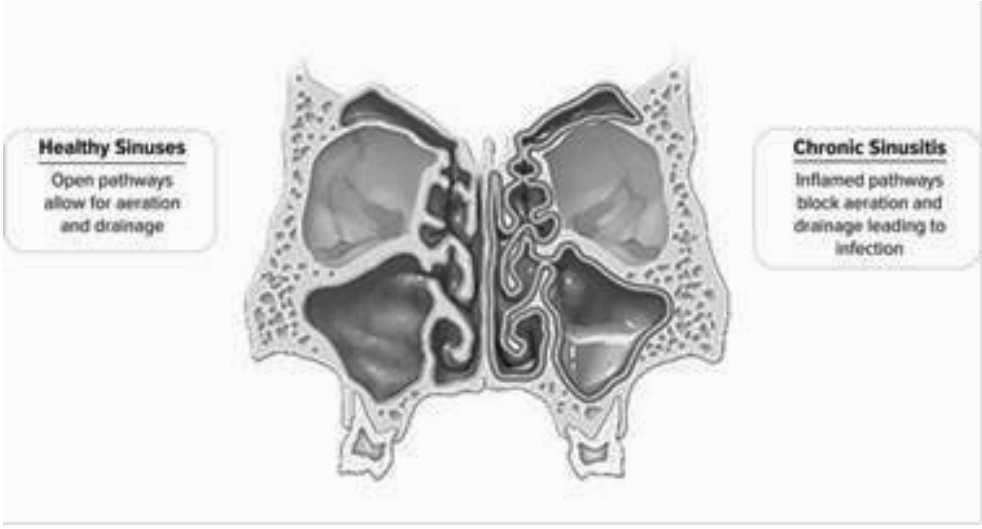
- continuing to expand our portfolio of products based on our unique localized steroid releasing technology;
- utilizing our existing technology for further penetration among ENT physicians across sites of care;
- generating clinical evidence to support unencumbered access and expanded use cases;
- continuing to expand internationally;
- investing in appropriate infrastructure to remediate, upgrade, and scale;
- managing working capital and cash burn; and
- establishing sustainable long-term growth.

We are continuing to develop our sales force in order to expand communication of the benefits of our commercial products to physicians in the two different markets that PROPEL and SINUVA serve as well as the added benefits of VENSURE and CUBE navigation across the continuum of care. This is also being accomplished through building clinical evidence and the health economic case with third-party payors to establish reimbursement, as seen with the evolution from a single J-code for both PROPEL and SINUVA to separate codes as well as Pass-Through status during 2020 and early 2021. SINUVA in particular enjoys strong payor coverage and is covered for 75% of patients with private health insurance and 90% of patients with government-sponsored health insurance. We seek to grow our revenue by increasing the frequency of use of our products among current physician customers, by adding new physician users, increasing patient enrollment rates, and entering new markets.

CRS and Market Opportunity

Chronic rhinosinusitis ("CRS") is an inflammatory condition in which the sinus lining becomes swollen and inflamed, leading to significant patient morbidity including difficulty breathing, chronic headaches, recurrent infections, bodily pain and loss of sense of smell and taste. These persistent symptoms can severely impact a patient's well-being, resulting in frequent doctor visits and can lead to chronic fatigue and depression. The condition significantly reduces work productivity from

absenteeism and reduced on-the-job effectiveness, which is especially meaningful given the average CRS patient age of approximately 37 years. The debilitating patient symptoms and quality of life impairments attributed to CRS create a significant healthcare burden to patients, insurers and employers.



We believe the significant unmet need across the continuum of CRS equates to a global market of approximately $20 billion with multiple technology segments in which to compete. Included in this is a significant demand in the U.S. market. According to the Centers for Disease Control and Prevention ("CDC") approximately 12% of the U.S. adult population, or 29 million people, are affected by CRS, making it more prevalent than heart disease and asthma. We estimate that there are more than 2 million adults with CRS who are managed by ENT physicians in the United States every year, many of whom we believe could benefit from products that incorporate our drug releasing bioabsorbable implant technology. We estimate that the total addressable market of the PROPEL family of products was approximately $650 million in 2019, of which we had a 16% penetration. We further estimate that the total addressable market of SINUVA was approximately $300 million in 2019, of which we had a 2% penetration. The recent acquisition of Fiagon will allow us access to the estimated $250 million U.S. sinus balloon market and expand our European presence. While our primary commercial focus is the U.S. market, both PROPEL and PROPEL Mini received CE Markings, permitting them to be marketed in Europe. Our commercialization strategy considers several factors including regulatory requirements, reimbursement coverage for our products, and key opinion leader support. Our initial focus is on Germany and the United Kingdom, where we have begun to build our capabilities and develop a market, particularly with the increased adoption of PROPEL. In addition, we believe the use of SINUVA in the hospital setting, along with the increased adoption of PROPEL in the physician office setting of care, in conjunction with balloon dilation and following post-surgical debridement will contribute to early success in these markets. Going forward, we will continue to assess our capability to penetrate additional markets in the Asia Pacific and Japan.

For the years ended December 31, 2020, 2019 and 2018, we generated revenue of $80.6 million, $109.1 million and $108.5 million, respectively, and incurred a net loss of $72.3 million, $43.0 million and $22.9 million, for each respective year. Our revenues have been generated predominantly from the sale of our PROPEL family of products and SINUVA, and is almost entirely derived from within the United States. No single customer accounted for more than 10% of our revenue during the years ended December 31, 2020, 2019 and 2018. As of December 31, 2020, we had an accumulated deficit of $303.1 million. The net losses are a result of our election to invest in long term growth initiatives such as research and development, commercialization of our existing and future products, as well as enhancing our executive and management functions. For more information, see "Management's Discussion and Analysis of Financial Condition and Results of Operations."

Current Treatments and Their Limitations

The treatment of CRS often entails a combination of medical management and surgical intervention to treat the underlying inflammation of the sinus lining, while addressing the secondary symptoms caused by obstruction of the natural drainage pathways. The first line of therapy for CRS is medical management, which typically includes prescribed antibiotics, anti-inflammatory steroids, and decongestants. Topical steroid sprays have poor efficacy due to their limited ability to reach the site of the disease, fast clearance of drug from the site of delivery, and poor patient compliance. Prolonged use of oral steroids may also lead to systematic complications which limit their use to short courses.

In cases where patients' symptoms continue to persist despite medical management, a physician may recommend functional endoscopic sinus surgery ("FESS"). In the FESS procedure, the physician enlarges the inflamed and obstructed sinus pathways by displacing and/or removing inflamed tissue and bone in order to facilitate normal sinus drainage and aeration. First

introduced in the United States in the 1980s, FESS is considered the standard of care for surgical intervention to treat CRS. During most procedures, the honeycomb-like cells of the ethmoid sinuses are removed, resulting in one large open cavity. ENTs may also enlarge the frontal and other sinuses by either surgically removing tissue or dilating the ostia, or opening, with a balloon.

FESS is typically performed under general anesthesia in an operating room. During the procedure, a physician inserts an endoscope into the nasal cavity to provide visualization of the patient's anatomy. Surgical instruments, powered cutting tools and balloon dilation devices are used to remove or dilate obstructive tissue and bone. Following the surgical intervention, physicians often pack the newly opened ethmoid sinuses with gauze or other obstructive sinus packing materials to hold the sinus cavities open. Although FESS can improve symptoms and quality of life, it does not correct the underlying cause of the inflammation and patients who undergo FESS procedures often experience significant pain and require continued post-operative therapy to maintain improvements. We believe that the limitations of medical management and lack of disease resolution after FESS lead to undertreatment of many CRS patients. We estimate that only a third of patients recommended for sinus surgery proceed with the potentially beneficial procedure, which we believe is due to its limitations and high risk for additional medical management and surgical revision.

Trend for treatment in the physician office setting of care

Multiple technological advances, including balloon sinus dilation devices, have expanded the treatable CRS patient population. Sinus dilation is now utilized by physicians in their offices to treat patients with mild CRS who may not be willing to undergo or are not candidates for sinus surgery performed under general anesthesia in the operating room setting. The ability to treat patients in the office with sinus dilation has spurred interest in the ENT physician community for additional products that facilitate treatment of patients in the office setting of care.

While balloon dilation has been introduced to open frontal, maxillary and sphenoid sinuses, or dependent sinuses, in a less invasive manner, balloon dilation procedures are not designed to treat disease in the most commonly involved sinuses, the ethmoids, and this procedure does not address the underlying inflammation associated with CRS. We believe an opportunity exists to reach these undertreated patients by providing a more effective option to address inflammatory disease, while improving the overall outcomes of FESS.

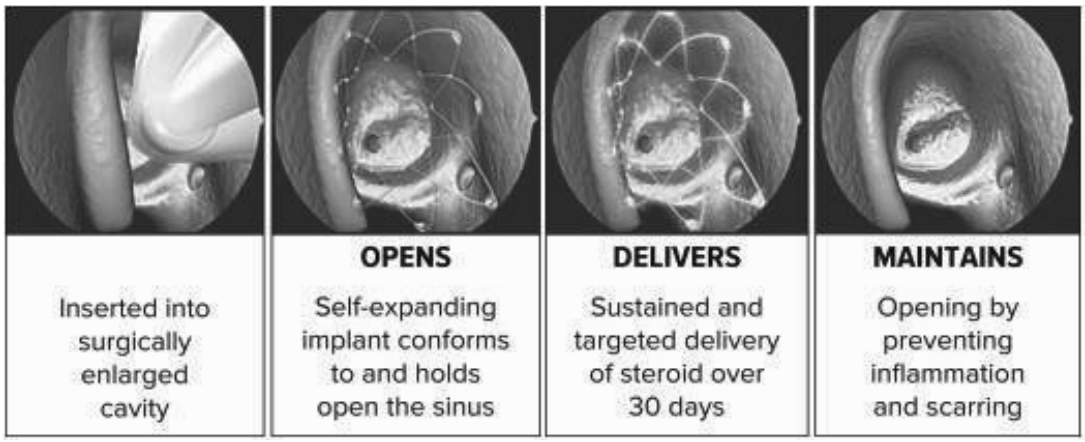
Our Product Offerings

The PROPEL Family

Our PROPEL family of steroid releasing implants are clinically proven to improve outcomes for 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. The following is a description of the products in the PROPEL family.

- PROPEL is a self-expanding implant designed to conform to and hold open the surgically enlarged sinus while gradually releasing an anti-inflammatory steroid over a period of approximately 30 days and is absorbed into the body over a period of approximately six weeks. PROPEL clinical outcomes have been reported in a meta-analysis of prospective, multicenter, randomized, controlled, double-blind clinical studies to improve surgical outcomes, demonstrating a 35% relative reduction in the need for postoperative interventions compared to surgery alone. A physician may treat a patient with PROPEL by inserting it into the ethmoid sinuses.
- PROPEL Mini is a smaller version of PROPEL and is approved for use in both the ethmoid and frontal sinuses. PROPEL Mini is used preferentially by physicians compared with PROPEL when treating smaller anatomies or following less extensive procedures. PROPEL Mini has also been shown by our clinical studies to reduce the need for postoperative interventions, including a 38% relative reduction in the need for postoperative interventions in the frontal sinus, compared to surgery alone with standard postoperative care.
- PROPEL Contour is designed to facilitate treatment of the frontal and maxillary sinus ostia, or openings, of the dependent sinuses in procedures performed in both the operating room and in the office setting of care. PROPEL Contour's lower profile, hourglass shape and malleable delivery system are designed for use in the narrow and difficult to access sinus ostia. In PROPEL Contour's pivotal clinical study, the product demonstrated a 65% relative reduction in the need for postoperative interventions in the frontal sinus ostia compared to surgery alone with standard postoperative care as well as a 63% reduction in occlusion and 73% reduction in the need for surgical interventions.

The graphic below illustrates the operation of the PROPEL family in the ethmoid sinuses:



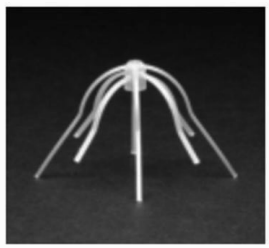
We designed the steroid drug release of the PROPEL products to have a duration of approximately 30 days to match the postoperative healing cycle characterized in published medical literature. We selected mometasone furoate as the anti-inflammatory agent among numerous evaluated compounds based on three important characteristics: absorbability, binding affinity and low systemic bioavailability. The compound preferentially absorbs into the sinus lining instead of the surrounding mucous fluid. The drug has a high glucocorticoid receptor binding affinity, making it highly potent in preventing inflammation once within tissue. Glucocorticoid receptors are the molecules in the surface membranes of cells throughout the body to which corticosteroids chemically bind. Additionally, the compound has low systemic bioavailability, meaning that it has negligible systemic safety side effects.

As of December 31, 2020, we estimate that approximately 3,200 accounts have stocked our PROPEL family of products for use by ENT physicians. Based on the number of units shipped as of December 31, 2020, we estimate that physicians have treated approximately 399,000 patients with our PROPEL family of products.

SINUVA

Following sinus surgery, the underlying chronic inflammation associated with CRS can lead to recurrent obstruction of the sinus cavity over time, especially in patients afflicted with polyps, a sign of severe inflammation. Improving care of such chronic patients holds meaningful opportunity to significantly reduce healthcare costs by reducing the need for revision surgery. We have designed the SINUVA steroid releasing implant to be placed in the physician office setting following a routine visit as an alternative treatment option for patients who are candidates for revision surgery. The implant is based on the same drug releasing bioabsorbable implant technology as the PROPEL family of products but is designed to have greater radial strength in order to dilate an obstructed, polyp-filled sinus cavity, and deliver drug for an extended period of time. SINUVA was subject to regulation as a drug product and we received approval from the FDA to commercialize SINUVA in the United States under an NDA. We believe SINUVA could be an appealing alternative to patients who have previously undergone FESS but continue to suffer from polyp recurrence.

SINUVA implant in delivery system and expanded



Our family of drug releasing implants consists of polymers that control local drug release and provide structural support to adjacent tissues during the healing process. We believe the development, manufacturing and regulatory approval for products incorporating this technology requires capabilities in polymer science, drug delivery, analytical testing and combination products. These competencies allow our technical team to tailor drug formulation, polymer design, drug release duration, implant radial strength, and degradation period to meet different clinical needs. We may apply these competencies to the development of new products over time. Such new products, or changes that we make in the therapeutic agent used in our products will require FDA approval prior to commercialization in the United States.

VENSURE

The VENSURE Navigable and Stand-alone balloon offerings are sterile, single-use devices designed to remodel the bony structures within the sinuses. The distal end of the device includes an atraumatic tip and can be shaped to fit the frontal, maxillary, and sphenoid sinuses using the bending tool provided with the device. Since the distal end of the device is re-shapeable, one balloon can be modified to work on multiple sinuses within the same patient. Both versions of the product enable a physician to track the device into the sinuses using endoscopic visualization, while the VENSURE Navigable balloon allows for image-guided visualization when connected to the CUBE Navigation system. After confirmation of placement of both devices, the balloon can be inflated with saline solution, using the inflator to expand the outflow track of the targeted sinus. A suction tube may be connected directly to the fitting of the Stand-alone balloon device to provide active suction. We believe VENSURE provides for complementary use with PROPEL Contour for dilation and localized drug delivery as navigation becomes more prevalent.

CUBE Navigation

The 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. The sensor carrier containing localizer elements detects a signal within a low-energy magnetic field delivered from the navigation unit. The navigation software then displays the location of the sinus dilation instrument's tip within multiple patient imaging planes and other anatomic renderings. CUBE can be integrated seamlessly into existing video towers and microscopes. We believe that CUBE navigation supports surgery and balloon dilation in all settings of care.

Our Technology Platform

Our drug releasing bioabsorbable implant technology consists of a polymer-based implant that is coated with a drug and polymer matrix. In fabricating the implant, we use polymers that are bioabsorbable and, over time, gradually and fully absorb into the body. The polymers chosen are materials with established safety profiles and have been used in medical devices for over 30 years.

Our implants are designed to be self-expanding, which facilitates insertion when compressed, and expand to conform to the surrounding anatomy after insertion. The ability to control radial strength is important in enabling us to address different diseases at different states. For example, in some instances an implant may be used to maintain an already open passageway. In other situations, an implant with significantly greater strength may mechanically dilate a diseased passageway.

Our expertise in drug delivery allows us to effectively pair appropriate polymer delivery matrices with desired therapeutic agents. This allows selection of a therapeutic agent based on its clinical effectiveness and tailoring of the platform accordingly. In the case of PROPEL, we considered the wide range of off-patent corticosteroids, chose the one best suited for treatment of sinus inflammation, and customized the polymer coating to achieve the desired drug delivery.

Clinical Trial Highlights

PROPEL and PROPEL Mini

PROPEL Ethmoid Sinus Studies. The safety and efficacy of PROPEL in the ethmoid sinuses has been studied in three prospective, multicenter clinical trials conducted in the United States enrolling a total of 205 patients. The principal safety and efficacy information is derived from the ADVANCE II randomized clinical trial and is supported by the ADVANCE clinical trial and an initial pilot study. A meta-analysis that pooled data from the ADVANCE II study and the initial pilot study provides further evidence of efficacy. In all three studies, implants were placed following ethmoid sinus surgery, or ethmoidectomy, which entails removal of the honeycomb-like partitions between the ethmoid sinuses in order to create larger sinus cavities.

Compared to the control implant, the drug releasing implant provided a 35% relative reduction in postoperative interventions, a 51% relative reduction in adhesion lysis and a 40% relative reduction in oral steroid intervention. The relative reduction in frank polyposis was 46%. Additional efficacy endpoints of significant, or severe, adhesions and middle turbinate lateralization, determined by clinical investigators at the study centers, were reduced by 70% ($p=0.0013$) and 75% ($p=0.0225$), respectively.

PROPEL Mini Frontal Sinus Study. We have completed a prospective, randomized blinded multicenter clinical trial to support an expanded indication for placement of PROPEL Mini in the frontal sinuses called PROGRESS. Approximately 30% of patients undergoing sinus surgery for CRS suffer from frontal sinus disease. We enrolled 80 patients in the study using an intra-patient control design to assess both safety and efficacy of PROPEL Mini when placed following surgery of the frontal sinus, compared to surgery alone. The primary efficacy endpoint is the reduction in need for postoperative interventions such as the need for surgical intervention or oral steroids. In August 2015, we announced preliminary topline data from the PROGRESS trial, designed to evaluate the safety and efficacy of PROPEL Mini when placed in the frontal sinuses following surgery, showing that the study met its primary efficacy endpoint and demonstrating a statistically significant 38% relative reduction in the need for postoperative interventions compared to surgery alone. In March 2016, we received approval to expand the indication of PROPEL Mini to treat patients undergoing frontal sinus surgery.

PROPEL Contour

In February 2017, we received FDA approval for PROPEL Contour, a steroid releasing implant designed to facilitate treatment of the frontal and maxillary sinus ostia, or openings, of the dependent sinuses, which we believe represents opportunity for adoption in a variety of settings. In the operating room, PROPEL Contour has the potential to lead to expanded adoption of steroid releasing implants overall by providing physicians with a range of products needed to customize treatment based on their patients' disease and anatomy. We believe PROPEL Contour's lower profile, malleable delivery system will increase usage particularly in those patients whose frontal sinuses are more challenging to access. Since sinus surgeries typically involve treatment of one or more of the ethmoid, maxillary or frontal sinuses, we believe the PROPEL Contour greatly increases the chance that a PROPEL product will be used. We announced results of the second cohort of patients in the PROGRESS study in May 2016. This phase of the PROGRESS study was an 80-patient prospective randomized blinded multicenter trial designed to assess the safety and efficacy of PROPEL Contour when placed in the frontal sinuses following sinus surgery. This study demonstrated a statistically significant 65% relative reduction in the need for post-operative interventions, such as the need for additional surgical procedures or need for oral steroid prescription, compared to surgery alone with standard post-operative care.

SINUVA

In December 2017, we received FDA approval for SINUVA, a steroid releasing implant for the treatment of nasal polyposis in adult patients who have had ethmoid surgery. The SINUVA implant is intended to be placed in the physician office setting of care. This product's primary mode of action is as a drug, and for this reason we were required to obtain an NDA approval from the FDA, rather than a PMA approval. In order to support the NDA application with the FDA, we completed four studies of SINUVA: a pilot study, a pharmacokinetic study, RESOLVE and RESOLVE II. In July 2016, we completed enrollment of the RESOLVE II pivotal trial, which was a prospective, multicenter, randomized, controlled, blinded study of 300 patients. Both co-primary endpoints were met, including improvement in patient-reported nasal obstruction/congestion score ($p=0.0074$) and reduction in bilateral polyp grade as evaluated by a panel of three sinus surgeons ($p=0.0073$). In addition, several pre-specified secondary endpoints were met, including the reduction in the proportion of patients still indicated for repeat sinus surgery, reduction in ethmoid obstruction, and improvement in sense of smell. The RESOLVE study ($n=100$) included ocular exams, and patients were followed for six months to assess longer-term outcomes. Compared to the control group, the treatment group demonstrated greater reduction from baseline to day 90 in nasal congestion/obstruction score and bilateral polyp grade (judged by an independent panel), but these primary endpoint results did not reach statistical significance ($p=0.1365$ and 0.0985, respectively). According to clinical investigator grading, the treatment group demonstrated statistically significant improvements in both bilateral polyp grade ($p<0.02$) and percent ethmoid sinus obstruction ($p<0.0001$) throughout the entire six-month study period. In a post-hoc analysis of nasal congestion/obstruction scores in a subset of 67 patients with at least grade 2 polyposis on each side at baseline, this outcome trended towards statistical significance in favor of the treatment group ($p=0.0505$). Longer-term, the study showed that at six months, control patients were at 3.6x higher risk of remaining indicated for revision surgery than treated patients. The findings from the RESOLVE study were used to inform the pivotal RESOLVE II study design.

In November 2017, we commenced the ENCORE study, a 50-patient multicenter, open-label study focused on evaluation of the safety of a repeat placement of SINUVA in a population of CRS patients with nasal polyps. Study findings showed no serious adverse events related to the implants during the measurement period and no serious adverse events related to a repeat placement during the interval studied.

Research and Development

We continue to invest in research and development in order to expand our portfolio of products and improve our existing products. This will be achieved through a series of clinical studies on existing as well as pipeline products. We plan to initiate our EXPAND study in the second quarter of 2021, which will assess the VENSURE balloon and PROPEL Contour's collective ability to improve healing and patency rates through localized drug delivery post-balloon dilation, as well as other outcomes. The primary endpoint will be evaluated at 30 days. In order to expand our global reach, we also plan to make clinical and regulatory investments in order to expand PROPEL in Europe. Our PROPEL OPEN registry trial is in place to fulfill EU Medical Device Regulation ("MDR") requirements and collect local data in order to support our commercial efforts. Other clinical trials initiated in the past include our investigational ASCEND drug-coated sinus balloon study initiated in December 2018. The ASCEND study was a prospective, randomized, blinded, multi-center trial of 70 patients that assessed the safety and efficacy of our ASCEND product. The ASCEND product was randomized against an uncoated balloon and, similar to clinical studies for our PROPEL family of products, the primary endpoint was evaluated at 30 days. This study assessed the ASCEND product's ability to improve patency rates, as well as a number of other endoscopic parameters. The trial did not meet its primary endpoint of frontal sinus patency grade at day 30, as judged by an independent reviewer. The secondary endpoints were analyzed for informative purposes. The ASCEND product showed significant differences in several important secondary endpoints favoring the treatment side including reduction in inflammation and polypoid edema at all timepoints through day 30, as assessed by both the clinical investigators and the independent reviewer. There was also a notable reduction in the need for oral steroid interventions at day 30, as determined by the independent reviewer. This study gives us valuable insight into the performance of our novel drug-coated balloon, enabling us to refine our clinical and regulatory pathway.

