2019 ANNUAL REPORT

Dexcom

The Dexcom G6 Continuous Glucose Monitoring (CGM) System. Smart devices sold separately.

TO OUR STAKEHOLDERS

At Dexcom, our mission of empowering people to take control of diabetes drives everything we do. This mission extends to all members of the diabetes community. Through our Continuous Glucose Monitoring (CGM) systems, we give patients the real-time information they need to manage their blood glucose and improve outcomes.[1] We allow clinicians to adapt and optimize diabetes therapies for their patients based on clear, precise data. And we bring renewed peace of mind to friends and family, who can stay in step with their loved one's glucose levels. Included in this letter are a few stories of those whose lives have been impacted by our CGM systems, and those working to further our mission.

Building on the 2018 approval and launch of the game-changing Dexcom G6 Continuous Glucose Monitoring system, we continued to gain momentum in 2019.

Through the hard work of our teams and the growing awareness of the benefits of Dexcom CGM technology, we delivered yet another year of significant achievements:

BRIAN LUCIDO

Dexcom Warrior since December 2017

As an avid cyclist and traveler, Dexcom allowed Brian to train and compete in a 2,800 mile mountain bike race in 2017, cycling for two straight weeks. He went on to take first place as the only person with diabetes out of 200 riders and continues biking across the U.S. today. "The key to success is a positive attitude. What you have to be is a person who keeps going and doesn't quit."

- Our revenue growth exceeded 40% for the second consecutive year.
- New patient additions continued to grow significantly. Our estimates indicate approximately 650,000 customers worldwide were actively benefitting from our real-time CGM at the close of 2019.
- The three-year follow-up to the COMISAIR study showed that real-time CGM helped patients increase the amount of time in range (TIR) by an average of nearly five hours per day, independent of insulin delivery method.[2]
- We received approval for the Dexcom G6 Pro CGM System, the first and only single use, professional CGM that gathers real-time glucose data over a 10-day period and offers both a blinded and unblinded mode.

We are thrilled by the progress toward our corporate mission reflected in these achievements, and hopeful for the opportunities ahead.

[1]Beck, RW, et al. JAMA. 2017;317(4):371-378; Welsh, JB et al. Diabetes Technol Ther. 2019;21(3).

[2]Šoupal J, Petruželková J, Grunberger G, et al. Glycemic Outcomes in Adults with T1D Are Impacted More by Continuous Glucose Monitoring Than by Insulin Delivery Method: 3 Years of Follow-Up from The COMISAIR Study. Diabetes Care 2019 Sep; dc190888.

ACCESS AND AWARENESS DRIVES GLOBAL GROWTH AND PROFITABILITY

In 2019, we sharpened our focus on extending access opportunities and increasing global awareness of the benefits of Dexcom CGM technology. This focus drove U.S. revenue growth of 42% and international revenue growth of 48%, as well as our first full year of GAAP profitability.

We began 2019 with an ambitious goal. Given the large numbers of people standing to benefit from Dexcom CGM, we set out to double manufacturing capacity of G6 over the course of the year. Thanks to the innovative work of our teams, we met this goal and better positioned the company for sustainable growth in 2020 and beyond.

We also made great progress with our long-term strategic initiatives. We significantly expanded pharmacy access for our patients in the U.S., increasing the total number of people with access through this channel by more than 50% as compared to 2018. In conjunction with our emphasis on device interoperability, we advanced further toward connected devices with our insulin delivery partners. These efforts included the FDA approval of the first automated insulin delivery system to incorporate both our Dexcom G6 CGM system and our algorithm technology.

As new patient growth continues to accelerate, we plan to continue our capacity expansion efforts in 2020 as we seek to extend our growth momentum. The rollout of G6 to the Medicare population is ongoing, and we plan to introduce or expand the launch of G6 in certain international markets in which we are aiming to broaden access. At the same time, we continue to invest heavily in our next-generation, fully disposable G7 CGM system. With a significant form factor reduction, we believe that G7 has the potential to positively impact the lives of our customers.

STRONG FINANCIAL PERFORMANCE

Our strong financial performance in 2019 represents years of hard work from the Dexcom team to develop industry-leading technology that addresses the needs of the diabetes community. The company's $1.476 billion in revenue in 2019 reflects more than $440 million of dollar growth over 2018, and 43% growth in total. We also achieved a significant milestone by concluding our first-full year of GAAP profitability, with net income totaling $101 million. These results include ongoing investments that we believe position the company for even greater growth and profitability as we push for increased access and expanded use of Dexcom CGM in additional populations.

2019 FINANCIAL HIGHLIGHTS

- Revenue grew 43% versus the prior year to $1.476 billion
- We achieved our first full year of GAAP profitability and significant improvement to operating margin
- U.S. revenue grew 42% and international revenue grew 48%
- We maintained our balance sheet flexibility, ending 2019 with greater than $1.5 billion in cash and cash equivalents

BROADENING OUR HORIZONS AND ENHANCING CUSTOMER EXPERIENCE

We are investing to maximize Dexcom's long-term growth profile and to ensure that our customer support teams are sufficient to serve our growing patient base. The following reflect two key initiatives that we developed in 2019:

New Markets team explores additional opportunities for Dexcom CGM

In May 2019, we announced the formation of the New Markets team within the Dexcom organization. Clearly, the problem of uncontrolled glucose levels is not limited to people with Type 1 diabetes and Type 2 diabetes on intensive insulin therapy. We believe that Dexcom CGM technology can offer tangible benefits to the broader Type 2 population, those with prediabetes, pregnant women and their babies, and patients in the hospital setting. Our New Markets team is actively pursuing these broader market opportunities in order to extend Dexcom's growth trajectory and maximize the global health benefits from our sensor technology. We have begun to see compelling early data and look forward to updating you as these initiatives progress in the future.

Global business services operation scaled to enhance customer support

Given the recent growth of the business as well as our belief in the long-term potential of Dexcom's sensor technology, we recognize the importance of customer experience to the success of our business. Over the course of 2019, we built an extensive global business services team to enhance our ability to serve our growing patient base. The business services team drove improvement to several of our core customer service metrics during 2019 and, we believe, will be a key asset for the company in 2020 and beyond.

PRESSING FORWARD

It's hard to believe that we're only 18 months removed from the launch of G6. Since then, we experienced significant revenue and profitability growth; made great progress in key initiatives related to customer access, strategic partnerships and manufacturing operations; and invested in Dexcom's future. Our excitement for the future is unwavering.

Even with strong new patient growth in 2019, we are convinced that there remains significant runway ahead of us in our core markets. Simply put, a majority of people around the world on intensive insulin therapy continue to rely on fingersticks to monitor blood sugar. With this in mind, our focus is clear: we must continue to drive access and awareness in our current markets and extend the benefits of our technology to additional geographies and customer populations.

Of course, the growth that we have experienced since the launch of G6 does not come without its challenges. I'm deeply grateful to our employees for once again working relentlessly to meet these challenges head-on to deliver for patients, families and healthcare providers. I would like to thank the Dexcom team for their continued commitment to everyone we serve.

I would also like to thank you, our shareholders, for your ongoing support. Together we are bringing our mission to life by empowering people around the world to take control of diabetes. I look forward to updating you on our continued progress.

Kevin Sayer
Chairman, President and Chief Executive Officer

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-K

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

For the fiscal year ended December 31, 2019

☐ **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 000-51222

DEXCOM, INC.
(Exact name of Registrant as specified in its charter)

Delaware	**33-0857544**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification No.)**

6340 Sequence Drive, San Diego, CA 92121
(Address of Principal Executive Offices, including area code)

(858) 200-0200
(Registrant's Telephone Number, including area code)

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

Title of Each Class	Trading Symbol(s)	Name of Each Exchange on Which Registered
Common Stock, $0.001 Par Value Per Share	**DXCM**	**The Nasdaq Stock Market LLC (Nasdaq Global Select Market)**

Securities registered pursuant to Section 12(g) of the Exchange 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 15(d) of the Exchange 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 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 is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of June 28, 2019, the last business day of the Registrant's most recently completed second fiscal quarter, the aggregate market value of the registrant's common stock held by non-affiliates of the registrant was approximately $13,556.6 million based on the closing sales price of $149.84 per share as reported on the Nasdaq Global Select Market.

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date.

Class	Outstanding at February 7, 2020
Common stock, $0.001 par value per share	91,594,142

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's definitive proxy statement relating to its 2020 Annual Meeting of Stockholders (the Proxy Statement) are incorporated by reference in Part III, Items 10 through 14 of this Annual Report on Form 10-K, as specified in the responses to those item numbers. Except with respect to information specifically incorporated by reference in the Form 10-K, the Proxy Statement is not deemed to be filed as part hereof.

DexCom, Inc.
Table of Contents

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

Except for historical financial information contained herein, the matters discussed in this Form 10-K may be considered forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, and subject to the safe harbor created by the Securities Litigation Reform Act of 1995. Such statements include declarations regarding our intent, belief, or current expectations and those of our management. Prospective investors are cautioned that any such forward-looking statements are not guarantees of future performance and involve a number of risks, uncertainties and other factors, some of which are beyond our control; actual results could differ materially from those indicated by such forward-looking statements. Important factors that could cause actual results to differ materially from those indicated by such forward-looking statements include, but are not limited to: (i) that the information is of a preliminary nature and may be subject to further adjustment; (ii) those risks and uncertainties identified under "Risk Factors"; and (iii) the other risks detailed from time-to-time in our reports and registration statements filed with the Securities and Exchange Commission, or SEC. Except as required by law, we undertake no obligation to revise or update publicly any forward-looking statements, whether as a result of new information, future events or otherwise.

PART I

Item 1 - BUSINESS

Overview

We are a medical device company primarily focused on the design, development and commercialization of continuous glucose monitoring, or CGM, systems for use by people with diabetes and by healthcare providers. We received approval from the United States (U.S.) Food and Drug Administration, or FDA, and commercialized our first product in 2006. We launched our latest generation system, the DexCom G6® integrated Continuous Glucose Monitoring System, or G6, in 2018. Unless the context requires otherwise, the terms "we," "us," "our," the "company," or "DexCom" refer to DexCom, Inc. and its subsidiaries.

Products

DexCom G6®

In March 2018, we obtained marketing authorization from the FDA for the G6 via the *de novo* process. The G6 is the first type of CGM system permitted by the FDA to be used as part of an integrated system with other compatible medical devices and electronic interfaces, which may include automated insulin dosing systems, insulin pumps, blood glucose meters or other electronic devices used for diabetes management. G6 and substantially equivalent devices of this generic type that may later receive marketing authorization are referred to as integrated continuous glucose monitoring systems, or iCGMs, and have been classified as Class II devices by the FDA. Along with this classification, the FDA established criteria, called special controls, which outline requirements for assuring CGM accuracy, reliability and clinical relevance, and which also describe the type of studies and data required to demonstrate acceptable CGM performance. The G6 is designed to allow our transmitter to run an algorithm to generate a glucose value and to communicate directly to a patient's compatible mobile device, including iPhone®, iPod touch®, iPad®, and certain Android® mobile devices. A patient's glucose data can also be displayed on wearable devices, like the Apple Watch® and Wear OS by Google devices. The G6 transmitter has a labeled useful life of three months. Data from the G6 can be integrated with DexCom CLARITY®, our cloud-based reporting software, for personalized, easy-to-understand analysis of trends that may improve diabetes management. In the United States, the G6 is covered by Medicare as well as those commercial insurers that reimburse for the DexCom G5 Mobile Continuous Glucose Monitoring System, subject to satisfaction of certain eligibility and coverage criteria.

In June 2018, we received Conformité Européenne Marking, or CE Mark, approval for the G6, which allows us to market the system in the European Union and the countries in Asia and Latin America that recognize the CE Mark, as well as New Zealand, though certain countries may require compliance with certain local administrative requirements and/or additional marketing authorizations (for example, the inclusion of medical devices on the Australian Register of Therapeutic Goods in Australia).

In October 2019, we also received marketing authorization from the FDA for the DexCom G6 Pro, or G6 Pro, which allows healthcare professionals to purchase the G6 for use with their patients. The G6 Pro has many of same features as the G6 and is intended for healthcare professionals to use with their patients ages two years and up. The G6 Pro may be used in a blinded or unblinded mode for up to 10 days.

For the G6, the sensor is inserted by the user and is intended to be used continuously for up to 10 days, after which it may be replaced with a new disposable sensor. Our transmitter is reusable until it reaches the end of its use life. Our receiver is also reusable. As we establish an installed base of customers using our products, we expect to generate an increasing portion of our revenues through recurring sales of our disposable sensors.

The G6 carries forward important features of prior generation DexCom CGM systems:

- **Continuous glucose readings.** Automatically sends glucose readings to a DexCom receiver or compatible mobile device every five minutes.
- **Mobile app and sharing.** Compatibility with mobile device applications allows for sharing glucose information with other people for added support and care coordination.
- **Customizable alarms and alerts.** Personalized alert schedule immediately warns the user of pending dangerous high and low blood sugars.

The G6 also has a number of new or improved features compared to our prior generation devices:

- **Finger stick elimination.** No finger sticks are needed for calibration or diabetes treatment decisions, consistent with the instructions for use.
- **Easy sensor application.** Complete redesign of the sensor applicator allows for one-touch, simple self-insertion.
- **Discreet and low profile.** A redesigned transmitter with a 28% lower profile than the previous generation DexCom CGM system makes the device comfortable and easy to wear under clothing.
- **Medication blocking.** New feature allows for more accurate glucose readings without interference from common medications taken at typical indication doses, such as acetaminophen.
- **Predictive low alert.** New alert feature intended to predict hypoglycemia before it hits to help avoid dangerous low blood sugar events.
- **Extended 10-day sensor.** Up to 10-day sensor use allows for 43% longer wear than previous generation DexCom CGM systems.

Other than with respect to the foregoing, the G6 is equivalent to our prior generation CGM systems in its technical capabilities and its indications. Since the G6 is classified by the FDA as a Class II device, it is subject to special controls and modifications of, or revisions to, the device may be made under the 510(k) process.

DexCom G5® Mobile

In August 2015, we received approval from the FDA for the DexCom G5 Mobile Continuous Glucose Monitoring System, also referred to as the G5 Mobile. The G5 Mobile is designed to allow our transmitter to run the Software 505 algorithm, and to communicate directly to a patient's compatible mobile device, including iPhone, iPod touch, iPad, and certain Android mobile devices. The G5 Mobile transmitter has a labeled useful life of three months. Data from the G5 Mobile can be integrated with DexCom CLARITY. In September 2015, we launched the G5 Mobile in certain countries in Europe.

Similar to the G6, the disposable sensor is inserted by the user and is intended to be used continuously for up to seven days, after which it may be replaced with a new sensor. The related transmitter is reusable until it reaches the end of its use life, and the related receiver is also reusable. In December 2016, the FDA approved the G5 Mobile as the first CGM system in the United States to have a non-adjunctive indication. The non-adjunctive indication expands the lawfully permitted use of the G5 Mobile as a replacement to finger stick glucose testing for diabetes treatment decisions. With the new label indication, the G5 Mobile only requires two finger sticks per day for calibration. In the countries and regions outside of the United States that recognize the CE Mark, as well as the United States and Canada, the G5 Mobile also does not require confirmatory finger sticks when making treatment decisions, although a minimum of two finger sticks a day remain necessary for calibration. Approval of the non-adjunctive indication was also an important and necessary step in enabling people with Medicare to access CGM.

Except with respect to the foregoing, the G5 Mobile is functionally equivalent to our earlier generation CGM systems in its technical capabilities and its regulatory requirements and indications.

DexCom G4® PLATINUM

The DexCom G4 PLATINUM CGM system, or G4 PLATINUM, replaced our DexCom SEVEN PLUS system beginning in 2012, when it was approved for up to seven days of continuous use by adults with diabetes. Since 2012, we have marketed the G4 PLATINUM under a CE Mark in the European Union, the countries in Asia and Latin America that recognize the CE Mark, New Zealand and Australia, and in the United States with approval from the FDA. We received approvals for a pediatric indication under the CE Mark in February 2013 and from the FDA in February 2014, enabling us to market and sell this system to persons two years old and older who have diabetes. In June 2014, we received approval from the FDA for an expanded indication for the G4 PLATINUM for professional use, which allows healthcare professionals to purchase the G4 PLATINUM system for use with multiple patients. Healthcare professionals can use the insights gained from a G4 PLATINUM professional

session to adjust therapy and to educate and motivate patients to modify their behavior after viewing the effects that specific foods, exercise, stress and medications have on their glucose levels. In October 2014, we launched our Software 505 algorithm for the G4 PLATINUM, an algorithm which enabled our systems to achieve a single digit MARD, a measure of the accuracy of continuous glucose monitoring.

DexCom Share®

In 2015, we received approval from the FDA for the G4 PLATINUM with DexCom Share, or Share, and began commercializing this product in the United States in the first quarter of 2015 using a secure wireless connection between a patient's G4 PLATINUM receiver and an app. We now offer this feature through the G6 and the G5 Mobile apps as well as the Share2 app, which works with the G4 PLATINUM receiver with Share. The Share remote monitoring system uses an app on the patient's iPhone, iPod touch, iPad or Android mobile device to transmit glucose information to the cloud and then to apps on the mobile devices of up to five designated recipients, or "followers," who can remotely monitor a patient's glucose information and receive alert notifications anywhere they have an Internet or cellular connection. A patient's glucose data can also be displayed on a patient's or follower's wearable device, such as the Apple Watch and Wear OS by Google devices, when used in conjunction with the patient's or follower's iPhone or Android mobile device.

Data and Insulin Delivery Collaborations

We have entered into multiple collaboration agreements that leverage our technology platform to integrate our CGM products with insulin delivery systems. The general purpose of these development and commercial relationships is to integrate our technology into the insulin pump or pen product offerings of the respective partner, enabling the partner's insulin delivery device to receive and display glucose readings from our transmitter and, in some cases, use the glucose readings for semi-automated insulin delivery. Currently, we have announced significant insulin delivery partnerships with Eli Lilly, Insulet, Novo Nordisk and Tandem Diabetes. In addition to these major partners, we are working with other companies that are pursuing varying strategies surrounding semi-automated insulin delivery and data analytics to improve outcomes and ease-of-use in diabetes management.

Verily Collaboration

On November 20, 2018, we entered into an Amended and Restated Collaboration and License Agreement with Verily Life Sciences LLC (an Alphabet Company) and Verily Ireland Limited (collectively, Verily), which we refer to as the Restated Collaboration Agreement. This replaced our original Collaboration and License Agreement with Verily from August 2015, as amended in October 2016, and eliminated any future royalty obligations under the original agreement. Pursuant to the Restated Collaboration Agreement, we and Verily have agreed to continue to jointly develop a certain next-generation CGM product, and potentially one or more additional CGM products, for which we will have exclusive commercialization rights.

The Restated Collaboration Agreement also provides us with an exclusive license to use intellectual property of Verily resulting from the collaboration, and certain Verily patents, in the development, manufacture and commercialization of blood-based or interstitial glucose monitoring products more generally (subject to certain exclusions, which are outside the CGM field as it is commonly understood). It also provides us with non-exclusive license rights under Verily's other intellectual property rights to develop, manufacture, and commercialize those kinds of glucose monitoring products and certain CGM-product companion software functionalities. The Restated Collaboration Agreement requires us to use commercially reasonable efforts to develop, launch, and commercialize the CGM product(s) that are the subject of the collaboration according to certain timing and other objectives, and provides for one executive sponsor from each of us and Verily to meet periodically and make decisions related to the collaboration (within a limited scope of authority) by consensus.

In consideration of Verily's performance of its obligations under the joint development plan of the Restated Collaboration Agreement, the licenses granted to us and the amendment of the original agreement, we have made upfront and incentive payments, and will make potential future milestone payments upon the achievement of certain goals, as follows:

- On December 28, 2018, we made an initial payment of $250.0 million in shares of our common stock, calculated under the Restated Collaboration Agreement to be 1,840,943 shares of our common stock, allocated between Verily and Onduo, LLC, subject to certain transfer restrictions.
- During 2019, we paid $3.2 million for the completion of certain development obligations before the agreed-upon deadline.
- Additional milestone payments of up to $275.0 million may become due and payable by us upon the achievement of future product regulatory approval and revenue milestones. At our election, we may make these milestone payments in shares of our common stock, also allocated between Verily and Onduo, LLC, with the number of shares being calculated based on the same share value that was used for purposes of the initial payment, adjusted for stock splits, dividends, and the like, subject to customary closing conditions, including any required antitrust approvals applicable to the issuance of such shares. Alternatively, at our election, we may make any of these milestone payments in cash. Any such cash

payment would be equal to the number of shares that would otherwise be issued for the given milestone payment (calculated as described above) multiplied by the value of our stock on the date the relevant milestone is achieved, adjusted for stock splits, dividends, and the like.

Future Products

We plan to develop future generations of technologies focused on improved performance and convenience and that will enable intelligent insulin administration. We are also exploring how to extend our offerings to other opportunities, including for people with Type 2 diabetes that are non-insulin using, people with pre-diabetes, people who are obese, people who are pregnant, and people in the hospital setting. We will continue to develop a networked platform with open architecture, connectivity and transmitters capable of communicating with other devices and software systems. We also intend to expand our efforts to accumulate CGM patient data and metrics and apply predictive modeling and machine learning to generate interactive CGM insights that can inform patient behavior.

Background

Diabetes is a disease with significant adverse consequences for human health throughout the world. The International Diabetes Federation, or IDF, estimates that in 2019, 463 million adults (aged 20-79) around the world had diabetes, including 31 million in the United States. IDF estimates that by 2045, the worldwide incidence of people suffering from diabetes will reach 700 million. According to the Centers for Disease Control and Prevention's National Vital Statistics Reports for 2017, diabetes was the seventh leading cause of death by disease in the United States, excluding comorbidities associated with the disease. According to the Congressional Diabetes Caucus website, diabetes is the leading cause of kidney failure, adult-onset blindness, lower-limb amputations, and a significant cause of heart disease, stroke, high blood pressure and nerve damage. According to the IDF, there were an estimated 4.2 million deaths attributable to diabetes globally in 2019 between the ages of 20 and 79 years. The American Diabetes Association, or ADA, Fast Facts, revised in August 2017, states that diabetes is the primary cause of death for more than 80,000 Americans each year, and contributes to the death of more than 250,000 Americans annually.

Among people of all ages, 2017 data indicated the following: An estimated 24.7 million people or 7.6% of the U.S. population had been diagnosed with diabetes. In addition to those newly diagnosed, the Congressional Diabetes Caucus website reports that every 24 hours there are: 238 amputations in people with diabetes, 120 people who enter end-stage kidney disease programs, and 48 people who go blind.

According to the ADA, one in every four healthcare dollars was spent on treating people with diabetes in 2017, and the direct medical costs and indirect expenditures attributable to diabetes in the United States were an estimated $327 billion, an inflation-adjusted increase of approximately 26% since 2012. Of the $327 billion in overall expenses, the ADA estimated that approximately $237 billion were direct costs associated with diabetes care, chronic complications and excess general medical costs, and $90 billion were indirect costs. The ADA also found that in 2017, average medical expenditures among people with diagnosed diabetes were 2.3 times higher than for people without diabetes. According to the IDF, 2017 expenditures attributable to diabetes were estimated to be $760 billion globally. The IDF estimates that expenditures attributable to diabetes will grow to $845 billion globally by 2045.

Continuous Glucose Monitoring

We believe continuous glucose monitoring has the potential to enable more people with diabetes to achieve and sustain tight glycemic control with minimal disruption to their daily lives.

The landmark 1993 Diabetes Control and Complications Trial, or DCCT, demonstrated that improving blood glucose control lowers the risk of developing diabetes-related complications by up to 50%. The study also demonstrated that people with Type 1 diabetes achieved sustained benefits with intensive management. However, according to an article published in *The New England Journal of Medicine* in November 2014, in two national registries, only 13% to 15% of people with diabetes met treatment guidelines for good glycemic control, and more than 20% had very poor glycemic control.

Various clinical studies and real world evidence also demonstrate the benefits of continuous glucose monitoring in the management of Type 1 diabetes and insulin-requiring Type-2 diabetes, when compared to regimens relying on self-monitoring of blood glucose. Results of several early clinical trials established that CGM usage was associated with improved glycemic outcomes. For instance, a Juvenile Diabetes Research Foundation, or JDRF, study published in the *New England Journal of Medicine* in 2008, and the extension phase of the study, published in *Diabetes Care* in 2009, demonstrated that continuous glucose monitoring improved A1c levels and reduced incidence of hypoglycemia for patients over the age of 25 and for all patients of all ages who utilized continuous glucose monitoring regularly. In 2016, the first randomized, controlled study focusing solely on the benefit of continuous glucose monitoring for diabetes patients using multiple daily injections insulin therapy showed DexCom CGM system users on multiple daily injections of insulin therapy achieved a one percent average A1c reduction after 24 weeks of regular use, compared to their baseline. Study participants also increased time spent in their target

A1c range and spent less time in hypoglycemia and hyperglycemia when they used a DexCom CGM system compared to those who used only a standard blood glucose meter to monitor their glucose. This DIaMonD (Multiple Daily Injections and Continuous Glucose Monitoring in Diabetes) study is the first-of-its-kind in demonstrating the impact of CGM only, without insulin pumps or other therapeutic interventions, on A1c and hypoglycemia in participants using a multiple daily injection insulin regimen.

Real-time alerts and multi-device integration further differentiate CGM-based and self-monitoring of blood glucose, or SMBG, based diabetes regimens. Alerts triggered by existing or impending abnormal glucose values are associated with less exposure to hypo- and hyperglycemia in large real-world data sets, and multi-device integration allows some CGM systems to communicate with automated insulin delivery systems. One such automated insulin delivery system that uses the G6 was studied in a large clinical trial that associated its use with numerous quality-of-life and glycemic benefits.

In late 2019, the ADA, in its Standards of Medical Care in Diabetes, recognized CGM as a useful tool in diabetes management, citing level "A" evidence in Type 1 diabetes and level "B" evidence in Type 2 diabetes and pregnancy. The ADA recommends continued access and use "as close to daily as possible" for maximal benefit. We believe Dexcom's CGM technology contributes to better glycemic outcomes and improved quality of life by allowing informed diabetes treatment decisions.

A 2019 white paper from IQVIA also outlines the potential benefit offered by use of CGM systems, suggesting that increasing time-in-range to industry standards for Type 1 and Type 2 insulin-using patients would result in significant cost savings to the economic system and the prevention of major complications.

Our current target market consists primarily of people with Type 1 and Type 2 diabetes who utilize insulin pump therapy or who utilize multiple daily insulin injections. We continue to target people with Type 2 diabetes on multiple daily injection therapy and expect to expand our target market to include all people with diabetes, people with pre-diabetes, people who are obese, people who are pregnant, and people with diabetes in the hospital setting. Although the majority of our revenue has been generated in the United States, we have expanded our operations to include certain countries in Africa, Asia, Europe, Latin America, and the Middle East, as well as Australia, Canada, and New Zealand.

Commercial Operations

We have built a direct sales organization in the United States, Canada and certain countries in Europe to call on healthcare professionals, including endocrinologists, physicians and diabetes educators, who can educate and influence patient adoption of continuous glucose monitoring. We believe that focusing efforts on these participants is important given the instrumental role they each play in the decision-making process for diabetes therapy. To complement our direct sales efforts, we have entered into distribution arrangements in the United States and internationally that allow distributors to sell our products. We believe our direct, highly specialized and focused sales organization and our domestic and international distribution agreements are sufficient for us to support our sales efforts for at least the next twelve months.

Product revenues are generated from the sale of our CGM systems through a direct sales force in the United States, Austria, Canada, Germany, Switzerland and the United Kingdom as well as through distribution arrangements in the United States, Australia and New Zealand, and certain countries in Africa, Asia, Europe, Latin America, and the Middle East.

Market Opportunity

Diabetes

Diabetes is a chronic, life-threatening disease for which there is no known cure. The disease is caused by the body's inability to produce or effectively utilize the hormone insulin. This inability prevents the body from adequately regulating blood glucose levels. Glucose, the primary source of energy for cells, must be maintained at certain concentrations in the blood in order to permit optimal cell function and health. Normally, the pancreas provides control of blood glucose levels by secreting the hormone insulin to decrease blood glucose levels when concentrations are too high. In people with diabetes, the body does not produce sufficient levels of insulin, or fails to utilize insulin effectively, causing blood glucose levels to rise above normal. This condition is called hyperglycemia and often results in acute complications as well as chronic long-term complications such as heart disease, limb amputations, loss of kidney function and blindness. When blood glucose levels are high, people with diabetes often administer insulin in an effort to decrease blood glucose levels. Unfortunately, insulin administration can drive blood glucose levels below the normal range, resulting in hypoglycemia. In cases of severe hypoglycemia, people with diabetes risk acute complications, such as loss of consciousness or death. Due to the drastic nature of acute complications associated with hypoglycemia, many people with diabetes are reluctant to reduce blood glucose levels. Consequently, these individuals often remain in a hyperglycemic state, increasing their odds of developing long-term chronic complications. Diabetes is typically classified into two major groups: Type 1 and Type 2.

Type 1 Diabetes

According to the ADA, as of 2017 there were an estimated 1.3 million people with Type 1 diabetes in the United States. Type 1 diabetes is an autoimmune disorder that usually develops during childhood and is characterized by an absence of insulin, resulting from destruction of the insulin producing cells of the pancreas. Individuals with Type 1 diabetes must rely on frequent insulin injections in order to regulate and maintain blood glucose levels.

According to JDRF, 40,000 people are diagnosed with Type 1 diabetes each year in the United States and between the years 2001 and 2009 there was a 21% increase in the prevalence of Type 1 diabetes in people under the age of 20. In addition, according to the ADA in 2019, nearly 18,000 youth are newly diagnosed with Type 1 diabetes every year in the United States.

Type 2 Diabetes

According to the ADA, in 2012 there were approximately 27.8 million people in the United States with Type 2 diabetes. Type 2 diabetes is a metabolic disorder which results when the body is unable to produce sufficient amounts of insulin or becomes insulin resistant. Depending on the severity of Type 2 diabetes, individuals may require diet and nutrition management, exercise, oral medications or insulin injections to regulate blood glucose levels. We estimate that approximately 6.0 million Type 2 patients must use insulin to manage their diabetes.

Type 2 diabetes is occurring with increasing frequency in young people, with the increase in prevalence related to an increase in obesity amongst children. According to the Centers for Disease Control and Prevention, as of 2016, approximately 18.5% of children and adolescents aged 2-19 years, or 13.7 million children, in the United States were obese. Childhood obesity has more than doubled in children and quadrupled in adolescents in the past 30 years.

Diabetes and Glucose Management in the Hospital Setting

There are various subgroups of people with diabetes, including in-hospital patients, who present significant management challenges. According to the ADA, diabetes-related inpatient hospitalizations totaled 40.3 million days and 22.2 million outpatient visits in 2017, with outpatient visits increasing 48% since 2012. Additionally, market research shows that over 1.6 million patients are admitted with hyperglycemia prior to elective surgery, which results in delays and increased length of stay. Once admitted, studies conducted by *Hospital Health Network* in 2013 and AACE in 2011 suggest that approximately 28% of patients experience hyperglycemia and 5% of patients experience hypoglycemia, both of which are preventable. After discharge, patients who experienced hyperglycemia or hypoglycemia in the hospital have a higher rate of readmission within 30 days. Approximately 30% of all health care expenditures incurred by people with diabetes come from higher rates of hospital admission and longer average lengths of stay per admission, constituting the single largest contributor to the medical cost of diabetes. Of the $486 billion in national expenditures for hospital inpatient care in 2017, approximately $123 billion is incurred by people who have diabetes, of which $70 billion is directly attributed to their diabetes.

Importance of Glucose Monitoring

Blood glucose levels can be affected by many factors, including the carbohydrate and fat content of meals, exercise, stress, illness or impending illness, hormonal releases, variability in insulin absorption and changes in the effects of insulin in the body. Given the many factors that affect blood glucose levels, maintaining glucose within a normal range is difficult, resulting in frequent and unpredictable excursions above or below normal blood glucose levels. People with diabetes administer insulin or ingest carbohydrates throughout the day in order to maintain blood glucose levels within normal ranges. People with diabetes frequently overcorrect and fluctuate between hyperglycemic and hypoglycemic states, often multiple times during the same day. As a result, many people with diabetes are routinely outside the normal blood glucose range.

In an attempt to maintain blood glucose levels within the normal range, people with diabetes must first measure their blood glucose levels. Often, after measuring their blood glucose levels, people with diabetes make therapeutic adjustments. As adjustments are made, additional blood glucose measurements may be necessary to gauge the individual's response to the adjustments. More frequent testing of blood glucose levels provides people with diabetes with information that can be used to better understand and manage their diabetes. The ADA recommends that most people with Type 1 diabetes test their blood glucose levels at least three or more times per day, and that significantly more frequent testing may be required to reach A1c targets safely without hypoglycemia.

Clinical outcomes data support the notion that an important component of effective diabetes management is frequent monitoring of blood glucose levels. The landmark 1993 DCCT consisting of patients with Type 1 diabetes, and the 1998 UK Prospective Diabetes Study, consisting of patients with Type 2 diabetes, demonstrated that people with diabetes who intensively managed their blood glucose levels delayed the onset and slowed the progression of diabetes-related complications. The DCCT demonstrated that intensive management reduced the risk of complications by 76% for eye disease, 60% for nerve disease and 50% for kidney disease, but also found that it led to a three-fold increase in the frequency of hypoglycemic events. In the December 2005 edition of the *New England Journal of Medicine*, the authors of a peer-reviewed study concluded that intensive diabetes therapy has long-term beneficial effects on the risk of cardiovascular disease in patients with Type 1 diabetes. The

study showed that intensive diabetes therapy reduced the risk of cardiovascular disease by 42% and the risk of non-fatal heart attack, stroke or death from cardiovascular disease by 57%.

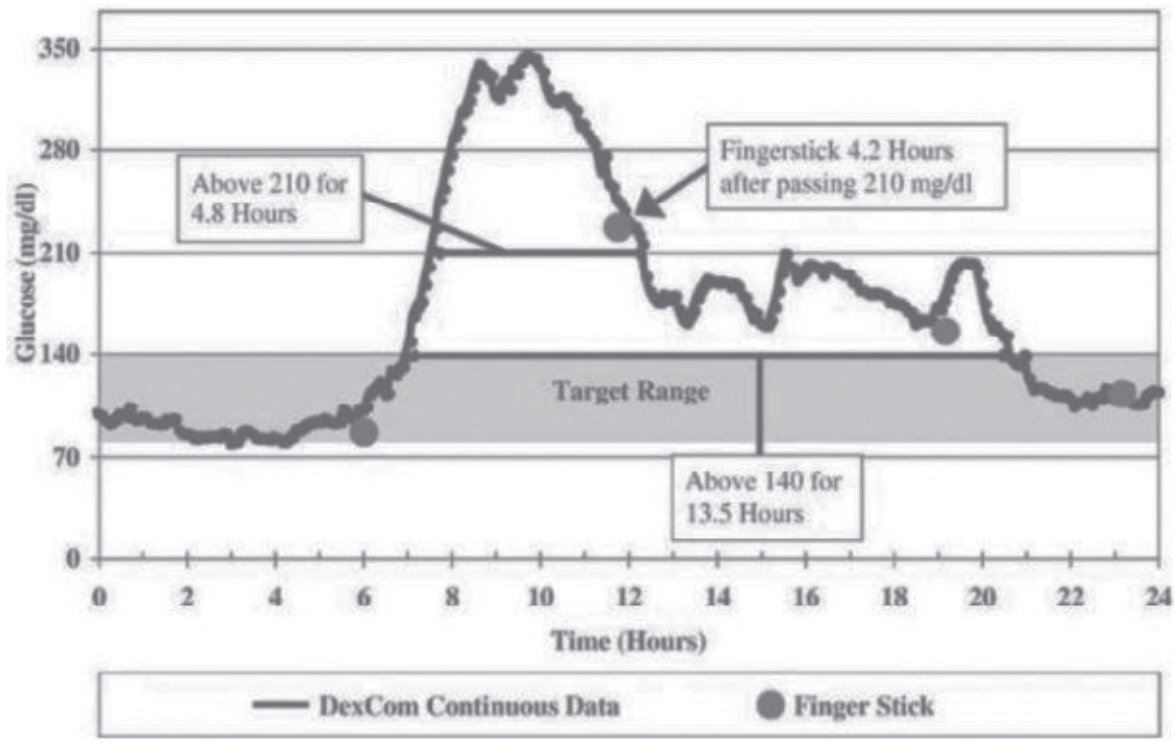
Limitations of Existing Glucose Monitoring Products

Single-point finger stick devices are the most prevalent devices for glucose monitoring. These devices require taking a blood sample with a finger stick, placing a drop of blood on a test strip and inserting the strip into a glucose meter that yields a single point in time blood glucose measurement. We believe that these devices suffer from several limitations, including:

- **Limited Information.** Even if people with diabetes test several times each day, each measurement represents a single blood glucose value at a single point in time. Given the many factors that can affect blood glucose levels, excursions above and below the normal range often occur between these discrete measurement points in time. Without the ability to determine whether their blood glucose level is rising, falling or holding constant, and the rate at which their blood glucose level is changing, the individual's ability to effectively manage and maintain blood glucose levels within normal ranges is severely limited. Further, people with diabetes cannot test themselves during sleep, when the risk of hypoglycemia is significantly increased.

  The following graph shows the limited information provided by four single-point measurements during a single day using a traditional single-point finger stick device, compared to the data provided by our continuous sensor. The data presented in the graph is from a clinical trial we completed in 2003 with a CGM system, where the patient was blinded to the continuous glucose data. The continuous data indicates that, even with four finger sticks in one day, the patient's blood glucose levels were above the target range of 80-140 milligrams per deciliter ("mg/dl") for a period of 13.5 hours.

Single Day Continuous Data



- **Inconvenience.** The process of measuring blood glucose levels with single-point finger stick devices can cause significant disruption in the daily activities of people with diabetes and their families. People with diabetes using single-point finger stick devices must stop whatever they are doing several times per day, self-inflict a painful prick and draw blood to measure blood glucose levels. To do so, people with diabetes must always carry a fully supplied kit that may include a spring-loaded needle, or lancet, disposable test strips, cleansing wipes and the meter, and then safely dispose of the used supplies. This process is inconvenient and may cause uneasiness in social situations.
- **Difficulty of Use.** To obtain a sample with single-point finger stick devices, people with diabetes generally prick one of their fingertips or, occasionally, a forearm with a lancet. They then squeeze the area to produce the blood sample and another prick may be required if a sufficient volume of blood is not obtained the first time. The blood sample is then placed on a disposable test strip that is inserted into a blood glucose meter. This task can be difficult for individuals with decreased tactile sensation and visual acuity, which are common complications of diabetes.

- **Pain.** Although the fingertips are rich in blood flow and provide a good site to obtain a blood sample, they are also densely populated with highly sensitive nerve endings. This makes the lancing and subsequent manipulation of the finger to draw blood painful. The pain and discomfort are compounded by the fact that fingers offer limited surface area, so tests are often performed on areas that are sore from prior tests. People with diabetes may also suffer pain when the finger prick site is disturbed during regular activities.

The DexCom Solution

Our G4 PLATINUM, G5 Mobile and G6 systems offer the following advantages to people with diabetes:

- **Improved Outcomes.** Results of a major multicenter clinical trial funded by the JDRF demonstrated that patients with Type 1 diabetes who used continuous glucose monitoring devices to help manage their disease experienced significant improvements in glucose control. Data published in a peer-reviewed article based on the pivotal trial for our first-generation system demonstrated that patients using the system showed statistically significant improvements in glucose levels within the target range when compared to patients relying solely on single-point finger stick measurements. Additional peer-reviewed published data has demonstrated that patients with access to seven days of continuous glucose data statistically improved glucose control by further increasing their time spent with glucose levels in the target range, thereby reducing time spent in both hyperglycemic and hypoglycemic ranges. Finally, peer reviewed data published from the DIaMonD study demonstrated that DexCom CGM system users on multiple daily injection insulin regimen achieved a one percent average reduction in hemoglobin A1c levels, a measure of the average amount of glucose in the blood over the prior three months, after 24 weeks of regular use, compared to their baseline. Study participants also increased time spent in their target A1c range and spent less time in hypoglycemia and hyperglycemia when they used a DexCom CGM system compared to those who used only a standard blood glucose meter to monitor their glucose.
- **Access to Real-Time Values, Trend Information and Alerts.** At their fingertips, people with diabetes can view their current glucose value, along with a graphical display of the historical trend information on our receiver or alternate display device. Without continuous monitoring, the individual is often unaware if his or her glucose is rising, declining or remaining constant. Access to continuous real-time glucose measurements provides people with diabetes information that may aid in attaining better glucose control. Additionally, our G4 PLATINUM, G5 Mobile and G6 systems alert people with diabetes when their glucose levels approach inappropriately high or low levels so that they may intervene.
- **Intuitive User Interface.** We have developed a user interface that we believe is intuitive and easy to use. The G5 Mobile and G6 receiver are compact with an easy-to-read color display, simple navigation tools, audible alerts and graphical display of trend information. Similar benefits are available via the interfaces we have made available on compatible mobile devices. These devices can serve as substitutes for our receivers or alternate display units in certain geographies.
- **Convenience and Comfort.** Our G4 PLATINUM, G5 Mobile and G6 systems provide people with diabetes with the benefits of continuous monitoring, without having to perform finger stick tests for every measurement. Additionally, the disposable sensor that is inserted under the skin is a very thin wire, minimizing potential discomfort associated with inserting or wearing the disposable sensor. The external portion of the sensor, attached to the transmitter, is small, has a low profile and is designed to be easily worn under clothing. The wireless receiver is the size of a small smart phone and can be carried discreetly in a pocket or purse. We believe that convenience is an important factor in achieving widespread adoption of a CGM system.
- **Connectivity to Wearables and Others.** Patients can monitor their glucose levels and trends on compatible wearable devices, such as Apple Watch and Wear OS by Google devices, when used with a compatible mobile device. Also, our Share remote monitoring systems enable users of our G4 PLATINUM with Share, G5 Mobile and G6 systems to have their sensor glucose information remotely monitored by their family, friends or designated recipient, or follower, by wirelessly transmitting data from the user's smart phone to the cloud and then to the follower's mobile device. Several followers can remotely monitor a patient's glucose information and receive secondary alert notifications from almost anywhere with an Internet connection via each follower's mobile device.

While we believe the G4 PLATINUM, G5 Mobile and G6 systems offer these advantages, people with diabetes may not perceive the benefits of continuous glucose monitoring and may be unwilling to change their current treatment regimens. Furthermore, our G4 PLATINUM, G5 Mobile and G6 systems are only available by prescription in the United States and may not appeal to all types of people with diabetes. Many international jurisdictions do not require a prescription for the dispensing of a specific device to a patient, however, the device must have received necessary regulatory approvals (e.g., Australia, Singapore and Germany). In the United Kingdom and Germany, CGMs and most related supplies do not require a prescription to purchase; however, a prescription is required for coverage. The G4 PLATINUM and G5 Mobile systems prompt the user to replace the sensor no later than the seventh day, and the G6 prompts the user to replace the sensor no later than the tenth day.

The G4 PLATINUM is not indicated as a replacement device for single-point finger stick devices in the United States, must be calibrated initially using measurements from two single-point finger stick tests and thereafter at least every 12 hours

using single-point finger stick tests, and may be more costly to use than other glucose measurement devices. In the United States, Canada and the countries and regions outside of the United States that recognize the CE Mark, our G5 Mobile system no longer requires confirmatory finger sticks when making treatment decisions although it does require two single-point finger stick tests each day for calibration. In the United States, Canada and the countries and regions outside of the United States that recognize the CE Mark, our G6 does not require confirmatory finger sticks when making treatment decisions or finger stick tests each day for calibration, although it does require finger stick tests when symptoms do not match readings and when readings are unavailable.

Our Strategy

Our objective is to remain a leading provider of CGM systems and related products to enable people with diabetes to more effectively and conveniently manage their disease. We are also developing and commercializing products that integrate our CGM technologies into the insulin delivery systems or data platforms of our respective partners. In addition, we continue to pursue development partnerships with other insulin delivery companies, including automated insulin delivery systems. To achieve these objectives, we are focusing on the following business strategies:

- Establishing and maintaining our technology platform as the leading approach to CGM and leveraging our development expertise to rapidly bring products to market, including for expanded indications.
- Driving the adoption of our ambulatory products through a direct sales and marketing effort, as well as key distribution arrangements.
- Driving additional adoption through technology integration partnerships such as our current partnerships with Eli Lilly, Insulet, Novo Nordisk, Tandem Diabetes and others.
- Seeking broad coverage policies and reimbursement for our products from private third-party payors and national health systems.
- Driving increased utilization and adoption of our products through a cloud-based data repository platform that enables people with diabetes to aggregate and analyze data from numerous diabetes devices and share the data with their healthcare providers and other individuals involved in their diabetes management and care.
- Expanding the use of our products to other patient care settings and patient demographics, including use in the hospital setting, people with Type 2 diabetes and people who are pregnant.
- Providing a high level of customer support, service and education.
- Pursuing the highest safety and quality levels for our products.

Our Technology Platform

We believe we have a broad technology platform that will support the development of multiple products for continuous glucose monitoring.

Sensor Technology

The key enabling technologies for our sensors include biomaterials, membrane systems, electrochemistry and low power microelectronics. Our membrane technology consists of multiple polymer layers configured to selectively allow the appropriate mix of glucose and oxygen to travel through the membrane and react with a glucose specific enzyme to create an extremely low electrical signal, measured in pico-amperes. This electrical signal is then translated into glucose values. We believe that the capability to measure very low levels of an electrical signal and to accurately translate those measurements into glucose values is also a unique and distinguishing feature of our technology. We have also developed technology to allow sensitive electronics to be packaged in a small, fully contained, lightweight sealed unit that minimizes inconvenience and discomfort for the user.

Receiver and Transmitter Technology

G4 PLATINUM uses proprietary radiofrequency, and G5 Mobile and G6 use Bluetooth, to wirelessly transmit information from the transmitter, which sits in a pod atop the sensor, to our receiver or to a compatible mobile device. We have developed technology for reliable transmission and reception and have consistently demonstrated a high rate of successful transmissions from transmitter to receiver or compatible mobile device in our clinical trials. Our receiver or the mobile device, via our G5 Mobile and G6 apps, then displays both real-time and trended glucose values, and provides alerts and alarms. We have used our extensive database of continuous glucose data to create and refine software, algorithms and other technology for the display of data to customers.

Products in Development

We have gained our technology expertise by learning to design implants that can withstand the rigors of functioning within the human body for extended periods of time, as well as other issues such as device sealing, miniaturization, durability and sensor geometry.

We are leveraging this technology platform to enhance the capabilities of our current products (including obtaining expanded indications of use) and to develop additional CGM products. We plan to develop future generations of technologies focused on improved performance and convenience and that will enable intelligent insulin administration. Over the longer term, we plan to continue to develop and improve networked platforms with open architecture, connectivity and transmitters capable of communicating with other devices.

We also continue to pursue and support development partnerships with insulin pump companies and companies or institutions developing insulin delivery systems, including automated insulin delivery systems.

In the future, we intend to seek additional indications for our CGM technology, including applications in pregnancy and hospital monitoring. Eventually, we may apply our technological expertise to products beyond glucose monitoring.

Disposable Sensor and Reusable Transmitter

Our sensor includes a tiny wire-like electrode coated with our sensing membrane system. This disposable sensor comes packaged with an integrated insertion device and is contained in a small plastic housing platform, or pod. The base of the pod has adhesive that attaches it to the skin. The sensor is intended to be easily and reliably inserted by the user by exposing the adhesive, placing the pod against the surface of the skin of the abdomen or upper buttocks for people ages 2-17, and pushing down on the insertion device. The insertion device first extends a narrow gauge needle containing the sensor into the subcutaneous tissue and then retracts the needle, leaving behind the sensor in the tissue and the pod adhered to the skin. The user then disposes of the insertion device and snaps the transmitter to the pod.

After a stabilization period with the G6, the user will begin receiving CGM data on his or her mobile device or dedicated receiver through the ten-day usage period. After a stabilization period with the G5 Mobile, the user is required to calibrate the sensor with two measurements from a single-point finger stick device and the disposable sensor begins wirelessly transmitting the continuous glucose data at specific intervals to the handheld receiver or compatible mobile device. Users are prompted by the receiver or mobile app, if using the G5 Mobile, to calibrate the system twice per day with finger stick measurements throughout the use period to ensure reliable operation. Calibration may be accomplished by using any FDA cleared blood glucose meter. Currently, the G4 PLATINUM system is indicated for use as an adjunctive device to complement, not replace, information obtained from standard home blood glucose monitoring devices. Our G6 and G5 Mobile systems both have labeling from the FDA and CE Mark permitting their use as a replacement for finger sticks for making therapeutic adjustments, although the G5 Mobile still requires two daily finger stick calibrations.

The disposable sensor contained in the G6 system is intended to function for up to ten days and the G5 Mobile and G4 PLATINUM systems are intended to function for up to seven days, after which the sensor should be replaced. To replace a sensor, the user simply removes the pod and attached sensor from the skin and discards them while retaining the reusable transmitter. A new sensor and pod can then be inserted and used with the same receiver and transmitter for a subsequent use period. We are aware of reports from the field, however, that patients have been able to use the G6 and the G5 Mobile and G4 PLATINUM sensors for periods longer than ten or seven days, respectively.

Handheld Receiver

Our small handheld receiver is carried by the user and wirelessly receives continuous glucose values from the transmitter. Proprietary algorithms and software, developed from our extensive database of continuous glucose data from clinical trials, are programmed into the G4 PLATINUM receiver to process the glucose data from the sensor and display it on a user-friendly graphical user interface. For the G5 Mobile and G6, the algorithm resides on the transmitter, which then sends the processed glucose data to the receiver. With a push of a button, the user can access their current glucose value and one-, three-, six-, twelve- and twenty-four-hour trended data. Additionally, when glucose values are inappropriately high or low, the receiver provides an audible alert or vibrates. The receiver is a self-contained, durable unit with a rechargeable battery.

Compatible Mobile Devices

With our G5 Mobile and G6 systems, the functionalities of our proprietary receiver can be obtained through the use of a compatible mobile device, such as an iOS or Android device, and our mobile applications, depending on the patient's geographic location. A receiver may be required as the primary display device or a backup to the mobile device in some jurisdictions, including the United States.

Sales and Marketing

We have built a direct sales organization to call on health care professionals, such as endocrinologists, physicians and diabetes educators, who can educate and influence patient adoption of continuous glucose monitoring. We believe that focusing efforts on these participants is important given the instrumental role they each play in the decision-making process for diabetes therapy, and to ensure that health care professionals and patients are knowledgeable about our products and their functionality. We focus on delivering this important information to participants to drive adoption of our G4 PLATINUM, G5 Mobile and G6 systems. We directly market our products in the United States, Austria, Canada, Germany, Ireland, Switzerland, and the United Kingdom primarily to endocrinologists, physicians and diabetes educators. Although the number of diabetes patients is significant, the number of physicians and educators influencing these patients is relatively small. As of 2018, we estimate there were approximately 6,500 clinical endocrinologists who treat diabetes in the United States. As a result, we believe our direct, highly specialized and focused sales organization is sufficient for us to support our sales efforts for the foreseeable future.

We also are increasing our direct to consumer marketing efforts to increase awareness of our CGM systems and drive new patient leads to our website. We target people with Type 1 and insulin intensive Type 2 diabetes. We advertise on television, in print, digital and video media, CRM, offer sponsorships, host or participate in diabetes related events, conduct public relations and maintain a brand ambassador program. Our campaigns target people with diabetes.

We use a variety of marketing tools to drive adoption, ensure continued usage and establish brand loyalty for our continuous glucose monitoring systems by:

- creating awareness of the benefits of continuous glucose monitoring and the advantages of our technology with endocrinologists, physicians, diabetes educators and people with diabetes;
- providing strong and simple educational and training programs to healthcare providers and people with diabetes to ensure easy, safe and effective use of our systems; and
- maintaining a readily accessible telephone and web-based technical and customer support infrastructure, which includes clinicians, diabetes educators and reimbursement specialists, to help referring physicians, diabetes educators and people with diabetes as necessary.

Our sales organization competes with the experienced and well-funded marketing and sales operations of our competitors. As compared to some of our competitors, we have relatively limited experience maintaining and managing a direct sales organization, and it is a difficult, expensive and time-consuming process. To continue to be successful we must:

- recruit and retain adequate numbers of effective sales personnel;
- effectively train our sales personnel in the benefits of our products;
- establish and maintain successful sales, marketing, training and education programs to educate endocrinologists, physicians, diabetes educators and patients about our products;
- manage geographically disbursed operations; and
- effectively train our sales personnel on the applicable fraud and abuse laws that govern interactions with healthcare practitioners as well as current and prospective patients and maintain active oversight and auditing measures to ensure continued compliance.

Competition

The market for blood glucose monitoring devices is intensely competitive, subject to rapid change and significantly affected by new product introductions and other market activities of industry participants. In selling the G4 PLATINUM, G5 Mobile and G6 systems, we compete directly with the Diabetes Care division of Abbott Laboratories; Medtronic plc's Diabetes Group; Roche Diabetes Care, a division of Roche Diagnostics; privately-held LifeScan, Inc.; and Ascensia Diabetes Care, each of which manufactures and markets products for the single-point finger stick device market. Collectively, these companies currently account for the majority of the worldwide sales of self-monitored glucose testing systems.

Several companies are developing or commercializing products for continuous or periodic monitoring of glucose levels in the interstitial fluid under the skin that compete directly with our products. In 2015, Abbott Diabetes Care, Inc. launched a consumer flash or intermittent scan glucose monitoring system, FreeStyle Libre outside the United States. Abbott first received FDA approval for a professional-use version of this system in September 2016 for use in the United States for which readings are only made available to the patient through consultation with their healthcare provider. Abbott first received FDA approval for the consumer version of this system in September 2017 for use in the United States. Medtronic plc's Diabetes Group markets and sells a standalone glucose monitoring product called Guardian Connect, which has launched both internationally and in the United States after receiving FDA approval in 2018.

Medtronic and other third parties have developed or are developing, insulin pumps integrated with continuous glucose monitoring systems that provide, among other things, the ability to suspend insulin administration while the user's glucose levels are low and to automate basal or bolus insulin dosing. Medtronic launched its 670G insulin delivery system in 2017.

We believe that the principal competitive factors in our market include:

- safe, reliable and high-quality performance of products;
- cost of products and eligibility for reimbursement;
- comfort and ease of use of products;
- effective sales, marketing and distribution networks;
- brand awareness and strong acceptance by healthcare professionals and people with diabetes;
- customer service and support and comprehensive education for people with diabetes and diabetes care providers;
- speed of product innovation and time to market;
- regulatory expertise; and
- technological leadership and superiority.

For additional information, see our Risk Factors, including *We operate in a highly competitive market and face competition from large, well-established medical device manufacturers with significant resources, and, as a result, we may not be able to compete effectively*.

Manufacturing

We currently manufacture our products at our headquarters in San Diego, California and at our manufacturing facility in Mesa, Arizona. As of December 31, 2019, our headquarters facilities had approximately 31,000 square feet of laboratory space and approximately 28,000 square feet of controlled environment rooms. Our Mesa, Arizona facility has approximately 14,000 square feet of laboratory space and approximately 33,000 square feet of controlled environment rooms. There are technical challenges to increasing manufacturing capacity, including FDA qualification of new manufacturing facilities, equipment design and automation, material procurement, problems with production yields, and quality control and assurance. We have focused significant effort on continual improvement programs in our manufacturing operations intended to improve quality, yields and throughput. We have made progress in manufacturing to enable us to supply adequate amounts of product to support our commercialization efforts, however we cannot guarantee that supply will not be constrained going forward. Additionally, the production of our continuous glucose monitoring systems must occur in a highly controlled and clean environment to minimize particles and other yield- and quality-limiting contaminants. Developing and maintaining commercial-scale manufacturing facilities has and will continue to require the investment of substantial additional funds and the hiring and retaining of additional management, quality assurance, quality control and technical personnel who have the necessary manufacturing experience.

We manufacture our G4 PLATINUM, G5 Mobile and G6 systems with certain components supplied by outside vendors and other components that we manufacture internally. Key components that we manufacture internally include our wire-based sensors. The remaining components and assemblies are purchased from outside vendors. We then assemble, test, package and ship the finished systems, which may include a reusable transmitter, a receiver and disposable sensors.

We purchase certain components and materials used in manufacturing from single sources due to quality considerations, costs or constraints resulting from regulatory or other requirements. As of December 31, 2019, those single sources include suppliers of application-specific integrated circuits used in our transmitters, seals used for the applicator and certain polymers used to synthesize polymeric membranes for our sensors.

The advantages of the manufacturing facility in Mesa, Arizona include increasing our capacity to:

- mitigate the constraints we anticipated in our headquarters facilities continuing in 2020;
- geographically diversify our manufacturing base to mitigate the risks of having all of our manufacturing located in earthquake and fire-prone California; and
- help manage certain of our operating expenses by taking advantage of Arizona's lower costs and taxes relative to California.

Third-Party Reimbursement

As a medical device company, reimbursement from Medicare, Medicaid or other governmental healthcare programs or systems, and private third-party healthcare payors is an important element of our success. In January 2017, the Centers for Medicare and Medicaid, or CMS, established a classification of "Therapeutic Continuous Glucose Monitors" as durable medical equipment under Medicare Part B, subject to payment by Medicare under certain coverage conditions to be determined

by CMS, by local Medicare Administrative Contractors or on a patient claim by claim basis. This is a decision we had pursued for many years and which was made possible by the FDA's decision in December 2016 to approve a non-adjunctive indication, or use, for our G5 Mobile system, as described further in the *Government Regulation* section below. Similarly, in September 2016, Germany's Federal Joint Committee agreed to provide reimbursement for continuous glucose monitoring systems under certain conditions which we believe we meet.

Our G4 PLATINUM system is not classified as a Therapeutic CGM by CMS and thus remains ineligible for reimbursement within the Medicare-eligible population. Reimbursement of our G4 PLATINUM system, or any future system that does not meet the requirements for Therapeutic CGMs under Medicare Part B or the requirements of another governmental healthcare system, will be limited to those customers covered by third-party payors that have adopted coverage policies for continuous glucose monitoring devices that include our products.

As of December 31, 2019, the seven largest private third-party payors, in terms of the number of covered lives, have issued coverage policies for the category of continuous glucose monitoring devices. In addition, we have negotiated contracted rates with all seven of those third-party payors for the purchase of our G4 PLATINUM, G5 Mobile and G6 systems by their members. Many of these coverage policies reimburse for our products under durable medical equipment benefits, are restrictive in nature and require the patient to comply with extensive documentation and other requirements to demonstrate medical necessity under the policy. Customers who are insured by payors that do not offer coverage for our devices will have to bear the financial cost of the products. We have personnel with reimbursement expertise to assist customers in obtaining reimbursement from private third-party payors. We also maintain a field-based reimbursement team charged with calling on third-party private payors to obtain coverage decisions and contracts. We have continued our efforts to create and liberalize coverage policies with third-party payors, including obtaining reimbursement for our products under pharmacy benefits and for more people with diabetes.

Medicare, Medicaid, other governmental health programs, health maintenance organizations and other third-party payors are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement of medical devices, and, as a result, their coverage policies may be restrictive, or they may not cover or provide adequate payment for our products. In order to obtain reimbursement arrangements, we may have to agree to a net sales price lower than the net sales price we might charge in other sales channels or that we have charged in the past. Our revenue may be limited by the continuing efforts of government and third-party payors to contain or reduce the costs of healthcare through various increasingly sophisticated means, such as requiring prospective reimbursement and second opinions, purchasing in a bundle, or redesigning benefits. Furthermore, we are unable to predict what effect the current or any future healthcare reform will have on our business, or the effect these matters will have on our customers. Our dependence on the commercial success of the G4 PLATINUM, G5 Mobile and G6 systems makes us particularly susceptible to any cost containment or reduction efforts. Accordingly, unless government and other third-party payors provide adequate coverage and reimbursement for the G4 PLATINUM, G5 Mobile and G6 systems, people without coverage who have diabetes may not use our products.

Additionally, Medicare does not cover any items or services that are not "reasonable and necessary." Medicare covers the CGM system, which includes supplies necessary for the use of the device, under the Durable Medical Equipment, or DME, benefit category. In order to be covered under this benefit, one component of the CGM system must meet the criteria for a durable medical device. To date, the receiver satisfied this criteria.

In some foreign markets, pricing and profitability of medical devices are subject to government control. In the United States, we expect that there will continue to be federal and state proposals for similar controls.

Also, the managed care trends and the consolidation in the health care industry in the United States and proposed legislation intended to reduce the cost of government insurance programs could significantly impact the purchase of health care services and products and has resulted in lower prices for our products or the exclusion of our products from certain reimbursement programs. For additional information, see Risk Factors *Managed care trends and consolidation in the health care industry could have an adverse effect on our revenues and results of operations*. and *Health care policy changes, including U.S. health care reform legislation, may have a material adverse effect on our business*.

Intellectual Property

Protection of our intellectual property is a strategic priority for our business. We rely on a combination of patents, copyrights, trademarks, tradenames, trade secrets, nondisclosure agreements and other measures to establish and protect our proprietary rights.

As of December 31, 2019, we had 516 issued U.S. patents in force, and numerous U.S. published patent applications pending. We believe it will take up to five years, and possibly longer, for our pending U.S. patent applications to result in issued patents. As of December 31, 2019, we had 50 granted European patents, and numerous European patent applications and published international applications pending under the Patent Cooperation Treaty. Our patents began expiring in 2017. We also have 31 registered U.S. trademarks, 21 registered European Community trademarks, and many other trademark registrations

and pending trademark applications around other parts of the world. In addition, we have entered into exclusive and non-exclusive licenses in the ordinary course of business relating to a wide array of technologies or other intellectual property rights or assets. Our Restated Collaboration Agreement with Verily provides us with an exclusive license to use intellectual property of Verily resulting from the collaboration, and certain Verily patents in the development, manufacture and commercialization of blood-based or interstitial glucose monitoring products more generally (subject to certain exclusions, which are outside the CGM field as it is commonly understood). It also provides us with non-exclusive license rights under Verily's other intellectual property rights to develop, manufacture and commercialize those kinds of glucose monitoring products and certain CGM-product companion software functionalities.

Our patents and patent applications seek to protect aspects of our core membrane and sensor technologies and our product concepts for continuous glucose monitoring. We believe that our patent position provides us with sufficient rights to protect our current and proposed commercial products. However, our patent applications may not result in issued patents, and any patents that have been issued or might be issued may not protect our intellectual property rights. Furthermore, we operate in an industry characterized by extensive patent litigation, and our patents may not be upheld if challenged. Any patents issued to us may be challenged by third parties as being invalid or unenforceable, and patent litigation may result in significant damage awards and injunctions that could prevent the manufacture and sale of affected products or result in significant royalty payments in order to continue selling the products. Third parties may also independently develop similar or competing technology that avoids our patents. The steps we have taken may not prevent the misappropriation of our intellectual property, particularly in foreign countries where the laws may not protect our proprietary rights as fully as in the United States. We also face risks associated with intellectual property infringement. For additional information, see our Risk Factors, including *We are subject to claims of infringement or misappropriation of the intellectual property rights of others, which could prohibit us from shipping affected products, require us to obtain licenses from third parties or to develop non-infringing alternatives, and subject us to substantial monetary damages and injunctive relief. We may also be subject to other claims or suits.* and *Our inability to adequately protect our intellectual property could allow our competitors and others to produce products based on our technology, which could substantially impair our ability to compete*.

We also rely on trade secrets, technical know-how and continuing innovation to develop and maintain our competitive position. We seek to protect our proprietary information and other intellectual property by generally requiring our employees, consultants, contractors, suppliers, outside scientific collaborators and other advisors to execute non-disclosure and assignment of invention agreements on commencement of their employment or engagement. Agreements with our employees also forbid them from bringing the proprietary rights of third parties to us. We also generally require confidentiality or material transfer agreements from third parties that receive our confidential data or materials. We cannot guarantee that employees and third parties will abide by the confidentiality or assignment terms of these agreements. Despite measures taken to protect our intellectual property, unauthorized parties might copy aspects of our products or obtain and use information that we regard as proprietary.

Government Regulation

The medical devices that we manufacture are subject to regulation by numerous regulatory bodies, including the U.S. FDA and comparable international regulatory agencies. These agencies require manufacturers of medical devices to comply with applicable laws and regulations governing the development, testing, manufacturing, labeling, marketing and distribution of medical devices. Devices are generally subject to varying levels of regulatory control, the most comprehensive of which requires that a clinical evaluation program be conducted before a device receives approval for commercial distribution. In addition, healthcare regulatory bodies in the United States and around the world impose a range of requirements related to the payment for medical devices and the procedures in which they are used, including laws intended to prevent fraud, waste, and abuse of healthcare dollars.

U.S. Laws and Regulations

At the U.S. federal level, our products are medical devices subject to extensive and ongoing regulation by the FDA. The U.S. Federal Food, Drug and Cosmetic Act, referred to as the FDCA, and the FDA's implementing regulations govern product design and development, pre-clinical and clinical testing, pre-market clearance, authorization or approval, establishment registration and product listing, product manufacturing, product labeling, product storage, advertising and promotion, product sales, distribution, recalls and field actions, servicing and post-market clinical surveillance. A number of U.S. states also impose licensing and compliance regimes on companies that manufacture or distribute prescription devices in the state.

In addition, the delivery of our devices in the U.S market is subject to regulation by the U.S. Department of Health and Human Services and comparable state agencies responsible for reimbursement and regulation of payment for health care items and services. U.S. laws and regulations are imposed primarily in connection with the Medicare and Medicaid programs, as well as the government's interest in regulating the quality and cost of health care.

FDA Regulation

Unless an exemption applies, each medical device we wish to commercially distribute in the United States will require either prior 510(k) clearance, prior *de novo* down-classification and a related grant of marketing authorization, or prior approval from the FDA through the premarket approval, or PMA process. The FDA classifies medical devices into one of three classes. Devices requiring fewer controls because they are deemed to pose lower risk are placed in Class I or II. Class I devices are subject to general controls such as labeling, pre-market notification, and adherence to the FDA's manufacturing requirements, which are contained in the Quality System Regulation, or QSR. Class II devices are subject to special controls such as performance standards, post-market surveillance, FDA guidelines, or particularized labeling, as well as general controls. Some Class I and Class II devices are exempted by regulation from the pre-market notification (i.e., 510(k) clearance) requirement, and/or the requirement of compliance with substantially all of the QSR. As an example, the mobile applications that comprise the Share System were classified by the FDA as Class II exempt. With the mobile applications classified as Class II exempt, we must comply with certain general and special controls required by the FDA but we do not need prior FDA review to commercialize changes to the mobile applications. Some devices are placed in Class III, which requires approval of a PMA application, if they are deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or certain implantable devices, or to be "not substantially equivalent" either to a previously 510(k) cleared device or to a "preamendment" Class III device in commercial distribution before May 28, 1976 for which PMA applications have not been required.

If a previously unclassified new medical device does not qualify for the 510(k) pre-market notification process because no predicate device to which it is substantially equivalent can be identified, the device is automatically classified into Class III. The Food and Drug Administration Modernization Act of 1997 established a new route to market for low to moderate risk medical devices that are automatically placed into Class III due to the absence of a predicate device, called the "Request for Evaluation of Automatic Class III Designation," or the *de novo* classification procedure. This procedure allows a manufacturer whose novel device is automatically classified into Class III to request down-classification of its medical device into Class I or Class II on the basis that the device presents low or moderate risk, rather than requiring the submission and approval of a PMA. Prior to the enactment of the Food and Drug Administration Safety and Innovation Act, or FDASIA, in July 2012, a medical device could only be eligible for *de novo* classification if the manufacturer first submitted a 510(k) pre-market notification and received a determination from the FDA that the device was not substantially equivalent. FDASIA streamlined the *de novo* classification pathway by permitting (under Section 513(f)(2) of the FDCA) manufacturers to request *de novo* classification directly without first submitting a 510(k) pre-market notification to the FDA and receiving a not substantially equivalent determination. FDASIA sets a review time for FDA of 120 days following receipt of the *de novo* application, but FDA does not always meet this timeline and has publicly only committed to a review goal of 150 days for 50% of applications. If the manufacturer seeks reclassification into Class II, the manufacturer must include a draft proposal for special controls that are necessary to provide a reasonable assurance of the safety and effectiveness of the medical device. The FDA may reject the reclassification petition if it identifies a legally marketed predicate device that would be appropriate for a 510(k) or determines that the device is not low to moderate risk or that general controls would be inadequate to control the risks and special controls cannot be developed. If the FDA agrees with the down-classification, the *de novo* applicant will then receive authorization to market the device, and a classification regulation will be established for the device type. The device can then be used as a predicate device for future 510(k) submissions by the manufacturer or a competitor. In December 2018, the FDA issued proposed regulations to govern the *de novo* classification process, which if finalized would further impact this path to market.

As an alternative to the *de novo* process, a company could also file a reclassification petition, or the FDA could initiate such a process, seeking to change the automatic Class III designation of a novel postamendment device under Section 513(f)(3) of the FDCA. The FDA issued a final rule (to take effect March 17, 2019) to clarify the process where the FDA initiates such reclassification (issuance of a proposed reclassification order; optional panel consultation; and final reclassification order published in the Federal Register).

Our G4 PLATINUM and G5 Mobile systems (excluding associated Share System functionalities and mobile applications) have been classified as devices requiring PMA approval. A PMA application must be supported by valid scientific evidence, which typically requires extensive data, including technical, pre-clinical, clinical, manufacturing and labeling data, to demonstrate to the FDA's satisfaction the safety and efficacy of the device. A PMA application also must include a complete description of the device and its components, a detailed description of the methods, facilities and controls used to manufacture the device, and proposed labeling. After a PMA application is submitted and found to be sufficiently complete, the FDA begins an in-depth review of the submitted information. During this review period, the FDA may request additional information or clarification of information already provided. Also during the review period, an advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA. In addition, the FDA generally will conduct a pre-approval inspection of the manufacturing facility to evaluate compliance with QSR, which requires manufacturers to implement and follow design, testing, control, documentation and other quality assurance procedures.

FDA review of a PMA application generally takes between one and three years, but may take significantly longer. The FDA can delay, limit or deny approval of a PMA application for many reasons, including:

- our systems may not be safe or effective to the FDA's satisfaction;
- the data from our pre-clinical studies and clinical trials may be insufficient to support approval;
- the manufacturing process or facilities we use may not meet applicable requirements; and
- changes in FDA approval policies or adoption of new regulations may require additional data.

If an FDA evaluation of a PMA application or manufacturing facilities is favorable, the FDA will either issue an approval letter, or approvable letter, which usually contains a number of conditions which must be met in order to secure final approval of the PMA. When and if those conditions have been fulfilled to the satisfaction of the FDA, the agency will issue a PMA approval letter authorizing commercial marketing of a device, subject to the conditions of approval and the limitations established in the approval letter. If the FDA's evaluation of a PMA application or manufacturing facilities is not favorable, the FDA will deny approval of the PMA or issue a not approvable letter. The FDA may also determine that additional trials are necessary, in which case the PMA approval may be delayed for several months or years while the trials are conducted and data is submitted in an amendment to the PMA. The PMA process can be expensive, uncertain and lengthy and a number of devices for which FDA approval has been sought by other companies have never been approved by the FDA for marketing.

New PMA applications or PMA supplements may be required for modifications to the manufacturing process, labeling, device specifications, materials or design of a device that is approved through the PMA process. PMA supplements often require submission of the same type of information as an initial PMA application, except that the supplement is limited to information needed to support any changes from the device covered by the approved PMA application and may or may not require as extensive clinical data or the convening of an advisory panel.

Clinical trials are almost always required to support a PMA application and are sometimes required for a 510(k) clearance. These trials generally require submission of an application for an investigational device exemption, or IDE to the FDA. The IDE application must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE application must be approved in advance by the FDA for a specified number of patients, unless the product is deemed a non-significant risk device and eligible for abbreviated IDE requirements. Generally, clinical trials for a significant risk device may begin once the IDE application is approved by the FDA and the study protocol and informed consent are approved by appropriate institutional review boards at the clinical trial sites. The FDA's approval of an IDE allows clinical testing to go forward, but does not bind the FDA to accept the results of the trial as sufficient to prove the product's safety and efficacy, even if the trial meets its intended success criteria. All clinical trials must be conducted in accordance with the FDA's IDE regulations, which govern investigational device labeling, prohibit promotion, and specify an array of Good Clinical Practice requirements, which include among other things, recordkeeping, reporting and monitoring responsibilities of study sponsors and study investigators. Clinical trials must further comply with the FDA's regulations for institutional review board approval and for informed consent and other human subject protections. Required records and reports are subject to inspection by the FDA. The results of clinical testing may be unfavorable or, even if the intended safety and efficacy success criteria are achieved, may not be considered sufficient for the FDA to grant approval or clearance of a product. The commencement or completion of any of our clinical trials may be delayed or halted, or be inadequate to support approval of a PMA application, for numerous reasons, including, but not limited to, the following:

- the FDA or other regulatory authorities do not approve a clinical trial protocol or a clinical trial, or place a clinical trial on hold;
- patients do not enroll in clinical trials at the rate we expect;
- patients do not comply with trial protocols;
- patient follow-up is not at the rate we expect;
- patients experience adverse side effects;
- patients die during a clinical trial, even though their death may not be related to our products;
- institutional review boards and third-party clinical investigators may delay or reject our trial protocol;
- third-party clinical investigators decline to participate in a trial or do not perform a trial on our anticipated schedule or consistent with the clinical trial protocol, good clinical practices or other FDA requirements;
- DexCom or third-party organizations do not perform data collection, monitoring and analysis in a timely or accurate manner or consistent with the clinical trial protocol or investigational or statistical plans;
- third-party clinical investigators have significant financial interests related to DexCom or the study that the FDA deems to make the study results unreliable, or DexCom or investigators fail to disclose such interests;
- regulatory inspections of our clinical trials or manufacturing facilities, which may, among other things, require us to undertake corrective action or suspend or terminate our clinical trials;
- changes in governmental regulations or administrative actions applicable to our trial protocols;

- the interim or final results of the clinical trial are inconclusive or unfavorable as to safety or effectiveness; and
- the FDA concludes that the results from our trial and/or trial design are inadequate to demonstrate safety and effectiveness of the product.

In November 2011, we received 510(k) clearance from the FDA to market to clinics a data management service, which helps healthcare providers and patients see, understand and use blood glucose meter data to diagnose and manage diabetes. In 2014, we submitted a request to the FDA via the *de novo* process and the FDA agreed that our data management services with CGM data is classified as Class I.

Our data transfer service allows researchers to control the transfer of data from certain diabetes devices to research tools and databases according to their own research workflows.

The infrastructure of the data management service is considered "medical device data systems," or MDDS, and does not require 510(k) clearance. MDDS are hardware or software products that transfer, store, convert formats, and display medical device data. An MDDS does not modify the data or modify the display of the data, and it does not by itself control the functions or parameters of any other medical device. MDDS are not intended to be used for active patient monitoring. On February 15, 2011, the FDA issued a regulation down-classifying MDDS from Class III (high-risk) to Class I (low-risk). Since down-classifying MDDS, the FDA gained additional experience with these types of technologies, and determined that these devices pose a low risk to the public. Therefore, the FDA stated in 2014 guidance that it did not intend to enforce compliance with the regulatory controls that apply to MDDS devices, including registration and listing, premarket review, postmarket reporting, and QSR for manufacturers of these types of devices. In 2016, the 21st Century Cures Act amended the Food, Drug, and Cosmetic Act's definition of "device" to exclude certain software functions, thus products meeting the definition of MDDS are no longer considered devices and thus are not subject to FDA regulatory requirements.

Additional functions of, or intended uses for, our software platform may require us to obtain either 510(k) clearance or PMA approval from the FDA. To obtain 510(k) clearance, we must submit a pre-market notification demonstrating that the software system is substantially equivalent to a previously cleared 510(k) device or a pre-amendment device that was in commercial distribution before May 28, 1976 for which the FDA has not yet called for the submission of a PMA application. The FDA's 510(k) clearance pathway generally takes from three to twelve months from the date the application is completed, but can take significantly longer. After a medical device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a significant change in its intended use, requires a new 510(k) clearance.

In March 2018, we obtained marketing authorization for our G6 as an integrated continuous glucose monitoring, iCGM, system for determining glucose (sugar) levels in children aged two and older and adults with diabetes, via the *de novo* process.

After a device is authorized for marketing and placed in commercial distribution, numerous regulatory requirements apply. These include:

- establishment registration and device listing;
- QSR, which requires manufacturers to follow design, testing, control, storage, supplier/contractor selection, complaint handling, documentation and other quality assurance procedures;
- labeling regulations, which prohibit the promotion of products for unapproved or off-label uses or indications and impose other restrictions on labeling, advertising and promotion;
- medical device reporting regulations, which require that manufacturers report to the FDA if a device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur;
- voluntary and mandatory device recalls to address problems when a device is defective and/or could be a risk to health; and
- corrections and removal reporting regulations, which require that manufacturers report to the FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDCA that may present a risk to health.

Also, the FDA may require us to conduct post-market surveillance studies or order us to establish and maintain a system for tracking our products through the chain of distribution to the patient level. The FDA and the Food and Drug Branch of the California Department of Health Services enforce regulatory requirements by conducting periodic, unannounced inspections and market surveillance. Inspections may include the manufacturing facilities of our subcontractors.

Failure to comply with applicable regulatory requirements, including those applicable to the conduct of our clinical trials, can result in enforcement action by the FDA, which may lead to any of the following sanctions:

- warning letters or untitled letters that require corrective action;

- fines and civil penalties;
- unanticipated expenditures;
- delays in approving or refusal to approve our future continuous glucose monitoring systems or other products;
- FDA refusal to issue certificates to foreign governments needed to export our products for sale in other countries;
- suspension or withdrawal of FDA approval;
- product recall or seizure;
- interruption of production;
- operating restrictions;
- injunctions; and
- criminal prosecution.

We and our contract manufacturers, specification developers, and some suppliers of components or device accessories, are also required to manufacture our products in compliance with current Good Manufacturing Practice requirements set forth in the QSR. The QSR requires a quality system for the design, manufacture, packaging, labeling, storage, installation and servicing of marketed devices, and includes extensive requirements with respect to quality management and organization, device design, buildings, equipment, purchase and handling of components or services, production and process controls, packaging and labeling controls, device evaluation, distribution, installation, complaint handling, servicing, and record keeping. The FDA evaluates compliance with the QSR through periodic unannounced inspections that may include the manufacturing facilities of our subcontractors. If the FDA believes we or any of our contract manufacturers or regulated suppliers are not in compliance with these requirements, it can shut down our manufacturing operations, require recall of our products, refuse to approve new marketing applications, institute legal proceedings to detain or seize products, enjoin future violations, or assess civil and criminal penalties against us or our officers or other employees. Any such action by the FDA would have a material adverse effect on our business. We may be unable to comply with all applicable FDA regulations.

U.S. Fraud and Abuse Laws and Other Compliance Requirements

The healthcare industry is subject to various U.S. federal and state laws pertaining to healthcare fraud and abuse. Violations of these laws are punishable by criminal and civil sanctions, including, in some instances, exclusion from participation in U.S. federal and state healthcare programs, including Medicare and Medicaid.

Anti-kickback Laws. The federal Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, receiving, offering or providing remuneration directly or indirectly to induce either the referral of an individual, or the furnishing, recommending, or arranging of a good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid. The definition of "remuneration" has been broadly interpreted to include anything of value, including such items as gifts, discounts, the furnishing of supplies or equipment, credit arrangements, waiver of payments, and providing anything at less than its fair market value. The Department of Health and Human Services - Office of the Inspector General, or OIG, has issued regulations, commonly known as safe harbors, that set forth certain provisions which, if satisfied in their entirety, will assure healthcare providers and other parties that they will not be prosecuted under the federal Anti-Kickback Statute. The failure of a transaction or arrangement to fit precisely within one or more safe harbors does not necessarily mean that it is illegal or that prosecution will be pursued. However, conduct and business arrangements that do not fully satisfy each applicable safe harbor element may result in increased scrutiny by government enforcement authorities or invite litigation by private citizens under federal whistleblower laws.

The penalties for violating the federal Anti-Kickback Statute include imprisonment for up to ten years, fines of up to $100,000 per violation and possible exclusion from federal healthcare programs such as Medicare and Medicaid. Many states have adopted prohibitions similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for healthcare services reimbursed by any source, not only by the government programs such as Medicare and Medicaid.

Federal False Claims Act. The federal False Claims Act prohibits knowingly presenting, or causing to be presented a false claim or the knowing use of false statements or records to obtain payment from the federal government. When an entity is determined to have violated the False Claims Act, it must pay three times the actual damages sustained by the government, plus mandatory civil penalties of between $11,181 and $22,363 for each separate false claim. Suits filed under the False Claims Act, known as "qui tam" actions, can be brought by any individual on behalf of the government and such individuals (known as "relators" or, more commonly, as "whistleblowers") may share in any amounts paid by the entity to the government in fines or settlement. In addition, certain states have enacted laws modeled after the federal False Claims Act. Qui tam actions have increased significantly in recent years, causing greater numbers of healthcare companies to have to defend a false claim action, even before the validity of the claim is established and even if the government decides not to intervene in the lawsuit. Healthcare companies may decide to agree to large settlements with the government and/or whistleblowers to avoid the cost and negative publicity associated with litigation. Federal enforcement agencies also have showed increased interest in

pharmaceutical companies' product and patient assistance programs, including reimbursement and co-pay support services, and a number of investigations into these programs have resulted in significant civil and criminal settlements. In addition, the Affordable Care Act amended federal law to provide 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 civil False Claims Act. Criminal prosecution is possible for knowingly making or presenting a false or fictitious or fraudulent claim to the federal government.