Impact of the COVID-19 Pandemic

Prior to the COVID-19 pandemic, our efforts to enhance commercial execution and improve market access infrastructure were beginning to yield benefits as sales until the end of February 2020 were consistent with our expectations. However, sales declined towards the end of the first quarter and throughout the second quarter as the various COVID-19 restrictions were implemented and remained in effect. However, we began to see meaningful change in the business environment towards the end of May with increased procedure volumes as select areas of the country emerged from shelter-in-place orders and restrictions on elective medical procedures were eased. This trend continued in June and throughout the remainder of 2020 as we continued to see improvements in the elective procedure market. Our business has been and will continue to be impacted by patients' decisions to undergo sinus surgeries as ENT ASC and office procedure volumes recover. Our operations may be further impacted by COVID-19 due to changes in our manufacturing operations as a result of the easing of certain restrictions

of the shelter-in-place orders issued by local and federal authorities. We continue to remain flexible in our approach to continuing our operations in light of rapidly developing laws and restrictions surrounding the COVID-19 pandemic. While the second half of 2020 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.

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

- Protect Health and Safety: Virtually all roles where physical presence for manufacturing operations is not required remain working from home, based on state and county guidelines, and non-essential business travel is limited.
- Maintain Customer Focus: All patient-support teams remain available to assist customers and patients, while strictly adhering to applicable restrictions, safety precautions and procedures.
- Reduce Costs: In response to the COVID-19 pandemic, we took pre-emptive actions in the first quarter of 2020 to curtail spending and to reduce use of cash as revenues are and will continue to be materially impacted. We have also considered the incremental costs of business operations during the pandemic and expect these costs to remain until the current crisis subsides. The cost reduction actions included a) reducing our workforce by approximately 25% and furloughing an additional 5% of our workforce, b) substantially reducing new hiring, c) suspending near-term production, d) reducing discretionary operating expenses and capital expenditures, and e) delaying clinical research projects. As a result of these actions, we achieved significant cost reductions that, along with an improved operating environment as the pandemic restrictions eased, allowed us to meet our target liquidity levels at year end. We expect cost control measures to remain in place until the current crisis subsides. However, we will still continue to support our customers, physicians and patients.

Seasonality

We expect revenue from our PROPEL family of products, SINUVA, VENSURE, CUBE, and accessories 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.

Competition

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 Inc., Olympus Corp., Johnson & Johnson, Stryker Corp., 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.

Because of the size of the market opportunity for the treatment of CRS, potential competitors have historically dedicated and will continue to dedicate significant resources to aggressively promote their products or develop new products. New product developments that could compete with us more effectively are possible because of the prevalence of CRS and the extensive research efforts and technological progress that exist within the market. Large medical device companies with ENT divisions, such as Medtronic, also have capability in drug releasing stents. 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.

Further, several more cost-effective alternatives exist to our products which include, but are not limited to: oral steroids, packing materials, spacers, and off-label practices not supported by clinical data. While we believe our products have significant advantages over sinus packing materials, spacers and other treatment options, they are expensive relative to packing materials and may not be fully reimbursed by third-party payors. As a result, ENT physicians may choose to use oral steroid delivery or packing/spacing materials or a combination of the two, which are less expensive, in lieu of our products.

We believe that our continued ability to compete favorably depends on:

- expanding our commercial operations to incorporate acquired products, customers, and new markets;
- continuing to innovate and maintain scientifically-advanced technology;
- having reimbursement in place to support broad adoption of our products;
- developing technologies for applications in the sinuses and other areas of ENT;
- attracting and retaining skilled personnel;
- obtaining patents or other intellectual property protection for our products; and
- conducting clinical studies and obtaining and maintaining regulatory approvals.

Intellectual Property

As of December 31, 2020, we owned 176 issued patents globally, of which 47 were issued U.S. patents, and we owned 73 pending patent applications globally, of which 17 were pending patent applications in the United states. Subject to payments of required maintenance fees, annuities and other charges, our issued patents have expiration dates between 2021 and 2039, of which 38 will expire between 2021 and 2026, and the remaining 138 will expire after 2026.

As of December 31, 2020, our trademark portfolio contained 88 trademark registrations, 13 of which were U.S. trademark registrations, as well as six pending trademark applications, all of which were U.S. trademark applications.

We also rely upon trade secrets, know-how, continuing technological innovation, and may rely upon licensing opportunities in the future, to develop and maintain our competitive position. We protect our proprietary rights through a variety of methods, including confidentiality agreements and proprietary information agreements with suppliers, employees, consultants and others who may have access to proprietary information.

Manufacturing and Supply

We predominantly manufacture our steroid releasing implants at our facility in Menlo Park, California with components supplied by external suppliers. CUBE navigation equipment and instruments are manufactured in Hennigsdorf, Germany, and VENSURE sinus dilation balloons are procured from a third-party manufacturer. We perform inspections of these components before use in our manufacturing operations. Using these components, we assemble, inspect, test and package our implants, and send them to a third-party sterilization vendor. After sterilization, we perform inspections of the finished implants internally and via third-party laboratories to determine compliance with our specifications, after which we place the implants into our inventory and ultimately ship the finished products to customers. In addition, with the acquisition of Fiagon, we inherited the relationships with their existing distribution network which allows us to expand our global reach.

The active pharmaceutical ingredient ("API") and a number of our critical components used in our implants are supplied to us from single source suppliers. We rely on single source suppliers for some of our polymer materials, extrusions, molded components, and off-the-shelf components. Our ability to commercially supply our products and to develop our product candidates depends, in part, on our ability to successfully obtain the API and polymer materials used in these products in accordance with regulatory requirements and in sufficient quantities for commercialization and clinical testing. We have manufacturing, supply or service agreements with a number of our single source suppliers. Each of these suppliers manufactures the components they produce for us or tests our components and devices to our specifications. For example, in January 2020, we extended the agreement we had entered into in 2014 with Hovione Inter Ltd. ("Hovione") pursuant to which we are required to purchase 80% of our API produced according to our specifications from Hovione, in quantities to be specified in 12-month forecasts provided by us and updated on a quarterly basis. This agreement is in effect until January 2025. In addition, we have agreements with companies that provide sterilization services and analytical testing for our products, as well as suppliers from which we purchase injection molded components to our specifications, our API and our customized packaging components. We typically seek to negotiate new agreements with these vendors in advance of the expiration of the current agreements. We intend to maintain sufficient supplies of the API and components from these single source suppliers in the event that our agreements with one or more of these suppliers were to terminate to enable us to continue to manufacture our implants for a sufficient amount of time necessary to obtain another source of API or components. To date, we have not experienced any significant supply constraints or delays in procuring components and materials, and while our suppliers have generally met our demand for their products or services on a timely basis in the past, they may be unable or unwilling to meet our needs in the future.

We continue to improve our manufacturing capabilities and increase capacity as we plan for enhanced commercialization of our portfolio of products. We are committed to continuous improvement and to maintaining compliance with applicable regulations. We have facilities that are FDA-registered medical device and facilities that are FDA-registered drug

manufacturers. Additionally, our facilities are ISO certified, as applicable. We are required to maintain compliance with the regulations required for the countries we distribute our products. We are periodically audited by such agencies, including the FDA and European regulatory authorities ("Notified Bodies") as applicable. During 2020, we extended the lease term of the Menlo Park facility to December 31, 2027.

Government Regulation

United States Regulation of Medical Devices and Drugs

We are subject to numerous federal requirements. Compliance with diverse and changing legal requirements is costly, time-consuming, and requires significant resources. Our products and any product candidates that contain both device and drug components are regulated as combination products by the FDA. The FDA's Office of Combination Products designates a primary mode of action for such drug-device combination products, with the respective primary Center within the FDA leading the regulatory review for the product, in consultation with the secondary designated Center. The FDA determined that the primary mode of action for our PROPEL family of products was that of a medical device, so these products have been approved and are regulated as medical devices. By comparison, the primary mode of action of SINUVA was designated to be its drug properties, so this product has been FDA approved and is regulated as a drug.

FDA regulations require us to register as a medical device and drug product manufacturer with the FDA. Additionally, the California Department of Health Services, ("CDHS") requires us to register as a medical device and drug manufacturer within the state. Because of this, the FDA and other regulatory bodies inspect us on a routine basis for compliance with current good manufacturing practices. These regulations require that we manufacture our products and maintain related documentation in a prescribed manner with respect to manufacturing, testing and control activities, and product release for distribution. We have undergone and expect to continue to undergo regular current good manufacturing practice inspections in connection with the manufacture of our products at our facility.

Medical Devices

Our PROPEL family of products are regulated in the United States as Class III medical devices by the FDA under the Federal Food, Drug and Cosmetic Act ("FDCA"). The FDA classifies medical devices into one of three classes based upon controls the FDA considers necessary to reasonably ensure their safety and effectiveness. Class I devices are subject to general controls such as labeling, adherence to good manufacturing practices and maintenance of product complaint records but are usually exempt from premarket notification requirements. VENSURE devices are Class I but required 510(k) clearance. Class II devices are subject to the same general controls and also are subject to special controls such as performance standards, and FDA guidelines, and may also require clinical testing prior to clearance as substantially equivalent to a predicate device under Section 510(k) of the FDCA approval. CUBE navigation systems are regulated as Class II medical devices. Class III devices are subject to the highest level of controls and rigorous clinical testing to demonstrate safety and effectiveness and generally require a PMA, or a PMA supplement approval prior to their sale.

Manufacturers must file an Investigational Device Exemption ("IDE") application if human clinical studies of a device are required and if the investigational use of the device represents a potential for significant risk to the patient. The IDE application must be supported by data, typically including the results of animal and engineering testing of the device. If the IDE application is approved by the FDA, human clinical studies may begin at a specific number of investigational sites with a maximum number of patients, as approved by the FDA. The clinical studies must be conducted under the review of an independent institutional review board to ensure the protection of the patients' rights.

Generally, upon completion of these human clinical studies, a manufacturer seeks approval of a Class III medical device from the FDA by submitting a PMA application. A PMA application must be supported by extensive data, including the results of the clinical studies, as well as testing and literature to establish the safety and effectiveness of the device. PMA approval may be conditioned upon the conduct of certain post-approval studies, such as long-term follow-up studies.

Drugs

The clinical testing, manufacturing, labeling, serialization, storage, distribution, record keeping, advertising, promotion, import, export and marketing, among other things, of our product SINUVA and any future drug products we may develop and seek to commercialize, are subject to the FDA's drug authority and are governed by extensive regulation by governmental authorities in the United States and other countries. The FDA, under the FDCA, regulates pharmaceutical products in the United States. The steps required before a drug may be approved for marketing in the United States generally include:

- preclinical laboratory tests and animal tests conducted under Good Laboratory Practices ("GLP");
- submission to the FDA of an Investigational New Drug, or IND, application for human clinical testing, which must become effective before human clinical trials commence;

- adequate and well-controlled human clinical trials to establish the safety and efficacy of the product and conducted in accordance with Good Clinical Practices, or GCP;
- the submission to the FDA of an NDA;
- FDA acceptance, review and approval of the NDA; and
- satisfactory completion of an FDA inspection of the manufacturing facilities at which the product is made to assess compliance with current Good Manufacturing Practices ("cGMPs").

Post-Approval Regulation

Following approval, the manufacturer remains subject to continuing regulation by the FDA and other agencies, including, among other things, monitoring and record-keeping activities, reporting of adverse experiences, complying with promotion and advertising requirements, which include restrictions on promoting products for unapproved uses or patient populations (known as ''off-label use'') and limitations on industry-sponsored scientific and educational activities. Although physicians may prescribe legally available products for off-label uses, manufacturers may not market or promote such uses. Prescription drug promotional materials must be submitted to the FDA in conjunction with their first use. Further, if there are any modifications to the products, including changes in indications, labeling or manufacturing processes or facilities, FDA or other international approvals may be required, which may require the development of additional data or preclinical studies and clinical trials.

The FDA or other agencies, may also place other conditions on drug approvals including the requirement for a Risk Evaluation and Mitigation Strategy ("REMS") to assure the safe use of the product.

FDA and other agency regulations require that products be manufactured in specific approved facilities and in accordance with cGMP regulations. The discovery of violative conditions, including failure to conform to cGMP regulations, could result in enforcement actions, and the discovery of problems with a product after approval may result in restrictions on a product, manufacturer or holder of an approved PMA or NDA, etc., including product recall.

Other Healthcare Laws and Health Reform

Our current and future arrangements with healthcare providers, third-party payors, customers, and others may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations, including but not limited to federal and state anti-kickback, false claims, transparency, health information privacy and security laws. Violations of applicable healthcare laws and regulations may result in significant civil, criminal and administrative penalties, damages, disgorgement, fines, imprisonment, exclusion of products from government funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and/or oversight if a corporate integrity agreement or similar agreement is executed to resolve allegations of non-compliance with these laws and the curtailment or restructuring of operations. In addition, violations may also result in reputational harm, diminished profits and future earnings.

Additionally, in the United States and some foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed reforms of the healthcare system in an effort to contain costs, improve quality, and expand access to care, including the proposed modification to some of the aforementioned laws. In the United States, there have been, and continue to be, a number of healthcare-related legislative initiatives that have significantly affected the healthcare industry. These reform initiatives may, among other things, result in modifications to the aforementioned laws and/or the implementation of new laws affecting the healthcare industry. Similarly, a significant trend in the healthcare industry is cost containment. Third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular products and procedures. Our ability to commercialize our products successfully depends in part on the extent to which coverage and adequate reimbursement is available from third-party payors. As such, cost containment reform efforts may result in an adverse effect on our operations.

For more information, see "Risk Factors."

Foreign Regulation

In order for us to introduce our products in countries outside of the United States, we must obtain regulatory approvals and comply with extensive product and quality system regulations in other countries. These regulations, including the requirements for approvals or clearance and the time required for regulatory review, vary from country to country. Some countries have regulatory review processes that are substantially longer than U.S. processes. Failure to obtain regulatory approval in a timely manner and meet all of the local requirements including language and specific safety standards in any foreign country in which we plan to market our products could prevent us from marketing products in such countries or subject

us to sanctions and fines. We believe we are in material compliance with all statutes and regulations applicable to our operations.

Commercialization of medical products in Europe is regulated by the European Union ("EU"). The EU presently requires that all medical products bear the CE mark for compliance with the Medical Device Directive ("MDD") as amended. The CE mark is an international symbol of adherence to certain essential principles of safety and performance mandated in applicable European medical product directives, which once affixed, enables a product to be sold in member countries of the EU and those affiliated countries that accept the CE mark. To obtain a CE mark, defined products must meet minimum standards of performance, safety, and quality, and then according to their classification, comply with one or more of a selection of conformity assessment routes. In order to maintain CE Markings, we must maintain compliance with ISO 13485. To maintain authorization to apply the CE mark, we are subject to annual surveillance audits and periodic re-certification audits. If we modify our existing products or develop new products in the future, we may need to apply for authorization to affix the CE mark to such products.

In May 2017, the MDR was implemented to replace the MDD. The MDR will come into effect in May 2021 and imposes stricter requirements for the marketing and sale of medical products and grants Notified Bodies increased post-market surveillance authority. We may be subject to risks associated with additional testing, modification, certification, or amendment of our existing market authorizations, or we may be required to modify existing products to comply with the official interpretations of these revised regulations. In addition, we may be required to reapply for CE marks under the MDR, in order to maintain our products in the EU Market after the expiration date of our current MDD CE marks. Failure to comply with the new regulations and obtain regulatory approval in a timely manner could prevent us from continuing to market our products in such countries.

Market Access and Reimbursement

We continue to make meaningful advancements in our reimbursement strategy to improve access in all settings of care for both PROPEL and SINUVA, as well as incorporate existing reimbursement programs for CUBE navigation equipment and accessories and balloon dilation. However, uncertainty exists as to the coverage and reimbursement status of any products for which we have or may obtain regulatory approval. Sales of our PROPEL family of products, SINUVA, and any of our other product candidates, will depend, in part, on the extent to which the products will be covered and the costs of the products will be adequately reimbursed by third-party payors, including government healthcare programs such as Medicare and Medicaid, commercial health insurers and managed care organizations. The process for securing coverage for a product is separate from the process for establishing a reimbursement rate for the product if separately payable. Third-party payors may limit coverage to specific patient subpopulations and may limit coverage based on product inclusion on an approved list, or formulary, which might not include all FDA-approved products for a particular indication. A payor's decision to provide coverage for a product does not ensure an adequate reimbursement rate.

Our PROPEL family of products are used primarily in the operating room of a hospital or ambulatory surgery center. These providers receive a facility fee for the sinus surgery procedure which is intended to pay for supplies used in this procedure, including the PROPEL family of products. SINUVA is a physician administered drug, used primarily in the physician office setting. However, payment is subject to payor coverage on the basis of either written medical policies related to the product or individual patient medical necessity. If, as a result of policies the payor has in place regarding these products, hospitals or other service providers are unable to receive adequate reimbursement to support the use of our products, 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 applied to the Centers for Medicare & Medicaid Services ("CMS") for a product-specific J code for SINUVA, and in July 2019, CMS announced their final decision to establish a new J code described as "J7401 Mometasone furoate sinus implant, 10 micrograms." This new J code became effective on October 1, 2019. CMS also made a final decision to eliminate the S1090 code, which was previously assigned to PROPEL, because they view it as duplicative to J7401. Subsequently, CMS approved SINUVA for transitional pass-through payment status for reimbursement under the Hospital Outpatient Prospective Payment System ("OPPS") and ASC Payment System. The new C code described as "C9122 Mometasone furoate, sinus implant, 10 micrograms", took effect on July 1, 2020. Pass-Through status lasts for three years and allows us to place SINUVA in the ASC and hospital settings. Moreover, 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." The new PROPEL and SINUVA codes are scheduled to take effect April 1, 2021. Prior to October 1, 2019, reimbursement submissions to cover the cost of SINUVA were reported to payors using the unassigned Healthcare Common Procedure Coding System, or HCPCS, code J3490.

For more information, see "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations."

Human Capital Resources

We believe that our continued success is reliant on the ability to attract and retain top talent. To facilitate talent attraction and retention, we strive to make Intersect ENT an inclusive and safe workplace, with opportunities for our employees to grow and develop in their careers, supported by competitive compensation and benefits programs.

As of December 31, 2020, we had 406 employees, consisting of 74 in manufacturing, 93 in research and development, and 239 in sales, general and administrative. Our employees are based in the U.S. and in several countries in Europe, primarily Germany and the UK.

In the attraction, development and retention of talent, we emphasize:

Compensation and Benefits. We strive to provide competitive compensation and benefits programs to attract and retain top talent and review these programs annually against the competitive landscape to ensure they continue to meet the needs of our employees. In addition to salaries, these programs include a variety of short and long-term incentive plans such as annual bonuses, equity awards, an Employee Stock Purchase Plan, a 401(k) Plan, healthcare and insurance benefits, health savings and flexible spending accounts, paid time off, family leave, family care resources, flexible work schedules, and employee assistance programs. In addition to our broad-based equity award programs, we have used targeted equity-based grants with vesting conditions to facilitate the retention and engagement of our talent.

Talent Development. We believe employees are our greatest asset and we strive to provide development and promotional opportunities in order to help our employees reach their potential. We provide formal and informal training opportunities designed to enhance learning and development. Consistent with our quarterly review process, we foster and encourage continuous manager and employee dialogue around performance and development.

Health, Safety and Wellness. We are committed to the health, safety and wellness of our employees. We provide our employees and their families with access to a variety of flexible and convenient health and wellness programs, including benefits that provide protection and security so they can have peace of mind concerning events that may require time away from work or that impact their financial well-being; that support their physical and mental health by providing tools and resources to help them improve or maintain their health status and encourage engagement in healthy behaviors. In response to the COVID-19 pandemic, we implemented significant changes that we determined were in the best interest of our employees, as well as the communities in which we operate, and which comply with government regulations. This includes having the vast majority of our employees work from home, while implementing additional safety measures for essential employees continuing critical on-site work.

Diversity, Equity, and Inclusion. One of our core values is diversity of thought, values, individual characteristics, beliefs and backgrounds. We are an equal opportunity employer and believe that diverse and differentiated views contribute to make us a better organization. It is our conscious effort to support the advancement of women and promote equal opportunity for all our employees within the workplace.

Corporate Information

We were incorporated in Delaware in October 2003 as Sinexus, Inc. We changed our name to Intersect ENT, Inc. in November 2009. Our offices are located at 1555 Adams Drive, Menlo Park, California 94025 and our telephone number is (650) 641-2100. Our website is www.intersectent.com. We completed our initial public offering in July 2014, and our common stock is listed on the Nasdaq Global Market under the symbol “XENT.”

Our periodic and current reports, registration statements, proxy and information statements and other information are available for inspection and copying at the SEC’s Public Reference Room at 100 F Street, NE, Washington, DC 20549 or may be obtained by calling the SEC at 1-800-SEC-0330. The SEC also maintains a website containing such information available free of charge to the public at www.sec.gov. We make available free of charge on or through our Internet website, our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC.

Item 1A. Risk Factors

RISK FACTORS

Before deciding to invest in us or to maintain or increase your investment, you should carefully consider the risks described below, in addition to the other information contained in this Annual Report on Form 10-K and in our other filings with the SEC. If any of the risks discussed in this report actually occur, they may materially harm our business, financial condition, operating results, cash flows or growth prospects. As a result, the market price of our common stock could decline, and you could lose all or part of your investment. Additional risks and uncertainties that are not yet identified or that we think are immaterial may also materially harm our business, financial condition, operating results, cash flows or growth prospects and could result in a complete loss of your investment.

Risks Related to 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 and the Centers ("CDC") for Medicare and Medicaid Services ("CMS") have issued guidelines which have led to, among other measures, the severe limitation or curtailment of elective procedures. Although certain measures have been relaxed, increases in the rate of COVID-19 cases may cause a tightening of these restrictions. We cannot predict when federal, state and local governments will lift these restrictions, nor when the CDC and other federal medical agencies will lift restrictions on elective procedures. These restrictions have caused, and we expect will continue to cause, severe reductions in demand for our products and corresponding sales revenue until the pandemic abates and the shelter-in-place orders are lifted, and perhaps afterwards as people take time to resume normal activities.

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

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

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

Even as shelter-in-place orders and other restrictions are lifted, it is uncertain as to when elective procedures will return to their original levels or if they will return to their original levels at all. Further, some physicians may not feel comfortable performing, and some patients may not feel comfortable undergoing, such procedures. Alternatively, at the point that restrictions are lifted, in whole or in part, there may be an increased demand for our products as delayed procedures are scheduled and performed. 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 severe disruption and volatility in global capital markets and 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.