Federal Physician Self-Referral Law. The Federal Physician Self-Referral Law, also referred to as the Stark Law, prohibits a physician (or an immediate family member of a physician) who has a financial relationship with an entity from referring patients to that entity for certain designated health services, including durable medical equipment such as the CGM receiver and supplies, payable by Medicare, unless an exception applies. The Stark Law also prohibits such an entity from presenting or causing to be presented a claim to the Medicare program for such designated health services provided pursuant to a prohibited referral, and provides that certain collections related to any such claims must be refunded in a timely manner. Because we bill Medicare for DME and related supplies, the company's financial relationships with referring physicians are governed by the Stark Law. Exceptions to the Stark Law include, among other things, exceptions for certain financial relationships, including both ownership and compensation arrangements. The Stark Law is a strict liability statute, therefore, to the extent that the statute is implicated and an exception does not apply, the statute is violated. In addition to the Stark Law, many states have implemented similar physician self-referral prohibitions that may extend to Medicaid, third party payors, and self-pay patients. Violations of the Stark Law must be reported and returned to Medicare in order to avoid potential liability under the federal False Claims Act for avoiding a known obligation to return identified overpayments. Violations of the Stark Law, the Anti-Kickback Statute, the Civil Monetary Penalties Law and/or the federal False Claims Act can also form the basis for exclusion from participation in federal and state healthcare programs.

Civil Monetary Penalties Law. The Civil Monetary Penalties Law, or CMPL, authorizes the imposition of substantial civil money penalties against an entity that engages in certain prohibited activities including but not limited to violations of the Stark Law or Anti-Kickback Statute, knowing submission of a false or fraudulent claim, employment of an excluded individual, and the provision or offer of anything of value to a Medicare or Medicaid beneficiary that the transferring party knows or should know is likely to influence beneficiary selection of a particular provider for which payment may be made in whole or part by a federal health care program,commonly known as the Beneficiary Inducement CMP. Remuneration is defined under the CMPL as any transfer of items or services for free or for less than fair market value. There are certain exceptions to the definition of remuneration for offerings that meet the Financial Need, Preventative Care, or Promoting Access to Care exceptions. Sanctions for violations of the CMPL include civil monetary penalties and administrative penalties up to and including exclusion from participation in federal health care programs.

State Analogs of Federal Fraud and Abuse Laws. Many U.S. states have their own laws intended to protect against fraud and abuse in the health care industry and more broadly. In some cases these laws prohibit or regulate additional conduct beyond what federal law affects. Penalties for violating these laws can range from fines to criminal sanctions.

HIPAA and Other Privacy Laws and Regulations. The Health Insurance Portability and Accountability Act of 1996, as amended by the American Recovery and Reinvestment Act of 2009, and implementing regulations, or HIPAA, created two new federal crimes: healthcare fraud and false statements relating to healthcare matters. The healthcare fraud statute prohibits knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private payors. A violation of this statute is a felony and may result in fines, imprisonment or exclusion from government sponsored programs. The false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services.

HIPAA, as well as a number of other federal and state privacy-related laws, also extensively regulate the use and disclosure of individually identifiable health information, known as "protected health information," and require covered entities, including health plans and most health care providers, to implement administrative, physical and technical safeguards to protect the security of such information. Certain provisions of the security and privacy regulations apply to business associates (entities that handle protected health information on behalf of covered entities), and business associates are subject to direct liability for violation of these provisions. In addition, a covered entity may be subject to criminal and civil penalties as a result of a business associate violating HIPAA, if the business associate is found to be an agent of the covered entity. The HIPAA privacy regulations and security regulations impose and will continue to impose significant costs on us in order to comply with these standards.

In addition, certain states have proposed or enacted legislation that will create new data privacy and security obligations for certain entities, such as the California Consumer Privacy Act that went into effect January 1, 2020.

FCPA and Other Anti-Bribery and Anti-Corruption Laws. The U.S. Foreign Corrupt Practices Act, or FCPA, prohibits U.S. corporations and their representatives from offering, promising, authorizing or making payments to any foreign

government official, government staff member, political party or political candidate in an attempt to obtain or retain business abroad. The scope of the FCPA would include interactions with certain healthcare professionals in many countries. Our present and future business has been and will continue to be subject to various other U.S. and foreign laws, rules and/or regulations.

Physician Payment Sunshine Act. Pursuant to the Patient Protection and Affordable Care Act that was signed into law in March 2010, the federal government enacted the Physician Payment Sunshine Act. As a manufacturer of U.S. FDA-regulated devices reimbursable by federal healthcare programs, we are subject to this law, which requires us to track and annually report certain payments and other transfers of value we make to U.S.-licensed physicians or U.S. teaching hospitals. We are also required to report certain ownership interests held by physicians and their immediate family members. In 2018 the law was extended to require tracking and reporting of transfers of value to physician assistants, nurse practitioners, and other mid-level practitioners. Reporting requirements will go into effect in 2022 for payments and transfers of value made to these additional practitioner-types in 2021. CMS has the potential to impose penalties of up to $1.15 million per year for violations of the Physician Payment Sunshine Act, depending on the circumstances, and payments reported also have the potential to draw scrutiny on payments to and relationships with physicians, which may have implications under the Anti-Kickback Statute, Stark Law and other healthcare laws.

In addition, there has been a recent trend of increased federal and state regulation of payments and other transfers of value provided to healthcare professionals and entities. Similar to the federal law, certain states also have adopted marketing and/or transparency laws relevant to device manufacturers, some of which are broader in scope. Certain states also mandate that device manufacturers implement compliance programs. Other states impose restrictions on device manufacturer marketing practices and require tracking and reporting of gifts, compensation, and other remuneration to healthcare professionals and entities. The need to build and maintain a robust compliance program with different compliance and/or reporting requirements increases the possibility that a healthcare company may violate one or more of the requirements, resulting in fines and penalties.

International Regulation

International sales of medical devices are subject to foreign government regulations, which may vary substantially from country to country. The time required to obtain approval in a foreign country may be longer or shorter than that required for FDA approval, and the requirements may differ. There is a trend towards harmonization of quality system standards among the European Union, United States, Canada and various other industrialized countries.

The primary regulatory body in Europe is that of the European Union, which includes most of the major countries in Europe. Other countries, such as Switzerland, have voluntarily adopted laws and regulations that mirror those of the European Union with respect to medical devices. The European Union has adopted numerous directives and standards regulating the design, manufacture, clinical trials, labeling and adverse event reporting for medical devices. Devices that comply with the requirements of a relevant directive will be entitled to bear the CE conformity marking, indicating that the device conforms to the essential requirements of the applicable directives and, accordingly, can be commercially distributed throughout Europe. The method of assessing conformity varies depending on the class of the product, but normally involves a combination of self-assessment by the manufacturer and a third-party assessment by a "Notified Body." This third-party assessment may consist of an audit of the manufacturer's quality system and specific testing of the manufacturer's product. An assessment by a Notified Body of one country within the European Union is required in order for a manufacturer to commercially distribute the product throughout the European Union. Outside of the European Union, regulatory approval needs to be sought on a country-by-country basis in order for us to market our products. The European Union regulatory bodies finalized a new Medical Device Regulation (MDR) in 2017, which replaced the existing Directives and provided three years for transition and compliance. The MDR will change several aspects of the existing regulatory framework. Other countries have adopted medical device regulatory regimes, such as the Classification Rules for Medical Devices published by the Hong Kong Department of Health, the Health Sciences Authority of Singapore regulation of medical devices under the Health Products Act, and Health Canada's risk classification system for invasive devices, among others. Each country may have its own processes and requirements for medical device licensing, approval, and regulation, therefore requiring us to seek regulatory approvals on a country-by-country basis.

Outside the United States a range of anti-bribery and anti-corruption laws, as well and some industry-specific laws and codes of conduct, apply to the medical device industry and interactions with government officials and entities and healthcare professionals. Laws include the UK Bribery Act of 2010. Further, the EU member countries have emphasized a greater focus on healthcare fraud and abuse and have indicated greater attention to the industry by the European Anti-Fraud Office. MedTech Europe, the medical device industry association, also introduced the Code of Ethical Business Practices, which came into effect on January 1, 2017. Countries in Asia have also become more active in their enforcement of anti-bribery laws and with respect to procurement and supply chain fraud.

In the European Union, increasingly stringent data protection and privacy rules that have and will continue to have substantial impact on the use of patient data across the healthcare industry became effective in May 2018. The EU General Data Protection Regulation, or GDPR, applies across the European Union and includes, among other things, a requirement for

prompt notice of data breaches to data subjects and supervisory authorities in certain circumstances and significant fines for non-compliance. The GDPR fine framework can be up to 20 million euros, or up to 4 % of the company's total global turnover of the preceding fiscal year, whichever is higher. The GDPR also requires companies processing personal data of individuals residing in the European Union to comply with EU privacy and data protection rules, even if the company itself does not have a physical presence in the European Union. Noncompliance could result in the imposition of fines, penalties, or orders to stop noncompliant activities. Due to the strong consumer protection aspects of the GDPR, companies subject to its purview are allocating substantial legal costs to the development of necessary policies and procedures and overall compliance efforts. We expect continued costs associated with maintaining compliance with GDPR into the future.

Environmental Regulation

Our research and development and clinical processes involve the handling of potentially harmful biological materials as well as hazardous materials. We are subject to federal, state and local laws and regulations governing the use, handling, storage and disposal of hazardous and biological materials and we incur expenses relating to compliance with these laws and regulations. If violations of environmental, health and safety laws occur, we could be held liable for damages, penalties and costs of remedial actions. These expenses or this liability could have a significant negative impact on our financial condition. We may violate environmental, health and safety laws in the future as a result of human error, equipment failure or other causes. Environmental laws could become more stringent over time, imposing greater compliance costs and increasing risks and penalties associated with violations. We are subject to potentially conflicting and changing regulatory agendas of political, business and environmental groups. Changes to or restrictions on permitting requirements or processes, hazardous or biological material storage or handling might require an unplanned capital investment or relocation. Failure to comply with new or existing laws or regulations could harm our business, financial condition and results of operations.

Advisory Boards and Consultants

We have relied upon the advice of experts in the development and commercialization of our products. Since 2005, we have used experts in various disciplines on a consulting basis as needed to solve problems or accelerate development pathways. We may continue to engage advisors from the academic, consultancy, governmental or other areas to assist us as necessary. Relationships between manufacturers and physicians, including in consultancy and advisory board roles, is subject to scrutiny under the Stark Law, the federal Anti-Kickback Statute, and their state law equivalents. Due to this scrutiny, we incur legal and consulting fees to ensure our relationships with physicians meet regulatory requirements, including that compensation paid to such physicians is within fair market value.

Employees

As of December 31, 2019, we had approximately 3,900 full-time employees and approximately 1,300 contract and temporary employees globally. None of our employees are represented by a labor union or covered by a collective bargaining agreement, except for our employees in our Mainz, Germany location that are represented by a Works Council. We have never experienced any employment-related work stoppages and we consider our employee relations to be good.

Available Information

Our Internet website address is www.dexcom.com. We provide free access to various reports that we file with or furnish to the SEC through our website, as soon as reasonably practicable after they have been filed or furnished. These reports include, but are not limited to, our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and any amendments to those reports. Our SEC reports can be accessed through the investor relations section of our website, or through www.sec.gov. Also available on our website are printable versions of our Audit Committee charter, Compensation Committee charter, Nominating and Corporate Governance Committee charter, and Code of Conduct and Business Ethics. Information on our website does not constitute part of this Annual Report on Form 10-K or other report we file or furnish with the SEC. Stockholders may request copies of these documents from:

DexCom, Inc.
6340 Sequence Drive
San Diego, CA 92121
(858) 200-0200

ITEM 1A - RISK FACTORS

Our short and long-term success is subject to numerous risks and uncertainties, many of which involve factors that are difficult to predict or beyond our control. Before making a decision to invest in, hold or sell our common stock, stockholders and potential stockholders should carefully consider the risks and uncertainties described below, in addition to the other information contained in or incorporated by reference into this Annual Report on Form 10-K, as well as the other information we file with the Securities and Exchange Commission. If any of the following risks are realized, our business, financial condition, results of operations and prospects could be materially and adversely affected. In that case, the value of our common stock could decline and stockholders may lose all or part of their investment. Furthermore, additional risks and uncertainties of which we are currently unaware, or which we currently consider to be immaterial, could have a material adverse effect on our business, financial condition or results of operations. Refer to our disclaimer regarding forward-looking statements at the beginning of our Management's Discussion and Analysis of Financial Condition and Results of Operations.

Risks Related to Our Business and Operations

If our manufacturing capabilities are insufficient to produce an adequate supply of product at appropriate quality levels, our growth could be limited and our business could be harmed.

We currently have limited resources and facilities for manufacturing sufficient quantities of product to meet expected demand. In the past, we have had difficulty scaling our manufacturing operations to provide a sufficient supply of product to support market demand and our commercialization efforts. From time to time, we have also experienced brief periods of backorder and, at times, have had to limit the efforts of our sales force to introduce our products to new customers. We have focused significant effort on continual improvement programs in our manufacturing operations intended to improve quality, yields and throughput. We have made progress in manufacturing to enable us to supply adequate amounts of product to support our commercialization efforts; however, we cannot guarantee that supply will not be constrained in the future. In order to produce our products in the quantities we anticipate will be necessary to meet market demand, we will need to adequately predict the market demand for our products and increase our manufacturing capacity by a significant factor over the current level to meet or exceed the anticipated market demand. In addition, we will have to modify our manufacturing design, reliability and process if and when our next-generation continuous glucose monitoring, or CGM, technologies are approved and commercialized. There are technical challenges to increasing manufacturing capacity, including equipment design and automation, materials procurement, manufacturing site expansion, problems with production yields and quality control and assurance. Continuing to develop commercial-scale manufacturing facilities will require the investment of substantial additional funds and the hiring and retention of additional management, quality assurance, quality control and technical personnel who have the necessary manufacturing experience. The scaling of manufacturing capacity is subject to numerous risks and uncertainties, and may lead to variability in product quality or reliability, increased construction timelines, as well as resources required to design, install and maintain manufacturing equipment, among others, all of which can lead to unexpected delays in manufacturing output. In addition, any changes to our manufacturing processes may trigger the need for submissions or notifications to, and in some cases advance approval from, the FDA or other regulatory authority because of the potential impact of changes on our previously cleared, approved and/or authorized devices. Our facilities are subject to inspections by the FDA and corresponding state agencies on an ongoing basis, and we must comply with Good Manufacturing Practices and FDA Quality Systems Regulations. We may be unable to adequately maintain, develop and expand our manufacturing process and operations or maintain compliance with FDA and state agency requirements, and manufacturing issues could impact our cleared and approved products. If we are unable to manufacture a sufficient supply of our current products or any future products for which we may receive approval or clearance, maintain control over expenses or otherwise adapt to anticipated growth, or if we underestimate growth, we may not have the capability to satisfy market demand, contractual obligations, and our business will suffer.

Manufacturing difficulties and/or any disruption at our facilities may adversely affect our manufacturing operations and related product sales, and increase our expenses.

Our products are manufactured at certain facilities, with limited alternate facilities. If an event occurs at one of our facilities that results in damage to, or closure of, one or more of such facilities, we may be unable to manufacture the relevant products at the previous levels or at all. Because of the time required to approve and lease a manufacturing facility, an alternate facility and/or a third-party may not be available on a timely basis to replace production capacity in the event manufacturing capacity is lost.

Additionally, the majority of our operations are conducted at facilities located in San Diego, California and Mesa, Arizona. We take precautions to safeguard our facilities, which include manufacturing protocols, insurance, health and safety protocols, and off-site storage of data. However, a natural or man-made disaster, such as fire, flood, earthquake, act of terrorism, cyber-attack or other disruptive event could cause substantial delays in our operations, damage or destroy our

manufacturing equipment, inventory, or records and cause us to incur additional expenses. Earthquakes are of particular significance since our primary manufacturing facilities in California are located in an earthquake-prone area. In the event our existing manufacturing facilities or equipment are affected by man-made or natural disasters, we may be unable to manufacture products for sale or meet customer demands or sales projections. If our manufacturing operations were curtailed or ceased, it would seriously harm our business. The insurance we maintain against fires, floods, earthquakes and other natural disasters and similar events may not be adequate to cover our losses in any particular case.

We depend upon third-party suppliers and outsource to other parties, making us vulnerable to supply disruptions, suboptimal quality, non-compliance and/or price fluctuations, which could harm our business.

We manufacture the majority of our products and procure important third-party services, such as sterilization services, at numerous facilities worldwide. We purchase many of the components, materials and services needed to manufacture these products from numerous suppliers in various countries. We have generally been able to obtain adequate supplies of such materials, components and services. However, we also rely on single and/or sole sources for certain components and materials used in manufacturing, such as for the application-specific integrated circuit that is incorporated into the transmitter and certain polymers used to synthesize the polymeric biointerface membranes for our products. In some cases, our agreements with these and other suppliers can be terminated by either party upon short notice. Our contract manufacturers may also rely on single-or sole- source suppliers to manufacture some of the components used in our products.

Although we work with our suppliers to try to ensure continuity of supply while maintaining quality, timeliness and reliability, the supply of these components, materials and services may be interrupted or insufficient. Our manufacturers and suppliers may also encounter problems during manufacturing for a variety of reasons, including the stringent regulations and requirements of regulatory agencies, including the U.S. FDA which may result in the failure to follow specific protocols and procedures, failure to comply with applicable regulations, failed FDA audit or inspection (for example, failures leading to Form 483 Observations and Warning Letters, or other enforcement actions), as well as equipment malfunction and environmental factors, any of which could delay or impede their ability to meet our demand.

In addition, if our sole- or single-source suppliers shift their manufacturing and assembly sites to other locations, these new sites may require additional FDA approval and inspection. Should any such FDA approval be delayed, or such inspection require corrective action, our supply of critical components may be constrained or eliminated. We may not be able to quickly establish additional or replacement suppliers, particularly for our single-source components, in part because of the FDA inspection and approval process and because of the custom nature of various parts we design. 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 or switch to competitive products.

Our reliance on these outside manufacturers and suppliers also subjects us to other risks that could harm our business, including:

- we may experience a reduction or interruption in supply, and may not be able to obtain adequate supply in a timely manner or on commercially reasonable terms from additional or replacement sources;
- our products are technologically complex and it is difficult to develop alternative supply sources;
- we are not a major customer of many of our suppliers, and these suppliers may therefore give other customers' needs higher priority than ours;
- our suppliers may make errors in manufacturing components that could negatively affect the quality, effectiveness or safety of our products or cause delays in shipment of our products;
- we may have difficulty locating and qualifying alternative suppliers for our single-source supplies;
- switching components may require product redesign and submission to the FDA of new applications such as a PMA or 510(k) supplement or possibly a separate PMA or 510(k), either of which could significantly delay production;
- our suppliers manufacture products for a range of customers, and fluctuations in demand for the products these suppliers manufacture for others may affect their ability to deliver components to us in a timely manner;
- our suppliers may make obsolete components that are critical to our products; and
- our suppliers may encounter financial and/or other hardships unrelated to our demand for components, including those related to changes in global economic conditions and/or disease outbreaks, which could inhibit their ability to fulfill our orders and meet our requirements.

We also outsource certain services to other parties, including inside sales, certain transaction processing, accounting, information technology, manufacturing, and other areas. Outsourcing of services to third parties could expose us to suboptimal quality of service delivery or deliverables and potentially result in repercussions such as missed deadlines or other timeliness

issues, erroneous data, supply disruptions, non-compliance (including with applicable legal or regulatory requirements and industry standards) and/or reputational harm, with potential negative effects on our results.

We also require the suppliers, service providers and business partners of components or services for our products and related services to comply with law and certain of our policies regarding sourcing practices, but we do not control them or their practices. If any supplier, service provider or business partner violates laws or implements unethical practices, there could be disruptions to our supply chain, cancellation of our orders, a termination of the relationship with the partner or damage to our reputation, and the FDA or other regulators could seek to hold us responsible for such violations.

Continued expansion of our operations may not be scaled at a pace sufficient to ensure that we can manufacture one or more of our continuous glucose monitoring products in quantities sufficient to meet market demand.

Our facility in Mesa, Arizona is designed to manufacture current and next-generation sensors and transmitters, but may not be scaled quickly enough to permit us to manufacture one or more of our CGM systems in quantities sufficient to meet market demand. There are risks associated with continued expansion of our manufacturing capacity in Mesa that include but are not limited to contractor issues and delays, licensing and permitting delays or rejections, limitations and delays on the installation of new or custom-ordered equipment, issues associated with validating such equipment, and processes or other aspects of ensuring we manufacture our products in compliance with current Good Manufacturing Practice and other requirements.

We are subject to cost-containment efforts that could result in reduced product pricing and/or sales of our products and cause a reduction in future revenue.

In the United States and other countries, government and private sector access to health care products continues to be a subject of focus, and efforts to reduce health care costs are being made by third-party payors. Most of our customers rely on third-party payors, including government programs and private health insurance plans, to cover the cost of our products. We expect that the continuing cost reduction and containment measures may reduce the cost or utilization of health care products and could lead to patients being unable to obtain approval for coverage or payment from these third-party payors.

We have experienced, and anticipate that we will continue to experience, downward pressure on product pricing. To the extent these cost containment efforts are not offset by greater patient access to our products, our future revenue may be reduced and our business may be harmed.

If we experience decreasing prices for our products and we are unable to reduce our expenses, including the per unit cost of producing our products, there may be a material adverse effect on our business, results of operations, financial condition and cash flows.

We have experienced, and anticipate that we will continue to experience, decreasing prices for our products due to pricing pressure from managed care organizations and other third-party payors, increased market power of our payors, as the medical device industry consolidates, and increased competition among suppliers, including manufacturing services providers. If the prices for our products and services decrease and we are unable to reduce our expenses, including the cost of sourcing materials, logistics and the cost to manufacture our products, our business, results of operations, financial condition and cash flows will be adversely affected.

We have incurred significant losses in the past and may incur losses in the future.

We have incurred significant operating losses in the past, including a net loss of $186.3 million for the twelve months ended December 31, 2018. As of December 31, 2019, we had an accumulated deficit of $695.7 million. We have financed our operations primarily through private and public offerings of equity securities and debt and the sales of our products. We have devoted substantial resources to:

- research and development relating to our continuous glucose monitoring systems;
- sales and marketing and manufacturing expenses associated with the commercialization of our G4 PLATINUM, G5 Mobile and G6 systems; and
- expansion of our workforce.

We expect our research and development expenses to increase in connection with our clinical trials and other development activities related to our products, including our next-generation sensors, transmitters and receivers, as well as other collaborations. We also expect that our general and administrative expenses will continue to increase due, among other things, to the additional operational and regulatory burdens applicable to public healthcare and medical device companies. As a result, it is possible that we could incur operating losses in the future. These losses, among other things, may have an adverse effect on our stockholders' equity.

If we do not successfully optimize and operate our distribution channel or we do not effectively expand and update certain aging and/or outdated infrastructure, our operating results and customer experience may be negatively impacted.

If we do not adequately predict market demand or otherwise optimize and operate our distribution channel successfully, it could result in excess or insufficient inventory or fulfillment capacity, increased costs, immediate shortages in product or component supply, or harm our business in other ways. In addition, if we do not adequately expand and update certain aging and/or outdated infrastructure that help us, among other things, manage our purchasing and inventory, it could negatively impact our operating results and customer experience.

If we are unable to continue the development of an adequate sales and marketing organization and/or if our direct sales organization is not successful, we may have difficulty achieving market awareness and selling our products in the future.

We must continue to develop and grow our sales and marketing organization and enter into partnerships or other arrangements to market and sell our products and/or collaborate with third parties, including distributors and others, to market and sell our products to maintain the commercial success of our G4 PLATINUM, G5 Mobile and G6 systems and to achieve commercial success for any of our future products. Developing and managing a direct sales organization is a difficult, expensive and time-consuming process.

To continue to develop our sales and marketing organization to successfully achieve market awareness and sell our products, we must:

- recruit and retain adequate numbers of effective and experienced sales and marketing personnel;
- effectively train our sales and marketing personnel in the benefits and risks of our products;
- establish and maintain successful sales, marketing, training and education programs that educate health care professionals, including endocrinologists, physicians and diabetes educators, so they can appropriately inform their patients about our products;
- manage geographically dispersed sales and marketing operations; and
- effectively train our sales and marketing personnel on the applicable fraud and abuse laws that govern interactions with healthcare practitioners as well as current and prospective patients and maintain active oversight and auditing measures to ensure continued compliance.

We currently employ sales and marketing personnel for the direct sale and marketing of our products in the United States, Canada and certain countries in Europe. Our direct sales and marketing team calls directly on healthcare providers and people with diabetes throughout the applicable country to initiate sales of our products. Our sales and marketing organization competes with the experienced, larger and well-funded marketing and sales operations of our competitors. We may not be able to successfully manage our dispersed sales force or increase our product sales at acceptable rates.

In some instances, we have also entered into distribution arrangements to leverage existing distributors (including wholesalers) already engaged in the distribution of drugs, devices and/or products in the diabetes marketplace. Our U.S. distribution partnerships include those distributors that are focused on accessing underrepresented regions and, in some instances, third-party payors that contract exclusively with distributors. Our European and other international distribution partners include those distributors that call directly on healthcare providers and patients to market and sell our products in Australia and New Zealand, and certain countries in Africa, Asia, Europe, Latin America, and the Middle East. Because of the competition for their services, we may be unable to partner with or retain additional qualified distributors. Further, we may not be able to enter into agreements with distributors on commercially reasonable terms, if at all. Our distributors might not have the resources to continue to support our recent rapid growth.

If we are unable to establish and maintain adequate sales, marketing and distribution capabilities or enter into and maintain arrangements with third parties to sell, market and distribute our products, our business may be harmed.

We have entered into distribution arrangements to leverage established distributors already engaged in the diabetes marketplace. Our distribution agreements with Byram and affiliates, Cardinal Health and affiliates (including Edgepark Medical Supplies), and AmerisourceBergen, our three most significant distributors, generated approximately 12%, 17%, and 10%, respectively, of our total revenue during the twelve months ended December 31, 2019. We cannot guarantee that these relationships will continue or that we will be able to maintain this volume of sales from these relationships in the future. A substantial decrease or loss of these sales could have a material adverse effect on our operating performance. To the extent that we enter into additional arrangements with third parties to perform sales, marketing, distribution and billing services in the United States, Europe or other countries, our product margins could be lower than if we directly marketed and sold our products. To the extent that we enter into co-promotion or other marketing and sales arrangements with other companies, any revenue received will depend on the skills and efforts of others, and we cannot predict whether these efforts will be successful. In addition, market acceptance of our products by physicians and people with diabetes in Europe or other countries will largely depend on our ability to demonstrate their relative safety, effectiveness, reliability, cost-effectiveness and ease of use. If we are

unable to do so, we may not be able to generate product revenue from our sales efforts in Europe or other countries. Finally, if we are unable to establish and maintain adequate sales, marketing and distribution capabilities, independently or with others, our future revenue may be reduced and our business may be harmed.

Although many third-party payors have adopted some form of coverage policy on continuous glucose monitoring devices, our products do not always have some form of coverage, including simple broad-based contractual coverage, with third-party payors and we frequently experience administrative challenges in obtaining reimbursement for our customers. If we are unable to obtain adequately broad reimbursement at acceptable prices for our products or any future products from third-party payors, we will be unable to generate significant revenue.

As a medical device company, reimbursement from government and/or commercial third-party healthcare payors, including Medicare and Medicaid, is an important element of our success. In January 2017, the Centers for Medicare & Medicaid Services, or CMS, established a classification of "Therapeutic Continuous Glucose Monitors" as durable medical equipment under Medicare Part B, subject to payment by Medicare under certain coverage conditions to be determined by CMS, by local Medicare Administrative Contractors or on a patient claim by claim basis. This is a decision we had pursued for many years and which was made possible by the FDA's decision in December 2016 to approve a non-adjunctive indication, or use, for our G5 Mobile system. In March 2017, CMS Medicare Administrative Contractors issued interim instructions for individual claim adjudication providing instructions and billing codes for the reimbursement of individual claims for therapeutic CGM reimbursement that apply to our G6 and G5 Mobile systems, and in May 2017, CMS Medicare Administrative Contractors issued a revision to an existing joint Local Coverage Determination, which establishes the Medicare conditions of coverage for therapeutic CGM, including G5 Mobile and G6 systems.

Similarly, in September 2016, Germany's Federal Joint Committee agreed to provide reimbursement for continuous glucose monitoring systems under certain conditions, which we believe are met by our G4 PLATINUM, G5 Mobile and G6 systems.

A number of regulatory and commercial hurdles remain relating to wide-scale sales where a government or commercial third-party payors provide reimbursement, including sales to Medicare beneficiaries. If we are unable to successfully address these hurdles, reimbursement of our products may be limited to a smaller subset of people with diabetes covered by Medicare or to those people with diabetes covered by other third-party payors that have adopted policies for CGM devices allowing for coverage of these devices if certain conditions are met. Adverse coverage or reimbursement decisions relating to our products by CMS, its Medicare Administrative Contractors, other state, federal or international payors, and/or third-party commercial payors could significantly reduce reimbursement, which could have an impact on the acceptance of, and demand for, our products and the prices that our customers are willing to pay for them.

As of December 31, 2019, the seven largest private third-party payors, in terms of the number of covered lives, have issued coverage policies for the category of CGM devices. In addition, we have negotiated contracted rates with all seven of those third-party payors for the purchase of our G4 PLATINUM, G5 Mobile and G6 systems by their members. However, people with diabetes without insurance that covers our products will have to bear the financial cost of them. In the United States, people with diabetes using existing single-point finger stick devices are generally reimbursed all or part of the product cost by Medicare or other third-party payors. The commercial success of our products in both domestic and international markets will substantially depend on whether timely and comprehensive third-party reimbursement is widely available for individuals that use them. While many third-party payors have adopted some form of coverage policy on CGM devices, typically, though not exclusively, under durable medical equipment benefits, those coverage policies frequently are restrictive and require significant medical documentation and other requirements in order for policy holders to obtain reimbursement, and as a result, we have difficulty improving the efficiency of our customer service group. Moreover, it is not uncommon for governmental, including federal and/or state, agencies and their contractors to conduct periodic routine billing and compliance reviews that may entail extensive documentation requests, cooperation with which may require significant time and resources, and may result in identification of overpayment that may need to be refunded.

In addition, Medicare, Medicaid, other governmental health programs, health maintenance organizations and other third-party payors are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement of new and existing medical devices, and, as a result, they may be restrictive, or they may not cover or provide adequate payment for our products. Many of these programs impose documentation and other eligibility requirements that make it more difficult to obtain reimbursement. In order to obtain additional reimbursement arrangements, including under pharmacy benefits, we may have to agree to a net sales price lower than the net sales price we might charge in other sales channels. Our revenue may be limited by the continuing efforts of government and third-party payors to contain or reduce the costs of healthcare through various increasingly sophisticated means, such as leveraging increased competition, increasing eligibility requirements such as second opinions and other documentation, purchasing in a bundle, or redesigning benefits. We are unable to predict what effect the current or any future healthcare reform will have on our business, or the effect these matters will have on our customers. Our dependence on the commercial success of the G4 PLATINUM, G5 Mobile and G6 systems makes us particularly susceptible to any cost containment or reduction efforts. Accordingly, unless government and other third-party

payors provide adequate coverage and reimbursement for the G4 PLATINUM, G5 Mobile and G6 systems, people without coverage who have diabetes may not use our products. Furthermore, payors are increasingly basing reimbursement rates on factors such as the effectiveness of the product, clinical outcomes associated with the product, and any factors that negatively impact the effectiveness or clinical outcomes (or cause a perception of any such negative impact), such as the results of a clinical trial, a product defect, or a product recall, which could negatively impact the reimbursement rate.

Medicare does not cover any items or services that are not "reasonable and necessary." In terms of CGM, Medicare covers the CGM system, which includes supplies necessary for the use of the device, under the Durable Medical Equipment (DME) benefit category. In order to be covered under this benefit, one component of the CGM system must meet the criteria for a durable medical device. To date, the receiver satisfied this criteria. To the extent that a receiver is not used by a Medicare beneficiary or CMS otherwise determines that the items and supplies ordered are not medically necessary, Medicare may not cover that CGM system or any associated supplies.

In some foreign markets, pricing and profitability of medical devices are subject to government control. In the United States, we expect that there will continue to be federal and state proposals for similar controls. Also, the trends toward managed healthcare in the United States and legislative efforts intended to reduce the cost of government insurance programs could significantly influence the purchase of healthcare services and products and may result in lower prices for our products or the exclusion of our products from reimbursement programs.

Our products may not continue to achieve market acceptance.

We expect that sales of our G4 PLATINUM system, G5 Mobile and G6 systems will account for substantially all of our product revenue for the foreseeable future. If and when we receive FDA or other regulators' approval for, and begin commercialization of, our next-generation CGM systems, we expect most patients will migrate onto those systems. Notwithstanding our prior experience in marketing and selling our products, we might be unable to successfully expand the commercialization of our existing products or begin commercialization of our next-generation CGM systems on a wide-scale for a number of reasons, including:

- with the relatively recent FDA authorizations to market our G6 system in the United States in March 2018 and the G6 Pro in the United States in October 2019, we have relatively limited experience selling our G6 and G6 Pro systems;
- our G6 system prompts the user to replace the sensor no later than the tenth day, which might make it expensive for users;
- widespread market acceptance of our products by physicians and people with diabetes will largely depend on our ability to demonstrate their relative safety, effectiveness, reliability, cost-effectiveness and ease of use;
- the limited size of our sales force;
- we may not have sufficient financial or other resources to adequately expand the commercialization efforts for our products;
- our FDA and other regulatory reviews and/or submissions may be delayed, or approved with limited product labeling;
- we may not be able to manufacture our products in commercial quantities commensurate with demand or at an acceptable cost;
- people with Type 2 diabetes do not generally receive broad reimbursement from third-party payors for their purchase of CGM products in the United States, since many payors require that a policy holder meet specific medical criteria to qualify for reimbursement, which may reduce widespread access to or use of our products;
- the uncertainties associated with establishing and qualifying new manufacturing facilities;
- people with diabetes may need to incur the costs of single-point finger stick devices, in addition to our systems;
- the relative immaturity of the CGM market internationally, and limited international reimbursement of CGM systems by third-party payors and government healthcare providers outside the United States;
- the introduction and market acceptance of competing products and technologies, which may have a lower cost or price, allow for a convenience improvement and allow for improved accuracy and reliability;
- our inability to obtain sufficient quantities of supplies at appropriate quality levels from our single- or sole-source and other key suppliers;
- our inability to manufacture products that perform in accordance with expectations of consumers; and
- rapid technological change may make our technology and our products obsolete.

In addition to the risks outlined above, the G6 has improved performance and is being adopted more quickly than anticipated. There is the risk that regulatory authorities will determine that the G4 PLATINUM or G5 Mobile systems are not as

effective as the G6 system and may change marketing approval, reimbursement or the extent of coverage for these products. Our G4 PLATINUM, G5 Mobile and G6 systems are more invasive than many other self-monitored glucose testing systems, including single-point finger stick devices, and people with diabetes may be unwilling to insert a sensor in their body, especially if their current diabetes management involves no more than two finger sticks per day. Moreover, people with diabetes may not perceive the benefits of CGM and may be unwilling to change their current treatment regimens. In addition, physicians tend to be slow to change their medical treatment practices because of perceived liability risks arising from the use of new products. Physicians may not recommend or prescribe our products unless and until (i) there is more long-term clinical evidence to convince them to alter their existing treatment methods, (ii) there are additional recommendations from prominent physicians that our products are effective in monitoring glucose levels, and (iii) reimbursement or insurance coverage is more widely available. We cannot predict when, if ever, healthcare professionals, including physicians, and people with diabetes may adopt more widespread use of CGM systems, including our systems. If our CGM systems do not achieve and maintain an adequate level of acceptance by people with diabetes, healthcare professionals, including physicians, and third party payors, our future revenue may be reduced and our business may be harmed.

We operate in a highly competitive market and face competition from large, well-established medical device manufacturers with significant resources, and, as a result, we may not be able to compete effectively.

The market for glucose monitoring devices is intensely competitive, subject to rapid change and significantly affected by new product introductions and other market activities of industry participants. In selling the G4 PLATINUM, G5 Mobile and G6 systems, we compete directly with the Diabetes Care division of Abbott Laboratories; Medtronic plc's Diabetes Group; Roche Diabetes Care, a division of Roche Diagnostics; privately-held LifeScan, Inc.; and Ascensia Diabetes Care, each of which manufactures and markets products for the single-point finger stick device market. Collectively, these companies currently account for the majority of the worldwide sales of self-monitored glucose testing systems.

Several companies are developing and/or commercializing products for continuous or periodic monitoring of glucose levels in the interstitial fluid under the skin that compete directly with our products. In 2015, Abbott Diabetes Care, Inc. launched a consumer flash or intermittent scan glucose monitoring system, FreeStyle Libre outside the United States. Abbott first received FDA approval for a professional-use version of this system in September 2016 for use in the United States for which readings are only made available to the patient through consultation with their healthcare provider. Abbott first received FDA approval for the consumer version of this system in September 2017 for use in the United States. Medtronic plc's Diabetes Group markets and sells a standalone glucose monitoring product called Guardian Connect, which has launched both internationally and in the United States after receiving FDA approval in 2018.

Medtronic and other third parties have developed or are developing insulin pumps integrated with CGM systems that provide, among other things, the ability to suspend insulin administration while the user's glucose levels are low and to automate basal and bolus insulin dosing. Medtronic launched its 670G insulin delivery system in 2017.

Some of the companies developing or marketing competing devices are publicly traded or divisions of publicly traded companies, and these companies may possess competitive advantages over us, including:

- greater name recognition;
- established relations with healthcare professionals, customers and third-party payors;
- established distribution networks;
- additional lines of products, and the ability to bundle products to offer higher discounts or incentives to gain a competitive advantage;
- greater experience in conducting research and development, manufacturing, clinical trials, obtaining regulatory approval for products and marketing approved products;
- the ability to integrate multiple products to provide additional features beyond CGM systems; and
- greater financial and human resources for product development, manufacturing, sales and marketing, and patent litigation.

As a result, we may not be able to compete effectively against these companies or their products, which may adversely impact our business.

Additionally, some of our competitors are not subject to the Stark Law, since they do not bill Medicare directly for similar CGM systems and products. As noted above, the Stark Law is a strict liability statute and therefore, in order to ensure continued compliance, we must satisfy highly technical exceptions. These compliance efforts may limit our ability to engage in marketing practices commonly utilized by our competitors and as a result, our sales volumes may not keep pace. Conversely, if we do not strictly satisfy all criteria of an applicable Stark Law exception, we run the risk of incurring substantially financial penalties in the form of fines and potential False Claims Act damages as well as potential exclusion from participation in federal healthcare programs.

Technological breakthroughs by us or our competitors could materially impact sales of current or future generations of our products.

The glucose monitoring market is subject to rapid technological change and product innovation. Our products are based on our proprietary technology, but a number of companies and medical researchers are pursuing new technologies for the monitoring of glucose levels. FDA or other regulatory approval of a commercially viable continuous glucose monitor or sensor produced by one of our competitors could significantly reduce market acceptance of our systems. Several of our competitors are in various stages of developing continuous or flash or intermittent scan glucose monitors or sensors, including non-invasive and invasive devices, and the FDA has approved a number of these competing products. In addition, certain development efforts throughout the diabetes industry, including that of the National Institutes of Health and other supporters of diabetes research are continually seeking ways to prevent, cure or improve treatment of diabetes. Therefore, our products may be rendered obsolete by technological breakthroughs in diabetes monitoring, treatment, prevention or cure.

In addition, in the periods leading up to the launch of new or upgraded versions of our CGM systems, our customers' anticipation of the release of those products may cause them to cancel, change or delay current period purchases of our current products, which could have a material adverse effect on our business, financial condition and results of operations.

Quality problems could lead to recalls or safety alerts, reputational harm, and could have a material adverse effect on our business, results of operations, financial condition and cash flows.

Quality is very important to us and our customers due to the serious and costly consequences of product failure, and our business exposes us to potential product liability risks that are inherent in the design, manufacture, and marketing of medical devices. Since the first commercial launch of our products in 2006, we have had periodic field failures related to our products and associated services, including reports of sensor errors, sensor failures, broken sensors, receiver malfunctions, audible alarms and alert failures, as well as server and transmitter failures. To comply with the FDA's medical device reporting requirements, we have filed reports of applicable field failures. Although we believe we have taken and are taking appropriate action aimed at reducing and/or eliminating field failures, we anticipate that we will have other product failures in the future. Product or component failures, manufacturing nonconformances, design defects, off-label use, or inadequate disclosure of product-related risks or product-related information with respect to our products, if they were to occur, could result in an unsafe condition or injury to, or death of, a patient. These problems could lead to recall of, or issuance of a safety alert relating to, our products, and could result in product liability claims and lawsuits.