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 $72.3 million, $43.0 million and $22.9 million for the years ended December 31, 2020, 2019 and 2018, respectively. As of December 31, 2020, we had an accumulated deficit of $303.1 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 office setting of care. Inadequate coverage and negative reimbursement policies for our products could affect their adoption and our future revenue.

We are early in our commercialization of SINUVA for use in the office setting of care. SINUVA is designated as a drug by the FDA and as such, providers or specialty pharmacies have been seeking reimbursement for the product using an unassigned J Code. We applied for a product-specific J code in the 2018 process, but it was not granted, and we reapplied in the 2019 process. In July 2019, CMS announced their final decision to establish a new J code described as "J7401 Mometasone furoate, sinus implant, 10 micrograms." This new J code became effective on October 1, 2019. CMS also made a final decision to eliminate the S1090 code, which was previously assigned to PROPEL, because they view it as duplicative to J7401. Subsequently, CMS approved SINUVA for transitional pass-through payment status for reimbursement under the Hospital Outpatient Prospective Payment System ("OPPS") and ASC Payment System. The new C code described as "C9122 Mometasone furoate, sinus implant, 10 micrograms", took effect on July 1, 2020. Pass-Through status lasts for three years and allows us to place SINUVA in the ASC and hospital settings. Moreover, 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." The new PROPEL and SINUVA codes are scheduled to take 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 office setting of care because sinus surgery is more typically performed in the operating room and because there is limited reimbursement for the PROPEL family of products available in the office setting of care. While there are a few payors that may provide such coverage, that can change, and the majority of payors consider this usage experimental and investigational and therefore would not cover reimbursement claims.

Our future growth depends on physician awareness and adoption of our steroid releasing implants 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 sinusitis. We have sponsored twelve multicenter, prospective studies of over 900 patients to track outcomes of treatment with our steroid releasing implants across multiple sinuses and settings of care. These clinical data have resulted in the highest level of evidence generated for any medical device used to improve the outcomes of sinus surgery. While the results of these studies collectively indicate a favorable safety and efficacy profile, the study designs and results may not be viewed as compelling to our physician customers. If physicians do not find our data compelling, they may choose not to use our products or limit their use. Additionally, the long-term effects of sinus interventions in conjunction with our steroid releasing implants beyond six months are not known. Certain ENT physicians, hospitals and surgery centers may prefer to see longer term efficacy data than we have produced. We cannot assure that any data that we or others generate will be consistent with that observed in these studies or meet the endpoints, nor that the results will be maintained beyond the time points studied. We also cannot assure that any data that may be collected will be compelling to the medical community because the data may not be scientifically meaningful and may not demonstrate that sinus procedures using our steroid releasing implants are an attractive option when compared against data from alternative treatments.

Each ENT physician's individual experience with our steroid releasing implants will vary, and we believe that physicians will compare actual long-term outcomes in their own practices using our steroid releasing implants against sinus surgery used in conjunction with traditional sinus packing techniques. A long-term, adequately-controlled clinical study comparing sinus surgery performed in conjunction with our steroid releasing implants against sinus surgery performed in conjunction with the

variety of traditional sinus packing techniques incorporated by physicians would be expensive and time-consuming and we have not conducted such a study. If the experience of physicians indicates that the use of our steroid releasing implants in functional endoscopic sinus surgery ("FESS") is not as safe or effective as other treatment options or does not provide a lasting solution to patients with chronic sinusitis, adoption of our products may suffer, and our business would be harmed.

We 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 fails 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 commercialize additional ENT products.

It is important to our business that we continue to build a more complete product offering within the ENT market. We are using our drug releasing bioabsorbable technology to develop new products for use in the physician office setting. Developing additional products is expensive and time-consuming and could divert management's attention away from our current sinus surgery products and harm our business. Even if we are successful in developing additional products, the success of any new product offering or enhancement to an existing product will depend on several factors, including our ability to:

- properly identify and anticipate ENT physician and patient needs;
- receive adequate reimbursement for such products;
- develop and introduce new products or product enhancements in a timely manner;
- avoid infringing upon the intellectual property rights of third parties;
- demonstrate, if required, the safety and efficacy of new products with data from preclinical studies and clinical trials;
- obtain the necessary regulatory clearances or approvals for new products or product enhancements;
- be fully FDA-compliant with marketing and manufacturing of new devices or modified products;
- provide adequate training to potential users of our products; and
- develop an effective and FDA-compliant, dedicated sales and marketing team.

If we are unsuccessful in developing and commercializing additional products in other areas of ENT, our ability to increase our revenue may be impaired.

Consolidation in the healthcare industry could lead to demands for price concessions, which may impact our ability to sell our products at prices necessary to support our current business strategies.

Healthcare costs have risen significantly over the past several decades, which has driven numerous cost reform initiatives by legislators, regulators and third-party payors. Cost reform has elicited a consolidation trend in the healthcare industry to aggregate purchasing power, which may create more requests for pricing concessions in the future. Additionally, group purchasing organizations, independent delivery networks and large single accounts may continue to use their market power to consolidate purchasing decisions for hospitals and ASC. We expect that market demand, government regulation, third-party coverage and reimbursement policies and societal pressures will continue to change the healthcare industry worldwide, resulting in further business consolidations and alliances among our customers, which may exert further downward pressure on the prices of our products and may adversely impact our business, results of operations, financial condition and prospects.

We compete or may compete in the future against other companies, some of which have longer operating histories, more established products and greater resources, which may prevent us from achieving significant market penetration or improved operating results.

Our industry is highly competitive, subject to change and significantly affected by new product introductions and other activities of industry participants. Many of the companies developing or marketing ENT products are publicly traded companies, including Medtronic, Olympus, Johnson & Johnson, Stryker, Lyra Therapeutics, and Smith & Nephew 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 chronic sinusitis, such as Regeneron Pharmaceuticals, Inc., who recently received FDA approval to market Dupixent for chronic rhinosinusitis with nasal polyposis.

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

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

The prevalence of sinus procedures being performed in the office has increased since sinus dilation products for use in the office setting received Category I 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 chronic sinusitis in a physician office with a sinus dilation product rather than through FESS procedures in the operating room, the volume of FESS procedures performed may not grow as anticipated and our ability to sell our products may be harmed.

We face the risk of product liability claims that could be expensive, divert management's attention and harm our reputation and business. We may not be able to maintain adequate product liability insurance.

Our business exposes us to the risk of product liability claims that are inherent in the testing, manufacturing and marketing of medical devices and drug products. This risk exists even if a device or product is approved for commercial sale by the FDA and manufactured in facilities licensed and regulated by the FDA, such as the case with our PROPEL family of products and SINUVA, or an applicable foreign regulatory authority. Our products and product candidates are designed to affect important bodily functions and processes. Any side effects, manufacturing defects, misuse or abuse associated with our products or our product candidates could result in patient injury or death. The medical device industry has historically been subject to extensive litigation over product liability claims, and we cannot offer any assurance that we will not face product liability suits. We may be subject to product liability claims if our steroid releasing implants cause, or merely appear to have caused, patient injury or death. In addition, an injury that is caused by the activities of our suppliers, such as those who provide us with components and raw materials, may be the basis for a claim against us. Product liability claims may be brought against us by consumers, healthcare providers or others selling or otherwise coming into contact with our products or product candidates, among others. If we cannot successfully defend ourselves against product liability claims, we will incur substantial liabilities and reputational harm. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- costs of litigation;
- distraction of management's attention from our primary business;
- the inability to commercialize our products or, if approved, our product candidates;
- decreased demand for our products or, if approved, product candidates;
- impairment of our business reputation;
- product recall or withdrawal from the market;
- withdrawal of clinical trial participants;
- substantial monetary awards to patients or other claimants; or
- loss of revenue.

While we may attempt to manage our product liability exposure by proactively recalling or withdrawing from the market any defective products, any recall or market withdrawal of our products may delay the supply of those products to our customers and may impact our reputation. We can provide no assurance that we will be successful in initiating appropriate market recall or market withdrawal efforts that may be required in the future or that these efforts will have the intended effect of preventing product malfunctions and the accompanying product liability that may result. Such recalls and withdrawals may also be used by our competitors to harm our reputation for safety or be perceived by patients as a safety risk when considering the use of our products, either of which could have an adverse effect on our business.

In addition, although we have product liability and clinical study liability insurance that we believe is appropriate, this insurance is subject to deductibles and coverage limitations. Our current product liability insurance may not continue to be available to us on acceptable terms, if at all, and, if available, coverage may not be adequate to protect us against any future product liability claims. If we are unable to obtain insurance at an acceptable cost or on acceptable terms with adequate coverage or otherwise protect against potential product liability claims, we will be exposed to significant liabilities, which may

harm our business. A product liability claim, recall or other claim with respect to uninsured liabilities or for amounts in excess of insured liabilities could have a material adverse effect on our business, financial condition and results of operations.

The misuse or off-label use of our products may harm our image in the marketplace, result in injuries that lead to product liability suits or result in costly investigations and sanctions by regulatory bodies if we are deemed to have engaged in the promotion of these uses, any of which could be costly to our business.

The products we currently market have been approved by the FDA for specific treatments. We train our marketing and direct sales force to not promote our products for uses outside of the FDA-approved indications for use, known as "off-label uses." We cannot, however, prevent a physician from using our products off-label, when in the physician's independent professional medical judgment, he or she deems it appropriate. There may be increased risk of injury to patients if physicians attempt to use our products off-label. Furthermore, the use of our products for indications other than those approved by the FDA or any foreign regulatory body may not effectively treat such conditions, which could harm our reputation in the marketplace among physicians and patients.

Physicians may also misuse our products or use improper techniques if they are not adequately trained, potentially leading to injury and an increased risk of product liability. If our products are misused or used with improper technique, we may become subject to costly litigation by our customers or their patients. Product liability claims could divert management's attention from our core business, be expensive to defend, and result in sizable damage awards against us that may not be covered by insurance. In addition, if the FDA or any foreign regulatory body determines that our promotional materials or training constitute promotion of an off-label use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fine or criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our business activities to constitute promotion of an off-label use, which could result in significant penalties, including, but not limited to, criminal, civil and administrative penalties, damages, fines, disgorgement, exclusion from participation in government healthcare programs, and the curtailment of our operations. Any of these events could significantly harm our business and results of operations and cause our stock price to decline.

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, including our investigational ASCEND drug-coated balloon, or for the approval of the use of our products in some foreign countries. Clinical testing takes many years, is expensive and carries uncertain outcomes. The initiation and completion of any of these studies may be prevented, delayed, or halted for numerous reasons, including, but not limited to, the following:

- the FDA, institutional review boards or other regulatory authorities do not approve a clinical study protocol, force us to modify a previously approved protocol, or place a clinical study on hold;
- patients do not enroll in, or enroll at a lower rate than we expect, or do not complete a clinical study;
- patients or investigators do not comply with study protocols;
- patients do not return for post-treatment follow-up at the expected rate;
- patients experience unexpected adverse event or side effects for a variety of reasons that may or may not be related to our products;
- sites participating in an ongoing clinical study withdraw, requiring us to engage new sites;
- difficulties or delays associated with establishing additional clinical sites;
- third-party clinical investigators decline to participate in our clinical studies, do not perform the clinical studies on the anticipated schedule, or are inconsistent with the investigator agreement, clinical study protocol, good clinical practices or other agency requirements;
- third-party organizations do not perform data collection and analysis in a timely or accurate manner;
- regulatory inspections of our clinical studies or manufacturing facilities require us to undertake corrective action or suspend or terminate our clinical studies;
- changes in federal, state, or foreign governmental statutes, regulations or policies;
- interim results are inconclusive or unfavorable as to immediate and long-term safety or efficacy;
- the study design is inadequate to demonstrate safety and efficacy; or
- the study does not meet the primary endpoints.

Clinical failure can occur at any stage of the testing. Our clinical studies may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical and non-clinical testing in addition to those we have planned. In October 2019, we announced our ASCEND trial did not meet its primary endpoint of frontal sinus patency grade at day 30, as judged by an independent reviewer. The ASCEND study was designed to analyze the secondary endpoints if the primary endpoint passed, to help with interpretation of the data and for use designing the subsequent pivotal study. The secondary endpoints were analyzed for informative purposes. The ASCEND product showed significant differences in several important secondary endpoints favoring the treatment side including reduction in inflammation and polypoid edema at all

timepoints through day 30, as assessed by both the clinical investigators and independent reviewer. There was also a notable reduction in the need for oral steroid interventions at day 30, as determined by the independent reviewer. This study gives us valuable insight into the performance of our novel drug-coated balloon, enabling us to refine our clinical and regulatory pathway. The ASCEND study evaluated a clinical version of our drug-coated balloon and we are making enhancements to the product to support the ultimate commercial design. We continue to plan to conduct our pivotal clinical studies utilizing the version of the product we intend on commercializing.

Our failure to adequately demonstrate the safety and efficacy of any of our products would prevent receipt of regulatory clearance or approval and, ultimately, the commercialization of that product or indication for use. Even if our future products are approved in the United States, commercialization of our products in foreign countries would require approval by regulatory authorities in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials. Any of these occurrences may harm our business, results of operations, financial condition and prospects.

Reimbursement in international markets may require us to undertake country-specific reimbursement activities, including additional clinical studies, which could be time-consuming and expensive and may not yield acceptable reimbursement rates.

In international markets, market acceptance of our products will likely depend in large part on the availability of reimbursement within prevailing healthcare payment systems. Reimbursement and healthcare payment systems in international markets vary significantly by country, and by region in some countries, and include both government-sponsored healthcare and private insurance. Securing separate payment for our products may require additional investment in clinical data to satisfy the requirements of health technology assessment organizations in these countries. We may not obtain international reimbursement approvals in a timely manner, if at all. In addition, even if we do obtain international reimbursement approvals, the level of reimbursement may not be enough to commercially justify expansion of our business into the approving jurisdiction. To the extent we or our customers are unable to obtain reimbursement for our steroid releasing implants in major international markets in which we seek to market and sell our products, our international revenue growth would be harmed, and our business and results of operations would be adversely affected.

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

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

In addition, Congress and the current administration each indicated interest in taking regulatory and other policy actions pertaining to drug pricing, including potential proposals relating to Medicare price negotiations, importation of drugs from other countries and facilitating value-based arrangements between manufacturers and payors. Additionally, individual states in the United States and local governments have also increasingly passed legislation and implemented regulations designed to control product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures. Moreover, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine which products to purchase and which suppliers to include in their programs. At this time, it is unclear whether any of these proposals will be pursued and how they would impact our products or our future product candidates. However, adoption of price controls and other cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures may prevent or limit our ability to generate revenue and attain profitability.

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

On January 31, 2020, the UK withdrew from the EU. The UK's withdrawal from the EU is commonly referred to as Brexit. Under the withdrawal agreement between the UK and the EU, the UK 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, manufacture, 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" 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, as we upgrade our systems to an enterprise resource planning, or 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.

Risks Relating to Regulatory Matters

Our products are subject to extensive regulation by the FDA, and other agencies, including the requirement to obtain approval prior to commercializing our products and the requirement to report adverse events and other ongoing reporting requirements. If we fail to obtain necessary FDA or other agency device or drug approvals for our products or are subject to regulatory enforcement action as a result of our failure to properly report adverse events or otherwise comply with regulatory requirements, our commercial operations would be harmed.

Our steroid releasing implants are subject to extensive regulation by the FDA and various other federal, state and foreign governmental authorities. The Premarket Approval ("PMA") and New Drug Application ("NDA") approval processes can be expensive and lengthy. Despite the time, effort and cost required to obtain approval, there can be no assurance that any product that we intend to commercialize in the future will be approved by the FDA or other agencies in a timely fashion, if at all.

Our currently marketed products are subject to Medical Device Regulation ("MDR") and drug postmarketing safety reporting obligations, which require that we timely report any incidents to the FDA. In the European Union, our CE Marked products are subject to vigilance reporting.

The FDA and state authorities have broad enforcement powers. Our failure to comply with applicable regulatory requirements could result in enforcement action by the FDA or state agencies, which may include any of the following sanctions:

- adverse publicity, warning letters, fines, injunctions, consent decrees and civil penalties;

- repair, replacement, recall or seizure of our products;
- operating restrictions or partial suspension or total shutdown of production;
- delaying or refusing our requests for approval of new products, new intended uses or modifications to our existing products;
- refusal to grant export approval for our products;
- withdrawing product approvals that have already been granted; and
- criminal prosecution.

If any of these enforcement actions were to be taken by the government, our business could be harmed.

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

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

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

In addition, events raising questions about the safety of certain marketed products may result in increased caution by the FDA and other regulatory authorities in reviewing new products based on safety, efficacy or other regulatory considerations and may result in significant delays in obtaining regulatory approvals. 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, or 340B, and under other similar government pricing programs

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

Federal law requires that a company must participate in the U.S. Department of Veterans Affairs ("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 will audit and examine our quality system for the manufacture, design, and release of our products and confirm adherence with applicable regulatory requirements. If we fail to maintain CE Markings in accordance with these requirements, we would be precluded from selling our products in the EEA. Any such action or circumstance may harm our reputation and business, and could have an adverse effect on our business, results of operations and financial condition.

Our products may in the future be subject to product recalls. A recall of our products, either voluntarily or at the direction of the FDA or another governmental authority, or the discovery of serious safety issues with our products, could have a significant adverse impact on us.

The FDA and similar foreign governmental authorities have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture. In the case of the FDA, the authority to require a recall must be based on an FDA finding that there is reasonable probability that the device would cause serious injury or death. In addition, foreign governmental bodies have the authority to require the recall of our products in their respective jurisdictions in the event of material deficiencies or defects in the design or manufacture of our products. We may, under our own initiative, recall a product if any material deficiency in our steroid releasing implants is found. The FDA requires that recalls be reported to the FDA within 10 working days after the recall is initiated. A government-mandated or voluntary recall by us or one of our international distributors could occur as a result of an unacceptable risk to health, component failures, malfunctions, manufacturing errors, design or labeling defects or other deficiencies and issues. Recalls of any of our products would divert managerial and financial resources and have an adverse effect on our reputation, results of operations and financial condition, which could impair our ability to produce our products in a cost-effective and timely manner in order to meet our customers' demands. In addition, corrective action to a recall may require regulatory approvals for product or manufacturing changes, which may take time to accomplish and may impact product availability in the marketplace. We may also be subject to liability claims, be required to bear other costs, or take other actions that may have a negative impact on our future sales and our ability to generate profits. Companies are required to maintain certain records of recalls, even if they are not reportable to the FDA. We may initiate voluntary recalls involving our products in the future that we determine do not require notification of the FDA. If the FDA disagrees with our determinations, they could require us to report those actions as recalls. A future recall announcement could harm our reputation with customers and negatively affect our sales. In addition, the FDA could take enforcement action for failing to report the recalls when they were conducted.

If the third parties on which we rely to conduct our clinical trials do not perform as contractually required or expected, we may not be able to obtain regulatory approval for or commercialize such product candidates.

We often must rely on third parties, such as medical institutions, clinical investigators and contract laboratories to conduct our clinical trials and provide data or prepare deliverables for our PMA or NDA submissions, including supplements thereto. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if these third parties need to be replaced, or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our clinical trials may be extended, delayed, suspended or terminated, and/or we may not be able to obtain regulatory approval for, or successfully commercialize, our products on a timely basis, if at all, and our business, operating results and prospects may be adversely affected. Furthermore, our third-party clinical trial investigators may be delayed in conducting our clinical trials for reasons outside of their control.

We may be subject to enforcement action if we engage in improper marketing or promotion of our products.

Our promotional materials and training methods must comply with FDA and other applicable laws and regulations, including the prohibition of the promotion of unapproved, or off-label use. Physicians may use our products off-label, as the FDA does not restrict or regulate a physician's choice of treatment within the practice of medicine. However, if the FDA determines that our promotional materials or training constitutes promotion of an off-label use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fine or criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our promotional or training materials to constitute promotion of an off-label use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. In that event, our reputation could be damaged, and adoption of the products could be impaired. Although our policy is to refrain from statements that could be considered off-label promotion of our products, the FDA or another regulatory agency could disagree and conclude that we have engaged in off-label promotion. In addition, the off-label use of our products may increase the risk of product liability claims. Product liability claims are expensive to defend and could divert our management's attention, result in substantial damage awards against us, and harm our reputation.

If we fail to comply with U.S. federal and state healthcare regulatory laws and applicable international healthcare regulatory laws, we could be subject to penalties, including, but not limited to, administrative, civil and criminal penalties, damages, fines, disgorgement, exclusion from participation in governmental healthcare programs, and the curtailment of our operations, any of which could adversely impact our reputation and business operations.

There are numerous U.S. federal and state healthcare regulatory laws, including, but not limited to, anti-kickback laws, false claims laws, privacy laws, and transparency laws. Our relationships with healthcare providers and entities, including but not limited to, physicians, hospitals, ASC, group purchasing organizations and our independent distributors are subject to scrutiny under these laws. Violations of these laws can subject us to 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 European Union's General Data Protection Regulation, or GDPR), or localized privacy laws (e.g., the California Consumer Privacy Act of 2018, effective beginning January 2020, mirroring a number of the key provisions in the GDPR);
- the Federal Trade Commission Act and similar laws regulating advertisement and consumer protections;
- the federal Foreign Corrupt Practices Act of 1997, which prohibits corrupt payments, gifts or transfers of value to foreign officials; and
- foreign or U.S. state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers.

Further, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or, collectively, the Affordable Care Act, among other things, amends the intent requirements of the federal Anti-Kickback Statute and certain criminal statutes governing healthcare fraud. A person or entity can now be found guilty of violating the statute without actual knowledge of the statute or specific intent to violate it. In addition, the Affordable Care Act provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act. Moreover, while we do

not submit claims and our customers make the ultimate decision on how to submit claims, from time-to-time, we may provide reimbursement guidance to our customers. If a government authority were to conclude that we provided improper advice to our customers or encouraged the submission of false claims for reimbursement, we could face action against us by government authorities. Any violations of these laws, or any action against us for violation of these laws, even if we successfully defend against it, could result in a material adverse effect on our reputation, business, results of operations and financial condition.

We have entered into consulting agreements with physicians, including some who influence the ordering of and use our products in procedures they perform. While we believe these transactions were structured to comply with all applicable laws, including state and federal anti-kickback laws, to the extent applicable, regulatory agencies may view these transactions as prohibited arrangements that must be restructured, or discontinued, or for which we could be subject to other significant penalties. We could be adversely affected if regulatory agencies interpret our financial relationships with ENT physicians who influence the ordering of and use our products to be in violation of applicable laws. This could subject us to the penalties described above.

Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available under such laws, it is possible that some of our business activities, including our relationships with healthcare providers and entities, including, but not limited to, physicians, hospitals, ASC, group purchasing organizations and our independent distributors and certain sales and marketing practices, including the provision of certain items and services to our customers, could be subject to challenge under one or more of such laws.

To enforce compliance with the healthcare regulatory laws, federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Responding to investigations can be time and resource consuming and can divert management's attention from the business. Additionally, as a result of these investigations, healthcare providers and entities may have to agree to additional onerous compliance and reporting requirements as part of a consent decree or corporate integrity agreement. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business.