Additionally, the production of our products must occur in a highly controlled and clean environment to minimize particles and other yield- and quality-limiting contaminants. Weaknesses in process control or minute impurities in materials may cause a substantial percentage of defective products. If we are not able to maintain stringent quality controls, or if contamination problems arise, our clinical development and commercialization efforts could be delayed, which would harm our business and our results of operations.

If we fail to meet any applicable product quality standards and our products are the subject of recalls or safety alerts, our reputation could be damaged, we could lose customers, our reputation could be harmed and our revenue and results of operations could decline.

We may never receive approval, marketing authorization or clearance from the U.S. FDA and other governmental agencies to market additional CGM systems, expanded indications for use of current and future generation CGM systems, future software platforms, or any other products under development.

In March 2018, via the *de novo* process, the FDA classified the G6 and substantially equivalent devices of this generic type ("integrated continuous glucose monitoring systems" or "iCGMs") into Class II, meaning that going forward products of this generic type may utilize the 510(k) pathway.

Any subsequent modification of our G6 that could significantly affect its safety or effectiveness (for example, a significant change in design or manufacture), or that would constitute a major change in its intended use, will require us to obtain a new 510(k) clearance or could require a new *de novo* submission or a PMA. The FDA requires each manufacturer to make this determination initially, but the FDA may review any such decision and may disagree with a manufacturer's determination. If the FDA disagrees with a manufacturer's determination, the FDA may require the manufacturer to cease marketing and/or recall the modified device until appropriate clearance or approval is obtained. Under these circumstances, the FDA may also subject a manufacturer to significant regulatory fines or other penalties.

If future product candidates are not deemed by the FDA to meet the criteria for submission under the 510(k) pathway, or for down-classification under the *de novo* process or otherwise, we would need to pursue a PMA. The PMA process requires us to prove the safety and effectiveness of our systems to the FDA's satisfaction. This process can be expensive, prolonged and uncertain, requires detailed and comprehensive scientific and human clinical data, and may never result in the FDA granting a PMA. In March 2018, our G6 system received *de novo* classification from the FDA to be a Class II medical device. The *de novo* classification under the generic name "integrated continuous glucose monitoring system," makes the G6 a predicate

device for future 510(k) submissions. Complying with this classification requires ongoing compliance with the general controls required by the federal Food Drug and Cosmetic Act and the special controls specified by the FDA's G6 order. Any future system or expanded indications for use of current generation systems will require approval of the applicable regulatory authorities. In addition, we intend to seek either 510(k) clearances or PMA approvals for certain changes and modifications to our existing software platform, but cannot predict when, if ever, those changes and modifications will be approved.

The FDA can refuse to grant a 510(k) clearance or a *de novo* request for marketing authorization, or delay, limit or deny approval of a PMA application or supplement for many reasons, including:

- the system may not be deemed by the FDA to be substantially equivalent to appropriate predicate devices under the 510(k) pathway;
- the system may not satisfy the FDA's safety or effectiveness requirements;
- the data from pre-clinical studies and clinical trials may be insufficient to support approval, clearance and/or marketing authorization;
- the manufacturing process or facilities used may not meet applicable requirements; and
- changes in FDA approval policies or adoption of new regulations may require additional data.

Even if approved or cleared by the FDA or foreign regulatory agencies, future generations of our CGM systems, expanded indications for use of current and future generation CGM systems, our software platforms or any other CGM system under development, may not be approved or cleared for the indications that are necessary or desirable for successful commercialization. We may not obtain the necessary regulatory approvals or clearances to market these CGM systems in the United States or outside of the United States. Any delay in, or failure to receive or maintain, approval or clearance for our products could prevent us from generating revenue from these products or achieving profitability. The uncertain timing of regulatory approvals for future generations of our products could subject our current inventory to excess or obsolescence charges, which could have an adverse effect on our business, financial condition and operating results.

If we are unable to successfully complete the pre-clinical studies or clinical trials necessary to support additional PMA, de novo, or 510(k) applications or supplements, we may be unable to commercialize our CGM systems under development, which could impair our business, financial condition and operating results.

To support current and any future additional PMA, 510(k), *de novo* applications or supplements, we together with our partners, must successfully complete pre-clinical studies, bench-testing, and in some cases clinical trials that will demonstrate that the product is safe and effective. Product development, including pre-clinical studies and clinical trials, is a long, expensive and uncertain process and is subject to delays and failure at any stage. Furthermore, the data obtained from the studies and trials may be inadequate to support approval of an application and the FDA may request additional clinical data in support of those applications, which may result in significant additional clinical expenses and may delay product approvals. While we have in the past obtained, and may in the future obtain, an investigational device exemption, or IDE, prior to commencing clinical trials for our products, FDA approval of an IDE application permitting us to conduct testing does not mean that the FDA will consider the data gathered in the trial to be sufficient to support approval of a PMA, *de novo* or 510(k) application or supplement, even if the trial's intended safety and effectiveness endpoints are achieved. Additionally, since 2009, the FDA has significantly increased the scrutiny applied to its oversight of companies subject to its regulations, including device marketing submissions, by hiring new investigators and increasing the frequency and scope of its inspections of manufacturing facilities. The ongoing oversight by the FDA's Center for Devices and Radiological Health could complicate the product approval process for certain of our and our partners' products, and we cannot predict the effect of such procedural changes and cannot ascertain if such changes will have a substantive impact on the approval of our products or our partners' products. If we fail to adequately respond to any changes to the 510(k) submission process and associated matters, our business may be adversely impacted.

Unexpected changes to the FDA or foreign regulatory approval processes could also delay or prevent the approval of our products submitted for review. For example, as part of the 21st Century Cures Act passed in 2016, Congress enacted several reforms that further affect medical device regulation both pre- and post-approval. In addition, the FDA is in the process of reviewing the 510(k) approval process and criteria and has announced initiatives to improve the current pre- and post-market regulatory processes and requirements associated with infusion pumps and other home use medical devices. As part of this effort, the FDA is reviewing the adverse event reporting and recall processes for insulin pumps. Any change in the laws or regulations that govern the clearance and approval processes relating to our current and future products could make it more difficult and costly to obtain clearance or approval for new products, or to produce, market and distribute existing products. The data contained in our submissions, including data drawn from our clinical trials, may not be sufficient to support approval of our products or additional or expanded indications. Medical device company stock prices have declined significantly in certain circumstances where companies have failed to meet expectations in regards to the timing of regulatory approval. If the FDA's response causes product approval delays, or is not favorable for any of our products, our stock price (and the market price of

our convertible notes) could decline substantially. In November 2018, the FDA announced that it plans to make further changes aimed at modernizing the 510(k) clearance pathway, creating further uncertainty.

The commencement or completion of any of our clinical trials may be delayed or halted, or be inadequate to support approval of FDA marketing applications or supplements, for numerous reasons, including, but not limited to, the following:

- the FDA or other regulatory authorities do not approve a clinical trial protocol or a clinical trial, or place a clinical trial on hold;
- patients do not enroll in clinical trials at the rate we expect;
- patients do not comply with trial protocols;
- patient follow-up does not occur at the rate we expect;
- patients experience adverse side effects;
- patients die during a clinical trial, even though their death may not be related to our products;
- institutional review boards and third-party clinical investigators may delay or reject our trial protocol;
- third-party clinical investigators decline to participate in a trial or do not perform a trial on our anticipated schedule or consistent with the investigator agreements, clinical trial protocol, good clinical practices or other FDA or institutional review board requirements;
- DexCom or third-party organizations do not perform data collection, monitoring and/or analysis in a timely or accurate manner or consistent with the clinical trial protocol or investigational or statistical plans;
- third-party clinical investigators have significant financial interests related to DexCom or the study that the FDA deems to make the study results unreliable, or DexCom or investigators fail to disclose such interests;
- regulatory inspections of our clinical trials or manufacturing facilities may, among other things, require us to undertake corrective action or suspend or terminate our clinical trials;
- changes in governmental regulations, policies or administrative actions applicable to our trial protocols;
- the interim or final results of the clinical trial are inconclusive or unfavorable as to safety or efficacy; and
- the FDA concludes that the results from our trial and/or trial design are inadequate to demonstrate safety and effectiveness of the product.

The results of pre-clinical studies do not necessarily predict future clinical trial results, and prior clinical trial results might not be repeated in subsequent clinical trials. Additionally, the FDA may disagree with our interpretation of the data from our pre-clinical studies and clinical trials, or may find the clinical trial design, conduct or results inadequate to prove safety or effectiveness, and may require us to pursue additional pre-clinical studies or clinical trials, which could further delay the approval of our products. If we are unable to demonstrate the safety and effectiveness of our products in our clinical trials to the FDA's satisfaction, we will be unable to obtain regulatory approval to market our products in the United States. In addition, the data we collect from our current clinical trials, our pre-clinical studies and other clinical trials may not be sufficient to support FDA approval, even if our endpoints are met.

We may also conduct clinical studies to demonstrate the relative or comparative effectiveness of CGM systems for the treatment of diabetes. These types of studies, which often require substantial investment and effort, may not show adequate, or any, clinical benefit for the use of CGM systems.

We depend on clinical investigators and clinical sites to enroll patients in our clinical trials and other third parties to manage the trials and to perform related data collection and analysis, and, as a result, we may face costs and delays that are outside of our control.

We rely on clinical investigators and clinical sites to enroll patients in our clinical trials, and other third parties to manage the trial and to perform related data collection and analysis. However, we may not be able to control the amount and timing of resources that clinical sites may devote to our clinical trials. If these clinical investigators and clinical sites fail to enroll a sufficient number of patients in our clinical trials or fail to ensure compliance by patients with clinical protocols or fail to comply with regulatory requirements, we will be unable to complete these trials, which could prevent us from obtaining regulatory approvals for our products. Our agreements with clinical investigators and clinical sites for clinical testing place substantial responsibilities on these parties and, if these parties fail to perform as expected, our trials could be delayed or terminated. If these clinical investigators, clinical sites or other third parties do not carry out their contractual duties or obligations or fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to their failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated, or the clinical data may be rejected by the FDA, and we may be unable to obtain regulatory approval for, or successfully commercialize, our products.

Potential long-term complications from our current or future products or other CGM systems under development may not be revealed by our clinical experience to date.

Based on our experience, complications from use of our products may include sensor errors, sensor failures, broken sensors, lodged sensors or skin irritation under the adhesive dressing of the sensor. Inflammation or redness, swelling, minor infection, and minor bleeding at the sensor insertion site are also possible risks with an individual's use of our products. However, if unanticipated long-term side-effects result from the use of our products or other glucose monitoring systems we have under development, we could be subject to liability and the adoption of our systems may become more limited. With respect to our G4 PLATINUM and G5 Mobile systems, our clinical trials have been limited to seven days of continuous use, and with respect to our G6, our clinical trials have been limited to ten days of continuous use. It is possible that the results from our clinical studies and trials may not be indicative of the clinical results obtained when we examine the patients at later dates. We cannot assure you that repeated, long-term use would not result in unanticipated adverse effects, potentially even after the sensor is removed.

We enter into collaborations with third parties that may not result in the development of commercially viable products or the generation of significant future revenues.

In the ordinary course of our business, we enter into collaborative arrangements to develop new products and to pursue new markets, such as our agreements with Eli Lilly, Insulet, Novo Nordisk and Tandem Diabetes, to integrate our CGM technology into their insulin delivery systems, and our amended agreement with Verily to develop one or more next-generation CGM products. Our Eli Lilly, Insulet, Novo Nordisk and Verily collaborations have not yet resulted in a commercial product. In December 2019, Tandem received FDA approval for its second sensor-augmented insulin delivery system, the t:slim X2™ Insulin Pump with Control-IQ™ technology, which integrates with our G6 system.

As a result of these development relationships, our operating results depend, to some extent, on the ability of our development partners to successfully commercialize their insulin delivery systems or monitoring products. Any factors that may limit our partners' ability to achieve widespread adoption of their systems, including competitive pressures, technological breakthroughs for the treatment or prevention of diabetes, adverse regulatory or legal actions relating to insulin pump products, or changes in reimbursement rates or policies of third-party payors relating to insulin pumps or similar products, could have an adverse impact on our operating results. For example, Animas announced in September 2017 that it has discontinued the manufacturing and sale of Animas® Vibe® and OneTouch Ping® insulin pumps, then exited the insulin pump business. Animas selected Medtronic as its partner to facilitate a seamless transition for patients, caregivers and healthcare providers. Patients using an Animas insulin pump are offered the option to transfer to a Medtronic pump. As Animas Vibe is compatible with DexCom's products, and Animas has served as a distributor for our products in certain geographies, the transition of Animas customers to Medtronic pumps, which are not integrated with our sensors, may adversely impact our revenues. As another example, UnitedHealthcare announced, effective July 1, 2016, that UnitedHealthcare Community Plan and Commercial members will no longer have an in-network choice among providers of insulin pumps, and designated Medtronic as its preferred, in-network provider. We do not have a relationship to integrate our CGM technology with Medtronic, which has developed an insulin pump augmented with its proprietary CGM system. The decision by UnitedHealthcare to establish Medtronic as its preferred provider of insulin pumps could result in a material reduction in the number of insulin pumps sold by other insulin pump manufacturers, including Tandem and Insulet. In addition, it is possible that other large third-party payors will establish preferred providers of insulin pumps, which may or may not include the pumps produced by our development partners.

Many of the companies that we collaborate with are also competitors or potential competitors who may decide to terminate our collaborative arrangement. In the event of such a termination, we may be required to devote additional resources to product development and commercialization, we may need to cancel some development programs and we may face increased competition. Additionally, collaborations may not result in the development of products that achieve commercial success and could be terminated prior to developing any products. Former collaborators may use the experience and insights they develop in the course of their collaborations with us to initiate or accelerate their development of products that compete with our products, which may create competitive disadvantages for us. Accordingly, we cannot provide assurance that any of our collaborations will result in the successful development of a commercially viable product or result in significant additional future revenues.

In addition, our development timelines are highly dependent on our ability to achieve clinical endpoints and regulatory requirements and to overcome technology challenges, and may be delayed due to scheduling issues with patients and investigators, requests from institutional review boards, product performance and manufacturing supply constraints, among other factors. In addition, support of these clinical trials requires significant resources from employees involved in the production of our products, including research and development, manufacturing, quality assurance, and clinical and regulatory personnel. Even if our development and clinical trial efforts succeed, the FDA may not approve the combined products or may require additional product testing and clinical trials before approving the combined products, which would result in product

launch delays and additional expense. If approved by the FDA, the combined products may not be accepted in the marketplace by physicians and people with diabetes.

Our success will depend on our ability to attract and retain our personnel, while controlling labor costs.

We depend to a significant degree on our senior management, especially Kevin Sayer, our President and Chief Executive Officer. Our success will depend on our ability to retain our senior management and to attract and retain qualified personnel in the future, including sales persons, scientists, clinicians, engineers and other highly skilled personnel. Competition for senior management personnel, as well as sales persons, scientists, clinicians and engineers, is intense and we may not be able to retain our personnel. The loss of the services of members of our senior management, scientists, clinicians or engineers could prevent the implementation and completion of our objectives, including the commercialization of our current products and the development and introduction of additional products. The loss of a member of our senior management or our professional staff would require the remaining executive officers to divert immediate and substantial attention to seeking a replacement. Each of our officers may terminate their employment at any time without notice and without cause or good reason. Additionally, volatility or a lack of positive performance in our stock price may adversely affect our ability to retain key employees.

We expect to continue to expand our operations and grow our research and development, manufacturing, sales and marketing, product development and administrative operations. We expect this expansion to place a significant strain on our management and it will require hiring a significant number of qualified personnel. Accordingly, recruiting and retaining such personnel will be critical to our success. There is intense competition from other companies and research and academic institutions for qualified personnel in the areas of our activities. If we fail to identify, attract, retain and motivate these skilled personnel, we may be unable to continue our development and commercialization activities.

We may undertake a reorganization of our workforce, which may result in a temporary reduction in the number of employees in certain locations. We would undertake a reorganization to reduce operating expenses, though we cannot guarantee any specific amount of long-term cost savings. Further, the turnover in our employee base could result in operational and administrative inefficiencies, which could adversely impact the results of our operations, stock price and customer relationships, and could make recruiting for future management and other positions more difficult.

We may conduct additional financings to continue the commercialization of our G4 PLATINUM, G5 Mobile and G6 systems, or the development and commercialization of our future generation CGM and other systems.

Our operations have consumed substantial amounts of cash since inception. We expect to continue to spend substantial amounts on commercialization of our products, including growth of our manufacturing capacity, and on research and development, including conducting clinical trials for our next-generation ambulatory CGM sensors and systems. Although we raised $389.0 million in net proceeds through the private sale of our convertible notes in June 2017, $75.0 million of which was used to repay our credit facility, $836.6 million in net proceeds through the private sale of our convertible notes in November 2018, $100.0 million of which we used to purchase shares of our common stock, and now have $195.6 million available to us under our credit facility (as reduced by our outstanding letters of credit), we could need funds to continue the commercialization of our current products and to develop and commercialize our next-generation sensors and systems or pursue other strategic initiatives. Additional financing may not be available on a timely basis on terms acceptable to us, or at all. Any additional financing may be dilutive to stockholders or may require us to grant a lender a security interest in our assets. The amount of funding we may need will depend on many factors, including:

- the revenue generated by sales of our products and other future products;
- the costs, timing and risks of delay of additional regulatory approvals;
- the expenses we incur in manufacturing, developing, selling and marketing our products;
- our ability to scale our manufacturing operations to meet demand for our current and any future products;
- the costs to produce our continuous glucose monitoring systems;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- the rate of progress and cost of our clinical trials and other development activities;
- the success of our research and development efforts;
- the emergence of competing or complementary technologies;
- the terms and timing of any collaborative, licensing and other arrangements that we may establish;
- the cost of ongoing compliance with legal and regulatory requirements, and third-party payors' policies;
- the cost of obtaining and maintaining regulatory or payor clearance or approval for our current or future products including those integrated with other companies' products; and
- the acquisition of business, products and technologies, although we currently have no commitments or agreements relating to any of these types of transactions.

If adequate funds are not available, we may not be able to commercialize our products at the rate we desire and/or we may have to delay the 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 sales, marketing, customer support or other resources devoted to our products. Any of these factors could harm our business and financial condition.

Uncollectible uninsured and patient due accounts could adversely affect our results of operations.

The primary collection risks for our accounts receivable relate to the uninsured patient accounts and patient accounts for which the primary insurance carrier has paid the amounts covered by the applicable agreement, but patient responsibility amounts (exclusions, deductibles and copayments) remain outstanding. In the event that we are unsuccessful in collecting payments owed by patients, and/or experience increases in the amount, or deterioration in the collectability, of uninsured and patient due accounts receivable, this could adversely affect our cash flows and results of operations. We may also be adversely affected by the growth in patient responsibility accounts as a result of increases in the adoption of plan structures, due to evolving health care policy and insurance landscapes that shift greater responsibility for care to individuals through greater exclusions and copayment and deductible amounts.

Environmental and social (E&S) regulations, policies and provisions, as well as customer demand, may make our supply chain more complex and may adversely affect our relationships with customers.

There is an increasing focus on the governance of environmental and social risks. A number of our customers have adopted, or may adopt, procurement policies that include E&S provisions that their suppliers must comply with, or they may seek to include such provisions in their terms and conditions. An increasing number of participants in the medical device industry are also joining voluntary E&S initiatives, such as the Responsible Business Alliance. These E&S provisions and initiatives are subject to change, can be unpredictable, and may be difficult and expensive for us to comply with, given the complexity of our supply chain and the outsourced manufacturing of certain components of our products. If we are unable to comply, or are unable to cause our suppliers to comply, with such policies or provisions, a customer may stop purchasing products from us, and may take legal action against us, which could harm our reputation, revenue and results of operations.

In addition, as part of their E&S programs, an increasing number of industry participants are seeking to source products that do not contain minerals sourced from areas where proceeds from the sale of such minerals are likely to be used to fund armed conflict, such as in the Democratic Republic of the Congo. This could adversely affect the sourcing, availability and pricing of minerals used in the manufacture of medical device, including our products. Since our supply chain is complex, we are not currently able to definitively ascertain the origins of all of the minerals and metals used in our products. As a result, we may face difficulties in satisfying these customers' demands, which may harm our sales and operating results.

Risks Related to Healthcare Industry Shifts and Changing Regulations

Managed care trends and consolidation in the health care industry could have an adverse effect on our revenues and results of operations.

Private third-party payors and other managed care organizations, such as pharmacy benefit managers, continue to take action to manage the utilization and control cost. Consolidation among managed care organizations has increased the negotiating power of managed care organizations and other private third-party payors. Private third-party payors, as well as governments, increasingly employ formularies to control costs by taking into account discounts in connection with decisions about formulary inclusion or favorable formulary placement. Failure to obtain or maintain timely adequate pricing or favorable formulary placement for our products, or failure to obtain such formulary placement at favorable pricing, could adversely impact revenue. Private third-party payors, including self-insured employers, often implement formularies with copayment tiers to encourage utilization of certain products and have also been raising co-payments required from beneficiaries, particularly for higher cost products. Private third-party payors also use additional measures such as value-based pricing/contracting to improve their cost containment efforts. Private third-party payors also are increasingly imposing utilization management tools, such as requiring prior authorization or requiring the patient to first fail on a lower cost product before permitting access to a higher cost product.

Many health care industry companies, including health care systems, distributors, manufacturers, providers, and insurers, are also consolidating or have formed strategic alliances. As the health care industry consolidates, competition to provide goods and services to industry participants may become more intense. This consolidation will continue to create larger enterprises with greater negotiating power, which they can try to use to negotiate price concessions or reductions for medical devices and components produced by us.

As the U.S. payor market consolidates further and we face greater pricing pressure from private third-party payors, who will continue to drive more of their patients to use lower cost alternatives, we may lose customers, our revenues may decrease and our business, financial condition, results of operations and cash flows may suffer.

Health care policy changes, including U.S. health care reform legislation, may have a material adverse effect on our business.

In response to perceived increases in health care costs in recent years, there have been and continue to be proposals by the federal government, state governments, regulators, and third-party payors to control these costs and, more generally, to reform the U.S. health care system. Certain of these proposals could limit the prices we are able to charge for our products or the amounts of reimbursement available for our products and could limit the acceptance and availability of our products. Further, while the United States has begun shifting to pay-for-performance rather than fee-for-service models and has been embracing many shared-risk arrangements, CMS and OIG specifically proposed to exclude medical device manufacturers from utilizing the new, more flexible Stark Law exceptions and Anti-Kickback Statute safe harbors under the Proposed Rules to Amend the Stark Law and Anti-Kickback Statute exceptions and safe harbors, part of the U.S. Department of Health and Human Services' Regulatory Sprint to Coordinated Care. This exclusion would not allow us to avail ourselves of the protections available under these exceptions and safe harbors, inviting greater scrutiny over our shared risk arrangements. The adoption of some or all of these proposals could have a material adverse effect on our business, financial condition and results of operations.

Comprehensive healthcare legislation, signed into law in the United States in March 2010, titled the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act of 2010, collectively, the ACA, imposes certain stringent compliance, recordkeeping, and reporting requirements on companies in various sectors of the life sciences industry, with which we may need to comply, and enhanced penalties for non-compliance with the new and revised healthcare laws. However, there are many programs and requirements under the ACA for which the consequences are not fully understood, and it is unclear what the full impact will ultimately be from the ACA. Costs of compliance with this legislation, or any future amendments thereto, may have a material adverse effect on our business, financial condition and results of operations.

The ACA also focuses on a number of Medicare provisions aimed at improving quality and decreasing costs. It is uncertain at this point what negative unintended consequences these provisions will have on patient access to new technologies. The Medicare provisions include value-based payment programs, increased funding of comparative effectiveness research, reduced hospital payments for avoidable readmissions and hospital acquired conditions, and pilot programs to evaluate alternative payment methodologies that promote care coordination, such as bundled physician and hospital payments.

We cannot predict whether the ACA will be repealed, replaced, or modified, or how such repeal, replacement or modification may be timed or structured. As a result, we cannot quantify or predict what the effect of such repeal, replacement, or modification might have on our business and results of operations. However, any changes that lower reimbursement for our products could materially and adversely affect our business, financial condition and results of operations.

There are pending federal Congressional proposals that would significantly expand government-provided health insurance coverage. Proposals range from establishing a single-payor, national health insurance system (e.g., Medicare for All Act of 2019 (H.R. 1384), to more limited buy-in options that would be available to individuals above a certain age (e.g., Medicare at 50 Act (S. 470). There is also legislation that would authorize states to permit individuals to "buy-in" to their state Medicaid program (e.g., State Public Option Act (S. 489, H.R. 1277)). If enacted, these proposals will likely have a significant impact on the healthcare industry. At this stage, we cannot predict how future legislation will affect our business.

Other legal, regulatory and commercial policy influences are subjecting our industry to significant changes, and we cannot predict whether new regulations or policies will emerge from U.S. federal or state governments, foreign governments, or third-party payors. Government and commercial payors may, in the future, consider healthcare policies and proposals intended to curb rising healthcare costs, including those that could significantly affect reimbursement for healthcare products such as our systems. These policies have included, and may in the future include: basing reimbursement policies and rates on clinical outcomes, the comparative effectiveness, and costs, of different treatment technologies and modalities; imposing price controls and taxes on medical device providers; and other measures. Future significant changes in the healthcare systems in the United States or elsewhere could also have a negative impact on the demand for our current and future products. These include changes that may reduce reimbursement rates for our products and changes that may be proposed or implemented by the current or future laws or regulations.

Risks Related to Non-Compliance with Laws, Regulations and Contractual Requirements

We conduct business in a heavily regulated industry and if we fail to comply with applicable laws and government regulations, we could become subject to penalties, excluded from participation in government programs, and/or be required to make significant changes to our operations.

The healthcare industry generally, and our business specifically, is subject to extensive foreign, federal, state and local laws and regulations, including those relating to:

- authorizations necessary for the investigation and commercial marketing of products;

- the pricing of our products and services;
- the distribution of our products and services;
- billing for products and services;
- the obligation to report and return identified overpayments;
- financial relationships with physicians and other referral sources;
- inducements and courtesies given to physicians and other health care providers and patients;
- labeling products;
- the characteristics and quality of our products and services;
- confidentiality, maintenance and security issues associated with medical records and individually identifiable health and other personal information;
- medical device adverse event reporting;
- prohibitions on kickbacks, including the Anti-Kickback Statute and related laws and/or regulations;
- any scheme to defraud any healthcare benefit program;
- physician and other healthcare professional payment disclosure requirements;
- use and disclosure of personal health information;
- privacy of health information and personal information;
- data protection and data localization;
- mobile communications;
- patient access and non-discrimination;
- patient consent;
- false claims; and
- professional licensure.

These laws and regulations are extremely complex and, in many cases, still evolving. If our operations are found to violate any of the foreign, federal, state or local laws and regulations which govern our activities, we may be subject to litigation, government enforcement actions, and applicable penalties associated with the violation, potentially including civil and criminal penalties, damages, fines, exclusion from participation in certain payor programs or curtailment of our operations. Compliance obligations under these various laws are oftentimes detailed and onerous, further contributing to the risk that we could be found to be out of compliance with particular requirements. The risk of being found in violation of these laws and regulations is further increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, particularly with respect to new and emerging technologies and remote delivery of services, and their provisions are open to a variety of interpretations.

The FDA, CMS, OIG, Department of Justice, states' attorneys general and other governmental authorities actively enforce the laws and regulations discussed above. In the United States, medical device manufacturers have been the target of numerous government prosecutions and investigations alleging violations of law, including claims asserting impermissible off-label promotion of medical devices, payments intended to influence the referral of federal or state healthcare business, and submission of false claims for government reimbursement. While we make every effort to comply with applicable laws, we cannot rule out the possibility that the government or other third parties could interpret these laws differently and challenge our practices under one or more of these laws. This likelihood of allegations of non-compliance is increased by the fact that under certain federal and state laws applicable to our business, individuals, known as relators, may bring an action on behalf of the government alleging violations of such laws, and potentially be awarded a share of any damages or penalties ultimately awarded to the applicable government body.

Under the United States Federal Food, Drug, and Cosmetic Act, medical devices are classified into one of three classes – Class I, Class II or Class III – depending on the degree of risk associated with each medical device and the extent of control needed to ensure safety and effectiveness. Our G6 has been classified as a Class II device. Class II devices are subject to various general and special controls, including the Quality System Regulations and 510(k) pre-market notification requirements.

From time to time, the FDA may disagree with the classification of a new Class II medical device and require the manufacturer of that device to apply for approval as a Class III medical device. In the event that the FDA determines that our Class II medical products should be classified as Class III medical devices, we could be precluded from marketing the devices for clinical use within the United States for months, years or longer, depending on the specific change in the classification. Reclassification of our Class II medical products as Class III medical devices could significantly increase our regulatory costs, including the timing and expense associated with required clinical trials and other costs.

Any action against us alleging a violation of these laws or regulations, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's time and attention from the operation of our business, and have a material effect on our business.

In addition, the laws and regulations impacting or affecting our business may change significantly in the future. Any new laws or regulations may adversely affect our business. A review of our business by courts or regulatory authorities may result in a determination that could adversely affect our operations. Also, the regulatory environment applicable to our business may change in a way that restricts or adversely impacts our operations.

Our failure to comply with laws, regulations and contract requirements relating to reimbursement of health care goods and services may subject us to penalties and adversely impact our reputation, business, financial condition and cash flows.

Our products are purchased principally by individual patients, who may be eligible for insurance coverage of their devices from various third-party payors, such as governmental programs (*e.g.*, Medicare, Medicaid, TRICARE, other federal and state health benefit plans, and comparable non-U.S. programs), private insurance plans, and managed care plans. The ability of our customers to obtain appropriate reimbursement for products and services from third-party payors is critical because it affects which products customers purchase and the prices they are willing to pay. As a result, our products are subject to regulation regarding quality and cost by the U.S. Department for Health & Human Services, including CMS, as well as comparable state and non-U.S. agencies responsible for reimbursement and regulation of health care goods and services. The principal U.S. federal laws that implicate reimbursement issues include those that prohibit (i) the filing of false or improper claims for federal payment, known as the federal civil False Claims Act, (ii) unlawful inducements for the referral of business reimbursable under federally-funded health care programs, known as the federal Anti-Kickback Statute, and (iii) health care service providers from seeking reimbursement for providing certain services to a patient who was referred by a physician who has certain types of direct or indirect financial relationships with the service provider, known as the federal Physician Self-Referral law, or commonly referred to as the "Stark Law." Many states have similar laws that apply to reimbursement by state Medicaid and other government-funded programs, as well as, in some cases, to all payors, including self-pay patients. In addition, the federal civil False Claims Act requires the reporting and returning of identified overpayments received from federal health care programs within 60 days of identification and quantification, and requires the exercise of reasonable diligence to investigate credible information regarding potential overpayments. Failure to timely refund known overpayments from federal healthcare programs, such as Medicare and Medicaid, would subject a company to civil False Claims Act liability. Insurance companies can also bring a private cause of action claiming treble damages against a manufacturer for causing a false claim to be filed under the federal Racketeer Influenced and Corrupt Organizations Act, or RICO. Additionally, as a manufacturer of U.S. FDA-approved devices reimbursable by federal healthcare programs, we are subject to the federal Physician Payments Sunshine Act, which requires us to annually report certain payments and other transfers of value we make to U.S.-licensed physicians or U.S. teaching hospitals. On October 25, 2018, President Trump signed into law the "Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act." This law, in part (under a provision entitled "Fighting the Opioid Epidemic with Sunshine"), extends the reporting and transparency requirements for physicians in the Physician Payments Sunshine Act, to physician assistants, nurse practitioners, and other mid-level practitioners. Reporting requirements will go into effect in 2022 for payments and transfers of value made to these additional practitioner-types in 2021.

We may be subject to these and other laws regulating the provision of, and reimbursement for, health care goods and services, both in our capacity as a medical device manufacturer and/or as a supplier of covered items and services to federal health care program beneficiaries, with respect to which items and services we submit claims for reimbursement from such programs. The laws and regulations of health care goods and services that apply to us, including those described above, are subject to evolving interpretations and enforcement discretion. As part of our compliance program, we have reviewed our sales contracts, marketing materials, and billing practices (among others) to reduce the risk of non-compliance with these and other foreign, federal and state laws. If a governmental authority was to conclude that we are not in compliance with applicable laws and regulations, we and our officers, directors and employees could be subject to criminal and civil penalties, including, for example, exclusion from participation as a supplier of product to beneficiaries covered by federal healthcare programs, including but not limited to Medicare and Medicaid. Any failure to comply with laws, regulations or contractual requirements relating to reimbursement and health care goods and services could adversely affect our reputation, business, financial condition and cash flows.

With respect to the federal Anti-Kickback Statute, Congress and the OIG have established a large number of statutory exceptions and regulatory safe harbors. An arrangement that fits squarely into an exception or safe harbor is immune from prosecution under the Anti-Kickback Statute.

We train and educate employees and marketing representatives on the Anti-Kickback Statute and their obligations thereunder, and we endeavor to comply with the applicable safe harbors. However, some of our arrangements, like many other common and non-abusive arrangements, may implicate the Anti-Kickback Statute and are not covered by a safe harbor, but

nevertheless do not present a material risk to beneficiaries or federal healthcare programs and, as such, would not likely invite government scrutiny or prosecution or warrant the imposition of sanctions. However, we cannot offer assurance that arrangements that do not squarely meet an exception or safe harbor will not be found to violate the Anti-Kickback Statute. Allegations of violations of the Anti-Kickback Statute can also trigger liability under the federal Civil Monetary Penalty Law and federal civil False Claims Act,thereby increasing the penalty structure for these violations.

Our financial relationships with referring physicians and their immediate family members must comply with the Stark Law by meeting an applicable exception. We attempt to structure our relationships to meet an exception to the Stark Law, but the regulations implementing the exceptions are detailed and complex, and we cannot assure you that every relationship complies fully with the Stark Law. Unlike the Anti-Kickback Statute, failure to meet an exception under the Stark Law results in a violation of the Stark Law, even if such violation is technical in nature. Violations of the Stark Law create overpayment liability under the federal civil False Claims Act and can also trigger separate penalties under the Civil Monetary Penalties Law. Knowing violations of the Stark Law carry increased civil monetary penalties and would likely be classified as the knowing submission of a false claim or knowingly making a false statement to the government, triggering liability under the federal civil False Claims Act. Certain Stark Law violations can also trigger exclusion from federal healthcare programs.

If we violate the Anti-Kickback Statute or Stark Law, or if we improperly bill for our services, or retain overpayments longer than 60 days after identification, or fail to act with reasonable diligence to investigate credible information regarding potential overpayments, we may be found to violate the federal civil False Claims Act, either under a suit brought by the government or by a private person under a *qui tam* relator, or "whistleblower," suit.

If we or our suppliers or distributors fail to comply with ongoing regulatory requirements, or if we have unanticipated problems with our products, the products could be subject to restrictions or withdrawal from the market.

Any product for which we obtain marketing approval, clearance or authorization will be subject to continual review and periodic inspections by the FDA and other regulatory bodies, which may include inspection of our manufacturing processes, post-approval clinical data and promotional activities for such product. The FDA's Medical Device Reporting, or MDR, regulations require that we report to the FDA any incident in which our product may have caused or contributed to a death or serious injury, or in which our product malfunctioned and, if the malfunction were to recur, it would likely cause or contribute to a death or serious injury.

If FDA determines that there is a reasonable probability that a device intended for human use would cause serious, adverse health consequences or death, the agency may issue a cease distribution and notification order and a mandatory recall order. We may also decide to recall a product voluntarily if we find a material deficiency, including unacceptable risks to health, manufacturing defects, design errors, component failures, labeling defects, or other issues. Recalls of our products could divert the attention of our management and have an adverse effect on our reputation, financial condition, and operating results.

We and our suppliers are also required to comply with the FDA's Quality System Regulation, or QSR, and other regulations which cover the methods and documentation of the design, testing, production, control, selection and oversight of suppliers or contractors, quality assurance, labeling, packaging, storage, complaint handling, shipping and servicing of our products. The FDA enforces the QSR through unannounced inspections.

Compliance with ongoing regulatory requirements can be complex, expensive and time-consuming. Failure by us or one of our suppliers or distributors to comply with statutes and regulations administered by the FDA, competent authorities and other regulatory bodies, or failure to take adequate response to any observations, could result in, among other things, any of the following actions:

- warning letters or untitled letters that require corrective action;
- delays in approving, or refusal to approve, our CGM systems;
- fines and civil or criminal penalties;
- unanticipated expenditures;
- FDA refusal to issue certificates to foreign governments needed to export our products for sale in other countries;
- suspension or withdrawal of clearance or approval by the FDA or other regulatory bodies;
- product recall or seizure;
- administrative detention;
- interruption of production, partial suspension, or complete shutdown of production;
- interruption of the supply of components from our key component suppliers;
- operating restrictions;
- court consent decrees;
- FDA orders to repair, replace, or refund the cost of devices;

- injunctions; and
- criminal prosecution.

The effect of these events can be difficult to quantify. If any of these actions were to occur, it would harm our reputation and cause our product sales and profitability to suffer. In addition, we believe events that could be classified as reportable events pursuant to MDR regulations are generally underreported by physicians and users, and any underlying problems could be of a larger magnitude than suggested by the number or types of MDRs filed by us. Furthermore, our key component suppliers may not currently be or may not continue to be in compliance with applicable regulatory requirements.

Even if regulatory approval or clearance of a product is granted, the approval or clearance may be subject to limitations on the indicated uses for which the product may be marketed or contain requirements for costly post-marketing testing or surveillance to monitor the safety or effectiveness of the product. Later discovery of previously unknown problems with our products, including software bugs, unanticipated adverse events or adverse events of unanticipated severity or frequency, manufacturing problems, or failure to comply with regulatory requirements such as the QSR, MDR reporting, or other post-market requirements may result in restrictions on such products or manufacturing processes, withdrawal of the products from the market, voluntary or mandatory recalls, fines, suspension of regulatory approvals, product seizures, injunctions, the imposition of civil or criminal penalties, or criminal prosecution. In addition, our distributors have rights to create marketing materials for their sales of our products, and may not adhere to contractual, legal or regulatory limitations that are imposed on their marketing efforts.

We may be liable for contamination or other harm caused by materials that we handle, and changes in environmental regulations could cause us to incur additional expense.

Our research and development and clinical processes involve the handling of potentially harmful biological materials as well as hazardous materials. We are subject to international and domestic (including federal, state and local) laws, rules and regulations governing the use, handling, storage and disposal of hazardous and biological materials and we incur expenses relating to compliance with these laws and regulations. If violations of environmental, health and safety laws occur, we could be held liable for damages, penalties and costs of remedial actions. These expenses or this liability could have a significant negative impact on our financial condition. We may violate environmental, health and safety laws in the future as a result of human error, equipment failure or other causes. Environmental laws could become more stringent over time, imposing greater compliance costs and increasing risks and penalties associated with violations. We are subject to potentially conflicting and changing regulatory agendas of political, business and environmental groups. Changes to or restrictions on permitting requirements or processes, hazardous or biological material storage or handling might require an unplanned capital investment or relocation. Failure to comply with new or existing laws or regulations could harm our business, financial condition and results of operations.

We could become the subject of governmental investigations, claims and litigation.

Health care companies are subject to numerous investigations by various governmental agencies. Further, under the False Claims Act, private parties have the right to bring *qui tam*, or "whistleblower," suits against companies that submit false claims for payments to, or improperly retain overpayments from, the government. Some states have adopted similar state whistleblower and false claims provisions. Depending upon whether the underlying conduct alleged in such inquiries or investigations could be considered systemic, the resolution could have a material, adverse effect on our financial position and results of operations.

Governmental agencies and their agents, such as CMS Medicare Administrative Contractors and other CMS contractors, as well as the OIG, state Medicaid programs, and other state and federal agencies may conduct audits of our operations, relating to covered items and services including those furnished to beneficiaries, health care providers and distributors. Commercial and government-funded managed care payors may conduct similar post-payment audits,. Depending on the nature of the conduct found in such audits and whether the underlying conduct could be considered systemic, the resolution of these audits could have a material adverse effect on our financial position and results of operations. We perform internal audits and monitoring to identify any potential issues.

CMS contracts with Recovery Audit Contractors, or RACs, on a contingency fee basis to conduct post-payment reviews to detect and correct improper payments in the fee-for-service Medicare program. The ACA expanded the RAC program's scope to include managed Medicare plans and Medicaid claims. RAC denials are appealable; however, there currently are significant delays in the assignment of new Medicare appeals to Administrative Law Judges, which negatively impacts our ability to appeal RAC payment denials. In addition, CMS employs various other program integrity contractors – including zone program integrity contractors, or ZPICs, Medicaid integrity contractors, or MICs, and unified program integrity contractors, or UPICs – to perform post-payment audits of claims and identify overpayments, and state Medicaid agencies and other contractors have increased their review and audit activities as well.