In certain cases, federal and state authorities pursue actions for false claims on the basis that manufacturers and distributors are promoting off-label uses of their products. Pursuant to FDA regulations, we can only market our products for cleared or approved uses. Although physicians are permitted to use medical devices for indications other than those cleared or approved by the FDA in their professional medical judgment, we are prohibited from promoting products for off-label uses. We market our products and provide promotional materials and training programs to physicians regarding the use of our products. If it is determined that our business activities, including our marketing, promotional materials or training programs constitute promotion of unapproved uses, we could be subject to significant fines in addition to regulatory enforcement actions, including the issuance of a warning letter, injunction, seizure and criminal penalty.

In addition, there has been a recent trend of increased federal and state regulation of payments and transfers of value provided to healthcare professionals or entities. The Physician Payments Sunshine Act that imposes annual reporting requirements on device and pharmaceutical manufacturers for payments and other transfers of value provided by them, directly or indirectly, to physicians (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 also will 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 eliminates the health insurer tax. Additionally, the Tax Cuts and Jobs Act of 2017 includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the Affordable Care Act on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate". Further, the Bipartisan Budget Act of 2018 ("BBA"), among other things, amends the Affordable Care Act, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole". Further, on December 14, 2018, a United States District Court Judge in the Northern District of Texas 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 Foreign Corrupt Practices Act ("FCPA"), and similar laws associated with any activities outside the United States could subject us to penalties and other adverse consequences.

We are subject to the FCPA and other anti-bribery legislation around the world. The FCPA prohibits covered entities and their intermediaries from engaging in bribery or making other prohibited payments, offers or promises to foreign officials for the purpose of obtaining or retaining business or other advantages. In addition, the FCPA imposes recordkeeping and internal controls requirements on publicly traded corporations and their foreign affiliates, which are intended to, among other things, prevent the diversion of corporate funds to the payment of bribes and other improper payments, and to prevent the establishment of "off books" slush funds from which such improper payments can be made. 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.

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 Annual Report on Form 10-K, 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 agreement with Deerfield could impair our financial condition and limit our operating flexibility.

Our indebtedness under our facility agreement with Deerfield could:

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

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

Risks Related to Our Common Stock

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 in control of us that stockholders may consider favorable, including transactions in which stockholders might otherwise receive a premium for their shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Because our board of directors is responsible for appointing the members of our management team, these provisions could in turn affect any attempt by our stockholders to replace current members of our management team. Among others, these provisions include that:

- our board of directors has the right to expand the size of our board of directors and to elect directors to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors;
- our stockholders may not act by written consent or call special stockholders' meetings; as a result, a holder, or holders, controlling a majority of our capital stock would not be able to take certain actions other than at annual stockholders' meetings or special stockholders' meetings called by the board of directors, the chairman of the board, the chief executive officer or the president;
- our certificate of incorporation prohibits cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- the affirmative vote of holders of at least 66-2/3% of the voting power of all of the then outstanding shares of voting stock, voting as a single class, will be required (a) to amend certain provisions of our certificate of incorporation, including provisions relating to the size of the board, removal of directors, special meetings, actions by written consent and cumulative voting and (b) to amend or repeal our bylaws, although our bylaws may be amended by a simple majority vote of our board of directors;
- stockholders must provide advance notice and additional disclosures in order to nominate individuals for election to the board of directors or to propose matters that can be acted upon at a stockholders' meeting, which may discourage or deter a potential acquiror from conducting a solicitation of proxies to elect the acquiror's own slate of directors or otherwise attempting to obtain control of our company; and

- our board of directors may issue, without stockholder approval, shares of undesignated preferred stock; the ability to issue undesignated preferred stock makes it possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to acquire us.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

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

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

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

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

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

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

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 1B. Unresolved Staff Comments

None.

Item 2. Properties

We occupy approximately 50,400 square feet of leased office and laboratory space as well as approximately 10,200 square feet of warehouse space located in Menlo Park, California. The lease of the office and laboratory space expire on December 31, 2027 while the lease of the warehouse expires on September 1, 2024. We also occupy approximately 3,500 square feet of office space in Austin, Texas, which will expire on January 31, 2024. In addition, we occupy approximately 7,300 square feet of space in Hennigsdorf, Germany for manufacturing and research and development, which will expire in February 2022. We believe that our facilities are sufficient to meet our current needs.

Item 3. Legal Proceedings

The information included in Note 11 to the consolidated financial statements included in Part IV of this Annual Report on Form 10-K is incorporated herein by reference.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Shares of our common stock are traded on the Nasdaq Global Market, or Nasdaq, under the symbol XENT.

As of March 2, 2021, there were approximately 14 stockholders of record. Because many of our shares are held by brokers and other institutions on behalf of stockholders, we are unable to estimate the total number of stockholders represented by these record holders.

Dividend Policy

We have never declared or paid any cash dividends on our capital stock, and we do not currently intend to pay any cash dividends on our capital stock in the foreseeable future. We currently intend to retain all available funds and any future earnings to support operations and to finance the growth and development of our business. Any future determination to pay dividends will be made at the discretion of our board of directors, subject to applicable laws and will depend upon, among other factors, our results of operations, financial condition, contractual restrictions and capital requirements. Our future ability to pay cash dividends on our capital stock may also be limited by the terms of any future debt or preferred securities or future credit facility.

Recent Sales of Unregistered Securities

There were no sales of equity securities by us that were not registered under the Securities Act of 1933, as amended, or the Securities Act, during fiscal year ended December 31, 2020, that have not been previously reported in a Quarterly Report on Form 10-Q or in a Current Report on Form 8-K.

Issuer Purchases of Equity Securities

None.

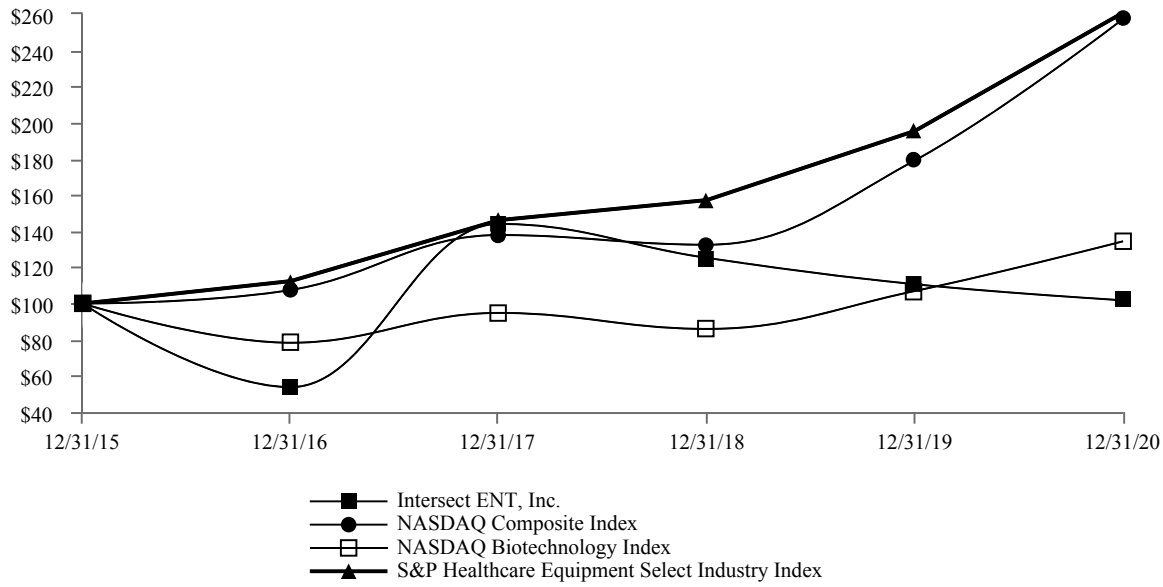
Performance Graph

The graph below compares the cumulative total return to security holders of our common stock with the comparable cumulative returns of the Nasdaq Composite and Biotechnology Indexes as well as the S&P Healthcare Equipment Select Industry Index. The graph assumes the investment of $100 on December 31, 2015 through December 31, 2020. Points on the graph represent the performance at year-end.

The information under the heading "Performance Graph" shall not be deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended.

CUMULATIVE TOTAL RETURN*

Among Intersect ENT, INC, the NASDAQ Composite Index, NASDAQ Biotechnology Index, and S&P Healthcare Equipment Select Industry Index



*$100 invested on December 31, 2015 in stock or index. Fiscal year ended December 31, 2020.

	Cumulative Total Return as of					
	12/31/15	12/31/16	12/31/17	12/31/18	12/31/19	12/31/20
Intersect ENT, Inc.	100.00	53.78	144.00	125.24	110.67	101.78
NASDAQ Composite Index	100.00	107.50	137.86	132.51	179.19	257.38
NASDAQ Biotechnology Index	100.00	78.32	94.81	85.97	106.95	134.42
S&P Healthcare Equipment Select Industry Index	100.00	112.41	146.10	157.21	195.48	260.82

The stock price performance included in this graph is not necessarily indicative of future stock price performance.

The material in this section is not "soliciting material" and is not deemed "filed" with the SEC and is not to be incorporated by reference into any filing of Intersect ENT, Inc. made under the Securities Act or the Exchange Act whether made before or after the date hereof and irrespective of any general incorporation language in any such filing except to the extent we specifically incorporate this section by reference.

Item 6. Selected Financial Data

Selected financial data is not presented here pursuant to early adoption of new SEC rules relating to this item. The statement of operations data for the years ended December 31, 2020, 2019, and 2018, and the balance sheet data as of December 31, 2020 and 2019, are presented in the audited consolidated financial statements in Part IV of this Annual Report on Form 10-K. The statement of operations data for the years ended December 31, 2018, 2017, and 2016, and the balance sheet data as of December 31, 2018, 2017, and 2016, are not included in this report, and are provided in Part IV of our Annual Reports on Form 10-K for the years ended December 31, 2018, 2017, and 2016.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our Consolidated Financial Statements and the related notes to those statements included elsewhere in this Annual Report. In addition to historical financial information, the following discussion and analysis contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. These forward-looking statements relate to future events or our future financial performance that involve risks, uncertainties and assumptions. Our actual results and timing of events may differ materially from those anticipated in these forward-looking statements as a result of many factors, including those discussed under "Risk Factors" and elsewhere in this report. Please see "Cautionary Information Regarding Forward-Looking Statements" at the beginning of this Form 10-K for additional information you should consider regarding forward-looking statements. We undertake no obligation to revise or update any forward-looking statements to reflect any event or circumstance that arises after the date of this report, or to conform such statements to actual results or changes in our expectations.

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. 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 surgical navigation system and instrumentation ("CUBE"), that complement our PROPEL and SINUVA sinus implants across all settings of care and extend our geographic reach. 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 VENSURE products received 510(k) clearance in August 2020. CUBE and VENSURE are both regulated as medical devices.

While our primary commercial focus is the U.S. market, both PROPEL and PROPEL Mini received CE Markings, permitting them to be marketed in Europe. Our commercialization strategy will consider several factors including regulatory requirements, reimbursement coverage for our products, and key opinion leader support. Our initial focus is on Germany and the United Kingdom, where we are working to build our capabilities and develop the market. Going forward, we will continue to assess our capability to penetrate additional markets in Europe, the Asia Pacific and Japan.

Our PROPEL family of steroid releasing implants are clinically proven to improve outcomes for chronic sinusitis patients following sinus surgery. PROPEL implants mechanically prop open the sinuses and release mometasone furoate, an advanced corticosteroid with anti-inflammatory properties, directly into the sinus lining, and then dissolve 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 to-date.

- PROPEL is a self-expanding implant designed to conform to and hold open the surgically enlarged sinus while gradually releasing an anti-inflammatory steroid over a period of approximately 30 days and is absorbed into the body over a period of approximately six weeks.
- PROPEL Mini is a smaller version of PROPEL and 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 is designed to facilitate treatment of the frontal and maxillary sinus ostia, or openings, of the dependent sinuses in procedures performed in both the operating room and in the office setting of care. PROPEL Contour's lower profile, hourglass shape and malleable delivery system are designed for use in the narrow and difficult to access sinus ostia.

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.

Our PROPEL family of products are used primarily in the operating room of a hospital or ambulatory surgery center. These providers receive a facility fee for the sinus surgery procedure which is intended to pay for supplies used in this procedure, including the PROPEL family of products. 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. CUBE navigation supports surgery and balloon dilation in all settings of care. We applied to the Centers for Medicare & Medicaid Services ("CMS") for a product-specific J code for SINUVA, and in July 2019, CMS announced their final decision to establish a new J code described as "J7401 Mometasone furoate sinus implant, 10 micrograms." This new J code became effective on October 1, 2019. CMS also made a final decision to eliminate the S1090 code, which was previously assigned to PROPEL, because they view it as duplicative to J7401. Subsequently, CMS approved SINUVA for transitional pass-through payment status for reimbursement under the Hospital Outpatient Prospective Payment System ("OPPS") and ASC Payment System. The new C Code described as "C9122 Mometasone furoate, sinus implant, 10 micrograms", took effect on July 1, 2020. Pass-Through status lasts for three years and allows us to place SINUVA in the ASC and hospital settings. Moreover, 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." The new PROPEL and SINUVA codes are scheduled to take effect April 1, 2021. Prior to October 1, 2019, reimbursement submissions to cover the cost of SINUVA were reported to payors using the unassigned Healthcare Common Procedure Coding System ("HCPCS") code J3490.

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. We plan to initiate the EXPAND study in the second quarter of 2021, which will assess the VENSURE balloon and PROPEL Contour's collective ability to improve healing and patency rates through localized drug delivery post-balloon dilation, as well as other outcomes. The primary endpoint will be evaluated at 30 days. In order to expand our global reach, we also plan to make clinical and regulatory investments in order to expand PROPEL in Europe. Our PROPEL OPEN registry trial is in place to fulfill EU Medical Device Regulation ("MDR") requirements and collect local data in order to support our commercial efforts. Other clinical trials initiated in the past include our investigational ASCEND drug-coated sinus balloon study initiated in December 2018.

Impact of the COVID-19 Pandemic

Prior to the COVID-19 pandemic, our efforts to enhance commercial execution and improve market access infrastructure were beginning to yield benefits as sales until the end of February 2020 were consistent with our expectations. However, sales declined towards the end of the first quarter and throughout the second quarter as the various COVID-19 restrictions were implemented and remained in effect. However, we began to see meaningful change in the business environment towards the end of May with increased procedure volumes as select areas of the country emerged from shelter-in-place orders and restrictions on elective medical procedures were eased. This trend continued in June and throughout the remainder of 2020 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 rapidly developing laws and restrictions surrounding the COVID-19 pandemic. While the second half of 2020 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

Our revenue has been derived almost exclusively from the sales of our PROPEL family of products, with limited sales of SINUVA beginning in March 2018, as well as sales of CUBE and VENSURE products beginning in the fourth quarter of 2020 with the acquisition of Fiagon. While performance until the end of February 2020 was relatively consistent with our expectations, our revenue substantially declined toward the end of the first quarter and throughout the second quarter as the various COVID-19 restrictions were implemented. With the return of outpatient procedures and a focus on office-based procedures, we began to see an increase in our performance and a positive upward trend toward the end of the second quarter and throughout the remainder of 2020. 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 revenue growth in 2021, based on the increased elective procedure volumes and enrollment trends in the fourth quarter. Once the disruption from the COVID-19 pandemic subsides, we expect our revenue to increase as we continue to expand our sales, marketing and reimbursement efforts in order to increase usage of our products. We also expect revenue from our PROPEL family of products to fluctuate from quarter to quarter due to seasonal variations in the volume of sinus surgery procedures performed, which has been impacted historically by factors including the status of patient healthcare insurance plan deductibles and the seasonal nature of allergies which can impact sinus-related symptoms. Revenue from SINUVA is recognized net of estimated product sales discounts, rebates, returns and other allowances as a reduction of revenue in the same period the related revenue is recognized. We will adjust these estimates if actual allowances vary from our estimates, which would affect revenue in the period such variances become known.

Our revenue is almost entirely derived from within the United States and no single customer accounted for more than 10% of our revenue during the years ended December 31, 2020, 2019 and 2018.

Cost of Sales and Gross Profit

We manufacture our PROPEL family of products and SINUVA in our facility in Menlo Park, California. CUBE navigation equipment and instruments are manufactured in Hennigsdorf, Germany, and VENSURE sinus dilation balloons are procured from a third-party manufacturer. Cost of sales consists primarily of manufacturing overhead costs, material costs, direct labor and other direct costs such as shipping costs. A significant portion of our cost of sales currently consists of manufacturing overhead costs. These overhead costs include compensation, including stock-based compensation and other operating expenses associated with the cost of quality assurance, material procurement, inventory control, facilities, information technology, equipment and operations supervision and manufacturing and warehouse management. Once the disruption from the COVID-19 pandemic subsides, we expect cost of sales to increase in absolute dollars again primarily as, and to the extent, our revenue grows, or we make additional improvements in our manufacturing capabilities.

Our gross margin has been and will continue to be affected by a variety of factors, including manufacturing costs and average selling prices. 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. Idle facility costs are charged to cost of goods sold in the period incurred. Manufacturing cost will change as our production volume and product mix changes. The per unit allocation of our manufacturing overhead costs may increase and our gross margin may decline as, and to the extent, production volume decreases.

Selling, General and Administrative Expenses

Selling, general and administrative, or SG&A, expenses consist primarily of compensation for personnel, including stock-based compensation, related to selling, marketing, finance, market access, reimbursement, business development, legal and human resource functions as well as costs related to any post-market studies. Additional SG&A expenses include commissions, training, travel expenses, promotional activities, conferences, trade shows, professional services fees, audit compliance expenses, insurance costs and general corporate expenses including allocated facilities and information technology expenses.

Research and Development Expenses

Research and development, or R&D, expenses consist primarily of compensation for personnel, including stock-based compensation, related to product development, regulatory affairs, clinical and medical affairs, and allocated facilities and information technology expenses. R&D expenses also may include expenses for clinical studies related to clinical trial design, site reimbursement, data management, travel expenses and the cost of manufacturing products for clinical trials. Finally, R&D expenses also include expenses related to the development of products and technologies such as consulting services and supplies.

Interest Expense

Interest expense consists primarily of the interest expense, accretion expense of debt discounts and purchase obligations, and amortization of debt issuance costs associated with our convertible notes, and imputed interest on deferred payments for the acquisition of Fiagon.

Other Income (Expense), Net

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

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.

Results of Operations

	Year Ended December 31,		
(in thousands, except percentages)	**2020**	**2019**	**2018**
Revenue	$ 80,554	$ 109,142	$ 108,472
Cost of sales	30,306	21,773	22,613
Gross profit	50,248	87,369	85,859
Gross margin	*62 %*	*80 %*	*79 %*
Operating expenses:			
Selling, general and administrative	98,550	108,480	91,603
Research and development	19,350	24,283	19,262
Total operating expenses	117,900	132,763	110,865
Loss from operations	(67,652)	(45,394)	(25,006)
Interest expense	(2,752)	—	—
Other income (expense), net	(2,331)	2,400	2,084
Loss before income taxes	(72,735)	(42,994)	(22,922)
Provision for income tax (benefit)	(416)	—	—
Net loss	$ (72,319)	$ (42,994)	$ (22,922)

Comparison of Years Ended December 31, 2020 and 2019

Revenue

(in thousands, except percentages)	2020	2019	Change $ 2020 to 2019	Change % 2020 to 2019
PROPEL family of products	$ 74,335	$ 104,657	$ (30,322)	(29)%
SINUVA	5,315	4,485	830	19 %
VENSURE, CUBE, and accessories	904	—	904	N/A
	$ 80,554	$ 109,142	$ (28,588)	(26)%

Revenue decreased by $28.6 million, or 26%, to $80.6 million during the year ended December 31, 2020, compared to $109.1 million during the year ended December 31, 2019. The decrease in revenue was due to a 29% decline in PROPEL sales, partially offset by a 19% increase in SINUVA sales. Lower PROPEL revenue resulted from a 31% decrease in unit sales, slightly offset by a 2% increase in average selling price. The decrease in unit sales for PROPEL was driven by a reduction in demand due to the impact of the COVID-19 pandemic. The increase in SINUVA sales was attributable to a 13% increase in unit sales during the year ended December 31, 2020 as well as a 5% increase in net revenue per unit from the year ended December 31, 2019. The increase in unit sales for SINUVA during the year ended December 31, 2020 was due to the improvement 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 year ended December 31, 2020 also included $0.9 million from sales from the initiation of sales from the acquired products, the CUBE navigation equipment and instruments and VENSURE sinus dilation balloons during the fourth quarter.

Based on current elective procedure volumes and enrollment trends, as well as the acquisition of Fiagon, we expect revenue growth in 2021. While we cannot predict the extent or duration of the impact of the COVID-19 pandemic on our financial and operating results, we believe that a recovery in procedures will continue, and that most patients will return for treatment.

Cost of Sales and Gross Margin

Cost of sales increased by $8.5 million, or 39%, to $30.3 million during the year ended December 31, 2020, compared to $21.8 million during the year ended December 31, 2019. The increase in cost of sales in 2020 was primarily due to the unfavorable impact of higher per unit manufacturing costs and $6.1 million of idle facility costs, partially offset by decreases in headcount as a result of cost reduction measures initiated in the first quarter of 2020. Also, the increase was attributable to $0.8 million in additional charges related to excess and obsolete inventory in response to the estimated impact of the COVID-19 pandemic. The increases were partially offset by lower PROPEL unit sales.

Gross margin for the year ended December 31, 2020, decreased to 62%, compared to 80% for the year December 31, 2019. While the gross margin for our products through the end of February 2020 was relatively consistent with our expectations, the decrease in gross margin during the remainder of 2020 was attributable to the unfavorable impact of higher per unit manufacturing costs as well as the charges related to the impact of COVID-19. The amount of these charges was approximately $6.9 million, representing an effect on our gross margin of approximately 9 percentage-points for the year ended December 31, 2020. Our gross margin recovered in the second half of the year as we resumed production and generated revenue.

As a result of the increase in procedure volumes and enrollments during the fourth quarter, we anticipate that there will be sequential revenue growth in 2021 from current levels. With the expected increase in demand and resumption of our manufacturing activities towards the end of the year, we do not expect idle facility costs to be incurred in 2021. However, idle facility costs could still be incurred in future periods until the current crisis subsides. We cannot reliably estimate the extent to which the COVID-19 pandemic will impact the cost of sales and gross margin for our products beyond the second quarter of 2021.

Selling, General and Administrative Expenses

SG&A expenses decreased by $9.9 million, or 9%, to $98.6 million during the year ended December 31, 2020, compared to $108.5 million during the year ended December 31, 2019. The decrease in SG&A expenses was primarily due to decreases in headcount and related expenses as a result of cost reduction measures initiated in the first quarter of 2020, in addition to lower

sales commissions from reduced sales, partially offset by transaction costs associated with the acquisition and integration of Fiagon of $4.0 million, which consisted largely of professional fees.

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

Research and Development Expenses

R&D expenses decreased by $4.9 million, or 20%, to $19.4 million during the year ended December 31, 2020, compared to $24.3 million during the year ended December 31, 2019. The decrease in R&D expenses was primarily due to decreases in headcount and related expenses as a result of cost reduction measures initiated in the first quarter of 2020, as well as a delay of clinical efforts. R&D projects include the development of the EXPAND study to be initiated in 2021, the PROPEL OPEN registry trial, and the ASCEND trial.