We are not presently aware of any governmental investigations involving our executives or us. However, any future

investigations of our executives, our managers or us could result in significant liabilities or penalties to us, as well as adverse publicity. Should we be found out of compliance with any of these laws, regulations or programs, depending on the nature of the findings, our business, our financial position and our results of operations could be negatively impacted.

Risks Related to the Privacy and Security

We are subject to complex and evolving U.S. and foreign laws and regulations regarding privacy, data protection, and other matters. Many of these laws and regulations are subject to change and uncertain interpretation, and could result in claims, changes to our business practices, monetary penalties, increased cost of operations, or declines in user growth or engagement, or otherwise harm our business.

We are subject to a number of foreign, federal and state laws and regulations protecting the use and confidentiality of certain patient health and personal information, including patient records, and restricting the use and disclosure of that protected information. These laws include foreign, federal and state medical privacy laws, breach notification laws and consumer protection laws.

In addition, foreign data protection, privacy, and other laws and regulations can be more restrictive than those in the United States. For example, data localization laws in some countries generally mandate that certain types of data collected in a particular country be stored and/or processed within that country. We may be subject to inquiries, investigations and audits in Europe and around the world, particularly in the areas of consumer and data protection, which will arise in the ordinary course of business and may increase in frequency as we continue to grow and expand our operations. Legislators and regulators may make legal and regulatory changes, or interpret and apply existing laws, in ways that make our products less useful to our customers, require us to incur substantial costs, expose us to unanticipated civil or criminal liability, or cause us to change our business practices. These changes or increased costs could negatively impact our business and results of operations in material ways.

In the ordinary course of our business, we collect and store sensitive data, such as our proprietary business information and that of our clients, contractors, vendors and others as well as personally identifiable information of our customers, vendors and others, which data may include full names, social security numbers, addresses, and birth dates, in our data centers and on our networks. Our employees, contractor and vendors may also have access to and may use personal health information in the ordinary course of our business. The secure processing, maintenance and transmission of this information is critical to our operations. Despite our security measures and business controls, our information technology and infrastructure may be vulnerable to attacks by hackers, breaches due to employee, contractor or vendor error, or malfeasance or other disruptions or subject to the inadvertent or intentional unauthorized release of information. Any such occurrence could compromise our networks and the information stored thereon could be accessed, publicly disclosed, lost or stolen. Any such access, disclosure or other loss of information could (i) result in legal claims or proceedings, and liability under laws that protect the privacy of personal information and regulatory penalties, (ii) disrupt our operations and the services we provide to our clients or (iii) damage our reputation, any of which could adversely affect our profitability, revenue and competitive position.

As we grow and expand our administrative, customer support or IT support services, we may also utilize the services of personnel and contractors located outside of the United States to perform certain functions. While we make every effort to review our applicable contracts and other payor requirements, a local, state, or federal government agency or one of our customers may find the use of offshore resources to be a violation of a legal or contractual requirement, which could result in termination of the contractual relationship, penalties, or changes in our business operations that could adversely affect our business, financial condition, and results of operations. Additionally, while we have implemented industry standard security measures for offshore access to protected health information and other personal information, unauthorized access or disclosure of such information by offshore personnel could (i) result in legal claims or proceedings, and liability under laws that protect the privacy of personal information and regulatory penalties, (ii) disrupt our operations and the services we provide to our clients, (iii) damage to our reputation or (iv) result in the termination of contractual relationships, penalties or the loss of coverage, any of which could adversely affect our profitability, revenue and competitive position.

Security breaches and other disruptions could compromise our information and expose us to liability, which would cause our business and reputation to suffer and could subject us to substantial liabilities.

The Administrative Simplification Provisions of the Health Insurance Portability and Accountability Act of 1996, as amended, and implementing regulations, or HIPAA, extensively regulate the use and disclosure of individually identifiable health information, known as "protected health information," and require covered entities, including health plans and most health care providers, to implement administrative, physical and technical safeguards to protect the security of such information. Certain provisions of the security and privacy regulations apply to business associates (entities that handle protected health information on behalf of covered entities), and business associates are subject to direct liability for violation of these provisions. In addition, a covered entity may be subject to penalties as a result of a business associate violating HIPAA, if the business associate is found to be an agent of the covered entity.

Covered entities must report breaches of unsecured protected health information to affected individuals without unreasonable delay and notification must also be made to the U.S. Department of Health & Human Services, Office for Civil Rights, or OCR and, in certain situations involving large breaches, to the media. Various U.S. state laws and regulations may also require us to notify affected individuals and state agencies in the event of a data breach involving individually identifiable information.

Violations of the HIPAA privacy and security regulations may result in criminal and civil penalties. The OCR enforces the regulations and performs compliance audits. In addition to enforcement by OCR, state attorneys general are authorized to bring civil actions seeking either injunction or damages in response to violations that threaten the privacy of state residents. OCR may resolve HIPAA violations through informal means, such as allowing a covered entity to implement a corrective action plan, but OCR has the discretion to move directly to impose monetary penalties and is required to impose penalties for violations resulting from willful neglect. We follow and maintain a HIPAA compliance plan, which we believe complies with the HIPAA privacy and security regulations, but there can be no assurance that OCR or other regulators will agree. The HIPAA privacy regulations and security regulations have and will continue to impose significant costs on us in order to comply with these standards.

There are numerous other laws and legislative and regulatory initiatives at the federal and state levels addressing privacy and security concerns. We also remain subject to federal or state privacy-related laws that are more restrictive than the privacy regulations issued under HIPAA. These laws vary and could impose additional penalties. For example, the Federal Trade Commission uses its consumer protection authority to initiate enforcement actions in response to alleged privacy and data security violations. California recently enacted the California Consumer Privacy Act, or CCPA, which goes into effect January 1, 2020. The CCPA, among other things, creates new data privacy obligations for covered companies and provides new privacy rights to California residents, including the right to opt out of certain disclosures of their information. The CCPA also creates a private right of action with statutory damages for certain data breaches, thereby potentially increasing risks associated with a data breach. The California Attorney General clarifying regulations will not be finalized until 2020. It remains unclear what, if any, additional modifications will be made to this legislation or how it will be interpreted. Therefore the effects of the CCPA are significant and will likely require us to modify our data processing practices, and may cause us to incur substantial costs and expenses to comply.

We are also subject to laws and regulations in foreign countries covering data privacy and other protection of health and employee information that may be more onerous than corresponding U.S. laws, including in particular the laws of Europe.

For instance, in the European Union, increasingly stringent data protection and privacy rules that have and will continue to have substantial impact on the use of patient data across the healthcare industry became effective in May 2018. The EU General Data Protection Regulation, or GDPR, applies across the European Union and includes, among other things, a requirement for prompt notice of data breaches to data subjects and supervisory authorities in certain circumstances and significant fines for non-compliance. The GDPR fine framework can be up to 20 million euros, or up to 4 % of the company's total global turnover of the preceding fiscal year, whichever is higher. The GDPR also requires companies processing personal data of individuals residing in the European Union to comply with EU privacy and data protection rules, even if the company itself does not have a physical presence in the European Union. Noncompliance could result in the imposition of fines, penalties, or orders to stop noncompliant activities. Due to the strong consumer protection aspects of the GDPR, companies subject to its purview are allocating substantial legal costs to the development of necessary policies and procedures and overall compliance efforts. We expect continued costs associated with maintaining compliance with GDPR into the future, and these provisions as interpreted by EU agencies, could negatively impact our business, financial condition and results of operations.

Cybersecurity risks and cyber incidents could result in the compromise of confidential data or critical data systems and give rise to potential harm to customers, remediation and other expenses, expose us to liability under HIPAA, consumer protection laws, or other common law theories, subject us to litigation and federal and state governmental inquiries, damage our reputation, and otherwise be disruptive to our business and operations.

Cyber incidents can result from deliberate attacks or unintentional events. We collect and store on our networks sensitive information, including intellectual property, proprietary business information and personally identifiable information of individuals, such as our customers and employees. The secure maintenance of this information and technology is critical to our business operations. We have implemented multiple layers of security measures to protect the confidentiality, integrity and availability of this data and the systems and devices that store and transmit such data. We utilize current security technologies, and our defenses are monitored and routinely tested internally and by external parties. Despite these efforts, threats from malicious persons and groups, new vulnerabilities and advanced new attacks against information systems create risk of cybersecurity incidents. These incidents can include, but are not limited to, gaining unauthorized access to digital systems for purposes of misappropriating assets or sensitive information, corrupting data, or causing operational disruption. Because the techniques used to obtain unauthorized access, disable or degrade service, or sabotage systems change frequently and may not immediately produce signs of intrusion, we may be unable to anticipate these incidents or techniques, timely discover them, or implement adequate preventative measures.

These threats can come from a variety of sources, ranging in sophistication from an individual hacker to malfeasance by employees, consultants or other service providers to state-sponsored attacks. Cyber threats may be generic, or they may be custom-crafted against our information systems. Over the past several years, cyber-attacks have become more prevalent and much harder to detect and defend against. Our network and storage applications, as well as those of our contractors, may be vulnerable to cyber-attack, malicious intrusion, malfeasance, loss of data privacy or other significant disruption and may be subject to unauthorized access by hackers, employees, consultants or other service providers. In addition, hardware, software or applications we develop or procure from third parties may contain defects in design or manufacture or other problems that could unexpectedly compromise information security. Unauthorized parties may also attempt to gain access to our systems or facilities through fraud, trickery or other forms of deceiving our employees, contractors and temporary staff.

There can be no assurance that we will not be subject to cybersecurity incidents that bypass our security measures, impact the integrity, availability or privacy of personal health information or other data subject to privacy laws or disrupt our information systems, devices or business, including our ability to deliver services to our customers. As a result, cybersecurity, physical security and the continued development and enhancement of our controls, processes and practices designed to protect our enterprise, information systems and data from attack, damage or unauthorized access remain a priority for us. As cyber threats continue to evolve, we may be required to expend significant additional resources to continue to modify or enhance our protective measures or to investigate and remediate any cybersecurity vulnerabilities. The occurrence of any of these events could result in:

- harm to customers;
- business interruptions and delays;
- the loss, misappropriation, corruption or unauthorized access of data;
- litigation, including potential class action litigation, and potential liability under privacy, security and consumer protection laws or other applicable laws;
- reputational damage;
- increase to insurance premiums; and
- foreign, federal and state governmental inquiries, any of which could have a material, adverse effect on our financial position and results of operations and harm our business reputation.

Failure to protect our information technology infrastructure against cyber-based attacks, network security breaches, service interruptions, or data corruption could significantly disrupt our operations and adversely affect our business and operating results.

We rely on information technology and telephone networks and systems, including the Internet, to process and transmit sensitive electronic information and to manage or support a variety of business processes and activities, including sales, billing, customer service, procurement and supply chain, manufacturing, and distribution. We use enterprise information technology systems to record, process, and summarize financial information and results of operations for internal reporting purposes and to comply with regulatory financial reporting, legal, and tax requirements. Our information technology systems, some of which are managed by third-parties, may be susceptible to damage, disruptions or shutdowns due to computer viruses, ransomware or other malware, attacks by computer hackers, failures during the process of upgrading or replacing software, databases or components thereof, power outages, hardware failures, telecommunication failures, user errors or catastrophic events. Although we have developed systems and processes that are designed to protect customer information and prevent data loss and other security breaches, including systems and processes designed to reduce the impact of a security breach at a third-party vendor, such measures cannot provide absolute security. If our systems are breached or suffer severe damage, disruption or shutdown and we are unable to effectively resolve the issues in a timely manner, our business and operating results may significantly suffer and we may be subject to litigation, government enforcement actions and other actions for which we could face financial liability and other adverse consequences which may include:

- additional government oversight of our operations;
- loss of existing customers;
- difficulty in attracting new customers;
- problems in determining product cost estimates and establishing appropriate pricing;
- difficulty in preventing, detecting, and controlling fraud;
- disputes with customers, physicians, and other health care professionals;
- increases in operating expenses, incurrence of expenses, including remediation costs;
- loss of revenues (including through loss of coverage or reimbursement);
- product development delays;

- disruption of key business operations; and
- diversion of attention of management and key information technology resources.

Unauthorized third parties may seek to access our devices or other products and services, or related devices, products, and services, and modify or use them in a way inconsistent with our FDA clearances and approvals, which may create risks to users.

Medical devices are increasingly connected to the internet, hospital networks, and other medical devices to provide features that improve healthcare and increase the ability of healthcare providers to treat patients and patients to manage their conditions. These same features may also increase cybersecurity risks and the risks of unauthorized access and use by third parties. As such, unauthorized third parties may seek to access our devices or other products and services, or related devices, products, and services, and modify or use them in a way inconsistent with our FDA clearances and approvals, which may create risks to users and potential exposure to the company.

Risks Related to our International Operations

Laws and regulations governing the export of our products could adversely impact our business.

The U.S. Department of the Treasury's Office of Foreign Assets Control, and the Bureau of Industry and Security at the U.S. Department of Commerce, administer certain laws and regulations that restrict U.S. persons and, in some instances, non-U.S. persons, in conducting activities, and transacting business with or making investments in certain countries, governments, entities and individuals subject to U.S. economic sanctions. Due to our international operations, we are subject to such laws and regulations, which are complex, restrict our business dealings with certain countries and individuals, and are constantly changing. Further restrictions may be enacted, amended, enforced or interpreted in a manner that materially impacts our operations.

Violations of these regulations are punishable by civil penalties, including fines, denial of export privileges, injunctions, asset seizures, debarment from government contracts and revocations or restrictions of licenses, as well as criminal fines and imprisonment. We have established procedures designed to assist with our compliance with such laws and regulations. However, we have only limited experience dealing with these laws and regulations and we cannot guarantee that our procedures will effectively prevent us from violating these regulations in every transaction in which we may engage. Any such violation could adversely affect our reputation, business, financial condition and results of operations.

The failure to comply with U.S. Foreign Corrupt Practices Act and similar worldwide anti-bribery laws in non-U.S. jurisdictions could materially adversely affect our business and result in civil and/or criminal sanctions.

The U.S. Foreign Corrupt Practices Act, the UK Bribery Act and similar worldwide anti-bribery laws in non-U.S. jurisdictions generally prohibit companies and their intermediaries from making improper payments to non-U.S. government officials and, in some instances, other persons for the purpose of obtaining or retaining business. Because of the predominance of government-sponsored healthcare systems around the world, most of our customer relationships outside of the United States are with governmental entities and are therefore potentially subject to such anti-bribery laws. Global enforcement of anti-corruption laws has increased substantially in recent years, with more frequent voluntary self-disclosures by companies, aggressive investigations and enforcement proceedings by U.S. and foreign governmental agencies, and assessment of significant fines and penalties against companies and individuals. Our international operations create the risk of unauthorized payments or offers of payments by one of our employees, consultants, sales agents, or distributors, because these parties are not always subject to our direct oversight and control. It is our policy to implement safeguards to educate our employees and agents on these legal requirements and discourage improper practices. However, our existing safeguards and any future improvements may prove to be less than effective, and our employees, consultants, sales agents, or distributors may engage in conduct for which we might be held responsible. In addition, the government agencies may seek to hold us liable for successor liability for anti-corruption law violations committed by any companies in which we invest or that we acquire. Any alleged or actual violations of these regulations may subject us to government scrutiny, severe criminal or civil sanctions and other liabilities, including exclusion from government contracting, and could disrupt our business, and result in a material adverse effect on our business, financial condition, and results of operations.

Current uncertainty in global economic and political conditions makes it particularly difficult to predict product demand and other related matters and makes it more likely that our actual results could differ materially from expectations.

Our operations and performance depend on worldwide economic and political conditions. These conditions have been adversely impacted by continued global economic uncertainty, political instability and military hostilities in multiple geographies, concerns over the potential downgrade of U.S. sovereign debt and continued sovereign debt, monetary and financial uncertainties in Europe and other foreign countries. These include potential reductions in the overall stability and suitability of the Euro as a single currency, given the economic and political challenges facing individual Eurozone countries.

These conditions have made and may continue to make it difficult for our customers and potential customers to afford our products, and could cause our customers to stop using our products or to use them less frequently. If that were to occur, our revenue may decrease and our performance may be negatively impacted. In addition, the pressure on consumers to absorb more of their own health care costs has resulted in some cases in higher deductibles and limits on durable medical equipment, which may cause seasonality in purchasing patterns. Furthermore, during economic uncertainty, our customers have had job losses and may continue to have issues gaining timely access to sufficient health insurance or credit, which could result in their unwillingness to purchase products or impair their ability to make timely payments to us. We cannot predict the reoccurrence of any economic slowdown or the strength or sustainability of the economic recovery, worldwide, in the United States, or in our industry. These and other economic factors could have a material adverse effect on our business, financial condition and results of operations.

We are subject to a variety of risks due to our international operations that could adversely affect our business, our operations or profitability and operating results.

Our operations in countries outside the United States, which accounted for approximately 21% of our revenues for the twelve months ended December 31, 2019, are accompanied by certain financial and other risks. In addition to opening offices in Austria, Canada, Germany, the Philippines, Switzerland and the United Kingdom, in connection with distributor acquisitions and otherwise, we intend to continue to pursue growth opportunities in sales outside the United States, especially in Asia (including Japan and Korea) and Europe, and we may increase our use of administrative and support functions from locations outside the United States, which could expose us to greater risks associated with our sales and operations. As we pursue opportunities outside the United States, we may become more exposed to these risks and our ability to scale our operations effectively may be affected. Additionally, we may experience difficulties in scaling these functions from locations outside the United States and may not experience the expected cost efficiencies.

Our profitability and international operations are, and will continue to be, subject to a number of risks and potential costs, including:

- local product preferences and product requirements;
- longer-term receivables than are typical in the United States;
- fluctuations in foreign currency exchange rates;
- less intellectual property protection in some countries outside the United States than exists in the United States;
- trade protection measures and import and export licensing requirements;
- workforce instability;
- fluctuations in trade policy and tariff regulations;
- political and economic instability; and
- the potential payment of U.S. income taxes on certain earnings of our subsidiaries outside the United States upon repatriation.

While it is impossible for us to predict whether these and other proposals will be implemented, or how they will ultimately impact us, they may materially impact our results of operations if, for example, our profits earned abroad are subject to U.S. income tax, or we are otherwise disallowed deductions as a result of these profits.

As another example, changes in foreign currency exchange rates may reduce the reported value of our foreign currency denominated revenues, expenses, and cash flows. We cannot predict changes in currency exchange rates, the impact of exchange rate changes, nor the degree to which we will be able to manage the impact of currency exchange rate changes.

As a final example, on June 23, 2016, the United Kingdom, or U.K., held a referendum in which voters approved an exit from the European Union, commonly referred to as “Brexit.” As a result of the referendum, the U.K. government is negotiating the terms of the U.K.’s future relationship with the European Union. Although it is unknown what those terms will be, it is possible that there will be greater restrictions on imports and exports and on the movement of people between the U.K. and European Union countries, and increased regulatory complexities.

Failure to obtain any required regulatory authorization in foreign jurisdictions will prevent us from marketing our products abroad.

We conduct limited commercial and marketing efforts in Africa, Asia, Australia, Canada, Europe, Latin America, the Middle East and New Zealand with respect to our CGM systems and may seek to market our products in other regions in the future. Outside the United States, we can market a product only if we receive a marketing authorization and, in some cases, pricing approval, from the appropriate regulatory authorities. The authorization and/or approval procedure varies among countries and can involve additional testing, and the time required to obtain any required authorization or approval may differ from that required to obtain FDA marketing authorization(s). The foreign regulatory authorization or approval process may

include all of the risks associated with obtaining FDA marketing authorization(s) in addition to other risks. We may not obtain foreign regulatory authorizations or approvals on a timely basis, if at all. Obtaining a marketing authorization from the FDA does not ensure authorization or approval by regulatory authorities in other countries, and authorization or approval by one foreign regulatory authority does not ensure authorization or approval by regulatory authorities in other foreign countries or by the FDA. In addition, in order to obtain the authorization to market our products in certain foreign jurisdictions, we may need to obtain a Certificate to Foreign Government from the FDA. The FDA may refuse to issue a Certificate to Foreign Government in certain instances, including without limitation, during the pendency of any outstanding warning letter. As a result, we may not be able to file for regulatory approvals or marketing authorizations and may not receive necessary approvals or authorizations to commercialize our products in any market outside the United States on a timely basis, or at all.

Risks Related to Intellectual Property Protection and Use

We are subject to claims of infringement or misappropriation of the intellectual property rights of others, which could prohibit us from shipping affected products, require us to obtain licenses from third parties or to develop non-infringing alternatives, and subject us to substantial monetary damages and injunctive relief. We may also be subject to other claims or suits.

Third parties have asserted, and may assert, infringement or misappropriation claims against us with respect to our current or future products. We are aware of numerous patents issued to third parties that may relate to aspects of our business, including the design and manufacture of CGM sensors and membranes, as well as methods for continuous glucose monitoring. Whether a product infringes a patent involves complex legal and factual issues, the determination of which is often uncertain. Therefore, we cannot be certain that we have not infringed the intellectual property rights of such third parties or others. Our competitors may assert that our CGM systems or the methods we employ in the use of our systems are covered by U.S. or foreign patents held by them. We have in the past settled some such allegations and may need to do so again in the future. For example, in July 2014, we entered into a Settlement and License Agreement with Abbott to settle all pending patent infringement legal proceedings brought by Abbott against us which is set to expire on March 31, 2021. This risk is exacerbated by the fact that there are numerous issued patents and pending patent applications relating to self-monitored glucose testing systems in the medical technology field. Because patent applications may take years to issue, there may be applications now pending of which we are unaware that may later result in issued patents that our products infringe. There could also be existing patents of which we are unaware that one or more components of our system may inadvertently infringe. As the number of competitors in the market for CGM systems grows, the possibility of patent infringement by us or a patent infringement claim against us increases. If we are unable to successfully defend any such claims as they may arise or enter into or extend settlement and license agreements on acceptable terms or at all, our business operations may be harmed. We have been and continue to be involved in various patent infringement actions, including:

On March 28, 2016, AgaMatrix, Inc., or AgaMatrix, filed a patent infringement lawsuit against us in the U.S. District Court for the District of Oregon, asserting that certain of our products infringe three patents held by AgaMatrix. (After filing suit, AgaMatrix reorganized its business and the Court granted AgaMatrix's motion to substitute the newly created entity WaveForm Technologies, Inc., as the plaintiff following AgaMatrix's transfer of the three asserted patents to WaveForm.) DexCom filed petitions for *inter partes* review with the Patent Trial and Appeal Board, or PTAB, of the U.S. Patent and Trademark Office, challenging each of the three asserted patents as being unpatentable in view of prior art. The PTAB issued a Final Written Decision for each of the first two patents on February 28, 2018, where the PTAB found the majority of asserted claims from the first patent unpatentable and the remaining claims under review not unpatentable. The PTAB found all claims under review from the second patent not unpatentable. On September 12, 2018, the PTAB found all of the asserted claims in the third patent unpatentable. In October 2018, we filed in the District Court a motion for summary judgment that all remaining asserted claims are invalid. The District Court granted that motion and, on August 23, 2019, entered judgment in our favor. On September 6, 2019, WaveForm appealed the judgment. The appeal is pending and no hearing date has been set.

We have also filed several lawsuits against AgaMatrix. We filed a patent infringement lawsuit against AgaMatrix in the United States District Court for the Central District of California, or C.D. Cal., in which a Final Judgment of non-infringement was entered by the C.D. Cal judge on February 23, 2018 and affirmed on appeal by the Federal Circuit on March 7, 2019. AgaMatrix was awarded attorneys' fees for this lawsuit. As of December 31, 2019, we have accrued an immaterial amount for those fees. The fee decision is currently on appeal to the Federal Circuit. On September 15, 2017, we filed a patent infringement lawsuit against AgaMatrix in the United States District Court for the District of Delaware, asserting certain single-point blood glucose monitoring products of AgaMatrix infringe two patents held by us. In addition, on September 18, 2017, we filed a Complaint against AgaMatrix in the International Trade Commission, referred to as the ITC, requesting that the ITC institute an investigation and issue an order excluding certain products of AgaMatrix from importation into or sale in the United States based on AgaMatrix's infringement of the same two patents asserted in the Delaware litigation. The investigation was terminated by the ITC on April 4, 2019 with a finding of non-infringement. The decision is currently on appeal.

Neither the outcome of these lawsuits nor the amount and range of potential loss associated with the lawsuits can be assessed at this time. Other than the attorneys' fees described above, as of December 31, 2019 we have accrued no amounts for contingent losses associated with these suits.

Any infringement or misappropriation claim could cause us to incur significant costs, place significant strain on our financial resources, divert management's attention from our business and harm our reputation. In addition, if the relevant patents are upheld as valid and enforceable and we are found to infringe such patents, we could be prohibited from selling any of our products that is found to infringe unless we could obtain licenses to use the technology covered by the patent or are able to design around the patent. We may be unable to obtain a license on terms acceptable to us, if at all, and we may not be able to redesign our products to avoid infringement. We may be unable to maintain or renew licenses on terms acceptable to us, if at all, and we may be prohibited from selling any of our products that required the technology covered by the relevant licensed patents. Even if we are able to redesign our products to avoid an infringement claim, we may not receive FDA approval for such changes in a timely manner or at all.

Any adverse determination in litigation or interference proceedings to which we are or may become a party relating to patents or other intellectual property rights could subject us to significant liabilities to third parties or require us to seek licenses from other third parties. If we are found to infringe third-party patents, a court could order us to pay damages to compensate the patent owner for the infringement, such as a reasonable royalty amount and/or profits lost by the patent owners, along with prejudgment and/or post-judgment interest. Furthermore, if we are found to willfully infringe third-party patents, we could, in addition to other penalties, be required to pay treble damages; and if the court finds the case to be exceptional, we may be required to pay attorneys' fees for the prevailing party. If we are found to infringe third-party copyrights or trademarks or misappropriate third-party trade secrets, based on the intellectual property at issue, a court could order us to pay statutory damages, actual damages, or profits, such as reasonably royalty, lost profits of the owners, unjust enrichment, disgorgement of profits, and/or a reasonable royalty, and the court could potentially award attorneys' fees or exemplary or enhanced damages. Although patent and intellectual property disputes in the medical device area have often been settled through licensing or similar arrangements, costs associated with such arrangements may be substantial and would likely include ongoing royalties. We may be unable to obtain necessary intellectual property licenses on satisfactory terms. If we do not obtain any such necessary licenses, we may not be able to redesign our products to avoid infringement and any redesign may not receive FDA approval or other requisite marketing authorization in a timely manner or at all. Adverse determinations in a judicial or administrative proceeding or failure to obtain necessary intellectual property licenses could prevent us from manufacturing and selling our products, which would have a significant adverse impact on our business. If litigation were to be initiated by intellectual property owners, there could significant legal fees and costs incurred in defending litigation (which may include filing administrative actions to attack the intellectual property) as well as a potential monetary settlement payment to the owners, even if the matter is resolved before going to trial. Moreover, the owners may take an overly aggressive approach and/or include multiple allegations in a single litigation.

In addition, from time to time, we are subject to various claims and suits arising out of the ordinary course of business, including commercial or employment related matters. Although individually we do not expect these claims or suits to have a material adverse effect on DexCom, in the aggregate they may divert significant time and resources from our staff.

Our inability to adequately protect our intellectual property could allow our competitors and others to produce products based on our technology, which could substantially impair our ability to compete.

Our success and our ability to compete depend, in part, upon our ability to maintain the proprietary nature of our technologies. We rely on a combination of patent, copyright and trademark law, and trade secrets and nondisclosure agreements to protect our intellectual property. However, such methods may not be adequate to protect us or permit us to gain or maintain a competitive advantage. Our patent applications may not issue as patents in a form that will be advantageous to us, or at all. Our issued patents, and those that may issue in the future, may be challenged, invalidated or circumvented, which could limit our ability to stop competitors from marketing related products. In addition, there are numerous recent changes to the patent laws and proposed changes to the rules of the U.S. Patent and Trademark Office, which may have a significant impact on our ability to protect our technology and enforce our intellectual property rights. For example, in September 2011, the United States enacted sweeping changes to its patent system under the Leahy-Smith America Invents Act, including changes that would transition the United States from a "first-to-invent" system to a "first-to-file" system and alter the processes for challenging issued patents. These changes could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

To protect our proprietary rights, we may in the future need to assert claims of infringement against third parties. The outcome of litigation to enforce our intellectual property rights in patents, copyrights, trade secrets or trademarks is highly unpredictable, could result in substantial costs and diversion of resources, and could have a material adverse effect on our business, financial condition and results of operations regardless of the final outcome of such litigation. In the event of an adverse judgment, a court could hold that some or all of our asserted intellectual property rights are not infringed, or are invalid or unenforceable, and could award attorney fees.

Despite our efforts to safeguard our unpatented and unregistered intellectual property rights, we may not succeed in doing so or the steps taken by us in this regard may not be adequate to detect or deter misappropriation of our technology or to prevent an unauthorized third party from copying or otherwise obtaining and using our products, technology or other information that we regard as proprietary. In addition, third parties may be able to design around our patents. Furthermore, the laws of foreign countries may not protect our proprietary rights to the same extent as the laws of the United States.

Litigation Risks

We face the risk of product liability claims and may be subject to damages, fines, penalties and injunctions, among other things.

Our business exposes us to the risk of product liability claims that is inherent in the testing, manufacturing and marketing of medical devices, including those which may arise from the misuse (including system hacking or other unauthorized access by third parties to our systems) or malfunction of, or design flaws in, our products. This liability may vary based on the FDA classification associated with our devices. Notably, the classification of our G6 system as a Class II medical device is likely to weaken our ability to rely on federal preemption of state law claims that assert liability against us for harms arising from use of the G6. We may be subject to product liability claims if our products cause, or merely appear to have caused, an injury. Claims may be made by customers, healthcare providers or others selling our products. The risk of product liability claims may increase now that our G5 Mobile system has obtained indications and approved labeling in the United States, in Canada, and in the countries utilizing the CE Mark that allow for our patients to make diabetes treatment decisions with our CGM system in conjunction with only two finger sticks required for calibration of the system and our G6 does not require confirmatory finger sticks when making treatment decisions or finger stick tests each day for calibration, although it does require finger stick tests when symptoms do not match readings and when readings are unavailable. The risk of claims may also increase if our products are subject to a product recall or seizure. An example of the difficulty of complying with the regulatory requirements associated with the manufacture of our products, we issued notifications to our customers regarding the audible alarms and alerts associated with our receivers.

Although we have insurance at levels 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, the coverage may not be adequate to protect us against any future product liability claims. Further, if additional products are approved for marketing, we may seek additional insurance coverage. 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 result in significant costs and significant harm to our business.

We may be subject to claims against us even if the apparent injury is due to the actions of others or misuse of the device or a partner device. Our customers, either on their own or following the advice of their physicians, may use our products in a manner not described in the products' labeling and that differs from the manner in which it was used in clinical studies and approved by the FDA. For example, our current systems are designed to be used by an individual continuously for up to seven days for our G4 PLATINUM and G5 Mobile system and up to 10 days for our G6 system, but the individual might be able to circumvent the safeguards designed into the systems and use the products for longer than seven or 10 days. Off-label use of products by customers is common, and any such off-label use of our products could subject us to additional liability, or require design changes to limit this potential off-label use once discovered. The CE Mark and the HealthCanada and FDA approvals for our G5 Mobile system include indications that allow patients to make diabetes treatment decisions based on the information generated by such system, although both regulators still require finger stick calibrations two times per day. In addition, other regulatory agencies may in the future approve similar diabetes treatment indications. We expect that such diabetes treatment indications could expose us to additional liability. These liabilities could prevent or interfere with our product commercialization efforts. Defending a suit, regardless of merit, could be costly, could divert management attention and might result in adverse publicity, which could result in the withdrawal of, or inability to recruit, clinical trial volunteers or result in reduced acceptance of our products in the market.

We may be subject to fines, penalties and injunctions if we are determined to be promoting the use of our products for unapproved or improper off-label uses.

Although we believe our promotional materials and practices comply with FDCA and other applicable laws and regulations, as may be amended from time to time, if the FDA or other regulatory body with competent jurisdiction over us, our activities or products takes the position that our marketing, promotional or other materials or activities constitute improper promotion or marketing of an unapproved or improper use, the FDA or other regulatory body could request that we modify our materials or practices, or subject us to regulatory enforcement actions, including the issuance of a warning letter, injunction, seizure, civil fine and criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might

take action if they consider promotional, marketing or other materials or activities to constitute improper promotion of an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. Recent court decisions have impacted the FDA's enforcement activity regarding off-label promotion in light of First Amendment considerations; however, there are still significant risks in this area in part due to the potential False Claims Act exposure.

Direct-to-consumer marketing and social media effort may expose us to additional regulatory scrutiny.

Our efforts to promote our products via direct-to-consumer marketing and social media initiatives may subject us to additional scrutiny of our practices of effective communication of risk information, benefits or claims, under the oversight of the FDA, FTC, or both.

In some instances in our advertising and promotion, we may make claims regarding our product as compared to competing products, which may subject us to heightened regulatory scrutiny, enforcement risk, and litigation risks.

The FDA applies a heightened level of scrutiny to comparative claims when applying its statutory standards for advertising and promotion, including with regard to its requirement that promotional labeling be truthful and not misleading. There is potential for differing interpretations of whether certain communications are consistent with a product's FDA-required labeling, and FDA will evaluate communications on a fact-specific basis.

In addition, making comparative claims may draw concerns from our competitors. Where a company makes a claim in advertising or promotion that its product is superior to the product of a competitor (or that the competitor's product is inferior), this creates a risk of a lawsuit by the competitor under federal and state false advertising or unfair and deceptive trade practices law, and possibly also state libel law. Such a suit may seek injunctive relief against further advertising, a court order directing corrective advertising, and compensatory and punitive damages where permitted by law.

Risks Relating to Our Public Company Status, Tax Laws and Growth Through Acquisition

We may face risks associated with acquisitions of companies, products and technologies and our business could be harmed if we are unable to address these risks.

If we are presented with appropriate opportunities, we could acquire or make other investments in complementary companies, products or technologies. We may not realize the anticipated benefit of our acquisitions, or the realization of the anticipated benefits may require greater expenditures than anticipated by us. We will likely face risks, uncertainties and disruptions associated with the integration process, including difficulties in the integration of the operations and services of any acquired company, integration of acquired technology with our products, diversion of our management's attention from other business concerns, the potential loss of key employees or customers of the acquired businesses and impairment charges if future acquisitions are not as successful as we originally anticipate. If we fail to successfully integrate other companies, products or technologies that we acquire, our business could be harmed. Furthermore, we may have to incur debt or issue equity or equity-linked securities to pay for any future acquisitions or investments, the issuance of which could be dilutive to our existing stockholders. In addition, our operating results may suffer because of acquisition-related costs or amortization expenses or charges relating to acquired intangible assets.

Compliance with regulations relating to public company corporate governance matters and reporting is time consuming and expensive.

Many laws and regulations, notably those adopted in connection with the Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, new SEC regulations and The Nasdaq Stock Market listing rules, impose obligations on public companies, such as ours, which have increased the scope, complexity and cost of corporate governance, reporting and disclosure practices. Compliance with these laws and regulations, including enhanced new disclosures, has required and will continue to require substantial management time and oversight and the incurrence of significant accounting and legal costs. The effects of new laws and regulations remain unclear and will likely require substantial management time and oversight and require us to incur significant additional accounting and legal costs. Additionally, changes to existing accounting rules or standards, such as the potential requirement that U.S. registrants prepare financial statements in accordance with International Financial Reporting Standards, may adversely impact our reported financial results and business, and may require us to incur greater accounting fees.

If we are unable to successfully maintain effective internal control over financial reporting, investors may lose confidence in our reported financial information and our stock price and our business may be adversely impacted.

As a public company, we are required to maintain internal control over financial reporting and our management is required to evaluate the effectiveness of our internal control over financial reporting as of the end of each fiscal year. If we are not successful in maintaining effective internal control over financial reporting, there could be inaccuracies or omissions in the consolidated financial information we are required to file with the SEC. Additionally, even if there are no inaccuracies or omissions, we will be required to publicly disclose the conclusion of our management that our internal control over financial reporting or disclosure controls and procedures are not effective. These events could cause investors to lose confidence in our reported financial information, adversely impact our stock price, result in increased costs to remediate any deficiencies, attract regulatory scrutiny or lawsuits that could be costly to resolve and distract management's attention, limit our ability to access the capital markets or cause our stock to be delisted from The Nasdaq Stock Market or any other securities exchange on which it is then listed.

We could be subject to changes in our tax rates, new U.S. or international tax legislation or additional tax liabilities.

We are subject to taxes in the United States and numerous foreign jurisdictions, where a number of our subsidiaries are organized. Due to economic and political conditions, tax rates in various jurisdictions may be subject to change. Our effective tax rates could be affected by numerous factors, including changes in the mix of earnings in countries with differing statutory tax rates, changes in the valuation of deferred tax assets and liabilities, and changes in tax laws or their interpretation, both in and outside the United States.

The U.S. government has recently enacted comprehensive tax legislation that includes significant changes to the taxation of business entities. These changes include, among others, (i) a permanent reduction to the corporate income tax rate, (ii) a partial limitation on the deductibility of business interest expense, (iii) a shift of the U.S. taxation of multinational corporations from a tax on worldwide income to a territorial system (along with certain rules designed to prevent erosion of the U.S. income tax base) and (iv) a one-time tax on accumulated offshore earnings held in cash and illiquid assets, with the latter taxed at a lower rate. The overall impact of this tax reform is uncertain, and our business and financial condition could be adversely affected. In addition, it is uncertain if and to what extent various states will conform to the newly enacted federal tax law.

Our tax returns and other tax matters also are subject to examination by the U.S. Internal Revenue Service and other tax authorities and governmental bodies. We regularly assess the likelihood of an adverse outcome resulting from these examinations to determine the adequacy of our provision for taxes. We cannot guarantee the outcome of these examinations. If our effective tax rates were to increase, particularly in the United States, or if the ultimate determination of our taxes owed is for an amount in excess of amounts previously accrued, our financial condition, operating results and cash flows could be adversely affected.

Valuation of share-based payments, which we are required to perform for purposes of recording compensation expense under authoritative guidance for share-based payment, involves assumptions that are subject to change and difficult to predict.

We record compensation expense in the consolidated statement of operations for share-based payments, such as employee stock options, restricted stock units and employee stock purchase plan shares, using the fair value method. The requirements of the authoritative guidance for share-based payment have and will continue to have a material effect on our future financial results reported under U.S. generally accepted accounting principles, or GAAP, and make it difficult for us to accurately predict the impact on our future financial results.

For instance, estimating the fair value of share-based payments is highly dependent on assumptions regarding the future exercise behavior of our employees and changes in our stock price. If there are errors in our input assumptions for our valuations models, we may inaccurately calculate actual or estimated compensation expense for share-based payments.

The authoritative guidance for share-based payment could also adversely impact our ability to provide accurate guidance on our future financial results as assumptions that are used to estimate the fair value of share-based payments are based on estimates and judgments that may differ from period to period. We may also be unable to accurately predict the amount and timing of the recognition of tax benefits associated with share-based payments as they are highly dependent on the exercise behavior of our employees and the price of our stock relative to the exercise price of each outstanding stock option.

For those reasons, among others, the authoritative guidance for share-based payment may create variability and uncertainty in the share-based compensation expense we will record in future periods, which could adversely impact our stock price and increase our expected stock price volatility as compared to prior periods.

Changes in financial accounting standards or practices or existing taxation rules or practices may cause adverse unexpected revenue and/or expense fluctuations and affect our reported results of operations.

A change in accounting standards or practices or a change in existing taxation rules or practices can have a significant effect on our reported results and may even affect our reporting of transactions completed before the change is effective. New accounting pronouncements and taxation rules and varying interpretations of accounting pronouncements and taxation practice have occurred and may occur in the future. The method in which we market and sell our products may have an impact on the manner in which we recognize revenue. In addition, changes to existing rules or the questioning of current practices may adversely affect our reported financial results or the way we conduct our business. Additionally, changes to existing accounting rules or standards, such as the potential requirement that U.S. registrants prepare financial statements in accordance with International Financial Reporting Standards, may adversely impact our reported financial results and business, and may further require us to incur greater accounting fees.

Risks Related to Our Common Stock

Our stock price is highly volatile and investing in our stock involves a high degree of risk, which could result in substantial losses for investors.

Historically, the market price of our common stock, like the securities of many other medical products companies, fluctuates and could continue to be volatile in the future. From January 1, 2019 through February 7, 2020, the closing price of our common stock on the Nasdaq Global Select Market was as high as $243.70 per share and as low as $111.38 per share.