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

Interest Expense

Interest expense of $2.8 million for the year ended December 31, 2020 was attributable to convertible notes entered into during the second quarter of 2020 as well as imputed interest on deferred payments for the acquisition of Fiagon. There were no similar expenses in the prior year.

Other Income (Expense), Net

Other income (expense), net, decreased by $4.7 million to $(2.3) million during the year ended December 31, 2020, compared to $2.4 million during the year ended December 31, 2019. The decrease in other income (expense), net, was attributable to a $1.2 million increase in fair value of our embedded derivative liability associated with convertible notes, a net foreign exchange loss of $1.6 million on the revaluation of the Fiagon purchase liability and respective forward contracts, and the overall effects of foreign exchange remeasurement, as well as significantly lower interest rates earned on investments.

Provision for Income Tax Benefit

Provision for income tax benefit of $0.4 million for the year ended December 31, 2020 was attributable to the foreign tax impact associated with the acquisition of Fiagon. There were no similar benefits in the prior year.

Comparison of Years Ended December 31, 2019 and 2018

Revenue

(in thousands, except percentages)	2019	2018	Change $ 2019 to 2018	Change % 2019 to 2018
PROPEL family of products	$ 104,657	$ 105,711	$ (1,054)	(1)%
SINUVA	4,485	2,761	1,724	62 %
	$ 109,142	$ 108,472	$ 670	1 %

Revenue increased by $0.7 million, or 1%, to $109.1 million during the year ended December 31, 2019, compared to $108.5 million during the year ended December 31, 2018. The increase in revenue was primarily attributable to growth in the adoption of SINUVA, which represented approximately 4% and 3% of our revenue during the years ended December 31, 2019 and 2018, respectively. SINUVA unit sales increased by 63% in 2019, while the net selling price remained consistent with 2018. The increase in SINUVA revenue was largely offset by lower revenue attributable to the PROPEL family of products. Lower PROPEL revenue in 2019 resulted from a 4% decrease in unit sales, offset by a 3% increase in average selling price.

Cost of Sales and Gross Margin

Cost of sales decreased by $0.8 million, or 4%, to $21.8 million during the year ended December 31, 2019, compared to $22.6 million during the year ended December 31, 2018. The decrease in cost of sales in 2019 was primarily attributable to the favorable impact of lower per unit manufacturing costs associated with higher production volumes and the lower unit sales of the PROPEL family of products, partially offset by manufacturing related charges. Cost of sales for the year ended December 31, 2018 was also impacted by a charge related to our decision not to commercialize the initial SINUVA production output.

Gross margin for the year ended December 31, 2019, increased to 80%, compared to 79% for the year December 31, 2018. The increase in gross margin in 2019 was primarily attributable to the favorable impact of lower per unit manufacturing costs associated with higher volumes and higher average selling price of the PROPEL family of products, partially offset by higher manufacturing related charges. Gross margin for the year ended December 31, 2018 was also impacted by a charge related to our decision not to commercialize the initial SINUVA production output.

Selling, General and Administrative Expenses

SG&A expenses increased by $16.9 million, or 18%, to $108.5 million during the year ended December 31, 2019, compared to $91.6 million during the year ended December 31, 2018. The increase in SG&A expenses was primarily due to the incremental stock-based compensation associated with the leadership change as well as an increase in headcount and related expenses to support the commercial launch of SINUVA, which was launched in March 2018, and the ongoing commercialization of our PROPEL family of products, partially offset by a refund related to previously paid medical device excise tax.

Research and Development Expenses

R&D expenses increased by $5.0 million, or 26%, to $24.3 million during the year ended December 31, 2019, compared to $19.3 million during the year ended December 31, 2018. The increase in R&D expenses was primarily due to development of our investigational ASCEND drug-coated sinus balloon and an increase in personnel related expenses.

Other Income (Expense), Net

Other income (expense), net, increased by $0.3 million to $2.4 million during the year ended December 31, 2019, compared to $2.1 million during the year ended December 31, 2018. The increase in other income (expense), net was primarily attributable to higher interest rates earned on our investments.

Liquidity and Capital Resources

Overview

As of December 31, 2020, we had cash, cash equivalents, and short-term investments of $88.0 million, compared to cash, cash equivalents and short-term investments of $90.6 million as of December 31, 2019. In addition, as of December 31, 2020, we had restricted cash of $17.5 million, compared to no restricted cash as of December 31, 2019.

Cash Flows

	Year Ended December 31,		
(in thousands)	**2020**	**2019**	**2018**
Net cash (used in) provided by:			
Operating activities	$ (35,694)	$ (27,251)	$ (13,840)
Investing activities	(22,745)	18,891	(10,002)
Financing activities	68,744	19,548	13,469
Effect of exchange rate changes on cash, cash equivalents, and restricted cash	64	—	—
Net increase (decrease) in cash, cash equivalents, and restricted cash	$ 10,369	$ 11,188	$ (10,373)

Net Cash Used in Operating Activities

During the year ended December 31, 2020, net cash used in operating activities was $35.7 million, consisting primarily of a net loss of $72.3 million and a decrease in net operating assets of $13.0 million, partially offset by non-cash charges of $23.7 million. The cash used in operations was due primarily 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, depreciation and amortization, revaluation of embedded derivatives, foreign exchange impacts, and non-cash lease expense. The decrease in net operating assets is primarily due to decreases in accounts receivable and inventory as well as increases in accounts payable and accrued compensation due to improved working capital management and lower production than the prior year.

During the year ended December 31, 2019, net cash used in operating activities was $27.3 million, consisting primarily of a net loss of $43.0 million and an increase in net operating assets of $7.1 million, partially offset by non-cash charges of $22.8 million. The cash used in operations was due primarily to an increase in headcount and related expenses to support the ongoing commercialization of our PROPEL family of products and the launch of SINUVA in March 2018. The non-cash charges primarily consisted of stock-based compensation expense. The increase in net operating assets is primarily due to an increase in inventory.

During the year ended December 31, 2018, net cash used in operating activities was $13.8 million, consisting primarily of a net loss of $22.9 million and an increase in net operating assets of $5.1 million, partially offset by non-cash charges of $14.2 million. The cash used in operations was due primarily to an increase in headcount and related expenses to support the ongoing commercialization of our PROPEL family of products and the launch of SINUVA in March 2018. The non-cash charges primarily consisted of stock-based compensation expense. The increase in net operating assets is primarily due to an increase in accounts receivable and inventory, partially offset by an increase in accounts payable.

Net Cash Provided by (Used in) Investing Activities

During the year ended December 31, 2020, net cash used in investing activities was $22.7 million, consisting primarily of net purchases of short-term investments of $39.7 million, purchases of property and equipment of $0.9 million, and $16.9 million related to the acquisition of Fiagon, partially offset by proceeds from the sale of short-term investments of $34.8 million.

During the year ended December 31, 2019, net cash provided by investing activities was $18.9 million, consisting primarily of net maturities of short-term investments of $22.6 million, partially offset by purchases of property and equipment of $3.7 million.

During the year ended December 31, 2018, net cash used in investing activities was $10.0 million, consisting primarily of net purchases of short-term investments of $7.9 million and purchases of property and equipment of $2.1 million.

Net Cash Provided by Financing Activities

During the year ended December 31, 2020, net cash provided by financing activities was $68.7 million, consisting of net proceeds from the issuance of convertible debt of $61.8 million and $6.9 million from the issuance of common stock upon exercises of employee stock options and purchases under our employee stock purchase plan.

During the year ended December 31, 2019, net cash provided by financing activities was $19.5 million, consisting of net proceeds from the issuance of common stock upon exercises of employee stock options and purchases under our employee stock purchase plan.

During the year ended December 31, 2018, net cash provided by financing activities was $13.5 million, consisting of net proceeds from the issuance of common stock upon exercises of employee stock options and purchases under our employee stock purchase plan.

Liquidity

Based on our current expectations of the operating environment in 2021 and 2022, we believe we have adequate cash and other resources to operate for at least twelve months from the issuance of this Annual Report on Form 10-K, including funding our working capital needs, capital expenditures, payments associated with the Fiagon acquisition, interest payments on long-term debt and lease payments. However, as a result of the COVID-19 pandemic, our rate of cash consumption compared to the prior year has increased as a result of decreased revenues, and may continue to do so. In response to the COVID-19 pandemic

in the first quarter of 2020, we took pre-emptive actions to curtail spending and to reduce the use of cash as revenues have been and may continue to be materially impacted. These cost reduction actions included a) furloughing and reducing our workforce by approximately 25%, b) substantially reducing new hiring, c) suspending near-term production in the second quarter of 2020, d) reducing discretionary operating expenses and capital expenditures, and e) delaying clinical research projects. As a result of these actions, we achieved significant cost reductions that, along with an improved operating environment as the pandemic restrictions eased, allowed us to meet our target liquidity levels at year end. In addition, during the second quarter of 2020, we entered into a Facility Agreement, providing for the issuance and sale of a $65.0 million principal amount of 4% Convertible Unsecured Senior Notes due in 2025. The net proceeds from the offering were $61.8 million after deducting the issuance costs payable by us.

Under the terms of the Purchase Agreement for the acquisition of Fiagon totaling €62.2 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, plus an estimated €2.2 million purchase price adjustment due 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 our current sources of liquidity are insufficient, we may seek to sell additional equity or debt securities or obtain credit facilities. If we raise additional funds by issuing equity securities, our stockholders would experience dilution. Any additional debt or equity financing that we raise may contain terms that are not favorable to us or our stockholders. Additional financing may not be available at all, or in amounts or on terms unacceptable to us. If we are unable to obtain additional financing, we may be required to delay the development, commercialization and marketing of our products.

Off-Balance Sheet Arrangements

As of December 31, 2020 and 2019, we were not a party to any off-balance sheet arrangements that have, or are reasonably likely to have, a current or future effect on our financial condition, changes in financial condition, revenue or expenses, results of operations, liquidity, capital expenditures or capital resources.

Contractual Obligations

The following table sets out our contractual obligations due by period as of December 31, 2020.

	Due by Period				
(in thousands)	Less Than 1 Year	1-3 Years	3-5 Years	More Than 5 Years	Total
Operating lease obligations	$ 3,996	$ 8,072	$ 8,184	$ 8,547	$ 28,799
Convertible notes	—	—	65,000	—	65,000
Deferred purchase obligation (1)	20,291	35,925	—	—	56,216
Purchase commitments	5,554	225	—	—	5,779
	$ 29,841	$ 44,222	$ 73,184	$ 8,547	$ 155,794

(1) Consists of three €15.0 million payments to be made on each anniversary date of the closing of the Fiagon acquisition in addition to a €2.2 million purchase price adjustment amount due in 2021. We have entered into foreign currency forward contracts in order to manage the foreign currency risk associated with these payments.

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.

While our significant accounting policies are more fully described in Note 2 of our Financial Statements included in this Annual Report, we believe the following discussion addresses our most critical accounting policies, which are those that are

most important to the portrayal of our financial condition and results of operations and require our most difficult, subjective and complex judgments.

Revenue Recognition

We recognize revenue when our customer obtains control of promised goods in an amount that reflects the consideration which we expect to receive in exchange for those goods. To determine revenue recognition for arrangements that we determine are within the scope of Topic 606, we perform the following five steps: (i) identify the contract with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when, or as, we satisfy the performance obligations. We only apply the five-step model to contracts when it is probable that we will collect the consideration we are entitled to in exchange for the goods we transfer to the customer. At contract inception, once the contract is determined to be within the scope of Topic 606, we assess the goods promised within each contract and determine those that are performance obligations and assess whether each promised good is distinct. The contracts are typically in the form of a purchase order from the customer. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when, or as, the performance obligation is satisfied. We must make assumptions regarding the future collectability of amounts receivable from customers to determine whether revenue recognition criteria have been met. The amount of variable consideration that is included in the net sales price may be constrained, and is included in the net sales price, or transaction price, only to the extent that we estimate it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. We expense shipping and handling costs as incurred and include them in the cost of sales. In those cases where shipping and handling costs are billed to customers, we classify the amounts billed as a component of revenue. Taxes collected from customers and remitted to governmental authorities are excluded from revenues. We expense any incremental costs of obtaining a contract as and when incurred as the expected amortization period of the incremental costs would have been less than one year.

The PROPEL family of products are regulated by the FDA as medical devices. We recognize revenue through sales of our PROPEL family of products to hospitals and ASC located almost entirely in the United States when control of the product is transferred to the customer, typically upon shipment of goods to the customer, satisfying our only performance obligation.

The FDA has approved SINUVA as a drug and it is therefore regulated as such. We sell SINUVA to a limited number of specialty pharmacies and specialty distributors in the United States, or Resellers. These Resellers subsequently sell SINUVA to health care providers. Revenue from SINUVA sales are recognized when control of the product is transferred to the Resellers, typically upon receipt of goods by the Reseller, satisfying our only performance obligation. We also recognize Reseller fees, prompt pay discounts, product sale discounts, rebates, returns and other allowances as a reduction of revenue in the same period the related revenue is recognized. In addition to the agreements with the Resellers, we enter into arrangements with governmental agencies that result in rebates, chargebacks and discounts with respect to the purchase of SINUVA. These amounts may include Medicaid and Tricare rebates, chargebacks related to Federal Supply Schedule of the General Services Administration, Distribution and Pricing Agreement with the Department of Defense and 340B of the Public Health Service Act as well as other allowances that may be offered within contracts between us and our direct or indirect customers relating to our sales of SINUVA, collectively referred to as “Discounts and Rebates.” Discounts and Rebates are based on amounts owed or expected to be owed on the related sales. These estimates take into consideration our historical experience, the shelf life of the product, current contractual and statutory requirements, specific known market events and trends and industry data. Overall, these reserves reflect our best estimates of the amount of consideration to which we are entitled based on the terms of the contract. If actual results in the future vary from our estimates, we will adjust these estimates, which would affect revenue and earnings in the period such variances become known. In the balance sheet, such amounts are generally classified as reductions of accounts receivable if the amount is payable to the Resellers, or a current liability if the amount is payable to a party other than the Reseller.

Inventories

Inventories are valued at the lower of cost, computed on a first-in, first-out basis, or net realizable value. The allocation of production overhead to inventory costs is based on normal production capacity. Abnormal amounts of idle facility costs, freight, handling costs, and consumption are expensed as incurred, and not included in allocable overhead. During the year ended December 31, 2020, as a result of a shut-down in production associated with the COVID-19 pandemic for part of the first quarter and throughout the second quarter, we recorded $5.5 million for idle facility costs due to our inability to use our manufacturing facility due to the shelter-in-place orders and our decision to suspend production until the third quarter of 2020. Production resumed in the third quarter and we recorded an additional $0.6 million in idle facility costs in the third quarter of 2020 due to subnormal production levels. In periods where the manufacturing is below normal capacity, we will record idle

facility charges. We maintain provisions for excess and obsolete inventory based on our estimates of forecasted demand and, where applicable, product expiration. Due to a decline in projected product sales, we increased our reserve for excess and obsolete inventory by $0.8 million during the first quarter of 2020. We will continue to monitor the effect of the COVID-19 pandemic on the business and will continue to reassess the need for inventory reserves in future periods.

Embedded Derivatives Related to Convertible Debt Instruments

The Convertible Notes due in May 2025 have embedded features which were required to be bifurcated upon issuance and then periodically remeasured to fair value separately as embedded derivatives. These embedded features include additional make-whole interest payments which may become payable to the lender upon certain events, such as a change in control, upon optional redemption by our company, or a sale of all or substantially all of our assets. The embedded features also include additional shares depending on the time to maturity and the stock price which may be added to an early conversion upon certain events. We have utilized a convertible lattice model to determine the fair value of the embedded features, which utilizes inputs including the common stock price, volatility of common stock, credit rating, probability of certain triggering events and time to maturity. The embedded features will be remeasured to fair value at each balance sheet date with a resulting gain or loss related to the change in the fair value being recorded to other income (expense), net in the consolidated statements of operations. As of December 31, 2020, the fair value of the embedded derivatives was $3.0 million and has been presented together with the Convertible Notes host instrument on the consolidated balance sheets. Changes in our assumptions used to value the embedded derivatives, such as our stock price and the estimated probability of triggering events, could result in material changes in the valuation in future periods. As of December 31, 2020, the maximum value of the liability if a triggering event had occurred would have been $26.4 million.

Goodwill and Acquired Intangible Assets

As of December 31, 2020, our acquired intangible assets include identifiable intangible assets of $21.2 million and goodwill of $46.6 million. Acquired identifiable intangible assets include developed technology, distribution network, customer relationships, and trademarks. All of our acquired identifiable intangible assets have finite lives and are amortized over the period of estimated benefit on a straight-line basis, reflecting the pattern of economic benefits associated with these assets. Goodwill represents the excess of the purchase price over the fair value of net identifiable assets and liabilities. Goodwill and acquired intangible assets with indefinite lives are not amortized, but are subject to an annual impairment review, or if circumstances indicate their carrying value may no longer be recoverable. There have been no such impairments.

The valuation and classification of acquired intangible assets and goodwill and the assignment of useful lives for purposes of amortization involves judgments and the use of estimates. The evaluation of these intangible assets and goodwill for impairment under established accounting guidelines is required on a recurring basis. Changes in business conditions could potentially require future adjustments to the assumptions made. No impairment charge or accelerated amortization has been recorded to date. A considerable amount of judgment is required in assessing impairment, which includes financial forecasts. If conditions are different from management's current estimates, material write-downs may be required, which would adversely affect our operations results.

Business Combinations

We record assets acquired and liabilities assumed at their respective fair values as of the acquisition date. The excess of the fair value of the purchase consideration transferred over the fair value of net assets acquired is recorded as goodwill. Deferred acquisition related consideration incurred is recorded at its present value and is increased to the ultimate payment amount using the effective interest rate method. The liability is discounted at a market participant's borrowing rate for debt instruments with similar maturities, security, and other characteristics. Because the purchase consideration is denominated in Euro, it will be remeasured to US Dollars at each subsequent reporting period, with any foreign currency gains and losses recognized in other income (expense). When determining the fair value of assets acquired and liabilities assumed, management is required to make certain estimates and assumptions, especially with respect to acquired intangible assets. We engaged a third-party specialist to assist with this determination. The estimates and assumptions used in valuing intangible assets include, but are not limited to, the amount and timing of projected future cash flows, the discount rate used to determine the present value of these cash flows, and the determination of the assets' life cycles. These estimates are inherently uncertain and, therefore, actual results may differ from the estimates made.

The deferred acquisition liability is payable in Euros and subject to foreign currency risk as it is remeasured at each balance sheet date. To mitigate these risks, we have entered into foreign exchange forward contracts to reduce the risk that our

earnings and cash flows will be adversely affected by changes in exchange rates. Due to differing notional amounts and the timing of when the forward contracts are operable, the impacts of foreign exchange may not be fully offset.

Stock-based Compensation

We maintain an equity incentive plan to provide long-term incentive for employees and members of the board of directors. The plan allows for the issuance of non-statutory and incentive stock options and restricted stock units to employees and non-statutory stock options to consultants and non-employee directors.

We are required to determine the fair value of equity incentive awards and recognize compensation expense for all equity incentive awards made to employees and directors. Stock-based compensation expense is recognized over the requisite service period in the statements of operations and comprehensive loss. We use the straight-line method for expense attribution and we elected to account for forfeitures when they occur.

The valuation model we use for calculating the fair value of awards for stock-based compensation expense, except for market-based awards, is the Black-Scholes option-pricing model, or the Black-Scholes model. For market-based awards, the Monte Carlo simulation model, or the Monte Carlo simulation, is used. Both the Black-Scholes model and Monte Carlo simulation require us to make assumptions and judgments about the variables used in the calculation, including the expected term (weighted average period of time that the options granted are expected to be outstanding), the volatility of our common stock and an assumed risk-free interest rate. The fair market value of our common stock is determined based on the closing price of our common stock on the Nasdaq Global Market. There is some subjectivity in determining the expected volatility due to a lack of history as a publicly traded company. Higher estimates of expected volatility would result in higher valuations of stock options and market-based awards and lower estimates of expected volatility would result in lower valuations for the stock options and market-based awards.

Recent Accounting Pronouncements

Please see Note 2 to the Consolidated Financial Statements included in this Annual Report.

Item 7A. Quantitative and Qualitative Disclosure About Market Risk

Interest Rate Risk

The risk associated with fluctuating interest rates is primarily limited to our cash equivalents and short-term investments which are carried at fair market value. We do not currently use or plan to use financial derivatives in our investment portfolio.

As of December 31, 2020 and 2019, we had cash, cash equivalents, and short-term investments of $88.0 million and $90.6 million, respectively. In addition, as of December 31, 2020, we had restricted cash of $17.5 million, compared to no restricted cash as of December 31, 2019. Cash equivalents and short-term investments are composed of money market funds, corporate debt securities and commercial paper. Our investment policy requires investments to be of high credit quality and generally limits the amount of credit exposure to any single issuer or group of issuers. Our objective is the preservation of capital and to maintain proper liquidity to meet our operating requirements while at the same time maximizing the income we receive from our financial instruments without significantly increasing risk. Because our short-term investments have a weighted average maturity of not more than one year, we believe the impact of a hypothetical 10% change in market interest rates at December 31, 2020 and 2019 would not have a material effect on our financial position, results of operations or cash flows.

We are exposed to market risk for changes in interest rates applicable to the $65.0 million of principal amount of Convertible Notes, bearing interest at 4.0% per annum with interest payable quarterly. The Convertible Notes will mature on May 9, 2025, unless earlier converted or redeemed in accordance with their terms. As of December 31, 2020, the entire principal amount was outstanding as well as $0.7 million in accrued interest. For our Convertible Notes, any changes in market interest rates will generally affect the fair value of the instrument, but not our earnings or cash flows.

Foreign Currency Risk

The majority of our revenue, expenses, and capital expenditures are transacted in U.S. dollars. However, our operating results are exposed to foreign currency risk, in particular the Euro, due to our acquisition of Fiagon. Furthermore, upon the acquisition of Fiagon, we recorded a purchase obligation of €47.2 million, representing three annual payments of €15.0 million, plus an estimated additional €2.2 million purchase price adjustment due in October 2021. We have entered into window foreign

exchange forward contracts for €45.0 million to significantly reduce the risk that our earnings and cash flows will be adversely affected by changes in exchange rates. These contracts are due in three annual tranches of €15.0 million, with timing closely aligned to the due dates of the purchase payments. As such, a 10% change in the exchange rate between the dollar and the Euro would not have a material impact on our financial position, results of operations, or cash flows.

Item 8. Financial Statements and Supplementary Data

Please see the Consolidated Financial Statements included in this Annual Report on Form 10-K, beginning on Page F-l following the signature page to this Form 10-K, which are incorporated by reference here.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. 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 December 31, 2020. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2020, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is a process designed by, or under the supervision of, our Chief Executive Officer and Chief Financial Officer to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that (1) pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the consolidated financial statements.