The market price of our common stock is influenced by many factors that are beyond our control, including the following:

- securities analyst coverage or lack of coverage of our common stock or changes in their estimates of our financial performance;
- variations in quarterly operating results;
- future sales of our common stock by our stockholders;
- investor perception of us and our industry;
- announcements by us or our competitors of significant agreements, acquisitions, or capital commitments or product launches or discontinuations;
- changes in market valuation or earnings of our competitors;
- negative business or financial announcements regarding our partners;
- general economic conditions;
- regulatory actions;
- legislation and political conditions; and
- terrorist acts.

Please also refer to the factors described elsewhere in this “Risk Factors” section. In addition, the stock market in general has experienced extreme price and volume fluctuations that have often been unrelated and disproportionate to the operating performance of companies in our industry. These broad market and industry factors may materially reduce the market price of our common stock, regardless of our operating performance.

Securities class action litigation has often been brought against public companies that experience periods of volatility in the market prices of their securities. Securities class action litigation could result in substantial costs and a diversion of our management’s attention and resources.

If our financial performance fails to meet the expectations of investors and public market analysts, the market price of our common stock could decline.

Our revenues and operating results may fluctuate significantly from quarter to quarter. We believe that period-to-period comparisons of our operating results may not be meaningful and should not be relied on as an indication of our future performance. If quarterly revenues or operating results fall below the expectations of investors or public market analysts, the trading price of our common stock could decline substantially. Factors that might cause quarterly fluctuations in our operating results include:

- our inability to manufacture an adequate supply of product at appropriate quality levels and acceptable costs;
- possible delays in our research and development programs or in the completion of any clinical trials;
- a lack of acceptance of our products in the marketplace by physicians and people with diabetes;

- the inability of customers to receive reimbursements from third-party payors;
- failures to comply with regulatory requirements, which could lead to withdrawal of products from the market;
- our failure to continue the commercialization of any of our CGM systems;
- competition;
- inadequate financial and other resources; and
- global and political economic conditions, political instability and military hostilities.

Failure to comply with covenants in our revolving credit agreement with JPMorgan Chase Bank and other syndicate lenders could result in our inability to borrow additional funds and adversely impact our business.

We have entered into a revolving credit agreement and a pledge and security agreement with JPMorgan Chase Bank and four other lenders to fund our business operations. These agreements impose numerous financial and other restrictive covenants on our operations, including covenants relating to our general profitability and our liquidity. As of December 31, 2019, we were in compliance with the covenants imposed by the loan and security agreement. If we violate these or any other covenants, any outstanding amounts under these agreements could become due and payable prior to their stated maturity dates, each lender could proceed against any collateral in our operating accounts and our ability to borrow funds in the future may be restricted or eliminated. These restrictions may also limit our ability to borrow additional funds and pursue other business opportunities or strategies that we would otherwise consider to be in our best interests.

Increasing our financial leverage could affect our operations and profitability.

In December 2018, we entered into a five-year $200.0 million revolving credit agreement. As of December 31, 2019, we had no outstanding borrowings, $4.4 million in outstanding letters of credit, and a total available balance of $195.6 million under our multi-currency revolving credit facility.

Our leverage ratio may affect the availability to us of additional capital resources as well as our operations in several ways, including:

- the terms on which credit may be available to us could be less attractive, both in the economic terms of the credit and the legal covenants;
- the possible lack of availability of additional credit;
- the potential for higher levels of interest expense to service or maintain our outstanding debt;
- the possibility of additional borrowings in the future to repay our indebtedness when it comes due; and
- the possible diversion of capital resources from other uses.

While we believe we will have the ability to service our debt and obtain additional resources in the future if and when needed, that will depend upon our results of operations and financial position at the time, the then-current state of the credit and financial markets, and other factors that may be beyond our control. Therefore, we cannot give assurances that sufficient credit will be available on terms that we consider attractive, or at all, if and when necessary or beneficial to us.

The issuance of shares by us in the future or sales of shares by our stockholders may cause the market price of our common stock to drop significantly, even if our business is performing well.

This issuance of shares by us in the future, including by conversion of our convertible notes in certain circumstances, the issuance of shares of our common stock to partners, including up to 2,025,036 shares of our common stock that we may issue to Verily and Onduo LLC pursuant to the Restated Collaboration Agreement, or sales of shares by our stockholders may cause the market price of our common stock to decline, perhaps significantly, even if our business is performing well. The market price of our common stock could also decline if there is a perception that sales of our shares are likely to occur in the future. This might also make it more difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate. Also, we may issue securities in connection with future financings and acquisitions, and those shares could dilute the holdings of other stockholders.

We do not intend to pay dividends for the foreseeable future.

We have never declared or paid cash dividends on our capital stock. We currently intend to retain any future earnings to finance the operation and expansion of our business, and we do not expect to declare or pay any dividends in the foreseeable future and the terms of our credit agreement restrict our ability to declare or pay dividends. As a result, stockholders (including holders of our convertible notes who receive shares of our common stock, if any, upon conversion of their notes) may only receive a return on their investment in our common stock if the market price of our common stock increases.

Anti-takeover effects of our charter documents and Delaware law could make a merger, tender offer or proxy contest difficult, thereby depressing the trading price of our common stock.

In addition, there are provisions in our certificate of incorporation and bylaws, as well as provisions in the Delaware General Corporation Law, that may discourage, delay or prevent a change of control that might otherwise be beneficial to stockholders. For example:

- our Board of Directors may, without stockholder approval, issue shares of preferred stock with special voting or economic rights;
- our stockholders do not have cumulative voting rights and, therefore, each of our directors can only be elected by holders of a majority of our outstanding common stock;
- a special meeting of stockholders may only be called by a majority of our Board of Directors, the Chairman of our Board of Directors, our Chief Executive Officer, our President or our Lead Independent Director;
- our stockholders may not take action by written consent;
- our Board of Directors is divided into three classes, only one of which is elected each year; and
- we require advance notice for nominations for election to the Board of Directors or for proposing matters that can be acted upon by stockholders at stockholder meetings.

Risks Related to Our Debt

We have indebtedness in the form of convertible senior notes, which could adversely affect our financial health and our ability to respond to changes in our business.

In June 2017, we completed an offering of $400.0 million aggregate principal amount of 0.75% convertible senior notes due 2022, or 2022 Notes, which offering we refer to as the 2017 Notes Offering. In November 2018, we completed an offering of $850.0 million aggregate principal amount of 0.75% convertible senior notes due 2023, or 2023 Notes, which offering we refer to as the 2018 Notes Offering. We refer to the 2017 Notes Offering and the 2018 Notes Offering together as the Notes Offerings, and we refer to the 2022 Notes and the 2023 Notes together as the Notes. As a result of the Notes Offerings, we incurred $1.250 billion principal amount of indebtedness, the principal amount of which we may be required to pay at maturity.

Holders of the Notes will have the right to require us to repurchase their notes upon the occurrence of a fundamental change (as defined in the indenture for each of the 2022 Notes and the 2023 Notes) at a purchase price equal to 100% of the principal amount of the notes to be purchased, plus accrued and unpaid interest, if any. In addition, each indenture for the Notes provides that we are required to repay amounts due under each indenture in the event that there is an event of default for the Notes that results in the principal, premium, if any, and interest, if any, becoming due prior to maturity date for the Notes. There can be no assurance that we will be able to repay this indebtedness when due, or that we will be able to refinance this indebtedness on acceptable terms or at all.

As a result of our level of increased debt after the completion of the Notes Offerings:

- our vulnerability to adverse general economic conditions and competitive pressures will be heightened;
- we will be required to dedicate a larger portion of our cash flow from operations to interest payments, limiting the availability of cash for other purposes;
- our flexibility in planning for, or reacting to, changes in our business and industry may be more limited; and
- our ability to obtain additional financing in the future for working capital, capital expenditures, acquisitions, general corporate purposes or other purposes may be impaired.

We cannot be sure that our leverage resulting from the level of increased debt after the completion of the Notes Offerings will not materially and adversely affect our ability to finance our operations or capital needs or to engage in other business activities. In addition, we cannot be sure that additional financing will be available when required or, if available, will be on terms satisfactory to us. Further, even if we are able to obtain additional financing, we may be required to use such proceeds to repay a portion of our debt.

We may be unable to repurchase the Notes upon a fundamental change when required by the holders or repay prior to maturity any accelerated amounts due under the notes upon an event of default or redeem the Notes unless specified conditions are met under our credit facility, and our future debt may contain limitations on our ability to pay cash upon conversion, repurchase or repayment of the Notes.

Holders of the Notes will have the right to require us to repurchase their Notes upon the occurrence of a fundamental change at a purchase price equal to 100% of the principal amount of the Notes to be purchased, plus accrued and unpaid interest, if any, to, but not including, the fundamental change purchase date. In addition, each indenture for the Notes provides

that we are required to repay amounts due under each indenture in the event that there is an event of default for the Notes that results in the principal, premium, if any, and interest, if any, becoming due prior to maturity date for the Notes. In addition, upon conversion of the Notes, unless we elect to deliver solely shares of our common stock to settle such conversion (other than cash in lieu of any fractional share), we will be required to make cash payments in respect of the Notes being converted. However, we may not have enough available cash or be able to obtain financing at the time we are required to repurchase Notes surrendered upon a fundamental change or repay prior to maturity any accelerated amounts or pay cash for Notes being converted.

In addition, our ability to purchase the Notes or repay prior to maturity any accelerated amounts under the Notes upon an event of default or pay cash upon conversions of the Notes may be limited by law, by regulatory authority or by agreements governing our indebtedness outstanding at the time, including our credit facility. Under our current credit facility we are only permitted to use cash to purchase the Notes or repay prior to maturity any accelerated amounts under the Notes if we meet certain conditions that are defined under the Credit Agreement. We may not meet these conditions in the future. Our failure to repurchase Notes at a time when the repurchase is required by the respective indenture (whether upon a fundamental change or otherwise under each indenture) or pay cash payable on future conversions of the Notes as required by the indenture would constitute a default under each indenture. A default under each indenture or the fundamental change itself could also lead to a default under agreements governing our existing or future indebtedness, including our credit facility. If the repayment of the related indebtedness were to be accelerated after any applicable notice or grace periods, we may not have sufficient funds to repay the indebtedness, repurchase the Notes or make cash payments upon conversions thereof.

We may still incur substantially more debt or take other actions which would intensify the risks discussed above.

We may incur substantial additional debt in the future, subject to the restrictions contained in our debt instruments, some of which may be secured debt. We are not restricted under the terms of the indentures governing the Notes from incurring additional debt, securing existing or future debt, recapitalizing our debt, or taking a number of other actions that are not limited by the terms of the indenture governing the convertible senior notes that could have the effect of diminishing our ability to make payments on the Notes when due.

The convertible note hedge and warrant transactions may affect the value of the 2023 Notes and our common stock.

In connection with the sale of the 2023 Notes, we entered into convertible note hedge, or the 2023 Note Hedge, transactions with certain financial institutions, or option counterparties. We also entered into warrant transactions with the option counterparties pursuant to which we sold warrants for the purchase of our common stock, or the 2023 Warrants. The 2023 Note Hedge transactions are expected generally to reduce the potential dilution upon any conversion of the 2023 Notes and/or offset any cash payments we are required to make in excess of the principal amount of converted 2023 Notes. The 2023 Warrant transactions could separately have a dilutive effect to the extent that the market price per share of our common stock exceeds the exercise price of the 2023 Warrants, which is $198.38.

The option counterparties and/or their respective affiliates may modify their hedge positions by entering into or unwinding various derivatives with respect to our common stock and/or purchasing or selling our common stock in secondary market transactions prior to the maturity of 2023 Notes (and are likely to do so during any observation period related to a conversion of 2023 Notes, or following any repurchase of Notes by us on any fundamental change repurchase date (as defined in the indenture for the 2023 Notes) or otherwise). This activity could also cause or avoid an increase or a decrease in the market price of our common stock or the 2023 Notes, which could affect note holders' ability to convert the 2023 Notes and, to the extent the activity occurs during any observation period related to a conversion of the 2023 Notes, it could affect the amount and value of the consideration that note holders will receive upon conversion of the 2023 Notes.

The potential effect, if any, of these transactions and activities on the market price of our common stock or the 2023 Notes will depend in part on market conditions and cannot be ascertained at this time. Any of these activities could adversely affect the value of our common stock and the value of the 2023 Notes (and as a result, the value of the consideration, the amount of cash and/or the number of shares, if any, that note holders would receive upon the conversion of the 2023 Notes) and, under certain circumstances, the ability of the note holders to convert the 2023 Notes.

We do not make any representation or prediction as to the direction or magnitude of any potential effect that the transactions described above may have on the price of the 2023 Notes or our common stock. In addition, we do not make any representation that the option counterparties will engage in these transactions or that these transactions, once commenced, will not be discontinued without notice.

We are subject to counterparty risk with respect to the 2023 Note Hedge transactions.

The option counterparties are financial institutions, and we will be subject to the risk that any or all of them may default under the 2023 Note Hedge transactions. Our exposure to the credit risk of the option counterparties will not be secured by any collateral. Recent global economic conditions have resulted in the actual or perceived failure or financial difficulties of many financial institutions. If an option counterparty becomes subject to insolvency proceedings, we will become an unsecured

creditor in those proceedings, with a claim equal to our exposure at that time under our transactions with that option counterparty. Our exposure will depend on many factors but, generally, an increase in our exposure will be correlated to an increase in the market price and in the volatility of our common stock. In addition, upon a default by an option counterparty, we may suffer adverse tax consequences and more dilution than we currently anticipate with respect to our common stock. We can provide no assurances as to the financial stability or viability of the option counterparties.

Servicing our debt requires a significant amount of cash, and we may not have sufficient cash flow from our business to pay our substantial debt.

Our ability to make scheduled payments of the principal of, to pay interest on or to refinance our indebtedness, including the Notes, depends on our future financial condition and operating performance, which is subject to economic, financial, competitive and other factors beyond our control. Our business may not continue to generate cash flow from operations in the future sufficient to satisfy our obligations under the Notes, our existing indebtedness and any future indebtedness we may incur and to make necessary capital expenditures. We may not maintain a level of cash flows from operating activities sufficient to permit us to pay the principal, premium, if any, and interest on (as well as any cash due upon conversion of) our debt, including the Notes.

If we are unable to generate such cash flow, we may be required to adopt one or more alternatives, such as reducing or delaying investments or capital expenditures, selling assets, refinancing or obtaining additional equity capital on terms that may be onerous or highly dilutive. These alternative measures may not be successful and may not permit us to meet our scheduled debt servicing obligations. Further, we may need to refinance all or a portion of our debt on or before maturity, and our ability to refinance the Notes, existing indebtedness or future indebtedness will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities on commercially reasonable terms or at all, which could result in a default on the Notes or our current and future indebtedness.

Our credit facility imposes restrictions on us that may adversely affect our ability to operate our business.

Our credit facility contains restrictive covenants relating to our capital raising activities and other financial and operational matters which may make it more difficult for us to obtain additional capital and to pursue business opportunities, including potential acquisitions. In addition, our credit facility and the agreements governing the notes each contain cross-default provisions whereby a default under one agreement would likely result in cross defaults under agreements covering other borrowings. For example, the occurrence of a default with respect to any indebtedness or any failure to repay debt when due in an amount in excess of $25.0 million that causes such indebtedness to become due prior to its scheduled maturity date would cause a cross default under the indenture governing the Notes. In addition, the occurrence of a default with respect to any indebtedness or any failure to repay debt when due in an amount in excess of $15.0 million that causes such indebtedness to become due prior to its scheduled maturity date would cause a default under our credit facility. The occurrence of a default under any of these borrowing arrangements would permit the holders of the Notes or the lenders under our credit facility to declare all amounts outstanding under those borrowing arrangements to be immediately due and payable. If the Note holders or the trustee under the indenture governing the Notes or the lenders under our credit facility accelerate the repayment of borrowings, we cannot assure you that we will have sufficient assets to repay those borrowings.

Conversion of the Notes will, to the extent we deliver shares upon conversion of such Notes, dilute the ownership interest of existing stockholders, including holders who had previously converted their Notes, or may otherwise depress our stock price.

The conversion of some or all of the Notes will dilute the ownership interests of existing stockholders to the extent we deliver shares upon conversion of any of the Notes. Any sales in the public market of the common stock issuable upon such conversion could adversely affect prevailing market prices of our common stock. In addition, the existence of the Notes may encourage short selling by market participants because the conversion of the Notes could be used to satisfy short positions, or anticipated conversion of the Notes into shares of our common stock could depress our stock price.

The conditional conversion feature of the Notes, if triggered, may adversely affect our financial condition and operating results.

In the event the conditional conversion feature of the Notes is triggered, holders of the Notes will be entitled to convert the Notes at any time during specified periods at their option. If one or more holders elect to convert their Notes, unless we elect to satisfy our conversion obligation by delivering solely shares of our common stock (other than cash in lieu of any fractional share), we would be required to settle a portion or all of our conversion obligation through the payment of cash, which could adversely affect our liquidity. In addition, even if holders of the Notes do not elect to convert their Notes, we could be required under applicable accounting rules to reclassify all or a portion of the outstanding principal of the Notes as a current rather than long-term liability, which would result in a material reduction of our net working capital.

The accounting method for convertible debt securities that may be settled in cash, such as the Notes, may have a material effect on our reported financial results.

Under GAAP, an entity must separately account for the debt component and the embedded conversion option of convertible debt instruments that may be settled entirely or partially in cash upon conversion, such as the Notes, in a manner that reflects the issuer's economic interest cost. The effect of the accounting treatment for such instruments is that the value of such embedded conversion option would be treated as original issue discount for purposes of accounting for the debt component of the Notes, and that original issue discount is amortized into interest expense over the term of the Notes using an effective yield method. As a result, we will be required to record a greater amount of non-cash interest expense because of the amortization of the original issue discount to the Notes' face amount over the term of the Notes and because of the amortization of the debt issuance costs. Accordingly, we will report greater interest expense and lower net income in our financial results because of the recognition of both the current period's amortization of the debt discount and the Notes' coupon interest, which could adversely affect our reported or future financial results, the trading price of our common stock and the trading price of the Notes.

In addition, if the conditional conversion feature of the Notes is triggered, even if holders do not elect to convert their Notes, we could be required under applicable accounting rules to reclassify all or a portion of the outstanding principal of the Notes as a current rather than long-term liability, which would result in a material reduction of our net working capital.

The fundamental change repurchase feature of the Notes may delay or prevent an otherwise beneficial attempt to take over DexCom.

The terms of the Notes require us to repurchase the Notes in the event of a fundamental change. A takeover of DexCom would trigger an option of the holders of the Notes to require us to repurchase the Notes. In addition, if a make-whole fundamental change occurs prior to the maturity date of the Notes, we will in some cases be required to increase the conversion rate for a holder that elects to convert its Notes in connection with such make-whole fundamental change. Furthermore, each indenture for the Notes prohibits us from engaging in certain mergers or acquisitions unless, among other things, the surviving entity assumes our obligations under the notes. These and other provisions of each indenture may have the effect of delaying or preventing a takeover of DexCom.

ITEM 1B - UNRESOLVED STAFF COMMENTS

None.

ITEM 2 - PROPERTIES

We lease real property to to support our business, including manufacturing, research and development, sales, marketing and administration. The following lists those properties that we believe are material to our business. We believe our facilities are suitable and adequate for our current and near-term needs, and that we will be able to locate additional facilities as needed.

Location	Approximate Square Feet	Purpose	Lease Expiration Dates
San Diego, CA	503,400	Laboratory, Manufacturing, Research and Development, Warehouse, General and Administrative, Sales and Marketing	2026 [(1)]
Mesa, AZ	148,800	General and Administrative, Laboratory, Manufacturing, Warehouse	2028 [(2)]

[(1)] Excludes renewals that would be at our option to extend the term of a lease for approximately 351,400 square feet of space expiring in 2023 for two additional three to five-year terms.

[(2)] Excludes renewals that would be at our option to extend the term of this lease for four additional five-year terms.

We also lease various administrative and customer support real properties throughout the world including the U.S., Canada, Germany, the Philippines, Switzerland and the United Kingdom.

ITEM 3 - LEGAL PROCEEDINGS

On March 28, 2016, AgaMatrix, Inc., or AgaMatrix, filed a patent infringement lawsuit against us in the U.S. District Court for the District of Oregon, asserting that certain of our products infringe three patents held by AgaMatrix. (After filing suit, AgaMatrix reorganized its business and the Court granted AgaMatrix's motion to substitute the newly created entity WaveForm Technologies, Inc., as the plaintiff following AgaMatrix's transfer of the three asserted patents to WaveForm.)

DexCom filed petitions for *inter partes* review with the Patent Trial and Appeal Board, or PTAB, of the U.S. Patent and Trademark Office, challenging each of the three asserted patents as being unpatentable in view of prior art. The PTAB issued a Final Written Decision for each of the first two patents on February 28, 2018, where the PTAB found the majority of asserted claims from the first patent unpatentable and the remaining claims under review not unpatentable. The PTAB found all claims under review from the second patent not unpatentable. On September 12, 2018, the PTAB found all of the asserted claims in the third patent unpatentable. In October 2018, we filed in the District Court a motion for summary judgment that all remaining asserted claims are invalid. The District Court granted that motion and, on August 23, 2019, entered judgment in our favor. On September 6, 2019, WaveForm appealed the judgment. The appeal is pending and no hearing date has been set.

We have also filed several lawsuits against AgaMatrix. We filed a patent infringement lawsuit against AgaMatrix in the United States District Court for the Central District of California, or C.D. Cal., in which a Final Judgment of non-infringement was entered by the C.D. Cal judge on February 23, 2018 and affirmed on appeal by the Federal Circuit on March 7, 2019. AgaMatrix was awarded attorneys' fees for this lawsuit. As of December 31, 2019, we have accrued an immaterial amount for those fees. The fee decision is currently on appeal to the Federal Circuit. On September 15, 2017, we filed a patent infringement lawsuit against AgaMatrix in the United States District Court for the District of Delaware, asserting certain single-point blood glucose monitoring products of AgaMatrix infringe two patents held by us. In addition, on September 18, 2017, we filed a Complaint against AgaMatrix in the International Trade Commission, referred to as the ITC, requesting that the ITC institute an investigation and issue an order excluding certain products of AgaMatrix from importation into or sale in the United States based on AgaMatrix's infringement of the same two patents asserted in the Delaware litigation. The investigation was terminated by the ITC on April 4, 2019 with a finding of non-infringement. The decision is currently on appeal.

Neither the outcome of these lawsuits nor the amount and range of potential loss associated with the lawsuits can be assessed at this time. Other than the attorneys' fees described above, as of December 31, 2019 we have accrued no amounts for contingent losses associated with these suits.

We are subject to various claims, complaints and legal actions that arise from time to time in the normal course of business, including commercial insurance, product liability and employment related matters. In addition, from time to time we may bring claims or initiate lawsuits against various third parties with respect to matters arising out of the ordinary course of our business, including commercial and employment related matters. We do not believe we are party to any currently pending legal proceedings, the outcome of which could have a material adverse effect on our business, financial condition or results of operations. There can be no assurance that existing or future legal proceedings arising in the ordinary course of business or otherwise will not have a material adverse effect on our business, financial condition or results of operations.

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

Market Information for Common Stock

DexCom's common stock is traded on the Nasdaq Global Select Market under the symbol "DXCM."

Stockholders

We had approximately 30 stockholders of record as of February 7, 2020. The number of beneficial owners of our common stock at that date was substantially greater than the number of record holders because a large portion of our common stock is held of record through brokerage firms in "street name."

Dividend Policy

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain any future earnings to finance the operation and expansion of our business, and we do not expect to declare or pay any dividends in the foreseeable future.

Recent Sales of Unregistered Securities

There were no unregistered sales of equity securities which have not been previously disclosed in a quarterly report on Form 10-Q or a current report on Form 8-K during the year ended December 31, 2019.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

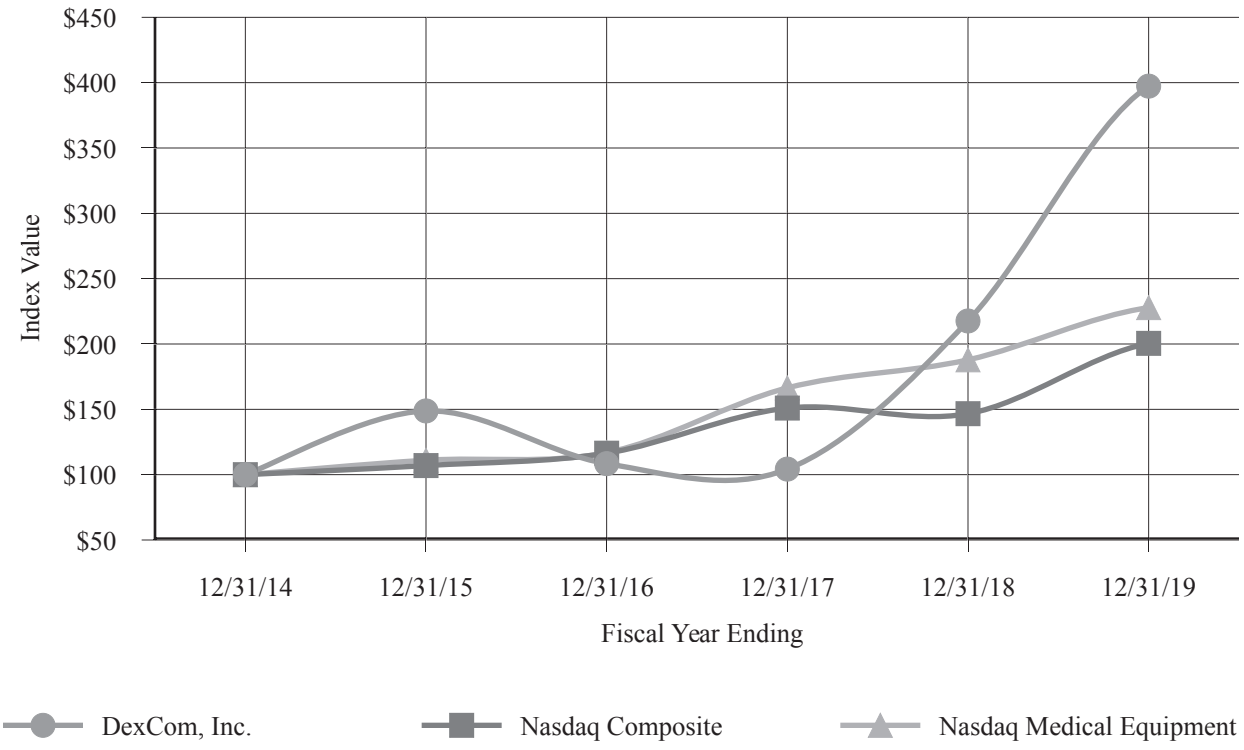
Neither we nor any affiliated purchaser repurchased any of our equity securities in fiscal year 2019.

Company Stock Price Performance

The graph below compares the cumulative total stockholder return on our common stock with the cumulative total returns on the Nasdaq Composite Index and the Nasdaq Medical Equipment Index over the five-year period ending December 31, 2019. The graph assumes that $100 was invested in DexCom common stock and in each of the other indices on December 31, 2014 and that all dividends were reinvested. The comparisons in the graph below are based on historical data and are not intended to forecast the possible future performance of DexCom's common stock.

The graph below and related information shall not be deemed "soliciting material" or be deemed to be "filed" with the SEC, nor shall such information be incorporated by reference into any future filing, except to the extent that we specifically incorporate it by reference into such filing.

COMPARISON OF FIVE-YEAR CUMULATIVE TOTAL RETURN* AMONG DEXCOM, INC. THE NASDAQ COMPOSITE INDEX AND THE NASDAQ MEDICAL EQUIPMENT INDEX



* $100 invested on December 31, 2014 in stock or index, including reinvestment of any dividends.

	December 31, 2014	December 31, 2015	December 31, 2016	December 31, 2017	December 31, 2018	December 31, 2019
DexCom, Inc.	**$ 100.00**	**$ 148.77**	**$ 108.45**	**$ 104.25**	**$ 217.62**	**$ 397.35**
Nasdaq Composite	**$ 100.00**	**$ 106.96**	**$ 116.45**	**$ 150.96**	**$ 146.67**	**$ 200.49**
Nasdaq Medical Equipment	**$ 100.00**	**$ 111.06**	**$ 116.87**	**$ 166.41**	**$ 187.88**	**$ 227.84**

ITEM 6 - SELECTED FINANCIAL DATA

The consolidated statements of operations data for the years ended December 31, 2019, 2018, and 2017 and the consolidated balance sheet data as of December 31, 2019 and 2018 have been derived from our audited consolidated financial statements included elsewhere in this Annual Report. The statements of operations data for the years ended December 31, 2016 and 2015 and the consolidated balance sheet data as of December 31, 2017, 2016 and 2015 have been derived from our audited consolidated financial statements not included in this Annual Report. The following selected financial data should be read in conjunction with our "Management's Discussion and Analysis of Financial Condition and Results of Operations" in Part II, Item 7 and our consolidated financial statements and related notes in Part II, Item 8 of this Annual Report.

	Twelve Months Ended December 31,				
(In millions, except per share data)	**2019**	**2018**	**2017**	**2016**	**2015**
Consolidated Statements of Operations Data:					
Product revenue	$ 1,476.0	$ 1,031.6	$ 718.5	$ 573.3	$ 400.7
Development grant and other revenue	—	—	—	—	1.3
Total revenue	1,476.0	1,031.6	718.5	573.3	402.0
Cost of sales	544.5	367.7	226.4	194.9	123.6
Gross profit	931.5	663.9	492.1	378.4	278.4
Operating expenses:					
Research and development	273.5	199.7	185.4	156.1	101.0
Collaborative research and development fees[1]	—	217.7	—	—	36.5
Selling, general and administrative	515.7	432.8	349.2	286.2	198.0
Total operating expenses	789.2	850.2	534.6	442.3	335.5
Operating income (loss)	142.3	(186.3)	(42.5)	(63.9)	(57.1)
Interest expense	(60.3)	(22.7)	(12.8)	(0.7)	(0.4)
Income (loss) from equity investments	(4.2)	80.1	—	—	—
Interest and other income (expense), net	26.4	2.4	6.7	(0.3)	—
Income (loss) before income taxes	104.2	(126.5)	(48.6)	(64.9)	(57.5)
Income tax expense	3.1	0.6	1.6	0.7	0.1
Net income (loss)	$ 101.1	$ (127.1)	$ (50.2)	$ (65.6)	$ (57.6)
Basic net income (loss) per share[2]	$ 1.11	$ (1.44)	$ (0.58)	$ (0.78)	$ (0.72)
Shares used to compute basic net income (loss) per share[2]	91.1	88.2	86.3	83.6	79.8
Diluted net income (loss) per share[2]	$ 1.10	$ (1.44)	$ (0.58)	$ (0.78)	$ (0.72)
Shares used to compute diluted net income (loss) per share[2]	92.3	88.2	86.3	83.6	79.8

	As of December 31,				
(In millions)	**2019**	**2018**	**2017**	**2016**	**2015**
Consolidated Balance Sheet Data:					
Cash, cash equivalents, and short-term marketable securities	$ 1,533.3	$ 1,385.6	$ 548.6	$ 123.7	$ 115.2
Working capital	1,609.2	1,477.1	605.8	177.6	164.4
Total assets	2,395.0	1,916.0	904.1	402.8	292.0
Long-term liabilities	1,152.2	1,030.3	345.8	16.6	3.9
Total stockholders' equity	$ 882.6	$ 663.3	$ 419.4	$ 283.8	$ 221.2

(1) See Note 2 to the consolidated financial statements in Part II, Item 8 of this Annual Report for a description of our Restated Collaboration Agreement with Verily Life Sciences LLC and Verily Ireland Limited.

(2) See Note 1 to the consolidated financial statements in Part II, Item 8 of this Annual Report for a description of the method used to compute basic and diluted net loss per share attributable to common stockholders.

This document, including the following Management's Discussion and Analysis of Financial Condition and Results of Operations, contains forward-looking statements that are not purely historical regarding DexCom's or its management's intentions, beliefs, expectations and strategies for the future. These forward-looking statements fall within the meaning of the federal securities laws that relate to future events or our future financial performance. In some cases, you can identify forward-looking statements by terminology such as "may," "will," "expect," "plan," "anticipate," "believe," "estimate," "intend," "potential" or "continue" or the negative of these terms or other comparable terminology. Forward-looking statements are made as of the date of this report, deal with future events, are subject to various risks and uncertainties, and actual results could differ materially from those anticipated in those forward looking statements. The risks and uncertainties that could cause actual results to differ materially are more fully described under "Risk Factors" and elsewhere in this report and in our other reports filed with the SEC. We assume no obligation to update any of the forward-looking statements after the date of this report or to conform these forward-looking statements to actual results. You should read the following discussion and analysis together with "Selected Financial Data" in Part II, Item 6 and our consolidated financial statements and related notes in Part II, Item 8 of this Annual Report.

Overview

We are a medical device company primarily focused on the design, development and commercialization of continuous glucose monitoring, or CGM, systems for use by people with diabetes and by healthcare providers. We received approval from the Food and Drug Administration, or FDA, and commercialized our first product in 2006. We launched our latest generation system, the DexCom G6® integrated Continuous Glucose Monitoring System, or G6, in 2018. Unless the context requires otherwise, the terms "we," "us," "our," the "company," or "DexCom" refer to DexCom, Inc. and its subsidiaries.

We sell our reusable transmitter and receiver, collectively referred to as "Reusable Hardware" and disposable sensors through a direct sales force in the United States, Canada and some countries in Europe, and through distribution arrangements in the United States, and certain countries in Africa, Asia, Europe, Latin America, and the Middle East, as well as Australia, Canada, and New Zealand. Most of our distributors stock our products and fulfill orders for our products from their inventory.

We plan to develop future generations of technologies that are focused on improved performance and convenience and that will enable intelligent insulin administration. We also are aggressively exploring how to extend our offerings to other opportunities, including for people with Type 2 diabetes that are non-insulin using, people with pre-diabetes, people who are obese, people who are pregnant, and people with diabetes in the hospital setting. We will continue to develop a networked platform with open architecture, connectivity and transmitters capable of communicating with other devices and software systems. We also intend to expand our efforts to accumulate CGM patient data and metrics and apply predictive modeling and machine learning to generate interactive CGM insights that can inform patient behavior.

For discussion related to the results of operations and changes in financial condition for fiscal 2018 compared to fiscal 2017 refer to Part II, Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations in our fiscal 2018 Form 10-K, which was filed with the United States Securities and Exchange Commission on February 21, 2019.

Critical Accounting Policies and Estimates

The discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which we have prepared in accordance with U.S. GAAP. The preparation of these consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the consolidated financial statements as well as the reported revenue and expenses during the reporting periods. On an ongoing basis, we evaluate our estimates and judgments. We base our estimates on 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.

While our significant accounting policies are more fully described in Note 1 to the consolidated financial statements in Part II, Item 8 of this Annual Report, we believe that the following accounting policies and estimates are most critical to a full understanding and evaluation of our reported financial results. Members of our senior management have discussed the development and selection of these critical accounting policies and their disclosure in this Annual Report with the Audit Committee of our Board of Directors.

Revenue Recognition

We generate our revenue from the sale of our Reusable Hardware and disposable sensors. Disposable sensors are sold separately. We also provide free-of-charge software and mobile applications for use with our Reusable Hardware and disposable sensors. In determining how revenue should be recognized, a five-step process is used, which requires judgment and estimates within the revenue recognition process. The primary judgments include identifying the performance obligations in the contract and determining whether the performance obligations are distinct. We exercise significant judgment when we determine the transaction price, including variable consideration adjustments. If the actual amounts of consideration that we receive differ from our estimates, we would adjust our estimates and that would affect reported revenue in the period that such variances become known. If any of these judgments were to change it could cause a material increase or decrease in the amount of revenue we report in a particular period.

We generally recognize revenue when control is transferred to our customers in an amount that reflects the net consideration to which we expect to be entitled. Transaction price is typically based on the contracted rates less an estimate of claim denials and historical reimbursement experience by payor, which include current and future expectations regarding reimbursement rates and payor mix. We recognize revenue only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. We estimate reductions for rebates based on contractual arrangements, estimates of products sold subject to rebate, known events or trends and channel inventory data. For more information, see *"Revenue Recognition"* in Note 1 to the consolidated financial statements in Part II, Item 8 of this Annual Report.

Disaggregation of Revenue.

We disaggregate revenue by geographic region and by major sales channel. We have determined that disaggregating revenue into these categories achieves the ASC Topic 606 disclosure objectives of depicting how the nature, amount, timing and uncertainty of revenue and cash flows are affected by economic factors. Reconciliations of revenue disaggregated by geographic location and by major sales channel to total revenue are provided in Note 10 to the consolidated financial statements in Part II, Item 8 of this Annual Report.

Share-Based Compensation

Share-based compensation expense is measured at the grant date based on the estimated fair value of the award and is recognized straight-line over the requisite service period of the individual grants, which typically equals the vesting period. We value time-based Restricted Stock Units ("RSUs") at the date of grant using the intrinsic value method. Certain RSUs granted to senior management vest based on the achievement of pre-established performance or market goals.

We estimate the fair value of performance-based RSUs at the date of grant using the intrinsic value method and the probability that the specified performance criteria will be met. We update our assessment of the probability that the specified performance criteria will be achieved each quarter and adjust our estimate of the fair value of the performance-based RSUs if necessary. The Monte Carlo methodology that we use to estimate the fair value of market-based RSUs at the date of grant incorporates into the valuation the possibility that the market condition may not be satisfied. Provided that the requisite service is rendered, the total fair value of the market-based RSUs at the date of grant must be recognized as compensation expense even if the market condition is not achieved. However, the number of shares that ultimately vest can vary significantly with the performance of the specified market criteria.

If any of the assumptions used change significantly, share-based compensation expense may differ materially from what we have recorded in the current period.

Fair Value of Financial Instruments

The authoritative guidance establishes a fair value hierarchy that is based on the extent and level of judgment used to estimate the fair value of assets and liabilities. In general, the authoritative guidance requires us to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. An asset or liability's categorization within the fair value hierarchy is based upon the lowest level of input that is significant to the measurement of its fair value. The three levels of input defined by the authoritative guidance are as follows:

Level 1—Uses unadjusted quoted prices that are available in active markets for identical assets or liabilities.

Level 2—Uses inputs other than quoted prices included in Level 1 that are observable, either directly or indirectly, through correlation with market data. These include quoted prices in active markets for similar assets or liabilities; quoted prices for identical or similar assets or liabilities in markets that are not active; and inputs to valuation models or other pricing methodologies that do not require significant judgment because the inputs used in the model, such as interest rates and volatility, can be corroborated by readily observable market data for substantially the full term of the assets or liabilities.

Level 3—Uses unobservable inputs that are supported by little or no market activity and that are significant to the determination of fair value. Level 3 assets and liabilities include those whose fair values are determined using pricing models, discounted cash flow methodologies, or similar valuation techniques and significant judgment or estimation.

We estimate the fair value of most of our cash equivalents using Level 1 inputs. We estimate the fair value of our marketable equity securities using Level 1 inputs and we estimate the fair value of our marketable debt securities using Level 2 inputs. We carry our other financial instruments, such as cash, accounts receivable, prepaid expenses and other current assets, accounts payable and accrued liabilities, at cost, which approximates the related fair values due to the short-term maturities of these instruments. See Note 1 and Note 3 to the consolidated financial statements in Part II, Item 8 of this Annual Report for more information about fair value measurements.

Accounts Receivable, Net and Related Valuation Accounts

We maintain an allowance for doubtful accounts for estimated losses resulting from the inability of our customers to make required payments. We evaluate the collectability of our accounts receivable based on a combination of factors. We regularly analyze customer accounts, review the length of time receivables are outstanding, review historical loss rates and assess current economic trends that may impact the level of credit losses in the future. Our allowance for doubtful accounts has generally been adequate to cover our actual credit losses. However, since we cannot reliably predict future changes in the financial stability of our customers, we may need to increase our reserves if the financial conditions of our customers deteriorate.

Excess and Obsolete Inventory

Inventory is valued at the lower of cost or net realizable value. We record adjustments to inventory for potentially excess, obsolete, or scrapped goods in order to state inventory at net realizable value. Factors influencing these adjustments include inventories on hand and on order compared to estimated future usage and sales for existing and new products, as well as judgments regarding quality control testing data and assumptions about the likelihood of scrap and obsolescence. Historically, our inventory reserves have been adequate to cover our actual losses. However, if actual product life cycles, product quality or market conditions differ from our assumptions, additional inventory adjustments that would increase cost of goods sold could be required.

Income Taxes

We estimate our income taxes based on the various jurisdictions where we conduct business. Significant judgment is required in determining our worldwide income tax provision. The calculation of our tax liabilities involves dealing with uncertainties in the application of complex tax laws and regulations and the potential for future adjustment of our uncertain tax positions by the Internal Revenue Service or other taxing jurisdictions. While we believe we have appropriate support for the positions taken on our tax returns, we regularly assess the potential outcomes of examinations by tax authorities in determining the adequacy of our provision for income taxes. We continually assess the likelihood and amount of potential adjustments and adjust the income tax provision, income taxes payable, and deferred taxes in the period in which the facts that give rise to a revision become known.

We use the asset and liability approach to recognize deferred tax assets and liabilities for the expected future tax consequences of temporary differences between the carrying amounts and the tax bases of assets and liabilities. Deferred tax assets and liabilities are determined using the enacted tax rates in effect for the years in which those tax assets are expected to be realized. Significant judgment is required to evaluate the need for a valuation allowance against deferred tax assets. We review all available positive and negative evidence, including projections of pre-tax book income, earnings history, and reliability of forecasting. A valuation allowance is established when it is more likely than not that some or all of the deferred tax assets will not be realized. As of December 31, 2019, we have maintained a full valuation allowance on our deferred tax assets since inception based on our historical losses and the uncertainty of generating future taxable income to utilize our loss and credit carryforwards. A future release of our valuation allowance will result in a material tax benefit recognized in the quarter of the release.

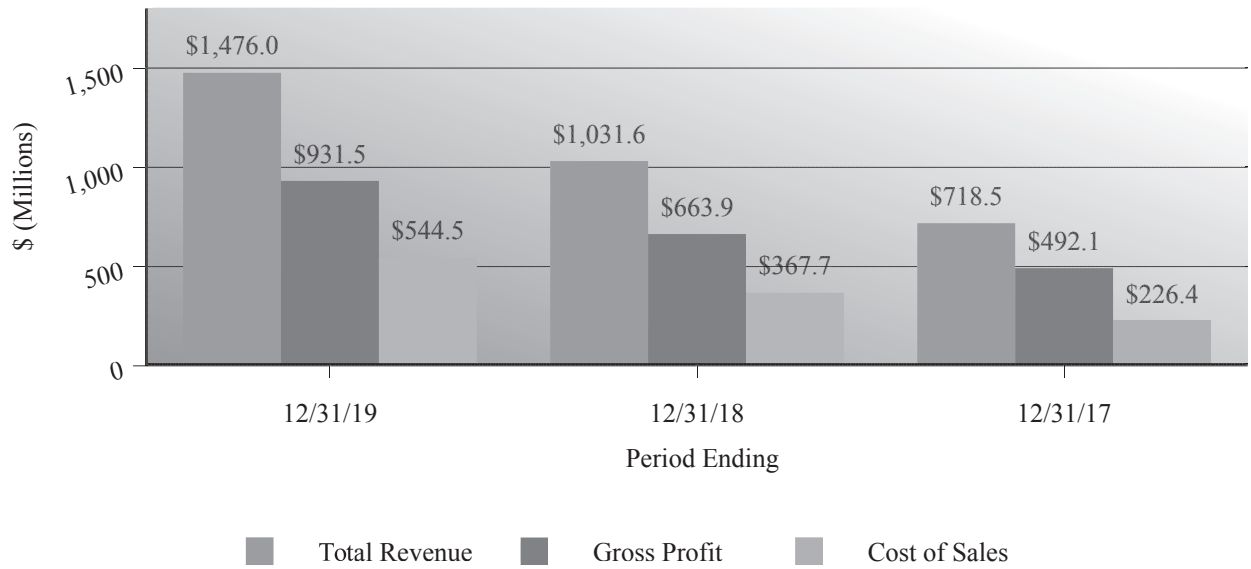
We recognize and measure benefits for uncertain tax positions using a two-step approach. The first step is to evaluate the tax position taken or expected to be taken in a tax return by determining if the weight of available evidence indicates that it is more likely than not that the tax position will be sustained upon audit, including resolution of any related appeals or litigation processes. For tax positions that are more likely than not of being sustained upon audit, the second step is to measure the tax benefit as the largest amount that is more than 50% likely of being realized upon settlement. Significant judgment is required to evaluate uncertain tax positions and is based upon a number of factors, including changes in facts or circumstances, changes in tax law, correspondence with tax authorities during the course of audits and effective settlement of audit issues. Changes in the recognition or measurement of uncertain tax positions could result in material increases or decreases in our income tax expense in the period in which we make the change, which could have a material impact on our effective tax rate and operating results.

Loss Contingencies

We are subject to certain legal proceedings, as well as demands, claims and threatened litigation that arise in the normal course of our business. We review the status of each significant matter quarterly and assess our potential financial exposure. If the potential loss from a claim or legal proceeding is considered probable and the amount can be reasonably estimated, we record a liability and an expense for the estimated loss and disclose it in our consolidated financial statements if it is significant. If we determine that a loss is possible and the range of the loss can be reasonably determined, we do not record a liability or an expense but we disclose the range of the possible loss. Significant judgment is required in the determination of whether a potential loss is probable, reasonably possible, or remote as well as in the determination of whether a potential exposure is reasonably estimable. We base our judgments on the best information available at the time. As additional information becomes available, we reassess the potential liability related to our pending claims and litigation and may revise our estimates. Any revision of our estimates of potential liability could have a material impact on our financial position and operating results.

Results of Operations

Financial Overview



	Twelve Months Ended December 31,			2019 - 2018		2018 - 2017	
(In millions)	2019	2018	2017	$ Change	% Change	$ Change	% Change
Total revenue	$1,476.0	$1,031.6	$ 718.5	$ 444.4	43%	$ 313.1	44%
Gross profit	931.5	663.9	492.1	267.6	40%	171.8	35%
Operating income (loss)	142.3	(186.3)	(42.5)	328.6	*	(143.8)	*
Net income (loss)	101.1	(127.1)	(50.2)	228.2	*	(76.9)	*
Basic net income (loss) per share	1.11	(1.44)	(0.58)	2.55	*	(0.86)	*
Diluted net income (loss) per share	$ 1.10	$ (1.44)	$ (0.58)	$ 2.54	*	$ (0.86)	*

* = Not Meaningful

Revenue, Cost of Sales and Gross Profit

	Twelve Months Ended December 31,			2019 - 2018		2018 - 2017	
(In millions)	2019	2018	2017	$ Change	% Change	$ Change	% Change
Total revenue	$1,476.0	$1,031.6	$ 718.5	$ 444.4	43%	$ 313.1	44%
Cost of sales	544.5	367.7	226.4	176.8	48%	141.3	62%
Gross profit	$ 931.5	$ 663.9	$ 492.1	$ 267.6	40%	$ 171.8	35%
Gross profit as a percent of total revenue	63%	64%	68%				

We expect that revenues we generate from the sales of our products will fluctuate from quarter to quarter. We typically experience seasonality, with lower sales in the first quarter of each year compared to the immediately preceding fourth quarter. This seasonal sales pattern relates to U.S. annual insurance deductible resets and unfunded flexible spending accounts.

Cost of sales includes direct labor and materials costs related to each product sold or produced, including assembly, test labor and scrap, as well as factory overhead supporting our manufacturing operations. Factory overhead includes facilities, material procurement and control, manufacturing engineering, quality assurance, supervision and management. These costs are primarily salary, fringe benefits, share-based compensation, facility expense, supplies and purchased services. All of our manufacturing costs are included in cost of sales.

Fiscal 2019 Compared to Fiscal 2018

Total revenue increased $444.4 million or 43% for the twelve months ended December 31, 2019 compared to the twelve months ended December 31, 2018. The 2019 revenue increase was primarily driven by increased sales volume of our disposable sensors due to the continued growth of our worldwide customer base, partially offset by pricing pressure due to the evolution of our channel strategy and product mix. Disposable sensor and other revenue comprised approximately 78% of total revenue and Reusable Hardware revenue comprised approximately 22% of total revenue for the twelve months ended December 31, 2019. Disposable sensor and other revenue comprised approximately 75% of total revenue and Reusable Hardware revenue comprised approximately 25% of total revenue for the twelve months ended December 31, 2018.

Cost of sales increased $176.8 million or 48% for the twelve months ended December 31, 2019 compared to the twelve months ended December 31, 2018 primarily due to increased sales volume. The gross profit of $931.5 million or 63% of total revenue for the twelve months ended December 31, 2019 increased $267.6 million compared to $663.9 million or 64% of total revenue for the same period in 2018. The 2019 increase in gross profit dollars was primarily driven by increased revenues, partially offset by higher warranty, freight, and excess and obsolete inventory charges compared to 2018. The decrease in gross margin percentage is primarily a function of the evolution of our channel strategy and product mix as we launch new products and expand internationally. Our gross martin percentage for the twelve months ended December 31, 2019 was also impacted by investments to scale infrastructure as we drove significant production capacity expansion in 2019.

Operating Expenses

	Twelve Months Ended December 31,			2019 - 2018		2018 - 2017	
(In millions)	2019	2018	2017	$ Change	% Change	$ Change	% Change
Research and development	$ 273.5	$ 199.7	$ 185.4	$ 73.8	37 %	$ 14.3	8%
as a % of total revenue	19%	19%	26%				
Collaborative research and development fee	—	217.7	—	(217.7)	*	217.7	*
as a % of total revenue	—%	21%	—%				
Selling, general and administrative	515.7	432.8	349.2	82.9	19 %	83.6	24%
as a % of total revenue	35%	42%	48%				
Total operating expenses	$ 789.2	$ 850.2	$ 534.6	$ (61.0)	(7)%	$ 315.6	59%
as a % of total revenue	53%	82%	74%				

* = Not Meaningful

Our research and development expenses primarily consist of engineering and research expenses related to our continuous glucose monitoring technology, clinical trials, regulatory expenses, quality assurance programs, materials and products for clinical trials. Research and development expenses are primarily related to employee compensation, including salary, fringe

benefits, share-based compensation, and temporary employee expenses. We also incur significant expenses to operate our clinical trials including clinical site reimbursement, clinical trial product and associated travel expenses. Our research and development expenses also include fees for design services, contractors and development materials.

Our selling, general and administrative expenses primarily consist of salary, fringe benefits and share-based compensation for our executive, financial, sales, marketing, information technology and administrative functions. Other significant expenses include commissions, marketing and advertising, IT software license costs, insurance, professional fees for our outside legal counsel and independent auditors, litigation expenses, patent application expenses and consulting expenses.

Fiscal 2019 Compared to Fiscal 2018

Research and Development Expense. Research and development expense increased $73.8 million or 37% for the twelve months ended December 31, 2019 compared to the same period of 2018. The increase was primarily due to $39.7 million in additional salaries, bonus, and payroll-related costs, $11.1 million in additional supplies costs, and $7.3 million in additional facilities costs. We continue to believe that focused investments in research and development are critical to our future growth and competitive position in the marketplace, and to the development of new and updated products and services that are central to our core business strategy.

Collaborative Research and Development Fee. Collaborative research and development fee decreased $217.7 million for the twelve months ended December 31, 2019 compared to the same period of 2018. During 2018, we recorded a one time $217.7 million collaborative research and development charge related to our collaboration and license agreement with Verily. See Note 2 to the consolidated financial statements in Part II, Item 8 of this Annual Report for more information about this collaboration agreement.

Selling, General and Administrative Expense. Selling, general and administrative expense increased $82.9 million or 19% for the twelve months ended December 31, 2019 compared to the same period of 2018. The increase was primarily due to higher sales-related costs commensurate with revenue growth and the continued commercialization of our products in the United States and international markets. Significant elements of the increase in selling, general, and administrative expenses included $20.5 million in additional third party service provider fees, $13.1 million in additional salaries, bonus and payroll-related costs, $11.0 million in additional consulting fees, $9.3 million in additional marketing costs, $8.6 million in additional depreciation, and $7.5 million in restructuring charges.

Non-Operating Income and Expenses

Interest Expense

Interest expense increased $37.6 million to $60.3 million for the twelve months ended December 31, 2019 compared to $22.7 million for the same period of 2018. The increase was primarily due to an additional interest expense for our 2023 Notes, which were issued in November 2018.

Income/Loss from Equity Investments

Loss from equity investments of $4.2 million for the twelve months ended December 31, 2019 and income from equity investments of $80.1 million for the twelve months ended months ended December 31, 2018 consist solely of realized and unrealized gains and losses on our equity investment in Tandem Diabetes Care, Inc. We sold all of our remaining equity investment in Tandem during the first quarter of 2019.

Interest and Other Income (Expense), Net

Interest income was $28.4 million and $10.5 million for the twelve months ended December 31, 2019 and 2018, respectively, and is related to our marketable debt securities portfolio. The increase in interest income was primarily related to an increase in the average invested balances during 2019 compared to 2018.

Other income (expense) for the twelve months ended December 31, 2019 and 2018 consists primarily of foreign currency transaction gains and losses due to the effects of foreign currency fluctuations.

Income Tax Expense

We recorded pre-tax income for the twelve months ended December 31, 2019, and pre-tax loss for the twelve months ended December 31, 2018. The income tax expense we recorded for 2019 is primarily attributable to state and foreign income tax expense. The nominal income tax expense we recorded for 2018 is primarily due to withholding and other income tax expenses in profitable jurisdictions.

Liquidity and Capital Resources

Overview, Capital Resources, and Capital Requirements

Our principal sources of liquidity are our existing cash, cash equivalents and marketable securities, cash generated from operations, proceeds from our convertible notes issuances, and access to our revolving line of credit. Our primary uses of cash have been for research and development programs, selling and marketing activities, capital expenditures, acquisitions of businesses, and debt service costs.

We expect that cash provided by our operations may fluctuate in future periods as a result of a number of factors, including fluctuations in our operating results, working capital requirements and capital deployment decisions. We have historically invested our cash primarily in U.S. dollar-denominated, investment grade, highly liquid obligations of U.S. government-sponsored enterprises, commercial paper, corporate debt, and money market funds. Certain of these investments are subject to general credit, liquidity and other market risks. The general condition of the financial markets and the economy may increase those risks and may affect the value and liquidity of investments and restrict our ability to access the capital markets.

Our future capital requirements will depend on many factors, including but not limited to:

- the revenue generated by sales of our approved products and other future products;
- the expenses we incur in manufacturing, developing, selling and marketing our products;
- the quality levels of our products and services;
- the third-party reimbursement of our products for our customers;
- our ability to efficiently scale our operations to meet demand for our current and any future products;
- the costs, timing and risks of delays of additional regulatory approvals;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- the rate of progress and cost of our clinical trials and other development activities;
- the success of our research and development efforts;
- the emergence of competing or complementary technological developments;
- the terms and timing of any collaborative, licensing and other arrangements that we may establish;
- the acquisition of businesses, products and technologies and our ability to integrate and manage any acquired businesses, products and technologies; and
- the evolution of the international expansion of our business.

We expect that existing cash and cash flows from our future operations will generally be sufficient to fund our ongoing core business. As current borrowing sources become due, we may be required to access the capital markets for additional funding. As we assess inorganic growth strategies, we may need to supplement our internally generated cash flow with outside sources. In the event that we are required to access the debt market, we believe that we will be able to secure reasonable borrowing rates. As part of our liquidity strategy, we will continue to monitor our current level of earnings and cash flow generation as well as our ability to access the market in light of those earning levels.

A substantial portion of our operations are located in the United States, and the majority of our sales since inception have been made in U.S. dollars. Accordingly, our assessment is that we have no material net exposure to foreign currency exchange rate fluctuations at this time. However, as our business in markets outside of the United States continues to increase, we will be exposed to foreign currency exchange risk related to our foreign operations. Fluctuations in the rate of exchange between the U.S. dollar and foreign currencies, primarily the British Pound, the Euro, and the Canadian Dollar, could adversely affect our financial results, including our revenues, revenue growth rates, gross margins, income and losses as well as assets and liabilities. We currently engage in limited hedging transactions to reduce foreign currency risks on certain intercompany balances. We will continue to monitor and manage our financial exposures due to exchange rate fluctuations as an integral part of our overall risk management program. Our cash, cash equivalents and short-term marketable securities totaled $1,533.3 million as of December 31, 2019. None of those funds were restricted and approximately 98% of those funds were located in the United States. We intend to reinvest a substantial portion of our foreign earnings in those businesses, and we currently do not anticipate that we will need funds generated by foreign operations to fund our domestic ones.

Our cash, cash equivalents and short-term marketable securities as of December 31, 2019 increased by $147.7 million from December 31, 2018 due to the factors described in “Cash Flows” below. We believe that our cash, cash equivalents, and marketable securities balances, projected cash contributions from our commercial operations, and our $200.0 million revolving line of credit, of which $195.6 million remains available, will be sufficient to meet our anticipated seasonal working capital

needs, capital expenditure requirements, contractual obligations, commitments, debt service requirements, and other liquidity requirements associated with our operations for at least the next 12 months.

Revolving Credit Agreement

In December 2018, we entered into an amended and restated five-year $200.0 million revolving Credit Agreement, including a sub-facility of up to $10.0 million for letters of credit. Subject to customary conditions and the approval of any lender whose commitment would be increased, we have the option to increase the maximum principal amount available under the Credit Agreement by up to an additional $300.0 million, resulting in a maximum available principal amount of $500.0 million. However, at this time none of the lenders have committed to provide any such increase in their commitments. Revolving loans under the Credit Agreement will be available for general corporate purposes, including working capital and capital expenditures. As of December 31, 2019, we had no outstanding borrowings, $4.4 million in outstanding letters of credit, and a total available balance of $195.6 million under the Credit Agreement. We monitor counterparty risk associated with the institutional lenders that are providing the credit facility. We currently believe that the credit facility will be available to us should we choose to borrow under it.

Senior Convertible Notes

The following table summarizes our outstanding convertible note obligations:

Issuance Date	Coupon	Aggregate Principal *(in millions)*	Maturity Date	Initial Conversion rate per share of common stock	Conversion Price per Share of Common Stock
June 2017	0.75%	$ 400.0	May 15, 2022	10.0918	$99.09
November 2018	0.75%	850.0	December 1, 2023	6.0869	$164.29
Total		$ 1,250.0			

We used a portion of the net proceeds from the offering of the Notes due 2022 (the 2022 Notes) to repay $75.0 million of borrowings under our existing credit facility in 2017. We used a portion of the net proceeds from the offering of the Notes due 2023 (the 2023 Notes) to repurchase 0.8 million shares of our common stock for $100.0 million in 2018. The remainder of the net proceeds from the Notes offerings are available for general corporate purposes and capital expenditures, including working capital needs. We may also use the net proceeds to expand our current business through in-licensing or acquisitions of, or investments in, other businesses, products or technologies; however, we do not have any significant commitments with respect to any such acquisitions or investments at this time.

2023 Note Hedge

In connection with the offering of the 2023 Notes, in November 2018 we entered into convertible note hedge transactions (the 2023 Note Hedge) with two of the initial purchasers of the 2023 Notes (the 2023 Counterparties) entitling us to purchase up to 5.2 million shares of our common stock at an initial price of $164.29 per share, each of which is subject to adjustment. The cost of the 2023 Note Hedge was $218.9 million and it will expire on December 1, 2023. The 2023 Note Hedge is expected to reduce the potential equity dilution upon any conversion of the 2023 Notes and/or offset any cash payments we are required to make in excess of the principal amount of converted 2023 Notes if the daily volume-weighted average price per share of our common stock exceeds the strike price of the 2023 Note Hedge. The strike price of the 2023 Note Hedge initially corresponds to the conversion price of the 2023 Notes and is subject to certain adjustments under the terms of the 2023 Note Hedge.

2023 Warrants

In November 2018, we also sold warrants (the 2023 Warrants) to the 2023 Counterparties to acquire up to 5.2 million shares of our common stock for cash proceeds of $183.8 million. The 2023 Warrants require net share settlement and a pro-rated number of warrants will expire on each of the 60 scheduled trading days starting on March 1, 2024.

See Note 5 to the consolidated financial statements in Part II, Item 8 of this Annual Report for more information about the terms of the Credit Agreement, 2022 Notes and the 2023 Notes, the 2023 Note Hedge, and the 2023 Warrants.

Cash Flows

The following table sets forth a summary of our cash flows for the periods indicated. See the consolidated financial statements in Part II, Item 8 of this Annual Report for complete statements of cash flows for these periods.

(In millions)	Twelve Months Ended December 31, 2019	2018	2017	Change 2019 - 2018	2018 - 2017
Net cash provided by operating activities	$ 314.5	$ 123.2	$ 92.0	$ 191.3	$ 31.2
Net cash used in investing activities	(1,015.2)	(139.8)	(144.4)	(875.4)	4.6
Net cash provided by financing activities	10.7	710.4	399.1	(699.7)	311.3
Effect of exchange rates on cash, cash equivalents, and restricted cash	(0.7)	1.8	0.3	(2.5)	1.5
Increase (decrease) in cash, cash equivalents and restricted cash	$ (690.7)	$ 695.6	$ 347.0	$ (1,386.3)	$ 348.6

As of December 31, 2019, we had $1,533.3 million in cash, cash equivalents and short-term marketable securities, which is an increase of $147.7 million compared to $1,385.6 million as of December 31, 2018. The primary cash flows during the twelve months ended December 31, 2019 and 2018 are described below.

Operating Cash Flows

Net cash provided by operating activities during 2019 was comprised of net income of $101.1 million, net adjustments of $207.3 million and $6.1 million of changes in working capital balances. Net adjustments were primarily related to share-based compensation, depreciation and amortization, non-cash interest expense for our senior convertible notes, and a loss on the sale of our remaining equity investment in Tandem Diabetes Care, Inc.

Net cash provided by operating activities during 2018 was comprised of a net loss of $127.1 million, offset by $291.2 million of net adjustments and $40.9 million of changes in working capital balances. Net adjustments were primarily related to share-based compensation, depreciation and amortization, and non-cash interest expense for our senior convertible notes, and realized and unrealized gains on our equity investment in Tandem Diabetes Care, Inc.

Investing Cash Flows

Net cash used in investing activities during 2019 was primarily comprised of $835.2 million for net purchases of marketable securities and other equity investments and $180.0 million for capital expenditures.

Net cash used in investing activities during 2018 was primarily comprised of $61.4 million for net purchases of marketable securities and other equity investments and $67.1 million for capital expenditures.

Financing Cash Flows

Net cash provided by financing activities during 2019 was primarily comprised of $11.9 million in proceeds from the issuance of common stock under our employee stock plans.

Net cash provided by financing activities during 2018 was primarily comprised of $836.6 million in net proceeds from the issuance of our 2023 Notes and $183.8 million in proceeds from the sale of the 2023 Warrants, partially offset by $218.9 million for the purchase of the 2023 Note Hedge and $100.0 million to purchase shares of our common stock.

Contractual Obligations

We are party to various leasing arrangements, primarily for office, manufacturing and warehouse space that expire at various times through March 2028.

The following table summarizes our outstanding contractual obligations as of December 31, 2019 and the effect those obligations are expected to have on our liquidity and cash flows in future periods:

(In millions)	Total[3]	Less than 1 Year[3]	1-3 Years[1]	3-5 Years[1]	More than 5 Years
Senior convertible notes [1]	$ 1,283.0	$ 9.4	$ 417.2	$ 856.4	$ —
Lease obligations [2]	120.9	18.7	34.7	29.7	37.8
Total	$ 1,403.9	$ 28.1	$ 451.9	$ 886.1	$ 37.8

[1] We issued senior convertible notes in May and June 2017 that are due in May 2022 and we issued senior convertible notes in November 2018 that are due in December 2023. The obligations presented above include both principal and interest for these notes. Although these notes mature in 2022 and 2023, they may be converted into cash and shares of

our common stock prior to maturity if certain conditions are met. Any conversion prior to maturity can result in repayment of the principal amounts sooner than the scheduled repayment as indicated in the table. See Note 5 to the consolidated financial statements in Part II, Item 8 of this Annual Report for further discussion of the terms of our senior convertible notes.

(2) Includes a finance lease obligation related to our Mesa, Arizona facility. See Note 6 to the consolidated financial statements in Part II, Item 8 of this Annual Report for more information.

We are also party to various purchase arrangements related to components used in manufacturing and research and development activities. As of December 31, 2019, we had approximately $165.8 million of open purchase orders and contractual obligations in the ordinary course of business, most of which are due within one year.

Off-Balance Sheet Arrangements

As of December 31, 2019, we did not have any significant off-balance sheet arrangements, as defined in Item 303(a)(4)(ii) of Regulation S-K.

Recent Accounting Guidance

For a description of recently issued accounting guidance that is applicable to our financial statements, see Note 1 to the consolidated financial statements in Part II, Item 8 of this Annual Report.

ITEM 7A - QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Risk

The primary objective of our investment activities is to preserve our capital for the purpose of funding operations while at the same time maximizing the income we receive from our investments without significantly increasing risk. To achieve these objectives, our investment policy allows us to maintain a portfolio of cash equivalents and short-term investments in a variety of securities, including money market funds, U.S. Treasury debt and corporate debt securities. Due to the short-term nature of our investments, we believe that we have no material exposure to interest rate risk.

Market Price Sensitive Instruments

In order to reduce potential equity dilution, in connection with the issuance of the 2023 Notes we entered into the 2023 Hedge which entitles us to purchase shares of our common stock. Upon conversion of the 2023 Notes, the 2023 Hedge is expected to reduce the equity dilution if the daily volume-weighted average price per share of our common stock exceeds the strike price of the hedge. We also entered into warrant transactions with the counterparties of the 2023 Hedge entitling them to acquire shares of our common stock. The warrant transactions could have a dilutive effect on our earnings per share to the extent that the price of our common stock during a given quarterly or annual measurement period exceeds the strike price of the warrants. See Note 5 to the consolidated financial statements in Part II, Item 8 of this Annual Report for more information.

Foreign Currency Exchange Risk

A substantial portion of our operations are located in the United States, and the majority of our sales since inception have been made in U.S. dollars. Accordingly, our assessment is that we have no material net exposure to foreign currency exchange rate fluctuations at this time. However, as our business in markets outside of the United States continues to increase, we will be exposed to foreign currency exchange risk related to our foreign operations. Fluctuations in the rate of exchange between the U.S. dollar and foreign currencies, primarily the British Pound, the Euro, and the Canadian Dollar, could adversely affect our financial results, including our revenues, revenue growth rates, gross margins, income and losses as well as assets and liabilities.

We translate the financial statements of our foreign subsidiaries with functional currencies other than the U.S. dollar into the U.S. dollar for consolidation using end-of-period exchange rates for assets and liabilities and average exchange rates during each reporting period for results of operations. We record net gains or losses resulting from the translation of foreign financial statements and the effect of exchange rate changes on intercompany receivables and payables of a long-term nature as a separate component of stockholders' equity. These adjustments will affect net income only upon sale or liquidation of the underlying investment in foreign subsidiaries.

We record exchange rate fluctuations resulting from the translation of the short-term intercompany balances between domestic entities and our foreign subsidiaries as foreign currency transaction gains or losses and include them in interest and other income (expense), net in our consolidated statement of operations. We occasionally enter into foreign currency forward

contracts for certain intercompany balances in order to partially offset the impact from fluctuation of the foreign currency rates. We entered into no foreign currency forward contracts during the year ended December 31, 2019.

As of December 31, 2019, a notional amount of $8.0 million was outstanding to hedge currency risk relating to certain intercompany balances. The resulting impact from the hedging activity on our consolidated financial statements was not significant for the year ended December 31, 2019. The fair values of these derivatives are based on quoted market prices, which are Level 1 inputs, and the derivative instruments are recorded in other current assets or other current liabilities in our balance sheets consistent with the nature of the instrument at period end. Derivative gains and losses are included in interest and other income, net in our consolidated statement of operations.

Notional principal amounts provide one measure of the transaction volume outstanding as of period end, but they do not represent the amount of our exposure to market loss. Estimates of fair value are based on applicable and commonly used pricing models using prevailing financial market information. The amounts ultimately realized upon settlement of these financial instruments, together with the gains and losses on the underlying exposures, will depend on actual market conditions during the remaining life of the instruments. We monitor and manage our financial exposures due to exchange rate fluctuations as an integral part of our overall risk management program, which recognizes the unpredictability of financial markets and seeks to reduce potentially adverse effects on our financial results.

ITEM 8 - CONSOLIDATED FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The information required is set forth under “Report of Independent Registered Public Accounting Firm,” “Consolidated Balance Sheets,” “Consolidated Statements of Operations,” “ Consolidated Statements of Comprehensive Income (Loss),” “Consolidated Statements of Stockholders’ Equity,” “Consolidated Statements of Cash Flows” and “Notes to Consolidated Financial Statements” on pages F-2 to F-39 of this Annual Report.

ITEM 9 - CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

Not applicable.

ITEM 9A - CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Regulations under the Securities Exchange Act of 1934 require public companies to maintain “disclosure controls and procedures,” which are defined to mean a company’s controls and other procedures that are designed to ensure that information required to be disclosed in the reports that it files or submits under the Securities Exchange Act of 1934 is accumulated and timely communicated to management, including our Chief Executive Officer and Chief Financial Officer, recorded, processed, summarized, and reported within the time periods specified in the Securities and Exchange Commission’s rules and forms. Our management, including our Chief Executive Officer and our Chief Financial Officer, conducted an evaluation as of the end of the period covered by this report of the effectiveness of our disclosure controls and procedures. Based on their evaluation as of December 31, 2019, our Chief Executive Officer and our Chief Financial Officer concluded that our disclosure controls and procedures were effective as of such date for this purpose.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during our last fiscal quarter that have materially affected, or are reasonably likely to materially affect our internal control over financial reporting.

Management’s Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rule 13a-15(f) under the Securities Exchange Act of 1934. Our internal control over financial reporting is designed to provide reasonable assurance to our management and Board of Directors regarding the preparation and fair presentation of published financial statements.

Our management, with the participation of the Chief Executive and Chief Financial Officers, assessed the effectiveness of our internal control over financial reporting as of December 31, 2019. In making this assessment, our management used the criteria set forth by the 2013 Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control —Integrated Framework. Based on this assessment, our management, with the participation of the Chief Executive and Chief Financial Officers, believes that, as of December 31, 2019, our internal control over financial reporting is effective based on those criteria. The effectiveness of our internal control over financial reporting as of December 31, 2019 has been audited by Ernst & Young LLP an Independent Registered Public Accounting Firm, as stated in their report which is included herein.

The certifications of our Chief Executive Officer and Chief Financial Officer required under Section 302 of the Sarbanes-Oxley Act have been filed as Exhibits 31.01 and 31.02 to this report.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation.

Limitation on Effectiveness of Controls

It should be noted that any system of controls, however well designed and operated, can provide only reasonable, and not absolute, assurance that the objectives of the system are met. The design of any control system is based, in part, upon the benefits of the control system relative to its costs. Control systems can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the control. In addition, over time, controls may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate. Because of these and other inherent limitations of control systems, we cannot guaranty that any design will succeed in achieving its stated goals under all potential future conditions, regardless of how remote.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders of DexCom, Inc.

Opinion on Internal Control over Financial Reporting

We have audited DexCom, Inc.'s internal control over financial reporting as of December 31, 2019, 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, DexCom, Inc. (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2019, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of DexCom, Inc. as of December 31, 2019 and 2018, the related consolidated statements of operations, comprehensive income (loss), stockholders' equity and cash flows for each of the three years in the period ended December 31, 2019, and the related notes and financial statement schedule listed in the Index at Item 15(a) and our report dated February 13, 2020 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 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 consolidated 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 Diego, California
February 13, 2020

ITEM 9B - OTHER INFORMATION

None.

PART III

ITEM 10 - DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information concerning our directors required by this Item is incorporated by reference to the section in our Proxy Statement entitled "Proposal No. 1 – Election of Directors."

The information concerning our executive officers required by this Item is incorporated by reference to the section in our Proxy Statement entitled "Executive Officers."

The information concerning compliance with Section 16(a) of the Securities Exchange Act of 1934 required by this Item is incorporated by reference to the section in our Proxy Statement entitled "Section 16(a) Beneficial Ownership Reporting Compliance."

We have adopted a written code of ethics for financial employees that applies to our principal executive officer, principal financial officer, principal accounting officer, controller and other employees of the finance department designated by our Chief Financial Officer. This code of ethics, titled the "Code of Conduct and Ethics for Chief Executive Officer and Senior Finance Personnel," is publicly available on our Internet website at https://dexcom.gcs-web.com/corporate-governance. The information contained on our Internet website is not incorporated by reference into this Annual Report on Form 10-K.

The information concerning the audit committee of the Board of Directors required by this Item is incorporated by reference to information set forth in the Proxy Statement.

The information concerning material changes to the procedures by which stockholders may recommend nominees to the Board of Directors required by this Item is incorporated by reference to information set forth in the Proxy Statement.

ITEM 11 - EXECUTIVE COMPENSATION

The information required by this Item concerning executive compensation and our Compensation Committee is incorporated by reference to information set forth in the Proxy Statement under the heading "Executive Compensation."

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 information set forth in the Proxy Statement under the headings "Principal Stockholders and Stock Ownership by Management" and "Equity Compensation Plan Information."

ITEM 13 - CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by this Item with respect to director independence is incorporated by reference to information set forth in the Proxy Statement.

The information concerning certain relationships and related transactions required by the Item is incorporated by reference to the section in our Proxy Statement entitled "Certain Transactions."

ITEM 14 - PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information concerning principal accountant fees and services required by this Item is incorporated by reference to the section in our Proxy Statement entitled "Ratification of Selection of Independent Registered Public Accounting Firm."

PART IV

ITEM 15 - EXHIBITS, FINANCIAL STATEMENT SCHEDULES

(a) The following documents are filed as part of this Annual Report:

1. Financial Statements.

The consolidated financial statements listed in Part II, Item 8 of this Annual Report.

2. Financial Statement Schedules.

For the three fiscal years ended December 31, 2019, Schedule II – Valuation and Qualifying Accounts.

Financial statement schedules not listed above have been omitted because information required to be set forth therein is not applicable, not required, or the information required by such schedules is shown in the consolidated financial statements or the notes thereto.

3. Exhibits.

		Incorporated by Reference				
Exhibit Number	Exhibit Description	Form	File No.	Date of First Filing	Exhibit Number	Provided Herewith
3.01	Registrant's Restated Certificate of Incorporation.	S-1/A	333-122454	March 3, 2005	3.03	
3.02	Amendment No. 1 to Registrant's Restated Certificate of Incorporation.	DEF 14 A	000-51222	April 20, 2017	Appendix B	
3.03	Registrant's Amended and Restated Bylaws.	8-K	000-51222	November 25, 2014	3.01	
4.01	Form of Specimen Certificate for Registrant's common stock.	S-1/A	333-122454	March 24, 2005	4.01	
4.02	Indenture, dated as of May 12, 2017, between DexCom, Inc. and U.S. Bank National Association (including the form of 0.75% Convertible Senior Notes due 2022)	8-K	000-51222	May 12, 2017	4.1	
4.03	Indenture, dated as of November 30, 2019, between DexCom, Inc. and U.S. Bank National Association (including the form of 0.75% Convertible Senior Notes due 2023)	8-K	000-51222	December 3, 2018	4.1	
4.04	Description of Securities Registered Under Section 12 of the Exchange Act.					X
10.01	Form of Indemnity Agreement between Registrant and each of its directors and executive officers.	S-1	333-122454	February 1, 2005	10.01	
10.02	Office Lease Agreement, dated March 31, 2006, between DexCom, Inc. and Kilroy Realty, L.P.	8-K	000-51222	April 7, 2006	99.01	
10.03	Offer letter between DexCom, Inc. and Steven R. Pacelli dated April 10, 2006.*	8-K	000-51222	April 13, 2006	99.01	
10.04	Form of Amended and Restated Executive Change of Control & Severance Agreement.*	10-K	000-51222	March 5, 2009	10.20	
10.05	Non-Exclusive Distribution Agreement, between RGH Enterprises, Inc. and DexCom, Inc., dated April 30, 2008.**	10-Q	000-51222	August 3, 2009	10.23	
10.06	Amended and Restated Development, Manufacturing, Licensing and Supply Agreement, between DSM PTG, Inc. and DexCom, Inc., dated February 19, 2010.**	10-K	000-51222	March 9, 2010	10.25	
10.07	First Amendment to Office Lease between DexCom, Inc. and Kilroy Realty, L.P., dated August 18, 2010.	10-Q	000-51222	November 4, 2010	10.27	

Exhibit Number	Exhibit Description	Incorporated by Reference				Provided Herewith
		Form	File No.	Date of First Filing	Exhibit Number	
10.08	Amendment Number One to Non-Exclusive Distribution Agreement, between RGH Enterprises, Inc. and DexCom, Inc., dated March 29, 2011.**	10-Q/A	000-51222	July 1, 2011	10.26	
10.09	Offer letter between DexCom, Inc. and Kevin Sayer dated May 3, 2011.*	10-Q	000-51222	August 3, 2011	10.28	
10.10	Amendment Number Two to Non-Exclusive Distribution Agreement between RGH Enterprises, Inc. and DexCom, Inc., dated March 28, 2013.**	10-Q	000-51222	May 1, 2013	10.27	
10.11	Amendment Number Three to Non-Exclusive Distribution Agreement between RGH Enterprises, Inc. and DexCom, Inc., dated December 4, 2013.**	10-K	000-51222	February 20, 2014	10.28	
10.12	Non-Exclusive Distribution Agreement between Dexcom, Inc. and Diabetes Specialty Center, LLC dated October 12, 2009, as amended on September 30, 2010, October 11, 2011, November 14, 2012 and November 1, 2013.**	10-K	000-51222	February 20, 2014	10.29	
10.13	Settlement and License Agreement by and among Abbott Diabetes Care, Inc. and DexCom, Inc., dated July 2, 2014.	10-Q	000-51222	August 6, 2014	10.31	
10.14	Amendment No. 5 to Non-Exclusive Distribution Agreement between DexCom, Inc. and Diabetes Specialty Center, LLC, dated March 14, 2014.	10-Q	000-51222	August 6, 2014	10.32	
10.15	Second Amendment to Office Lease between DexCom, Inc. and Kilroy Realty, L.P., dated October 1, 2014.	10-K	000-51222	February 25, 2015	10.32	
10.16	2015 Employee Stock Purchase Plan	DEF 14A	000-51222	April 13, 2015	Appendix A	
10.17	Form of Subscription Agreement under 2015 Employee Stock Purchase Plan	8-K	000-51222	June 2, 2015	10.2	
10.18	Sublease between DexCom, Inc. and Entropic Communications, LLC dated February 1, 2016.	10-Q	000-51222	April 27, 2016	10.36	
10.19	Amended and Restated Non-Exclusive Distribution Agreement with Byram Healthcare dated February 1, 2016.**	10-Q	000-51222	April 27, 2016	10.37	
10.20	Industrial Net Lease, Broadway dated April 28, 2016, by and between PRA/LB, L.L.C. and DexCom, Inc.	10-Q	000-51222	August 2, 2016	10.39	
10.21	Standard Form of Agreement dated May 2, 2016, by and between DexCom, Inc. and Skanska USA Building Inc.	10-Q	000-51222	August 2, 2016	10.40	
10.22	Amendment to Non-Exclusive Distribution Agreement dated April 30, 2016 by and between RGH Enterprises, Inc. d/b/a Cardinal Health at Home and DexCom, Inc. **	10-Q	000-51222	August 2, 2016	10.41	
10.23	Amendment No. 1 to Collaboration and License Agreement dated October 25, 2016 by and between DexCom, Inc. and Verily Life Sciences LLC (formerly Google Life Sciences LLC).	10-K	000-51222	February 28, 2017	10.42	
10.24	Severance and Change in Control Plan.	8-K	000-51222	June 6, 2017	10.20	

Exhibit Number	Exhibit Description	Incorporated by Reference				Provided Herewith
		Form	File No.	Date of First Filing	Exhibit Number	
10.25	Form of Participation Agreement to the Severance and Change in Control Plan.	8-K	000-51222	June 6, 2017	10.30	
10.26	First Amendment to Credit Agreement dated June 17, 2016 by and among DexCom, Inc., the Lenders, and JPMorgan Chase Bank, as Administrative Agent.	10-Q	000-51222	August 1, 2017	10.46	
10.27	Standard Form of Agreement dated May 1, 2017, by and between DexCom, Inc. and Skanska USA Building Inc.	10-Q	000-51222	August 1, 2017	10.47	
10.28	Offer Letter for Quentin S. Blackford dated July 28, 2017. *	8-K	000-51222	August 1, 2017	10.10	
10.29	Form of Indemnity Agreement	10-Q	000-51222	August 1, 2017	10.43	
10.30	Form of RSU Grant Agreement 2015 Plan Global Double Trigger	10-K	000-51222	February 27, 2018	10.51	
10.31	Form of RSU Grant Agreement 2015 Plan Global General	10-K	000-51222	February 27, 2018	10.52	
10.32	Amended and Restated Collaboration and License Agreement dated November 20, 2018 by and between DexCom, Inc., Verily Life Sciences LLC (an Alphabet Company) and Verily Ireland Limited.**	10-K	000-51222	February 21, 2019	10.60	
10.33	Amended and Restated Credit Agreement dated December 19, 2018 by and among DexCom, Inc., Bank of America, Silicon Valley Bank and Union Bank, and JPMorgan Chase Bank, as Administrative Agent.	10-K	000-51222	February 21, 2019	10.61	
10.34	Amended and Restated 2015 Equity Incentive Plan	8-K	000-51222	June 4, 2019	10.01	
10.35	Executive Deferred Compensation Plan	8-K	000-51222	June 4, 2019	10.02	
10.36	Form of RSU Grant Agreement 2015 Plan (Board Members - Annual Grant)	10-K	000-51222	February 13, 2020	10.36	X
10.37	Form of RSU Grant Agreement 2015 Plan (Board Members - Incoming Grant)	10-K	000-51222	February 13, 2020	10.37	X
10.38	Distribution Services Agreement dated November 7, 2015 between DexCom, Inc. and AmerisourceBergen Drug Corporation.****	10-K	000-51222	February 13, 2020	10.38	X
10.39	Amendment to the Distribution Services Agreement between Dexcom Inc. and AmerisourceBergen Drug Corporation.****	10-K	000-51222	February 13, 2020	10.39	X
10.40	Third Amendment to Office Lease between DexCom, Inc. and John Hancock Life Insurance Company, dated January 9, 2019.****	10-K	000-51222	February 13, 2020	10.40	X
10.41	Fourth Amendment to Office Lease between DexCom, Inc. and Sequence Tech. Center CA LLC, dated September 9, 2019.****	10-K	000-51222	February 13, 2020	10.41	X
10.42	Fifth Amendment to Office Lease between DexCom, Inc. and Sequence Tech. Center CA LLC, dated October 21, 2019.	10-K	000-51222	February 13, 2020	10.42	X
21.01	List of Subsidiaries					X
23.01	Consent of Independent Registered Public Accounting Firm					X
24.01	Power of Attorney (see signature page of this Form 10-K)					X

Exhibit Number	Exhibit Description	Incorporated by Reference				Provided Herewith
		Form	File No.	Date of First Filing	Exhibit Number	
31.01	Certification of Chief Executive Officer Pursuant to Securities Exchange Act Rule 13a-14(a).					X
31.02	Certification of Chief Financial Officer Pursuant to Securities Exchange Act Rule 13a-14(a).					X
32.01	Certification of Chief Executive Officer Pursuant to 18 U.S.C. Section 1350 and Securities Exchange Act Rule 13a-14 (b).***					X
32.02	Certification of Chief Financial Officer Pursuant to 18 U.S.C. Section 1350 and Securities Exchange Act Rule 13a-14 (b).***					X
101.INS	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					X
101.SCH	XBRL Taxonomy Extension Schema Document					X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document					X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document					X
101.LAB	XBRL Taxonomy Extension Label Linkbase Document					X
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document					X

* Represents a management contract or compensatory plan.