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on criteria established in "Internal Control — Integrated Framework (2013)" issued by the Committee of Sponsoring Organizations of the Treadway Commission, or COSO. Our management concluded that our internal control over financial reporting was effective as of December 31, 2020.

Our management has excluded Fiagon AG Medical Technologies from our assessment of internal control over financial reporting as of December 31, 2020, as permitted by the guidance issued by the Office of the Chief Accountant of the Securities and Exchange Commission that an assessment of a recent business combination may be omitted from management's report on internal control over financial reporting in the first year of consolidation.

Our independent registered public accounting firm, Ernst & Young LLP, has audited the effectiveness of our internal control over financial reporting as of December 31, 2020 as stated in their report which is included herein.

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 December 31, 2020, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and the Board of Directors of Intersect ENT, Inc.

Opinion on Internal Control Over Financial Reporting

We have audited Intersect ENT, Inc.'s internal control over financial reporting as of December 31, 2020, based on criteria established in Internal Control — Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, Intersect ENT, Inc. (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2020, based on the COSO criteria.

As indicated in the accompanying Managements' Report on Internal Control over Financial Reporting, management's assessment of and conclusion on the effectiveness of internal control over financial reporting did not include the internal controls of Fiagon AG Medical Technologies, which is included in the 2020 consolidated financial statements of the Company and constituted 31% and 99% of total and net assets, respectively, as of December 31, 2020 and 2% and 4% of revenues and net loss, respectively, for the year then ended. Our audit of internal control over financial reporting of the Company also did not include an evaluation of the internal control over financial reporting of Fiagon AG Medical Technologies.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of December 31, 2020 and 2019, the related consolidated statements of operations and comprehensive loss, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2020, and the related notes and our report dated March 9, 2021 expressed an unqualified opinion thereon.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Annual Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control Over Financial Reporting

A company's internal control over financial reporting is a process designed 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. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ Ernst & Young LLP

San Jose, California
March 9, 2021

Item 9B. Other Information

None.

PART III

Certain information required by Part III is omitted from this Annual Report and is incorporated herein by reference from our Definitive Proxy Statement, relating to our 2021 Annual Meeting of Stockholders to be held on June 3, 2021, pursuant to Regulation 14A of the Exchange Act, or Proxy Statement, which will be filed with the SEC within 120 days of December 31, 2020.

Item 10. Directors, Executive Officers and Corporate Governance

The information required by this Item concerning our directors and executive officers is incorporated by reference to the sections of our Proxy Statement under the headings "Proposal 1 — Election of Directors," "Board Committees and Meetings," "Stockholder Communications with the Board of Directors," "Management" and if applicable, "Delinquent Section 16(a) Reports."

Our written Code of Ethics applies to all of our directors and employees, including our executive officers, including without limitation our principal executive officer, principal financial officer, principal accounting officer or controller or persons performing similar functions. The Code of Ethics is available on our website at www.intersectent.com in the Investors section under "Corporate Governance." Changes to or waivers of the Code of Ethics will be disclosed on the same website. We intend to satisfy the disclosure requirement under Item 5.05 of Form 8-K regarding any amendment to, or waiver of, any provision of the Code of Ethics by disclosing such information on the same website.

Item 11. Executive Compensation

The information required by this Item is incorporated by reference to the sections of the Proxy Statement under the headings "Compensation Discussion and Analysis," "Executive Compensation," "Compensation Committee Interlocks and Insider Participation" and "Compensation of Non-Employee Board Members."

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The information required by this Item is incorporated by reference to the sections of the Proxy Statement under the headings "Security Ownership of Certain Beneficial Owners and Management" and "Securities Authorized for Issuance under Equity Compensation Plans."

Item 13. Certain Relationships and Related Transactions, and Director Independence

The information required by this Item is incorporated by reference to the sections of the Proxy Statement under the headings "Proposal 1 — Election of Directors" and "Certain Relationships and Related Party Transactions."

Item 14. Principal Accountant Fees and Services

The information required by this Item is incorporated by reference to the section of the Proxy Statement under the heading "Principal Accountant Fees and Services."

With the exception of the information specifically incorporated by reference in Part III to this Annual Report from our Proxy Statement, our Proxy Statement shall not be deemed to be filed as part of this report.

PART IV

Item 15. Exhibits and Financial Statement Schedules

(a) The following documents are filed as part of this Annual Report on Form 10-K:

(1) *Financial Statements*

The Financial Statements of the Company are included herein as required under Part II, Item 8, *Financial Statements and Supplementary Data*, of this Annual Report. See Index to Consolidated Financial Statements on page F-l.

(2) *Financial Statement Schedule*

Schedules not listed above have been omitted because information required to be set forth therein is not applicable or is shown in the financial statements or notes thereto.

(3) *Exhibits* (numbered in accordance with Item 601 of Regulation S-K)

See Part IV, Item 15(b) below.

(b) The following exhibits are filed or incorporated by reference into this Annual Report:

		Incorporation By Reference			
Exhibit	Description	Form	SEC File No.	Exhibit	Filing Date
3.1	Amended and Restated Certificate of Incorporation	8-K	001-36545	3.1	7/30/2014
3.2	Certificate of Designation of Preferences, Rights and Limitations of Series DF-1 Convertible Preferred Stock	8-K	001-36545	3.1	5/11/2020
3.3	Certificate of Amendment to Amended and Restated Certificate of Incorporation	8-K	001-36545	3.1	6/15/2020
3.4	Amended and Restated Bylaws	S-1	333-196974	3.4	7/9/2014
4.1	Form of Common Stock Certificate of the Registrant	S-1	333-196974	4.1	7/14/2014
4.2	Description of the Registrant's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934				
4.3	Form of Senior Convertible Note	8-K	001-36545	4.1	5/11/2020
4.4	Reference is made to Exhibits 3.1, 3.2, 3.3, and 3.4				
10.1**	Form of Indemnity Agreement between the Registrant and its directors and officers	S-1	333-196974	10.1	7/9/2014
10.2**	2003 Equity Incentive Plan, as amended, and Form of Stock Option Grant Notice, Option Agreement and Form of Notice of Exercise	S-1	333-196974	10.2	7/14/2014
10.3**	2013 Equity Incentive Plan and Form of Stock Option Grant Notice, Option Agreement and Form of Notice of Exercise	S-1	333-196974	10.3	7/14/2014
10.4**	2014 Equity Incentive Plan and Form of Stock Option Grant Notice, Option Agreement and Form of Notice of Exercise	S-1	333-196974	10.4	7/14/2014
10.5**	Form of Restricted Stock Unit Award Agreement and Restricted Stock Unit Grant Notice under the 2014 Equity Incentive Plan	8-K	001-36545	10.2	1/20/2017
10.6**	2014 Employee Stock Purchase Plan	S-1	333-196974	10.5	7/14/2014
10.7**	Amended and Restated 2014 Employee Stock Purchase Plan, as approved by Stockholders' on June 5, 2018	10-Q	001-36545	10.2	8/3/2018
10.8**	Offer Letter by and between the registrant and David A. Lehman, dated as of February 8, 2016	10-Q	001-36545	10.2	5/9/2016
10.9**	Offer Letter by and between the registrant and Christine R. Kowalski, dated as of October 26, 2018	10-K	001-36545	10.27	2/28/2019
10.10**	Amendment to Offer Letter by and between the registrant and Robert H. Binney, Jr., dated as of January 17, 2019	10-Q	001-36545	10.2	5/7/2019

Exhibit	Description	Incorporation By Reference			
		Form	SEC File No.	Exhibit	Filing Date
10.11**	Offer Letter by and between the registrant and Thomas A. West, dated as of June 24, 2019	10-Q	001-36545	10.1	8/5/2019
10.12**	Offer Letter by and between the registrant and Richard A. Meier, dated as of November 26, 2019	10-K	001-36545	10.25	2/27/2020
10.13**	Amendment to Offer Letter by and between the registrant and David A. Lehman dated as of November 26, 2019	10-K	001-36545	10.26	2/27/2020
10.14**	Offer Letter by and between the registrant and Patrick A. Broderick, dated as of November 12, 2020				
10.15**	Offer Letter by and between the registrant and Reyna M. Fernandez, dated as of November 13, 2020				
10.16**	Amended Non-Employee Director Compensation Policy				
10.17	Fiagon AG Medical Technologies Sale and Purchase Agreement, dated as of October 2, 2020	10-Q	001-36545	10.1	11/2/2020
10.18	Facility Agreement, dated as of May 11, 2020, by and among Intersect ENT, Inc., certain of Intersect ENT, Inc's subsidiaries from time to time party thereto as guarantors and Deerfield Partners, L.P.	8-K	001-36545	10.1	5/11/2020
10.19	Registration Rights Agreement, dated as of May 11, 2020, by and between Intersect ENT, Inc. and Deerfield Partners, L.P.	8-K	001-36545	10.2	5/11/2020
10.20	Lease by and between the registrant and Menlo Business Park, LLC, dated as of March 2, 2012	S-1	333-196974	10.7	6/23/2014
10.21	First Amendment to Lease by and between the registrant and Menlo Prepi I, LLC, dated as of December 17, 2014	8-K	001-36545	10.1	12/18/2014
10.22	Second Amendment to Lease by and between the registrant, Menlo Prepi I, LLC, , and TPI Investors 9, LLC, dated as of December 2, 2019	8-K	001-36545	10.1	12/5/2019
10.23	Third Amendment to Lease by and between the registrant, Menlo Prepi I, LLC, and TPI Investors 9, LLC, dated as of December 22, 2020	8-K	001-36545	10.1	12/23/2020
10.24†	Supply Agreement between the registrant and Hovione Inter AG., dated as of January 20, 2020	10-Q	001-36545	10.1	5/11/2020
10.25†	Supply Agreement by and between the registrant and AIM Plastics Inc., dated as of Supply January 28, 2014	S-1	333-196974	10.17	6/23/2014
10.26†	Amendment No. 1 to Supply Agreement by and between the registrant and AIM Plastics Inc., dated as of February 22, 2016	10-Q	001-36545	10.4	5/9/2016
10.27†	Supply Agreement by and between the registrant and Stephen Gould Corporation, dated as of November 14, 2013	S-1	333-196974	10.18	6/23/2014
10.28†	Amendment No. 1 to Supply Agreement by and between the registrant and Stephen Gould Corporation, dated as of October 7, 2015	10-K	001-36545	10.26	2/25/2016
10.29†	Amendment No. 2 to Supply Agreement by and between the registrant and Stephen Gould Corporation, dated as of August 17, 2016	10-K	001-36545	10.30	2/28/2017
10.30†	Master Services Agreement by and between the registrant and Polymer Solutions Incorporated, dated as of April 1, 2016	10-Q	001-36545	10.5	5/9/2016
10.31†	Analytical Testing Partnership Program 2018-2020 by and between the registrant and Exova Group Limited, dated as of April 26, 2018	10-K	001-36545	10.42	2/28/2019
10.32†	Processing Agreement by and between the registrant and Isomedix Operations Inc., dated as of February 1, 2019	10-Q	001-36545	10.1	5/7/2019

Exhibit	Description	Incorporation By Reference			
		Form	SEC File No.	Exhibit	Filing Date
23.1	Consent of Independent Registered Public Accounting Firm.				
24.1	Power of Attorney (see signature page hereto).				
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
32.1*	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
101.INS	Inline XBRL Instance Document — the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.				
101.SCH	Inline XBRL Taxonomy Extension Schema Document.				
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.				
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.				
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.				
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.				
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).				

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** Management compensatory contract or arrangement.

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

* Exhibit 32.1 is being furnished and shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liability of that section, nor shall such exhibit be deemed to be incorporated by reference in any registration statement or other document filed under the Securities Act of 1933, as amended, or the Exchange Act, except as otherwise specifically stated in such filing.

Item 16. Form 10-K Summary

None.

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.

Intersect ENT, Inc.

Date: March 9, 2021

By: /S/ THOMAS A. WEST

Thomas A. West
President and Chief Executive Officer

Date: March 9, 2021

By: /S/ RICHARD A. MEIER

Richard A. Meier
Chief Financial Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Thomas A. West and Richard A. Meier, jointly and severally, his or her attorneys-in-fact, each with the power of substitution, for him or her in any and all capacities, to sign any amendments to this Annual Report on Form 10-K, and to file the same, with exhibits thereto and other documents in connection therewith with the Securities and Exchange Commission, hereby ratifying and confirming all that each of said attorneys-in-fact, or his substitute or substitutes, may do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Name	Title	Date
/s/ THOMAS A. WEST Thomas A. West	President and Chief Executive Officer (Principal Executive Officer) and Director	March 9, 2021
/s/ RICHARD A. MEIER Richard A. Meier	Chief Financial Officer (Principal Financial and Accounting Officer)	March 9, 2021
/s/ KIERAN T. GALLAHUE Kieran T. Gallahue	Chairman of the Board and Director	March 9, 2021
/s/ TERESA L. KLINE Teresa L. Kline	Director	March 9, 2021
/s/ CYNTHIA L. LUCCHESE Cynthia L. Lucchese	Director	March 9, 2021
/s/ DANA G. MEAD, JR. Dana G. Mead, Jr.	Director	March 9, 2021
/s/ W. ANTHONY VERNON W. Anthony Vernon	Director	March 9, 2021

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INTERSECT ENT, INC.

Index to Consolidated Financial Statements

For the Three Fiscal Years Ended

December 31, 2020

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and the Board of Directors of Intersect ENT, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Intersect ENT, Inc. (the "Company") as of December 31, 2020 and 2019, the related consolidated statements of operations and comprehensive loss, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2020, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2020 and 2019, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2020, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2020, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) and our report dated March 9, 2021 expressed an unqualified opinion thereon.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Business combination

Description of the Matter

During 2020, the Company completed its acquisition of Fiagon AG for total purchase consideration of $68.9 million, as disclosed in Note 6 to the consolidated financial statements. The transaction was accounted for as a business combination.

Auditing the Company's accounting for its acquisition of Fiagon AG was complex due to the significant estimation required by management and involves the use of valuation specialists. The estimation includes the determination of the discount rate to measure the arrangement consideration. The Company used a discounted cash flow model to measure the intangible assets. The significant assumptions used to estimate the value of the intangible assets included discount rates and certain assumptions that form the basis of the forecasted results (e.g., revenue growth rates, operating profit margin and market participant synergies). These significant assumptions are forward looking and could be affected by future economic and market conditions.

How We Addressed the Matter in Our Audit

We tested the Company's controls over its accounting for acquisitions. For example, we tested controls over the recognition and measurement of consideration transferred and intangible assets, including the valuation models and underlying assumptions used to develop such estimates.

To test the fair value of the consideration, we performed audit procedures that included, among others, involving our valuation specialists to assist in evaluating the Company's determination of the appropriate discount rate. To test the estimated fair value of the intangible assets, we performed audit procedures that included, among others, evaluating the Company's use of the income approach and testing the significant assumptions used in the model, including the completeness and accuracy of the underlying data. For example, we compared the significant assumptions to current industry, market and economic trends, to the historical results of the acquired business and to the results of other guideline companies within the same industry. We involved our valuation specialists to assist in our evaluation of the significant assumptions.

Convertible debt

Description of the Matter

During 2020, the Company issued convertible notes that have embedded features which were required to be bifurcated upon issuance and periodically remeasured separately as embedded derivatives. The Company estimated the value of the embedded derivatives to be $1.8 million upon issuance and $3.0 million upon remeasurement as of December 31, 2020. As disclosed in Note 4, of the consolidated financial statements, the Company is required to use assumptions, such as the estimated probability of triggering events, to value the embedded derivatives. Changes in those estimates could result in material changes in the valuation of the embedded features. With the assistance of valuation specialists, the Company estimated the value of the embedded derivatives using a convertible lattice model.

Auditing the measurement of the Company’s embedded derivatives in the convertible debt is complex and involves the use of valuation specialists. Also, auditing the measurement of the embedded derivatives is highly judgmental due to the significant estimation required to determine the assumptions used in the valuation model, including the probability of triggering events.

How We Addressed the Matter in Our Audit

We obtained an understanding and evaluated the design and tested the operating effectiveness of controls over the Company’s use of the convertible lattice model, including the selection of the significant assumptions used in the model.

To test the estimated fair value of the Company’s embedded derivatives, we performed audit procedures that included, among others, engaging valuation specialists to perform a corroborative independent valuation, assessed the selection of significant assumptions and performing a sensitivity analysis based upon a range of assumed triggering event probabilities, to evaluate the changes in the fair value of the embedded derivatives that would result from changes in the assumptions.

/s/ Ernst & Young LLP

We have served as the Company’s auditor since 2008.

San Jose, California
March 9, 2021

INTERSECT ENT, INC.

CONSOLIDATED BALANCE SHEETS
(in thousands, except per share data)

	December 31,	
	2020	2019
Assets		
Current assets:		
Cash and cash equivalents	$ 13,521	$ 20,652
Short-term investments	74,506	69,986
Accounts receivable, net	14,592	19,113
Inventories, net	12,054	17,000
Prepaid expenses and other current assets	3,494	2,300
Total current assets	118,167	129,051
Property and equipment, net	5,624	6,312
Operating lease right-of-use assets	17,151	11,980
Intangible assets, net	21,193	—
Goodwill	46,639	—
Restricted cash	17,500	—
Other non-current assets	1,107	559
Total assets	$ 227,381	$ 147,902
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 6,042	$ 4,056
Accrued compensation	13,559	12,717
Deferred acquisition related consideration, current	21,071	—
Other current liabilities	3,575	2,163
Total current liabilities	44,247	18,936
Operating lease liabilities	17,736	10,886
Convertible notes, net	63,650	—
Deferred acquisition related consideration, non-current	33,167	—
Deferred tax liability	1,569	—
Other non-current liabilities	—	22
Total liabilities	160,369	29,844
Commitments and contingencies (note 11)		
Stockholders' equity:		
Preferred stock, $0.001 par value; Authorized shares: 9,994 at December 31, 2020 and 10,000 at December 31, 2019; Issued and outstanding shares: none	—	—
Series DF-1 convertible preferred stock, $0.001 par value; Authorized shares: 6 at December 31, 2020 and none at December 31, 2019; Issued and outstanding shares: none	—	—
Common stock, $0.001 par value; Authorized shares: 150,000; Issued and outstanding shares: 32,936 at December 31, 2020 and 32,235 at December 31, 2019	33	32
Additional paid-in capital	370,053	348,729
Accumulated other comprehensive income	1	53
Accumulated deficit	(303,075)	(230,756)
Total stockholders' equity	67,012	118,058
Total liabilities and stockholders' equity	$ 227,381	$ 147,902

See Accompanying Notes to Consolidated Financial Statements

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

	Year Ended December 31,		
	2020	2019	2018
Revenue	$ 80,554	$ 109,142	$ 108,472
Cost of sales	30,306	21,773	22,613
Gross profit	50,248	87,369	85,859
Operating expenses:			
Selling, general and administrative	98,550	108,480	91,603
Research and development	19,350	24,283	19,262
Total operating expenses	117,900	132,763	110,865
Loss from operations	(67,652)	(45,394)	(25,006)
Interest expense	(2,752)	—	—
Other income (expense), net	(2,331)	2,400	2,084
Loss before income taxes	(72,735)	(42,994)	(22,922)
Provision for income tax (benefit)	(416)	—	—
Net loss	(72,319)	(42,994)	(22,922)
Other comprehensive income:			
Unrealized (loss) gain on short-term investments, net	(52)	94	51
Comprehensive loss	$ (72,371)	$ (42,900)	$ (22,871)
Net loss per share, basic and diluted	$ (2.22)	$ (1.37)	$ (0.76)
Weighted average common shares used to compute net loss per share, basic and diluted	32,615	31,388	30,313

See Accompanying Notes to Consolidated Financial Statements

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

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2017	29,678	$ 30	$ 282,121	$ (92)	$ (164,840)	$ 117,219
Issuance of common stock and exercise of stock options	1,067	1	12,820	—	—	12,821
Stock-based compensation expense	—	—	13,825	—	—	13,825
Unrealized gain on short-term investments	—	—	—	51	—	51
Net loss	—	—	—	—	(22,922)	(22,922)
Balance at December 31, 2018	30,745	31	308,766	(41)	(187,762)	120,994
Issuance of common stock and exercise of stock options	1,490	1	19,547	—	—	19,548
Stock-based compensation expense	—	—	20,416	—	—	20,416
Unrealized gain on short-term investments	—	—	—	94	—	94
Net loss	—	—	—	—	(42,994)	(42,994)
Balance at December 31, 2019	32,235	32	348,729	53	(230,756)	118,058
Issuance of common stock and exercise of stock options	701	1	6,903	—	—	6,904
Stock-based compensation expense	—	—	14,421	—	—	14,421
Unrealized loss on short-term investments	—	—	—	(52)	—	(52)
Net loss	—	—	—	—	(72,319)	(72,319)
Balance at December 31, 2020	32,936	$ 33	$ 370,053	$ 1	$ (303,075)	$ 67,012

See Accompanying Notes to Consolidated Financial Statements

INTERSECT ENT, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

	Year Ended December 31,		
	2020	**2019**	**2018**
Operating activities:			
Net loss	$ (72,319)	$ (42,994)	$ (22,922)
Adjustments to reconcile net loss to cash used in operating activities:			
Depreciation and amortization	2,841	2,667	1,884
Non-cash lease expense	2,225	1,234	—
Stock-based compensation expense	14,958	20,149	13,233
Amortization of net investment premium (discount)	378	(1,201)	(889)
Amortization of debt transaction costs and accretion of debt discount	561	—	—
Interest expense on deferred acquisition related costs	494	—	—
Gain on foreign currency forward contracts	(833)	—	—
Foreign currency remeasurement	2,233	—	—
Change in fair value of embedded derivatives	1,248	—	—
Deferred income tax expense benefit	(436)	—	—
Changes in operating assets and liabilities:			
Accounts receivable, net	5,001	503	(3,027)
Inventories, net	6,578	(5,148)	(2,520)
Prepaid expenses and other assets	(564)	(14)	(476)
Accounts payable	1,483	(1,236)	2,086
Accrued compensation	498	437	(871)
Other liabilities	(40)	(1,648)	(338)
Net cash used in operating activities	(35,694)	(27,251)	(13,840)
Investing activities:			
Purchases of short-term investments	(139,350)	(110,267)	(130,501)
Maturities of short-term investments	99,606	132,885	122,615
Proceeds from sale of short-term investments	34,794	—	—
Purchases of property and equipment	(873)	(3,727)	(2,116)
Cash paid for acquisition, net	(16,922)	—	—
Net cash provided by (used in) investing activities	(22,745)	18,891	(10,002)
Financing activities:			
Proceeds from debt financing, net of issuance costs	61,841	—	—
Proceeds from issuance of common stock and exercise of stock options	6,903	19,548	13,469
Net cash provided by financing activities	68,744	19,548	13,469
Effect of exchange rate changes on cash, cash equivalents, and restricted cash	64	—	—
Net increase (decrease) in cash, cash equivalents, and restricted cash	10,369	11,188	(10,373)
Cash, cash equivalents, and restricted cash:			
Beginning of the period	20,652	9,464	19,837
End of the period	$ 31,021	$ 20,652	$ 9,464
Supplementary cash flow information of non-cash investing and financing activities:			
Right-of-use asset obtained in exchange for lease obligations	$ —	$ 117	$ —
Right-of-use asset remeasurement related to lease extension	7,129	11,525	—
Lessor funded building improvements	—	152	—
Deferred purchase consideration for a business combination	51,341	—	—
Property and equipment included in accounts payable	34	104	861
Supplementary cash flow information:			
Cash paid for interest on convertible notes	1,033	—	—

See Accompanying Notes to Consolidated Financial Statements

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 devices approved under a Premarket Approval ("PMA") and SINUVA is a drug that was approved under a New Drug Application ("NDA"). 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") and CUBE surgical navigation tools ("CUBE"), that complement the Company's PROPEL and SINUVA sinus implants and extend its geographic reach. 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 VENSURE products received 510(k) clearance in August 2020. In addition, the Company continues to invest in research and development in order to expand its portfolio of products and improve its existing products.

2. Summary of Significant Accounting Policies

Basis of Preparation

The 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 consolidated financial statements include the accounts of the Company and its consolidated subsidiaries. All intercompany balances and transactions have been eliminated upon consolidation.

Reclassifications

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

Risks and Uncertainties

The Company is subject to risks and uncertainties resulting from the COVID-19 pandemic. The Company cannot predict the extent or duration of the impact of the COVID-19 pandemic on its financial and operating results, as the information regarding the current environment is evolving rapidly. Due to the COVID-19 pandemic, the Company's business has been and will continue to be impacted by patients' decisions to undergo sinus surgeries as ENT ASC and office procedure volumes may fluctuate. The Company's operations may be further impacted by COVID-19 due to changes in our 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 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.

Concentration of Credit Risk

Financial instruments, which potentially subject the Company to concentrations of credit risk, consist principally of cash equivalents, short-term investments and accounts receivable. The Company believes that the credit risk in its accounts receivable is mitigated by its credit evaluation process, relatively short collection terms and diversity of its customer base. The Company generally does not require collateral and losses on accounts receivable have historically been within management's expectations.

The Company's investment policy limits investments to certain types of debt securities issued by the U.S. government, its agencies, and institutions with investment-grade credit ratings, as well as corporate debt or commercial paper issued by the highest quality financial and non-financial companies, and places restrictions on maturities and concentration by type and issuer. The Company is exposed to credit risk in the event of a default by the financial institutions holding its cash and cash equivalents and issuers of investments to the extent recorded on the balance sheets. The Company has limited its credit risk associated with cash, cash equivalents and short-term investments by placing its investments with banks it believes are highly creditworthy and with highly rated investments.

Cash, Cash Equivalents, and Restricted Cash

The Company considers all highly liquid securities, readily convertible to cash, that mature within 90 days or less from the date of purchase to be cash equivalents.

In association with the acquisition of Fiagon, the Company placed $17.5 million with an escrow agent with the seller as beneficiary. This balance is presented as restricted cash on the Company's consolidated balance sheets.

The following table summarizes the Company's cash, cash equivalents, and restricted cash at December 31, 2020 and 2019 (in thousands):

	December 31,	
	2020	2019
Cash and cash equivalents	$ 13,521	$ 20,652
Restricted cash	17,500	—
Total cash, cash equivalents, and restricted cash shown in the consolidated statement of cash flows	$ 31,021	$ 20,652

Short-term Investments

Short-term investments, which are classified as available-for-sale, represent highly liquid debt instruments with maturities greater than 90 days at date of purchase. Such investments are recorded at fair value and unrealized holding gains and losses are reported as a separate component of accumulated other comprehensive income (loss) in stockholders' equity until realized. The Company reviews its investment portfolio periodically to assess for other-than-temporary impairment. Should the Company determine that any unrealized losses on the investments are other-than-temporary, the amount of that impairment to be recognized in earnings will depend on whether the Company intends to sell the security or more likely than not will be required to sell the security before recovery of its amortized cost basis less any current period credit loss. Refer to the credit losses accounting policy for further discussion. The specific identification method is used to determine the cost of securities disposed of, with realized gains and losses reflected other income (expense), net in the statement of operations.

Inventories

Inventories are valued at the lower of cost, computed on a first-in, first-out basis, or net realizable value. The allocation of production overhead to inventory costs is based on normal production capacity. Abnormal amounts of facility expense, freight, handling costs, and consumption are expensed as incurred, and not included in allocable overhead. The Company maintains provisions for excess and obsolete inventory based on its estimates of forecasted demand and, where applicable, product expiration.

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 three 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.

Implementation Costs in a Cloud Computing Arrangement

The Company capitalizes qualified implementation costs incurred in a hosting arrangement that is a service contract for which it is the customer in accordance with the requirements for capitalizing costs incurred to develop internal-use software. These capitalized implementation costs are recorded within prepaid and other current assets or other non-current assets, and are generally amortized over the fixed, non-cancellable term of the associated hosting arrangement on a straight-line basis.

Impairment of Long-lived Assets

Long-lived assets consist primarily of property and equipment and are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. If circumstances require that a long-lived asset be tested for possible impairment, the Company compares the undiscounted cash flows expected to be generated and is performed at the lowest level of identifiable cash flows, which is at the individual asset level or at the asset group level. If the carrying amount of the long-lived asset is not recoverable on an undiscounted cash flow basis, an impairment is recognized to the extent that the carrying amount exceeds its fair value. The Company determines fair value using the income approach based on the present value of expected future cash flows or other appropriate measures of estimated fair value. The Company's cash flow assumptions consider historical and forecasted revenue and operating costs and other relevant factors.

Leases

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

Restructuring Activities

During the year ended December 31, 2020, as a response to the COVID-19 pandemic, the Company took pre-emptive actions to curtail spending as its business, revenues, and cash flows have been and are expected to be significantly impacted by the suspension of medical procedures involving its products. These actions included reducing its workforce by 96 employees, or approximately 25% of its workforce. In addition, the Company furloughed 18 employees, or approximately 5% of its workforce, and provided for the cost of certain benefits for those employees while furloughed. The charges related to these actions, including severance benefits for terminated employees and the benefits for furloughed employees, were approximately $0.2 million for the year ended December 31, 2020. The restructuring activities are complete and there are no remaining accrued liabilities related to restructuring activities as of December 31, 2020.

Embedded Derivatives Related to Convertible Debt Instruments

During 2020, the Company issued convertible debt with embedded derivatives that are required to be bifurcated from their host contract and remeasured to fair value at each balance sheet date. Any resulting gain or loss related to the change in the fair value of the embedded derivative is being recorded to other income (expense), net on the consolidated statements of operations. Changes in the Company's assumptions, such as the estimated probability of triggering events and other inputs to the valuation of the embedded derivatives, such as the Company's stock price, could result in material changes in the valuation in future periods.

Business Combinations

Business combinations are accounted for by using the acquisition method of accounting. Under the acquisition method, assets acquired, and liabilities assumed are recorded at their respective fair values as of the acquisition date in the Company's consolidated financial statements. The excess of the fair value of consideration transferred over the fair value of the net assets acquired is recorded as goodwill. Deferred acquisition related consideration incurred in connection with a business combination is recorded at its present value upon the acquisition, with any resulting accretion expense recorded as interest expense in the consolidated statements of operations.

Goodwill and Acquired Intangible Assets

Goodwill is not amortized but are tested for impairment at least annually during the third quarter, or if circumstances indicate their value may no longer be recoverable. Goodwill represents the excess of the purchase price over the fair value of net identifiable assets and liabilities. The Company operates in two segments and has combined them into a single reportable segment as one of them is insignificant and has a majority of economic characteristics that are similar in nature to the other.

Intangible assets acquired in a business combination are recorded at fair value. Identifiable finite-lived intangible assets are amortized over the period of estimated benefit on a straight-line basis, reflecting the pattern of economic benefits associated with these assets. The estimated useful lives of the Company's finite-lived intangible assets generally range from three to ten years.

Revenue Recognition

The Company recognizes revenue when its customer obtains control of promised goods, in an amount that reflects the consideration which the Company expects to receive in exchange for those goods. To determine revenue recognition for arrangements that the Company determines are within the scope of Topic 606, the Company performs the following five steps: (i) identify the contract with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when, or as, the Company satisfies the performance obligations. The Company only applies the five-step model to contracts when it is probable that the Company will collect the consideration it is entitled to in exchange for the goods it transfers to the customer. At contract inception, once the contract is determined to be within the scope of Topic 606, the Company assesses the goods promised within each contract and determines those that are performance obligations and assesses whether each promised good is distinct. The contracts are typically in the form of a purchase order from the customer. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when, or as, the performance obligation is satisfied. The Company's typical payment terms are between approximately 30 to 90 days. The Company expenses shipping and handling costs as incurred and includes them in the cost of sales. In those cases where shipping and handling costs are billed to customers, the Company classifies the amounts billed as a component of revenue. Taxes collected from customers and remitted to governmental authorities are excluded from revenues. The Company expenses any incremental costs of obtaining a contract as and when incurred as the expected amortization period of the incremental costs would have been less than one year.

The PROPEL family of products are regulated by the FDA as medical devices. The Company recognizes revenue through sales of its PROPEL family of products to hospitals and ambulatory surgery centers located almost entirely in the United States when control of the product is transferred to the customer, typically upon shipment of goods to the customer, satisfying the Company's only performance obligation.

The FDA has approved SINUVA as a drug and it is therefore regulated as such. The Company sells SINUVA to a limited number of specialty pharmacies and specialty distributors in the United States, ("Resellers"). These Resellers subsequently sell SINUVA to health care providers. Revenue from SINUVA sales are recognized when control of the product is transferred to the Resellers, typically upon receipt of goods by the Reseller, satisfying the Company's only performance obligation. The

Company recognizes Reseller fees, prompt pay discounts, product sales discounts, rebates, returns and other allowances as an estimated reduction of revenue in the same period the related revenue is recognized. In addition to the agreements with the Resellers, the Company enters into arrangements with governmental agencies that result in rebates, chargebacks and discounts with respect to the purchase of SINUVA. These amounts may include Medicaid and Tricare rebates, chargebacks related to Federal Supply Schedule of the General Services Administration, Distribution and Pricing Agreement with the Department of Defense and 340B of the Public Health Service Act as well as other allowances that may be offered within contracts between the Company and its direct or indirect customers relating to the Company's sales of SINUVA, collectively referred to as "Discounts and Rebates." Discounts and Rebates are based on amounts owed or expected to be owed on the related sales. These estimates take into consideration the Company's historical experience, the remaining shelf life of the product, current contractual and statutory requirements, specific known market events and trends and industry data. If actual results in the future vary from the Company's estimates, the Company will adjust these estimates, which would affect revenue and earnings in the period such variances become known. In the balance sheet, such amounts are generally classified as reductions of accounts receivable if the amount is payable to the Resellers, or a current liability if the amount is payable to a party other than the Reseller.

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 currently consists of manufacturing overhead costs. These overhead costs include the cost of quality assurance, material procurement, inventory control, facilities, information technology, equipment and operations supervision and management. Cost of sales also includes depreciation expense for production equipment, maintenance of operational processes, and certain direct costs such as shipping costs. Costs to enhance operational processes are recorded to selling, general and administrative expense or capitalized if appropriate, as incurred.

Research and Development

Research and development expenses consist primarily of product development, clinical and regulatory affairs, consulting services and other costs associated with products and technologies in development. These expenses include employee compensation, including stock-based compensation, supplies, quality assurance and related travel and allocated facilities and information technology expenses. Clinical expenses include clinical trial design, clinical site reimbursement, data management and travel expenses, and the cost of manufacturing products for clinical trials.

Foreign Currency

The functional currency of the Company's wholly-owned subsidiaries is the U.S. dollar. When the transactional currency is different than the functional currency, transaction gains and losses are included as a component of other income (expense), net. Monetary assets and liabilities denominated in foreign currencies are remeasured at exchange rates in effect at the balance sheet date. Non-monetary assets and liabilities denominated in foreign currencies are measured at rates in effect on the dates the assets were acquired or liabilities were assumed. Revenues and expenses related to monetary items are measured at rates of exchange prevailing on the transaction dates, while expenses relating to non-monetary items are measured at historical rates. Gains and losses on remeasurement are reflected in other income (expense), net when incurred. In November 2020, the Company entered into foreign currency forward contracts as economic hedges to protect against volatility of foreign exchange rate exposure of its deferred acquisition consideration liabilities, which are stated in Euros. The forward contracts are not designated for hedge accounting and are remeasured at fair value with gains or losses reported in other income (expense), net.

Credit Losses

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

Stock-based Compensation

The Company maintains equity incentive plans to provide long-term incentives for employees and members of the board of directors. The plans allow for the issuance of non-statutory and incentive stock options and restricted stock units to employees and non-statutory stock options to consultants and non-employee directors.

The Company is required to determine the fair value of equity incentive awards and recognize compensation expense for all equity incentive awards made to employees and directors, including employee stock options and restricted stock units. Stock-based compensation expense is recognized over the requisite service period in the statements of operations and comprehensive loss. The Company uses the straight-line method for expense attribution and has elected to account for forfeitures when they occur.

The valuation model used for calculating the fair value of awards for stock-based compensation expense, except for market-based awards, is the Black-Scholes option-pricing model (the "Black-Scholes model"). For market-based awards, the Monte Carlo simulation model (the "Monte Carlo simulation") is used. Both the Black-Scholes model and Monte Carlo simulation require the Company to make assumptions and judgments about the variables used in the calculation, including the expected term (weighted average period of time that the awards granted are expected to be outstanding), the volatility of the Company's common stock and an assumed risk-free interest rate. The risk-free rate is based on the U.S. Treasury yield curve in effect at the time of grant for periods corresponding with the expected term of the option.

Advertising Expenses

The Company expenses the costs of advertising, including promotional expenses, as incurred. Advertising expenses were $0.8 million, $1.2 million and $1.0 million during the years ended December 31, 2020, 2019 and 2018, respectively.

Income Taxes

The Company accounts for income taxes under the liability method. Under this method, deferred tax assets and liabilities are determined based on the differences between the financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates that will be in effect when the differences are expected to reverse. Valuation allowances against deferred tax assets are established when necessary to reduce deferred tax assets to the amounts expected to be realized. The Company's policy is to record interest related to uncertain tax positions within interest expense and any penalties within other income (expense), net in the statement of operations.

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):

	Year Ended December 31,		
	2020	2019	2018
Common stock options	3,172	3,209	3,688
Market-based performance stock options	427	427	—
Restricted stock units	488	511	350
Market-based performance stock units	130	89	—
Employee stock purchase plan shares	63	70	74
Stock issuable upon conversion of convertible note	6,309	—	—
	10,589	4,306	4,112

The Company uses the if-converted method for calculating any potential dilutive effects of the convertible note. The Company did not adjust the net loss for the year ended December 31, 2020 to eliminate any interest expense related to the Convertible Notes (see Note 10) 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.

Comprehensive Loss

Comprehensive loss consists of net loss and changes in unrealized gains and losses on short-term investments.

Segment, Geographical and Customer Concentration

The Company operates in two segments and has combined them into a single reportable segment as one of them is insignificant and has a majority of economic characteristics that are similar in nature to the other. The Company's long-lived tangible assets and revenue are predominantly based in the United States. No single customer accounted for more than 10% of revenue during the years ended December 31, 2020, 2019 and 2018, and no single customer accounted for more than 10% of accounts receivable at December 31, 2020 and 2019.

Accounting Pronouncements

Recently Adopted Accounting Standards

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

Effective January 1, 2020, the Company adopted ASU No.2018-15, *Intangibles (Topic 350): Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract,* which aligns the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software. This standard also required customers to amortize the capitalized implementation costs of a hosting arrangement that is a service contract over the term of the hosting arrangement. The adoption of the standard did not result in a material impact to the Company's consolidated financial statements.

Recent Issued Accounting Pronouncements Not Yet Adopted

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

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

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

evaluating the impact of the adoption of ASU 2020-08 on its consolidated financial statements, but does not expect the adoption to have a material impact.

3. Composition of Certain Financial Statement Items

Accounts Receivable, net (in thousands):

	December 31,	
	2020	2019
Accounts receivable	$ 15,079	$ 19,244
Allowance for doubtful accounts	(487)	(131)
	$ 14,592	$ 19,113

The reserve for credit losses on accounts receivable for the years ended December 31, 2020, 2019, and 2018 were as follows (in thousands):

	Year Ended December 31,		
	2020	2019	2018
Beginning	$ 131	$ 80	$ 150
Additions from acquisition	175	—	—
Charges, net of recoveries	221	94	54
Write-offs	(40)	(43)	(124)
Ending	$ 487	$ 131	$ 80

Inventories, net (in thousands):

	December 31,	
	2020	2019
Raw materials	$ 2,865	$ 2,830
Work-in-process	3,411	5,878
Finished goods	5,778	8,292
	$ 12,054	$ 17,000

In 2020, as a result of a shut-down in production associated with shelter-in-place orders by state authorities and the Company's decision to extend the suspension of production for an additional period of time, production volume was less than normal and the Company recorded associated expense of $6.1 million. Due to a decline in projected product sales, the Company also increased its reserve for excess and obsolete inventory by $0.8 million during the year ended December 31, 2020. Inventory reserves were $1.5 million and $1.7 million at December 31, 2020 and 2019, respectively.

Capitalized stock-based compensation expense of $0.3 million and $0.9 million was included in inventory as of December 31, 2020 and 2019, respectively.

Property and Equipment, net (in thousands):

	December 31,	
	2020	2019
Computer equipment and software	$ 2,159	$ 2,026
Furniture and office equipment	1,611	1,536
Laboratory and manufacturing equipment	8,939	7,972
Leasehold improvements	3,385	3,367
	16,094	14,901
Less: accumulated depreciation and amortization	(10,470)	(8,589)
	$ 5,624	$ 6,312

Disaggregation of Revenues

The following table disaggregates our product sales by product (in thousands):

	Year Ended December 31,		
	2020	2019	2018
PROPEL family of products	$ 74,335	$ 104,657	$ 105,711
SINUVA	5,315	4,485	2,761
VENSURE, CUBE, and accessories	904	—	—
	$ 80,554	$ 109,142	$ 108,472

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.

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 method for the embedded features. As of December 31, 2020, the fair value of the Company's Convertible Notes (see Note 10) was $107.6 million.

Cash, Cash Equivalents and Short-term Investments

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

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

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

There were no transfers in and out of Level 1 and Level 2 during the years ended December 31, 2020, 2019, and 2018.

As of December 31, 2020 and 2019, the Company had no investments with a contractual maturity of greater than one year.

Based on an evaluation of securities that have been in a loss position, the Company did not recognize any other-than-temporary impairment charges during the years ended December 31, 2020, 2019 and 2018. The Company considered various factors which included a credit and liquidity assessment of the underlying securities and the Company's intent and ability to hold the underlying securities until the estimated date of recovery of its amortized cost. The Company concluded that any unrealized losses on investments as of December 31, 2020 were not attributed to credit.

Convertible Notes Embedded Derivatives

The Convertible Notes due in 2025 (see Note 10) have embedded features which were required to be bifurcated upon issuance and then periodically remeasured separately as embedded derivatives. These embedded features include additional make-whole interest payments which may become payable to the lender upon certain events, such as a change in control, upon optional redemption by the Company, or a sale of all or substantially all of the Company's assets. The embedded features also include additional shares depending on the time to maturity and the stock price which may be added to an early conversion upon certain events. The Company has utilized a convertible lattice model to determine the fair value of the embedded features, which utilizes inputs including the common stock price, probability of certain triggering events, volatility of common stock,

credit rating, and time to maturity. The fair value measurements of the embedded derivatives are classified as Level 3 financial instruments. At December 31, 2020, the fair value of the embedded features was $3.0 million and has been presented together with the Convertible Notes host instrument on the consolidated balance sheets. Changes in the fair value of the Company's Level 3 liabilities were as follows (in thousands):

	December 31, 2020
Balance at December 31, 2019	$ —
Additions	1,800
Fair value adjustment	1,248
Balance at December 31, 2020	$ 3,048

5. Derivative Financial Instruments

The Company's deferred purchase consideration related to the Fiagon acquisition (see Note 6) 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.

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

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

	December 31, 2020
Notional amounts:	
Forward contracts	$ 55,025
Gross fair value recorded in:	
Prepaid expenses and other current assets	$ 275
Other non-current assets	$ 558

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

	Year Ended December 31, 2020
Recognized gains	$ 833
Foreign exchange losses related to balance sheet remeasurement	$ (2,388)

6. 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 estimated €2.2 million purchase price adjustment

due in October 2021. The total purchase consideration is denominated in Euro with an equivalent value of $68.9 million included an upfront cash payment of $17.6 million, and deferred payments of $51.3 million. An additional $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 second installment due in October 2021.

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 which are being amortized over a weighted-average period of 9.1 years. 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. The estimated fair value of assets acquired and liabilities assumed are provisional and are based on the information that was available as of the acquisition date. Measurement period adjustments could reflect new information pertaining to the purchase price consideration, deferred tax impacts and goodwill. Purchase price consideration is pending final agreement regarding the purchase price adjustment to be included in the installment payment due in October 2021. Deferred taxes are pending the results of a tax examination of pre-acquisition periods and preparation of 2020 foreign tax returns by the acquired companies.

In 2020, the Company has included the results of the acquired business, since its acquisition date, in its consolidated financial statements. For the year ended December 31, 2020, Fiagon contributed $0.9 million in revenue and $2.3 million in net loss. At the date of acquisition, the total amount of deferred consideration was recorded at its present value. At the end of each reporting period, accretion of the liability is recorded to interest expense in the consolidated statements of operations. For the year ended December 31, 2020, $0.5 million of interest expense was recorded. As of December 31, 2020, the present value of the deferred acquisition consideration was $54.2 million. The liability is discounted at a market participant's borrowing rate for debt instruments with similar maturities, security, and other characteristics. Total costs recognized with the transaction to date are $3.4 million of acquisition costs and $0.6 million of integration costs, which have been recognized in selling, general and administrative expense in the consolidated statements of operations.

The following unaudited pro forma condensed combined financial information gives effect to the acquisition of Fiagon as if it was consummated on January 1, 2019 (the beginning of the comparable reporting period), and includes pro forma adjustments including interest expense, cost of sales, foreign exchange and imputed interest impacts of the deferred consideration, amortization of intangibles, and direct and incremental transaction costs reflected in the historical financial statements. Specifically, the following adjustments were made:

- For the year ended December 31, 2020, the Company increased interest expense by $0.8 million, increased other expense from foreign currency remeasurement by $1.5 million, and reduced selling, general and administrative expenses by $0.6 million.

- For the year ended December 31, 2019, the Company increased cost of sales by $0.6 million, increased selling, general and administrative expenses by $6.5 million, including $4.0 million related to non-recurring

acquisition and integration costs, increased interest expense by $1.9 million, and increased other income by $1.2 million from foreign currency remeasurement.

	Year Ended December 31,	
	2020	2019
	(Unaudited, in thousands)	
Revenue	$ 82,797	$ 120,998
Net loss	(77,504)	(50,707)
Net loss per share, basic and diluted	(2.38)	(1.62)

Pro forma financial information is not necessarily indicative of the Company's actual results of operations if the acquisition had been completed at the date indicated, nor is it necessarily an indication of future operating results.

Goodwill

The Company completed a goodwill impairment assessment and determined that no indicators of impairment existed. As of December 31, 2020, there has been no impairment of goodwill.

Acquired Intangible Assets

The following table summarizes the components of gross intangible asset, accumulated amortization, and net intangible asset balances as of December 31, 2020 (in thousands):

	December 31, 2020		
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Developed technology	$ 19,100	$ (478)	$ 18,622
Distribution network	1,100	(92)	1,008
Customer relationships	1,500	(125)	1,375
Trademarks	200	(12)	188
Total intangible assets	$ 21,900	$ (707)	$ 21,193

Amortization expense related to intangible assets was $0.7 million for the year ended December 31, 2020.

The estimated future amortization expense related to intangible assets as of December 31, 2020 is as follows (in thousands):

	December 31, 2020
2021	$ 2,827
2022	2,827
2023	2,609
2024	1,948
2025	1,910
Thereafter	9,072
Total	$ 21,193

Actual amounts of amortization expense may differ from estimated amounts due to additional intangible asset acquisitions, impairment of intangible assets, accelerated amortization of intangible assets, and other events.

7. Leases

As of December 31, 2020, the Company has four leased facilities under operating lease agreements. Rent expense was $4.3 million, $2.4 million and $2.1 million during the years ended December 31, 2020, 2019 and 2018, respectively.

In December 2020, the Company entered into a third amendment (the "Third Amendment") to the lease of its headquarters to extend the lease expiration from September 1, 2024 to December 31, 2027. The extension of this operating lease increased the right of use asset by $7.1 million. The lease agreement requires the Company to pay executory costs such as real estate taxes, insurance and repairs.

Operating lease liabilities (in thousands):

	December 31,	
	2020	2019
Current portion presented in other current liabilities	$ 762	$ 1,336
Non-current portion presented in operating lease liabilities	17,736	10,886
	$ 18,498	$ 12,222

Cash paid for amounts included in the measurement of lease liabilities for the year ended December 31, 2020 was $2.2 million and was included in net cash used in operating activities in the consolidated statements of cash flows.

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

Years Ending December 31,	December 31, 2020
2021	$ 3,996
2022	3,984
2023	4,088
2024	4,126
2025	4,058
Thereafter	8,547
Total minimum payments	28,799
Less: present value adjustment	(7,782)
Less: tenant improvement allowance	(2,519)
Total	$ 18,498

	December 31,	
	2020	2019
Weighted-average remaining lease term (years)	6.8	4.7
Weighted-average discount rate	9.5 %	8.2 %

8. 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 Convertible Preferred Stock"). Each share of Series DF-1 Convertible 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 Convertible Preferred Stock. The Series DF-1 Convertible Preferred Stock does not have voting rights but is eligible for dividends or distributions on an as-converted basis.

2014 Equity Incentive Plan

In July 2014, the Company's board of directors approved the 2014 Equity Incentive Plan (the "2014 Plan"). Under the 2014 Plan, the Company may grant stock options, stock appreciation rights, restricted stock, restricted stock units and certain

other awards to individuals who are employees, officers, directors or consultants of the Company. A total of 4,750,000 shares of common stock were initially reserved for issuance under 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. The maximum number of shares that may be issued upon the exercise of incentive stock options ("ISOs") under the 2014 Plan is 10.0 million. ISOs and non-statutory stock options ("NSOs") may be granted with exercise prices at no less than 100% of the fair value of the common stock on the date of grant. ISOs granted under the 2014 Plan generally vest 25% after the completion of twelve months of service and the balance vests in equal monthly installments over the next 36 months of service and expire 10 years from the grant date. New shares are issued upon exercise of options under the stock plan. On January 1, 2020, the total number of shares of common stock reserved for issuance increased by 967,064 shares to 9,934,768 shares. As of December 31, 2020, 3,177,912 shares remained available for issuance. In January 2017, the Company began issuing restricted stock units ("RSUs") under the 2014 Plan. The RSUs generally vest annually over three years.

A summary of the Company's stock option activity, including market-based performance stock options and related information is as follows (in thousands, except price data):

	Year Ended December 31, 2020	
	Options	Weighted Average Exercise Price
Outstanding, beginning of period	3,636	$ 23.71
Granted	1,295	20.45
Exercised	(341)	16.23
Forfeited	(991)	28.17
Outstanding, end of period	3,599	22.01
Exercisable	1,682	22.46

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

The aggregate intrinsic value of options outstanding was $12.1 million and options outstanding and exercisable was $6.2 million, as calculated based on the closing price of the Company's common stock at the end of the period, the weighted-average remaining contractual term of options outstanding was 7.8 years and options outstanding and exercisable was 6.5 years. The aggregate intrinsic value of options exercised was $2.0 million, $11.4 million and $17.5 million during the years ended December 31, 2020, 2019 and 2018, respectively.

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

	Year Ended December 31, 2020	
	RSUs	Weighted Average Fair Value
Outstanding, beginning of period	511	$ 25.62
Awarded	353	23.44
Vested	(223)	24.03
Forfeited	(153)	28.43
Outstanding, end of period	488	23.88

As of December 31, 2020, the aggregate intrinsic value of RSUs outstanding was $11.2 million, calculated based on the closing price of the Company's common stock at the end of the period, and the weighted-average remaining vesting term of RSUs outstanding was 1.9 years.

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

	Year Ended December 31, 2020	
	PSUs	Weighted Average Fair Value
Outstanding, beginning of period	89	$ 14.22
Awarded	103	17.28
Forfeited	(62)	15.70
Outstanding, end of period	130	15.94

In February 2020, the Company granted 102,685 PSUs. The shares subject to the PSUs will vest on the third anniversary from the date of grant provided that certain 30-day trailing average stock price targets ($37, $46 and $55, respectively) are achieved at any time during the three-year period following the date of grant. Upon the end of the three-year period following the date of grant, any remaining unvested shares will be cancelled. The grant date fair value of the PSUs was $1.8 million, as estimated with the Monte Carlo simulation model, using the following assumptions: expected volatility of 46.7%; expected risk-free interest rate of 1.3%, and expected dividend yield of zero percent. The fair value of this award is expected to be recognized on a straight-line basis over the three-year service period from the date of grant.

As of December 31, 2020, the aggregate intrinsic value of PSUs outstanding was $3.0 million, calculated based on the closing price of the Company's common stock at the end of the period, and the weighted-average remaining vesting term of PSUs outstanding was 2.0 years.

2014 Employee Stock Purchase Plan

In July 2014, the Company's board of directors approved the 2014 Employee Stock Purchase Plan ("2014 ESPP"). The 2014 ESPP became effective on the effective date of the IPO. A total of 496,092 shares were initially reserved for issuance under the 2014 ESPP. 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"). The Company issued 0.1 million shares during December 31, 2020 and 0.2 million shares in each of the years ended December 31, 2019 and 2018.

9. Stock-Based Compensation Expense

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

	Year Ended December 31,		
	2020	2019	2018
Cost of sales	$ 1,805	$ 1,273	$ 703
Selling, general and administrative	11,493	15,709	10,063
Research and development	1,660	3,167	2,467
	$ 14,958	$ 20,149	$ 13,233

As of December 31, 2020, the total compensation expense related to unvested stock option, RSU, and PSU grants under the Company's 2014 plan not yet recognized was $27.4 million. This expense will be amortized on a straight-line basis over a weighted average period of 2.5 years and will be adjusted for subsequent forfeitures.

The Company estimates the fair value of stock-based compensation on the date of grant using the Black-Scholes option-pricing model. The Black-Scholes model determines the fair value of stock-based payment awards based on the fair market value of the Company's common stock on the date of grant and is affected by assumptions regarding a number of highly complex and subjective variables. These variables include, but are not limited to, the fair market value of the Company's common stock, volatility over the expected term of the awards and actual and projected employee stock option exercise behaviors. The Company has opted to use the "simplified method" for estimating the expected term of options, whereby the expected term equals the arithmetic average of the vesting term and the original contractual term of the option. Due to the Company's limited trading history and a lack of company specific historical and implied volatility data, the Company bases its

estimate of expected volatility by including the historical volatility of a group of similar companies that are publicly traded along with the Company's volatility. When selecting these public companies on which it has included in its expected stock price volatility, the Company generally selected companies with comparable characteristics to it, including enterprise value, stages of clinical development, risk profiles, position within the industry and with historical share price information sufficient to meet the expected life of the stock-based awards. The historical volatility data was computed using the daily closing prices for the included companies' shares during the equivalent period of the calculated expected term of the share-based payments. The Company will continue to analyze the historical stock price volatility and expected term assumptions as more historical data for the Company's common stock becomes available. The risk-free rate assumption is based on the U.S. Treasury instruments with maturities similar to the expected term of the Company's stock options. The expected dividend assumption is based on the Company's history of not paying dividends and its expectation that it will not declare dividends for the foreseeable future.

The fair value of options granted to employees or directors during the periods presented below were estimated as of the grant date using the Black-Scholes model assuming the weighted average assumptions listed in the following table:

	Year Ended December 31,		
	2020	2019	2018
Expected term (years)	6.0	6.0	6.0
Expected volatility	58.0 %	48.0 %	45.0 %
Risk-free interest rate	0.9 %	2.2 %	2.7 %
Dividend yield	0.0 %	0.0 %	0.0 %
Fair value	$ 10.87	$ 11.74	$ 15.82

The fair value of stock purchase rights granted under the 2014 ESPP to employees was estimated as of the grant date using the Black-Scholes model assuming the weighted average assumptions listed in the following table:

	Year Ended December 31,		
	2020	2019	2018
Expected term (years)	0.5	0.5	0.5
Expected volatility	82.0 %	49.0 %	49.0 %
Risk-free interest rate	0.1 %	2.0 %	2.5 %
Dividend yield	0.0 %	0.0 %	0.0 %
Fair value	$ 5.67	$ 6.71	$ 9.29

10. Convertible Notes

On May 11, 2020, in order to finance the Company's commercial activities as well as for general corporate purposes, the Company entered into a Facility Agreement (the "Facility Agreement") by and among the Company, as borrower, and Deerfield Partners, L.P. ("Deerfield"), as agent for itself and the lenders, providing for the issuance and sale by the Company to Deerfield of $65.0 million of principal amount of 4.0% unsecured senior convertible notes (the "Convertible Notes") upon the terms and conditions set forth in the Facility Agreement (the "Deerfield Financing"). The $65.0 million principal amount of the Convertible Notes is not payable until the maturity date of May 9, 2025, unless earlier converted or redeemed. The Convertible Notes are convertible into shares of the Company's common stock, at a conversion rate of 64.3501 shares per $1,000 principal amount of Convertible Notes, which represents an initial conversion price of $15.54. The net proceeds from the sale of the Convertible Notes were approximately $61.8 million after deducting the expenses payable by the Company.

The Convertible Notes bear interest at 4.0% per annum, payable quarterly in arrears on July 1, October 1, January 1 and April 1 of each year, commencing July 1, 2020. The Convertible Notes are convertible at any time at the option of the holders thereof, provided that Deerfield is prohibited from converting the Convertible Notes into shares of common stock if, as a result of such conversion, the converting holder (together with certain affiliates and "group" members) would beneficially own more than 4.985% of the total number of shares of common stock then issued and outstanding (the "Beneficial Ownership Cap"). Pursuant to the Convertible Notes, the holders of the Convertible Notes have the option to demand repayment of all outstanding principal, any unpaid interest accrued thereon, and make-whole interest in connection with a Major Transaction (as defined in the Convertible Notes), which shall include, among others, any acquisition or other change of control of the Company; the sale

or transfer of assets of the Company equal to more than 50% of the Enterprise Value (as defined in the Convertible Notes) of the Company; a liquidation, bankruptcy or other dissolution of the Company; or if at any time shares of the Company's common stock are not listed on an Eligible Market (as defined in the Convertible Notes). The Facility Agreement contains certain specified events of default, the occurrence of which would entitle the holders of the Convertible Notes to immediately demand repayment of all outstanding principal and accrued interest on the Convertible Notes, together with a make-whole payment as determined pursuant to the Facility Agreement. Such events of default include, among others, failure to make any payment under the Convertible Notes when due, failure to observe or perform any covenant under the Facility Agreement or the other transaction documents related thereto (subject in certain cases to specified cure periods), the failure of the Company to be able to pay debts as they come due, the commencement of bankruptcy or insolvency proceedings against the Company, a material judgment levied against the Company and a material default by the Company under other indebtedness.

On or after the date that is the second anniversary of the issuance date, the Company may redeem up to $32.5 million of the principal amount of Convertible Notes if:

- the volume weighted average price of the common stock on each of any twenty (20) trading days during a period of thirty (30) consecutive trading days ending on the date which an optional redemption notice is delivered;
- the volume weighted average price of the common stock on the last trading day of such period; and
- the closing price of the common stock on the last trading day of such period, in each case, are greater than 150% of the conversion price.

On or after the date that is the third anniversary of the issuance date, the Company may redeem up to the entire $65.0 million original principal amount of Convertible Notes if:

- the volume weighted average price of the common stock on each of any twenty (20) trading days during a period of thirty (30) consecutive trading days ending on the date which an optional redemption notice is delivered;
- the volume weighted average price of the common stock on the last trading day of such period; and
- the closing price of the common stock on the last trading day of such period, in each case, are greater than 200% of the conversion price.

The Company is obligated to notify the holders of the Convertible Notes no less than ten trading days nor more than sixty calendar days prior to any such redemption. During the period from the date on which the Company delivers an optional redemption notice until the date the optional redemption price is paid to holders, if a holder elects to convert its Convertible Notes, it will receive the shares otherwise issuable upon conversion of the Convertible Notes, plus an additional number of shares determined in accordance with the Convertible Notes. To the extent the holder would be prohibited due to the Beneficial Ownership Cap to convert its Convertible Notes during such period, such holder would be entitled to convert all or any portion of its Convertible Notes into shares of Series DF-1 Convertible Preferred Stock of the Company (such conversion, a "Preferred Stock Conversion"). The number of Series DF-1 Convertible 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 8 for discussion on the rights and privileges of Series DF-1 Convertible 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. The Company's management engaged a specialist to assist with the valuation. 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 December 31, 2020, the net carrying amount of the convertible notes is as follows (in thousands):

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

The convertible debt discount and transaction costs are being amortized to expense over the term of the Notes. For the year ended December 31, 2020, the accretion of the convertible debt discount and amortization of debt issuance costs was $0.6 million and was included in interest expense in the consolidated statements of operations. The accrued interest on the outstanding principal of $65.0 million as of December 31, 2020 was $0.7 million and was included in other current liabilities on the consolidated balance sheets.

11. Commitments and Contingencies

Contingencies

In the normal course of business, the Company enters into contracts and agreements that contain a variety of representations and warranties and provide for general indemnifications. The Company's exposure under these agreements is unknown because it involves claims that may be made against the Company in the future, but have not yet been made. The Company accrues a liability for such matters when it is probable that future expenditures will be made, and such amounts can be reasonably estimated.

Indemnification

The Company's amended and restated certificate of incorporation contains provisions limiting the liability of directors, and its amended and restated bylaws provide that the Company will indemnify each of its directors to the fullest extent permitted under Delaware law. The Company's amended and restated certificate of incorporation and amended and restated bylaws also provide its board of directors with discretion to indemnify its officers and employees when determined appropriate by the board. In addition, the Company has entered and expects to continue to enter into agreements to indemnify its directors and executive officers.

Litigation

The Company may at times be involved in litigation and other legal claims in the ordinary course of business. When appropriate in the Company's estimation, it may record reserves in its financial statements for pending litigation and other claims.

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's motion for preliminary approval of the proposed settlement is due on May 5, 2021. As of this filing, the Court has not yet set a date for the preliminary approval hearing. As of December 31, 2020, the Company has accrued anticipated settlement costs associated with this lawsuit of $0.3 million which is recorded in other current liabilities on the consolidated balance sheets.

Purchase Commitments

As of December 31, 2020, the Company had non-cancellable commitments to suppliers for purchases totaling $5.8 million.

12. Employee Retirement Plan

In January 2007, the Company established a qualified retirement plan under section 401(k) of the Internal Revenue Code ("IRC") under which participants may contribute up to 100% of their eligible compensation, subject to maximum deferral limits specified by the IRC. The Company may make a discretionary profit sharing contribution to each eligible employee, subject to limits specified by the IRC, on an annual basis, provided the employee is employed with the Company on the last day of the plan year which is December 31. In addition, the Company may also make matching contributions of an employee's eligible compensation. The Company's contributions will vest 25% per year over four years. Total matching contributions were $1.0 million, $1.1 million and $0.7 million during the years ended December 31, 2020, 2019 and 2018, respectively.

13. Income Taxes

The following table presents domestic and foreign components of loss before income taxes for the periods presented (in thousands):

	Year Ended December 31,		
	2020	2019	2018
Domestic	$ (70,801)	$ (42,994)	$ (22,922)
Foreign	(1,934)	—	—
	$ (72,735)	$ (42,994)	$ (22,922)

The provision for income taxes is composed of the following (in thousands):

	Year Ended December 31,		
	2020	2019	2018
Current:			
Federal	$ —	$ —	$ —
State	—	—	—
Foreign	20	—	—
Total current	20	—	—
Deferred:			
Federal	—	—	—
State	—	—	—
Foreign	(436)	—	—
Total deferred	(436)	—	—
Total provision for income tax benefit	$ (416)	$ —	$ —

The amount computed by applying the federal statutory rate to loss before income taxes reconciles to the provision for income taxes is as follows (in thousands):

	Year Ended December 31,		
	2020	2019	2018
Tax at federal statutory rate	$ (15,274)	$ (9,029)	$ (4,814)
State tax, net of federal benefit	(2,881)	(1,977)	(1,935)
Effect of foreign operations	(10)	—	—
Permanent items	234	299	406
Stock-based compensation	2,079	190	(2,219)
R&D tax credit	(282)	(782)	(893)
Change in valuation allowance	15,718	11,299	9,455
	$ (416)	$ —	$ —

Significant components of net deferred tax liabilities are as follows (in thousands):

	December 31,	
	2020	2019
Deferred tax assets:		
Net operating losses	$ 73,711	$ 54,722
R&D tax credit	9,538	8,944
Accruals and other	8,671	8,064
Operating lease liabilities	4,695	3,049
	96,615	74,779
Deferred tax liabilities:		
Depreciation and amortization	(6,257)	(5)
Operating lease right-of-use assets	(4,356)	(2,988)
	(10,613)	(2,993)
Gross deferred tax assets:	86,002	71,786
Valuation allowance	(87,571)	(71,786)
Net deferred tax liability	$ (1,569)	$ —

Deferred income taxes reflect the tax effects of NOLs and tax credit carryforwards and the net temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. In connection with the acquisition of Fiagon on October 2, 2020, a net deferred tax liability of $2.2 million was established, the most significant component of which is related to the book to tax basis differences associated with the acquired developed technology and customer relationships, as well as acquired net operating loss carry forwards. The amortization of the intangible assets also contributed to the deferred tax benefit recorded in the foreign jurisdictions in the current year.

Realization of the deferred tax assets is dependent upon the generation of future taxable income, if any, the amount and timing of which are uncertain. Based on available objective evidence, management believes it is more likely than not that the deferred tax assets are not recognizable and will not be recognizable until the Company has sufficient taxable income. Accordingly, the domestic net deferred tax assets have been fully offset by a valuation allowance. The valuation allowance increased by $15.8 million and $11.3 million during the years ended December 31, 2020 and 2019, respectively.

As of December 31, 2020, the Company's federal NOL carryforwards were $270.9 million, of which $148.4 million will begin to expire in 2026, and $122.5 million have an indefinite carryforward period. Federal research and development tax credits of $6.9 million will begin to expire in 2026. In addition, NOL carryforwards for state income tax purposes of $66.8 million will begin to expire in 2028 and state research and development tax credits of $6.4 million do not expire. Fiagon also had foreign net operating loss carryforwards of $16.0 million in Germany, which may be carried forward indefinitely.

Utilization of the NOL carryforwards may be subject to an annual limitation due to the ownership change limitations provided by the Internal Revenue Code of 1986 and similar state provisions. The annual limitation may result in the expiration of the NOL before utilization.

The Company had unrecognized tax benefits of $2.7 million and $2.5 million as of December 31, 2020 and 2019, respectively, associated with domestic taxes. Due to the Company's full valuation allowance against all domestic net deferred tax assets, the Company's unrecognized tax benefits, if recognized, would not affect the effective tax rate.

A reconciliation of the change in the unrecognized tax benefit during the year is as follows (in thousands):

	December 31,		
	2020	2019	2018
Beginning of year	$ 2,485	$ 2,107	$ 1,660
Additions for tax positions related to:			
Current year	169	378	332
Prior years	—	—	115
End of year	$ 2,654	$ 2,485	$ 2,107

The Company does not expect a significant change to its unrecognized tax benefits over the next twelve months. The unrecognized tax benefit may increase or decrease during the next twelve months for items that arise in the ordinary course of business.

The Company files income tax returns in the U.S. federal and various state jurisdictions. Tax years beginning in 2004 through 2020 remain open to examination by the major taxing authorities to which the Company is subject to. In the Company's foreign jurisdiction, Germany, the tax years subsequent to 2014 remain open to examination. The Company's policy is to record interest related to uncertain tax positions as interest expense and any penalties within other income (expense) in its statements of operations. The Company has not recorded any interest expense or penalties associated with unrecognized tax benefits.

14. Subsequent Event

In February 2021, the Company extended the lease of its facility in Austin, Texas by 36 months through January 31, 2024. The total amount of future rent payments under the amendment is $0.2 million.

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SENIOR LEADERSHIP

Thomas A. West
President and Chief Executive Officer

Richard A. Meier
Executive Vice President and Chief Financial Officer

Reyna M. Fernandez
Chief Human Resources Officer

Christine R. Kowalski
Executive Vice President and Chief Operating Officer

Patrick A. Broderick
Executive Vice President, General Counsel and Corporate Secretary

BOARD OF DIRECTORS

Kieran T. Gallahue (Chairman of the Board)
Former Chairman and Chief Executive Officer
CareFusion Corporation

Thomas A. West
President and Chief Executive Officer
Intersect ENT, Inc.

Teresa L. Kline
Former Executive Vice President
Henry Ford Health System
Former President and Chief Executive Officer
Health Alliance Plan

Cynthia L. Lucchese
Chief Strategy Officer
Penske Entertainment Corp.

Dana G. Mead, Jr.
Former President and Chief Executive Officer
HeartFlow, Inc.

Neil A. Hattangadi, M.D.
Co-Founder and Chief Executive Officer
Coritca Inc.

Elisabeth Sandoval-Little
Consultant - Biotech and Pharmaceuticals

ANNUAL MEETING OF STOCKHOLDERS

Held at 9:00 a.m. PDT on June 3, 2021
Online at
virtualshareholdermeeting.com/XENT2021

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INVESTOR INFORMATION

Exchange: The NASDAQ Global Market
Symbol: XENT

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The statements in this Annual Report relating to future events or results are forward-looking statements that involve many risks and uncertainties. Our actual results could differ materially from those contained in these forward-looking statements due to a number of factors. These and other risk factors that may cause actual results to differ are discussed in Part I, Item 1A — "Risk Factors" included in the Form 10-K which is part of this Annual Report.

intersect® ENT
TOTAL COMMITMENT

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