** Confidential treatment has been requested for certain portions of this document pursuant to an application for confidential treatment sent to the Securities and Exchange Commission. Such portions are omitted from this filing and were filed separately with the Securities and Exchange Commission.

*** This certification is not deemed "filed" for purposes of Section 18 of the Securities Exchange Act, or otherwise subject to the liability of that section. Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933 or the Securities Exchange Act of 1934, except to the extent that DexCom specifically incorporates it by reference.

**** Portions of this exhibit have been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K.

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, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

DEXCOM, INC.
(Registrant)

Dated: February 13, 2020

By: /S/ QUENTIN S. BLACKFORD

Quentin S. Blackford,
Chief Operating Officer and Chief Financial Officer
(Principal Financial and Accounting Officer)

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Kevin Sayer and Quentin Blackford, jointly and severally, his attorneys-in-fact, each with the power of substitution, for him in any and all capacities, to sign any amendments to this Report on Form 10-K and to file 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 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.

Signature	Title	Date
/S/ KEVIN R. SAYER **Kevin R. Sayer**	Chairman of the Board of Directors, President and Chief Executive Officer (Principal Executive Officer)	February 13, 2020
/S/ QUENTIN S. BLACKFORD **Quentin S. Blackford**	Chief Operating Officer and Chief Financial Officer (Principal Financial and Accounting Officer)	February 13, 2020
/S/ MARK FOLETTA **Mark Foletta**	Lead Independent Director	February 13, 2020
/S/ STEVE ALTMAN **Steve Altman**	Director	February 13, 2020
/S/ NICHOLAS AUGUSTINOS **Nicholas Augustinos**	Director	February 13, 2020
/S/ RICHARD COLLINS **Richard Collins**	Director	February 13, 2020
/S/ BRIDGETTE HELLER **Bridgette Heller**	Director	February 13, 2020
/S/ BARBARA KAHN **Barbara Kahn**	Director	February 13, 2020
/S/ JAY SKYLER **Jay Skyler, M.D.**	Director	February 13, 2020
/S/ ERIC TOPOL **Eric Topol, M.D.**	Director	February 13, 2020

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DEXCOM, INC.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders of DexCom, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of DexCom, Inc. (the Company) as of December 31, 2019 and 2018, the related consolidated statements of operations, comprehensive income (loss), stockholders' equity and cash flows for each of the three years in the period ended December 31, 2019, and the related notes and financial statement schedule listed in the Index at Item 15(a) (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, 2019 and 2018, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2019, 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, 2019, 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 February 13, 2020 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 Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of the critical audit matter 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 matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Estimation of transaction price and variable consideration for revenue recognition

Description of the Matter	As discussed in Note 1 of the consolidated financial statements, the Company recognizes revenue from contracted insurance payors and distributors based on a transaction price which reflects the net consideration to which the Company expects to be entitled. The transaction price is typically based on the contracted rates less an estimate of claim denials and historical reimbursement experience by payor, which include current and future expectations regarding reimbursement rates and payor mix. The Company estimates reductions for rebates based on contractual arrangements, estimates of products sold subject to rebate, known events or trends and channel inventory data. Auditing management's determination of transaction price including variable consideration involved a high degree of subjectivity in evaluating management's estimates. In determining transaction price, management develops estimates based on actual historical reimbursement experience by payor. In estimating variable consideration related to rebates, management applies contracted rates to estimates of products sold subject to rebate, known events or trends and channel inventory data.

How We Addressed the Matter in Our Audit

We obtained an understanding, evaluated the design and tested the operating effectiveness of controls over the Company's processes to determine transaction price and variable consideration, including the underlying assumptions.

Our audit procedures also included, among others, evaluating the significant assumptions and the accuracy and completeness of the underlying data used in management's calculations. For transaction price, this included testing management's estimate of the claim denials and historical reimbursement experience through a combination of underlying data validation by inspection of source documents and independent recalculation of management's analysis. For rebates, this included testing contractual rates, management's estimates of products sold subject to rebate, and inventory held by distributors at the end of the period, through a combination of underlying data validation by inspection of source documents, agreement to underlying contracts, review for consistency against historical data, and trending of inventory held at distributors versus inventory sold into the channel. In addition, we inspected the results of the Company's retrospective review analysis of rebates claimed, evaluated the estimates made based on historical experience and performed sensitivity analyses over the Company's significant assumptions.

/s/ Ernst & Young LLP
We have served as the Company's auditor since 2000
San Diego, California
February 13, 2020

DexCom, Inc.
Consolidated Balance Sheets

(In millions—except par value data)	December 31, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 446.2	$ 1,137.0
Short-term marketable securities	1,087.1	248.6
Accounts receivable, net	286.3	226.7
Inventory	119.8	70.7
Prepaid and other current assets	30.0	16.5
Total current assets	1,969.4	1,699.5
Property and equipment, net	321.3	183.1
Operating lease right-of-use assets	71.5	—
Goodwill	18.6	18.7
Other assets	14.2	14.7
Total assets	$ 2,395.0	$ 1,916.0
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued liabilities	$ 256.4	$ 147.1
Accrued payroll and related expenses	88.5	72.4
Operating lease liabilities, current portion	13.6	—
Deferred revenue	1.7	2.9
Total current liabilities	360.2	222.4
Long-term senior convertible notes	1,059.7	1,010.3
Operating lease liabilities, net of current portion	72.4	—
Other long-term liabilities	20.1	20.0
Total liabilities	1,512.4	1,252.7
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value, 5.0 million shares authorized; no shares issued and outstanding at December 31, 2019 and December 31, 2018, respectively	—	—
Common stock, $0.001 par value, 200.0 million shares authorized; 92.4 million and 91.6 million shares issued and outstanding, respectively, at December 31, 2019; 91.1 million and 90.0 million shares issued and outstanding, respectively, at December 31, 2018	0.1	0.1
Additional paid-in capital	1,675.9	1,560.6
Accumulated other comprehensive income	2.3	1.5
Accumulated deficit	(695.7)	(798.9)
Treasury stock at cost; 0.8 million shares at December 31, 2019	(100.0)	(100.0)
Total stockholders' equity	882.6	663.3
Total liabilities and stockholders' equity	$ 2,395.0	$ 1,916.0

See accompanying notes

DexCom, Inc.
Consolidated Statements of Operations

(In millions—except per share data)	Twelve Months Ended December 31, 2019	2018	2017
Revenue	$ 1,476.0	$ 1,031.6	$ 718.5
Cost of sales	544.5	367.7	226.4
Gross profit	931.5	663.9	492.1
Operating expenses			
Research and development	273.5	199.7	185.4
Collaborative research and development fee	—	217.7	—
Selling, general and administrative	515.7	432.8	349.2
Total operating expenses	789.2	850.2	534.6
Operating income (loss)	142.3	(186.3)	(42.5)
Interest expense	(60.3)	(22.7)	(12.8)
Income (loss) from equity investments	(4.2)	80.1	—
Interest and other income, net	26.4	2.4	6.7
Income (loss) before income taxes	104.2	(126.5)	(48.6)
Income tax expense	3.1	0.6	1.6
Net income (loss)	$ 101.1	$ (127.1)	$ (50.2)
Basic net income (loss) per share	$ 1.11	$ (1.44)	$ (0.58)
Shares used to compute basic net income (loss) per share	91.1	88.2	86.3
Diluted net income (loss) per share	$ 1.10	$ (1.44)	$ (0.58)
Shares used to compute diluted net income (loss) per share	92.3	88.2	86.3

See accompanying notes

DexCom, Inc.
Consolidated Statements of Comprehensive Income (Loss)

(In millions)	Twelve Months Ended December 31, 2019	2018	2017
Net income (loss)	$ 101.1	$ (127.1)	$ (50.2)
Other comprehensive income (loss), net of income taxes:			
Foreign currency translation gain (loss)	0.4	4.0	(1.4)
Unrealized gain (loss) on marketable debt securities	0.4	0.1	(0.2)
Total other comprehensive income (loss), net	0.8	4.1	(1.6)
Comprehensive income (loss)	$ 101.9	$ (123.0)	$ (51.8)

See accompanying notes

DexCom, Inc.
Consolidated Statements of Stockholders' Equity

(In millions)	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Treasury Stock	Total Stockholders' Equity
Balance at December 31, 2016	84.6	$ 0.1	$ 905.7	$ (1.0)	$ (621.0)	$ —	$ 283.8
Issuance of common stock under equity incentive plans	2.3	—	2.7	—	—	—	2.7
Issuance of common stock for Employee Stock Purchase Plan	0.1	—	7.4	—	—	—	7.4
Share-based compensation expense	—	—	106.7	—	—	—	106.7
Equity component of convertible 2022 Note issuance, net of issuance costs	—	—	70.6	—	—	—	70.6
Adoption of ASU 2016-09	—	—	0.6	—	(0.6)	—	—
Net loss	—	—	—	—	(50.2)	—	(50.2)
Other comprehensive loss	—	—	—	(1.6)	—	—	(1.6)
Balance at December 31, 2017	87.0	0.1	1,093.7	(2.6)	(671.8)	—	419.4
Issuance of common stock under equity incentive plans	1.8	—	1.9	—	—	—	1.9
Issuance of common stock for Employee Stock Purchase Plan	0.2	—	8.9	—	—	—	8.9
Share-based compensation expense	—	—	101.9	—	—	—	101.9
Issuance of common stock for collaborative research and development fee	1.8	—	217.7	—	—	—	217.7
Equity component of convertible 2023 Note issuance, net of issuance costs	—	—	171.6	—	—	—	171.6
Sale of warrants	—	—	183.8	—	—	—	183.8
Convertible note hedge	—	—	(218.9)	—	—	—	(218.9)
Purchases of treasury stock	(0.8)	—	—	—	—	(100.0)	(100.0)
Net loss	—	—	—	—	(127.1)	—	(127.1)
Other comprehensive income	—	—	—	4.1	—	—	4.1
Balance at December 31, 2018	90.0	0.1	1,560.6	1.5	(798.9)	(100.0)	663.3
Cumulative-effect adjustment from adoption of new lease accounting standard (Note 6)	—	—	—	—	2.1	—	2.1
Issuance of common stock under equity incentive plans	1.4	—	0.3	—	—	—	0.3
Issuance of common stock for Employee Stock Purchase Plan	0.2	—	11.6	—	—	—	11.6
Share-based compensation expense	—	—	102.7	—	—	—	102.7
Realization of tax benefit related to 2023 Note Hedge	—	—	0.7	—	—	—	0.7
Net income	—	—	—	—	101.1	—	101.1
Other comprehensive income	—	—	—	0.8	—	—	0.8
Balance at December 31, 2019	91.6	$ 0.1	$ 1,675.9	$ 2.3	$ (695.7)	$ (100.0)	$ 882.6

See accompanying notes

DexCom, Inc.
Consolidated Statements of Cash Flows

(In millions)	Twelve Months Ended December 31, 2019	2018	2017
Operating activities			
Net income (loss)	$ 101.1	$ (127.1)	$ (50.2)
Adjustments to reconcile net income (loss) to cash provided by operating activities:			
Depreciation and amortization	48.7	29.1	16.1
Share-based compensation	102.7	101.9	106.2
Non-cash interest expense	49.6	17.9	9.4
Non-cash collaborative research and development fee through issuance of common stock	—	217.7	—
Unrealized gain on equity investment	—	(36.0)	—
Realized (gain) loss on equity investment	4.2	(44.1)	—
Other non-cash income and expenses	2.1	4.7	7.9
Changes in operating assets and liabilities:			
Accounts receivable, net	(60.0)	(93.2)	(31.8)
Inventory	(49.1)	(25.5)	0.4
Prepaid and other assets	(7.2)	(3.0)	(6.7)
Operating lease right-of-use assets and liabilities, net	(2.4)	—	—
Accounts payable and accrued liabilities	109.0	56.2	21.1
Accrued payroll and related expenses	16.0	23.8	14.8
Deferred revenue, deferred rent and other liabilities	(0.2)	0.8	4.8
Net cash provided by operating activities	314.5	123.2	92.0
Investing activities			
Purchase of marketable securities	(2,030.4)	(452.5)	(171.8)
Proceeds from sale and maturity of marketable securities	1,196.4	392.1	93.4
Purchase of other equity investments	(1.2)	(1.0)	—
Purchase of property and equipment	(180.0)	(67.1)	(66.0)
Acquisitions, net of cash acquired	—	(11.3)	—
Net cash used in investing activities	(1,015.2)	(139.8)	(144.4)
Financing activities			
Net proceeds from issuance of common stock	11.9	10.8	10.1
Purchases of treasury stock	—	(100.0)	—
Proceeds from issuance of convertible debt, net of issuance costs	—	836.6	389.0
Proceeds from sale of warrants	—	183.8	—
Purchase of convertible note hedge	—	(218.9)	—
Proceeds from short-term borrowings	—	—	75.0
Repayment of short-term borrowings	—	—	(75.0)
Other financing activities	(1.2)	(1.9)	—
Net cash provided by financing activities	10.7	710.4	399.1
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(0.7)	1.8	0.3
Increase (decrease) in cash, cash equivalents and restricted cash	(690.7)	695.6	347.0
Cash, cash equivalents and restricted cash, beginning of period	1,137.1	441.5	94.5
Cash, cash equivalents and restricted cash, end of period	$ 446.4	$ 1,137.1	$ 441.5
Reconciliation of cash, cash equivalents and restricted cash, end of period:			
Cash and cash equivalents	$ 446.2	$ 1,137.0	$ 441.5
Restricted cash	0.2	0.1	—
Total cash, cash equivalents and restricted cash	$ 446.4	$ 1,137.1	$ 441.5

Supplemental disclosure of non-cash investing and financing transactions:			
Acquisition of property and equipment included in accounts payable and accrued liabilities	$ 14.2	$ 10.8	$ 6.3
Supplemental cash flow information:			
Cash paid during the year for interest	$ 10.4	$ 3.6	$ 2.4
Cash paid during the year for income taxes	$ 4.8	$ 2.3	$ 1.4

See accompanying notes

1. Organization and Significant Accounting Policies

Organization and Business

DexCom, Inc. is a medical device company focused on the design, development and commercialization of CGM system (s) for use by people with diabetes and by healthcare providers. Unless the context requires otherwise, the terms "we," "us," "our," the "company," or "DexCom" refer to DexCom, Inc. and its subsidiaries.

Basis of Presentation and Principles of Consolidation

The consolidated financial statements include the accounts of DexCom, Inc. and our wholly owned subsidiaries. All significant intercompany balances and transactions have been eliminated in consolidation. We have reclassified certain amounts previously reported in our financial statements to conform to the current presentation.

The functional currencies of our international subsidiaries are generally the local currencies. We translate the financial statements of our foreign subsidiaries into U.S. dollars using period-end exchange rates for assets and liabilities and average exchange rates for each period for revenue, costs and expenses. We include translation-related adjustments in comprehensive income (loss) and in accumulated other comprehensive income in the equity section of our consolidated balance sheet. Gains and losses resulting from certain intercompany transactions as well as transactions with customers and vendors that are denominated in currencies other than the functional currency of each entity give rise to foreign exchange gains or losses that we record in interest and other income, net in our consolidated statements of operations.

Use of Estimates

The preparation of consolidated financial statements in conformity with U.S. generally accepted accounting principles, or GAAP, requires us to make certain estimates and assumptions that affect the amounts reported in our financial statements and the disclosures made in the accompanying notes. Areas requiring significant estimates include pharmacy rebates, transaction price, net accounts receivable, excess or obsolete inventories and the valuation of inventory, and accruals for litigation contingencies. Despite our intention to establish accurate estimates and use reasonable assumptions, actual results may differ from our estimates.

Fair Value Measurements

The authoritative guidance establishes a fair value hierarchy that is based on the extent and level of judgment used to estimate the fair value of assets and liabilities. In general, the authoritative guidance requires us to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. An asset or liability's categorization within the fair value hierarchy is based upon the lowest level of input that is significant to the measurement of its fair value. The three levels of input defined by the authoritative guidance are as follows:

Level 1—Unadjusted quoted prices that are available in active markets for identical assets or liabilities.

Level 2—Inputs other than quoted prices included in Level 1 that are observable, either directly or indirectly, through correlation with market data. These include quoted prices in active markets for similar assets or liabilities; quoted prices for identical or similar assets or liabilities in markets that are not active; and inputs to valuation models or other pricing methodologies that do not require significant judgment because the inputs used in the model, such as interest rates and volatility, can be corroborated by readily observable market data for substantially the full term of the assets or liabilities.

Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to the determination of fair value. Level 3 assets and liabilities include those whose fair values are determined using pricing models, discounted cash flow methodologies, or similar valuation techniques and significant judgment or estimation.

We carry our marketable securities at fair value. We carry our other financial instruments, such as cash and cash equivalents, accounts receivable, prepaid expenses and other current assets, accounts payable and accrued liabilities, at cost, which approximates the related fair values due to the short-term maturities of these instruments. For more information see Note 3, "Fair Value Measurements."

Cash and Cash Equivalents

We consider highly liquid investments with a maturity of 90 days or less at the time of purchase to be cash equivalents.

Marketable Securities

We have classified our marketable securities with remaining maturity at purchase of more than three months and remaining maturities of one year or less as short-term marketable securities. We have also classified marketable securities with remaining maturities of greater than one year as short-term marketable securities based upon our ability and intent to use any and all of those marketable securities to satisfy the liquidity needs of our current operations.

We calculate realized gains or losses on our marketable securities using the specific identification method. We carry our marketable debt securities at fair value with unrealized gains and losses reported as a separate component of stockholders' equity in our consolidated balance sheets and included in comprehensive income (loss). Realized gains and losses on marketable debt securities are included in interest and other income, net in our consolidated statements of operations. We carry our marketable equity securities at fair value with realized and unrealized gains and losses reported in income on equity investments in our consolidated statements of operations.

We invest in various types of debt securities, including debt securities in government-sponsored entities, corporate debt securities, U.S. Treasury securities and commercial paper. We do not generally intend to sell these investments and it is not more likely than not that we will be required to sell the investments before recovery of their amortized cost bases, which may be at maturity. See Note 3, "Fair Value Measurements" and Note 4, "Balance Sheet Details – *Short-Term Marketable Securities*" for more information on our marketable debt securities and our marketable equity securities.

Accounts Receivable and Allowance for Doubtful Accounts

Accounts receivable are generally recorded at the invoiced amount for Distributors and at net realizable value for Direct customers, which is determined using estimates of claim denials and historical reimbursement experience without regard to aging category. Accounts receivable are not interest bearing. We evaluate the creditworthiness of significant customers and generally do not require collateral from our customers. We maintain an allowance for doubtful accounts for potential credit losses. Uncollectable accounts are written off against the allowance after appropriate collection efforts have been exhausted and when it is deemed that a customer account is uncollectable. Generally, receivable balances greater than one year past due are deemed uncollectable.

Concentration of Credit Risk and Significant Customers

Financial instruments which potentially subject us to concentrations of credit risk consist primarily of cash, cash equivalents, short-term marketable securities, and accounts receivable. We limit our exposure to credit risk by placing our cash and investments with high credit quality financial institutions. We have also established guidelines regarding diversification of our investments and their maturities that are designed to maintain principal and maximize liquidity. We review these guidelines periodically and modify them to take advantage of trends in yields and interest rates and changes in our operations and financial position.

The following table sets forth the percentages of total revenue or gross accounts receivable for customers that represent 10% or more of the respective amounts for the periods shown:

	Revenue			Gross Accounts Receivable	
	Twelve Months Ended December 31,			As of December 31,	
	2019	2018	2017	2019	2018
Distributor A	17%	15%	16%	21%	19%
Distributor B	12%	12 %	14%	*	15%
Distributor C	10%	*	*	*	*

* Less than 10%

Inventory

Inventory is valued at the lower of cost or net realizable value on a part-by-part basis that approximates first in, first out. We record adjustments to inventory for potentially excess, obsolete or scrapped goods in order to state inventory at net realizable value. Factors influencing these adjustments include inventories on hand and on order compared to estimated future usage and sales for existing and new products, as well as judgments regarding quality control testing data and assumptions about the likelihood of scrap and obsolescence. Once written down the adjustments are considered permanent and are not reversed until the related inventory is sold or disposed of.

Our products require customized products and components that currently are available from a limited number of sources. We purchase certain components and materials from single sources due to quality considerations, costs or constraints resulting from regulatory requirements.

Property and Equipment

Property and equipment is stated at cost less accumulated depreciation. We calculate depreciation using the straight-line method over the estimated useful lives of the assets. Estimated useful lives are generally three years for computer software and hardware, four to fifteen years for machinery and equipment, and five years for furniture and fixtures. Leasehold improvements are amortized over the shorter of the estimated useful lives of the assets or the remaining lease term. We include the amortization of assets that are recorded under finance leases in depreciation expense.

We review property and equipment for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. We estimate the recoverability of the asset by comparing the carrying amount to the future undiscounted cash flows that we expect the asset to generate. We estimate the fair value of the asset based on the present value of future cash flows for those assets. If the carrying value of an asset exceeds its estimated fair value, we would record an impairment loss equal to the difference.

Goodwill

We record goodwill when the fair value of consideration transferred in a business combination exceeds the fair value of the identifiable assets acquired and liabilities assumed. Goodwill and other intangible assets that have indefinite useful lives are not amortized, but we test them annually for impairment in the fourth quarter of our fiscal year and whenever events or changes in circumstances indicate that it is more likely than not that the fair value is less than the carrying value. Events that would indicate impairment and trigger an interim impairment assessment include, but are not limited to, current economic and market conditions, including a decline in market capitalization, a significant adverse change in legal factors, business climate or operational performance of the business, and an adverse action or assessment by a regulator.

We perform our goodwill impairment analysis at the reporting unit level, which aligns with DexCom's reporting structure and the availability of discrete financial information. We perform the first step of our annual impairment analysis by either comparing a reporting unit's estimated fair value to its carrying amount or doing a qualitative assessment of a reporting unit's fair value from the last quantitative assessment to determine if there is potential impairment. We may do a qualitative assessment when the results of the previous quantitative test indicated the reporting unit's estimated fair value was significantly in excess of the carrying value of its net assets and we do not believe there have been significant changes in the reporting unit's operations that would significantly decrease its estimated fair value or significantly increase its net assets. If a quantitative assessment is performed the evaluation includes management estimates of cash flow projections based on internal future projections and/or use of a market approach by looking at market values of comparable companies. Key assumptions for these projections include revenue growth, future gross margin and operating margin growth, and weighted cost of capital and terminal growth rates. The revenue and margin growth are based on increased sales of new and existing products as we maintain investments in research and development. Additional assumed value creators may include increased efficiencies from capital spending. The resulting cash flows are discounted using a weighted average cost of capital. Operating mechanisms and requirements to ensure that growth and efficiency assumptions will ultimately be realized are also considered in the evaluation, including the timing and probability of regulatory approvals for our products to be commercialized. We also consider DexCom's market capitalization as a part of our analysis.

If the estimated fair value of a reporting unit exceeds the carrying amount of the net assets assigned to that unit, goodwill is not impaired and no further analysis is required. If the carrying value of the net assets assigned to a reporting unit exceeds the estimated fair value of the unit, we perform the second step of the impairment test. In this step we allocate the fair value of the reporting unit calculated in step one to all of the assets and liabilities of that unit, as if we had just acquired the reporting unit in a business combination. The excess of the fair value of the reporting unit over the total amount allocated to the assets and liabilities represents the implied fair value of goodwill. If the carrying amount of a reporting unit's goodwill exceeds its implied fair value, we would record an impairment loss equal to the difference. We recorded no goodwill impairment charges for the twelve months ended December 31, 2019, 2018 or 2017.

The change in goodwill for the twelve months ended December 31, 2017 and December 31, 2019 consisted of translation adjustments on our foreign currency denominated goodwill. The change in goodwill for the twelve months ended December 31, 2018 consisted of goodwill we recorded for acquisitions that were not significant, individually or in the aggregate, and translation adjustments on our foreign currency denominated goodwill.

Intangible Assets and Other Long-Lived Assets

We amortize intangible assets with a finite life, such as acquired technology, customer relationships, trade names and trademarks, on a straight-line basis over their estimated useful lives, which range from two to five years. We review intangible assets that have finite lives and other long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. We estimate the fair value of the asset based on the present value of future cash flows for those assets. If the carrying value of an asset exceeds its estimated fair value, we would record an impairment loss equal to the difference.

Income Taxes

We account for income taxes under the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in income in the period that includes the enactment date.

We recognize deferred tax assets to the extent that we believe that these assets are more likely than not to be realized, which requires significant judgment. The realization of deferred tax assets is dependent, in part, upon future taxable income. In assessing whether our deferred tax assets will be realized, we consider all available evidence, both positive and negative. Such evidence includes historical earnings, future reversals of existing taxable temporary differences, estimates of future taxable income, and the feasibility of ongoing tax planning strategies. We have recorded a full valuation allowance on our net deferred tax asset balances for all periods presented because of the uncertainty related to utilization of our deferred tax assets.

We record uncertain tax positions in accordance with ASC 740 on the basis of a two-step process in which (1) we determine whether it is more likely than not that the tax positions will be sustained on the basis of the technical merits of the position and (2) for those tax positions that meet the more-likely-than-not recognition threshold, we recognize the largest amount of tax benefit that is more than 50 percent likely to be realized upon ultimate settlement with the related tax authority.

We file federal and state income tax returns in the United States and income tax returns in various other foreign jurisdictions with varying statutes of limitations. Due to net operating losses incurred, our income tax returns from inception to date are subject to examination by taxing authorities. We recognize interest expense and penalties related to income tax matters, including unrecognized tax benefits, as a component of income tax expense.

Warranty Accrual

Estimated warranty costs associated with a product are recorded at the time revenue is recognized. We estimate future warranty costs by analyzing historical warranty experience for the timing and amount of returned product, and expectations for future warranty activity based on changes and improvements to the product or process that are in place or will be in place in the future. We evaluate these estimates on at least a quarterly basis to determine the continued appropriateness of our assumptions.

Loss Contingencies

If the potential loss from a claim or legal proceeding is considered probable and the amount can be reasonably estimated, we record a liability and an expense for the estimated loss and disclose it in our financial statements if it is significant. If we determine that a loss is possible and the range of the loss can be reasonably determined, then we disclose the range of the possible loss. Significant judgment is required in the determination of whether a potential loss is probable, reasonably possible, or remote as well as in the determination of whether a potential exposure is reasonably estimable.

Comprehensive Income (Loss)

Comprehensive income (loss) consists of two elements, net income (loss) and other comprehensive income (loss). We report all components of comprehensive income (loss), including net income (loss), in our financial statements in the period in which they are recognized. Total comprehensive income (loss) is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources. We report net income (loss) and the components of other comprehensive income (loss), including foreign currency translation adjustments and unrealized gains and losses on marketable securities, net of their related tax effect to arrive at total comprehensive income (loss).

Revenue Recognition

We generate our revenue from the sale of our Reusable Hardware and disposable sensors, which we refer to in this section as "Components".

We adopted ASC Topic 606 effective January 1, 2018 using the modified retrospective method. Our revenue recognition policies under ASC Topic 606 are explained below.

Policy elections and practical expedients taken

- We report revenue net of taxes collected from customers, which are subsequently remitted to governmental authorities;
- We account for shipping and handling activities that are performed after a customer has obtained control of a good as fulfillment costs rather than as separate performance obligations;
- We do not assess whether promised goods or services are performance obligations if they are immaterial in the context of the contract with the customer; and
- If we expect, at contract inception, that the period between the transfer of control and corresponding payment from the customer will be one year or less, we do not adjust the amount of consideration for the effects of a significant financing component.

Contracts and performance obligations

We consider customer purchase orders, which in most cases are governed by agreements with distributors or third-party payors, to be contracts with a customer. For each contract, we consider the obligation to transfer Components to the customer, each of which are distinct, to be separate performance obligations. We also provide free-of-charge software, mobile applications and updates for our DexCom Share® remote monitoring system. The standalone selling prices of our free-of-charge software, mobile applications and updates are estimated based on an expected cost plus a margin approach.

Transaction price

Transaction price for the Components reflects the net consideration to which we expect to be entitled. Transaction price is typically based on the contracted rates less an estimate of claim denials and historical reimbursement experience by payor, which include current and future expectations regarding reimbursement rates and payor mix.

Variable consideration

Rebates. We estimate reductions for rebates based on contractual arrangements, estimates of products sold subject to rebate, known events or trends and channel inventory data.

Product Returns. In accordance with the terms of their distribution agreements, most distributors do not have rights of return outside of our limited warranty. The distributors typically have a limited time frame to notify us of any missing, damaged, defective or non-conforming products. We generally provide a "30-day money back guarantee" program whereby first-time end-user customers may return Reusable Hardware. Product returns have historically been immaterial.

Revenue recognition

The timing of revenue recognition is based on the satisfaction of performance obligations. Substantially all of the performance obligations associated with our Components are satisfied at a point in time, which typically occurs at shipment of our products. Terms of direct and distributor orders are generally Freight on Board (FOB) shipping point for U.S. orders or Free Carrier (FCA) shipping point for international orders. For certain of our distributors, control transfers at delivery of the product to the customer.

In cases where our free-of-charge software, mobile applications and updates are deemed to be separate performance obligations, revenue is recognized over time on a ratable basis over the estimated life of the related hardware component.

Our sales of Components include an assurance-type warranty.

Judgments and Estimates

In determining how revenue should be recognized, a five-step process is used, which requires judgment and estimates that can have a significant impact on the amount and timing of revenue we report. These judgments and estimates include identifying performance obligations in the contract, determining whether the performance obligations are separate, allocating the transaction price to each separate performance obligation, determining the timing of revenue recognition for separate performance obligations and estimating the amount of variable consideration to include in the transaction price.

Contract balances

Contract balances represent amounts presented in the consolidated balance sheets when either we have transferred goods or services to the customer or the customer has paid consideration to us under the contract. These contract balances include accounts receivable and deferred revenue. Payment terms vary by contract type and type of customer and generally range from 30 to 90 days.

Accounts receivable as of December 31, 2019 included unbilled accounts receivable of $3.6 million. Unbilled accounts receivable consists of revenue recognized for Components we have delivered but not yet invoiced to customers. We expect to invoice and collect all unbilled accounts receivable within twelve months.

We record deferred revenue when we have entered into a contract with a customer and cash payments are received or due prior to transfer of control or satisfaction of the related performance obligation. The table below shows revenue that we recognized as a result of changes in the contract liability balances in the periods shown.

	Twelve Months Ended December 31,	
(In millions)	**2019**	**2018**
Revenue recognized in the period from:		
Amounts included in contract liabilities at the beginning of the period	$ 2.6	$ 1.9

Our performance obligations are generally satisfied within 12 months of the initial contract date. As of December 31, 2019, the deferred revenue balance related to performance obligations that will be satisfied after 12 months was $2.1 million. and is included in other long-term liabilities on our consolidated balance sheets. As of December 31, 2018, we had no deferred revenue balance related to performance obligations that will be satisfied after 12 months.

Deferred cost of sales

Deferred cost of sales are associated with sales for which revenue recognition criteria are not met but product has shipped and released from inventory. Deferred cost of sales are included in prepaid and other current assets in our consolidated balance sheets.

Incentive compensation costs

We generally expense incentive compensation associated with our internal sales force when incurred because the amortization period for such costs, if capitalized, would have been one year or less. We record these costs in selling, general and administrative expense in our consolidated statement of operations.

Product Shipment Costs

We record the amounts we charge our customers for the shipping and handling of our products in revenue and we record the related costs as cost of sales in our statements of operations.

Research and Development

We expense costs of research and development as we incur them. Our research and development expenses primarily consist of engineering and research expenses related to our continuous glucose monitoring technology, clinical trials, regulatory expenses, quality assurance programs, materials and products for clinical trials. Research and development expenses primarily consist of employee compensation, including salary, fringe benefits, share-based compensation, and temporary employee expenses. We also incur significant expenses to operate our clinical trials that include clinical site reimbursement, clinical trial product, and associated travel expenses. Our research and development expenses also include fees for design services, contractors, and development materials.

Our CGM systems include certain software that we develop. We expense software development costs as we incur them until technological feasibility has been established, at which time we capitalize development costs until the product is available for general release to customers. To date, our software has been available for general release concurrent with the establishment of technological feasibility and, accordingly, we have not capitalized any development costs.

Advertising Costs

We expense advertising costs as we incur them to selling, general and administrative expenses. Advertising expense was $31.8 million, $25.4 million and $21.9 million for the twelve months ended December 31, 2019, 2018 and 2017, respectively.

Leases

We determine if an arrangement is a lease at inception. Lease right-of-use assets represent our right to use an underlying asset for the lease term and lease liabilities represent our obligation to make lease payments arising from the lease. Operating lease right-of-use assets and liabilities are recognized at commencement date based on the present value of lease payments over the lease term. The interest rate used to determine the present value of the future lease payments is our incremental borrowing rate, because the interest rate implicit in most of our leases is not readily determinable. Our incremental borrowing rate is estimated to approximate the interest rate on a collateralized basis with similar terms and payments, and in similar economic environments. The operating lease right-of-use asset also includes any lease payments made and excludes lease incentives. We have lease agreements with lease and non-lease components, which are generally accounted for separately. Our lease terms may include options to extend or terminate the lease when it is reasonably certain that we will exercise that option. Lease expense for lease payments is recognized on a straight-line basis over the lease term. Variable lease payments that do not depend on a rate or index, payments associated with non-lease components, and costs related to leases with terms of less than 12 months are expensed as incurred.

Share-Based Compensation

Share-based compensation expense is measured at the grant date based on the estimated fair value of the award and is recognized straight-line over the requisite service period of the individual grants, which typically equals the vesting period.

We value time-based Restricted Stock Units (“RSUs”) at the date of grant using the intrinsic value method. Certain RSUs granted to senior management vest based on the achievement of pre-established performance or market goals.

We estimate the fair value of performance/market-based RSUs at the date of grant using the intrinsic value method and the probability that the specified performance criteria will be met. We update our assessment of the probability that the specified performance criteria will be achieved each quarter and adjust our estimate of the fair value of the performance-based RSUs if necessary. The Monte Carlo methodology that we use to estimate the fair value of market-based RSUs at the date of grant incorporates into the valuation the possibility that the market condition may not be satisfied. Provided that the requisite service is rendered, the total fair value of the market-based RSUs at the date of grant must be recognized as compensation expense even if the market condition is not achieved. However, the number of shares that ultimately vest can vary significantly with the performance of the specified market criteria.

If any of the assumptions used change significantly, share-based compensation expense may differ materially from what we have recorded in the current period.

We account for forfeitures as they occur by reversing any share-based compensation expense related to awards that will not vest.

Net Income (Loss) Per Share

Basic net income (loss) per share attributable to common stockholders is calculated by dividing the net income (loss) attributable to common stockholders by the weighted-average number of common shares outstanding during the period. Diluted net income (loss) per share is computed using the weighted average number of common shares outstanding during the period and, when dilutive, potential common share equivalents.

Potentially dilutive common shares consist of shares issuable from stock options, unvested RSUs, warrants and the 2022 and 2023 Senior Convertible Notes. Potentially dilutive common share equivalents shares from outstanding stock options, warrants and unvested RSUs are determined using the average share price for each period under the treasury stock method. Potentially dilutive shares issuable upon conversion of our 2022 and 2023 Senior Convertible Notes are determined using the if-converted method.

The following table sets forth the computation of basic and diluted net income (loss) per share for the periods shown.

	Twelve Months Ended December 31,		
(In millions)	2019	2018	2017
Net income (loss)	$ 101.1	$ (127.1)	$ (50.2)
Net income (loss) per common share			
Basic	$ 1.11	$ (1.44)	$ (0.58)
Diluted	$ 1.10	$ (1.44)	$ (0.58)
Basic weighted average shares outstanding	91.1	88.2	86.3
Dilutive potential common stock outstanding:			
Stock options and employee stock purchase plan	—	—	—
Restricted stock units	1.2	—	—
2023 Warrants	—	—	—
2022 senior convertible notes	—	—	—
2023 senior convertible notes	—	—	—
Diluted weighted average shares outstanding	92.3	88.2	86.3

In periods of net losses, we exclude potentially dilutive common shares from the computation of the diluted net loss per share for those periods as the effect would be anti-dilutive.

Outstanding anti-dilutive securities not included in the diluted net income (loss) per share attributable to common stockholders calculations were as follows:

	Twelve Months Ended December 31,		
(In millions)	2019	2018	2017
Options outstanding to purchase common stock	—	0.1	0.4
Unvested restricted stock units	0.2	2.7	2.7
2023 Warrants	5.2	5.2	—
Senior convertible notes due 2022	4.0	4.0	4.0
Senior convertible notes due 2023	5.2	5.2	—
Total	14.6	17.2	7.1

Recently Adopted Accounting Pronouncements

In February 2016, the FASB issued Accounting Standards Update (ASU) No. 2016-02, *Leases (Topic 842)* (ASU 2016-02), which requires a lessee to recognize most leases on the consolidated balance sheet as lease liabilities with corresponding right-of-use assets. We adopted ASU 2016-02 utilizing the modified retrospective transition method at the beginning of the first quarter of 2019. See Note 6, "Leases and Other Commitments" for more information on the impact of our adoption of ASU 2016-02 and related disclosures.

In August 2017, the FASB issued ASU No. 2017-12, *Derivatives and Hedging* (ASU 2017-12), which is intended to more closely align hedge accounting with companies' risk management strategies, simplify the application of hedge accounting, and increase transparency regarding the scope and results of hedging programs. The guidance in this update is applied using a cumulative-effect adjustment to retained earnings at the beginning of the fiscal year of adoption. ASU 2017-12 is effective for public business entities for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. Our adoption of ASU 2017-12 at the beginning of the first quarter of 2019 did not have a significant impact on our consolidated financial statements.

Recently Issued Accounting Pronouncements Not Yet Adopted

In June 2016, the FASB issued ASU 2016-13, Financial Instruments - *Credit Losses: Measurement of Credit Losses on Financial Instruments*, which amends the impairment model by requiring entities to use a forward-looking approach based on expected losses to estimate credit losses on certain types of financial instruments, including trade receivables and available-for-sale debt securities. This update is effective for annual periods beginning after December 15, 2019, and interim periods within those periods, and early adoption is permitted. We expect to adopt the standard on its effective date in the first quarter of 2020. We believe the adoption will modify the way we analyze financial instruments, but currently do not expect the adoption to have a material financial impact on our consolidated financial statements.

In January 2017, the FASB issued ASU No. 2017-04, *Intangibles – Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment* (ASU 2017-04). This new guidance eliminates the requirement to calculate the implied fair value of goodwill to measure a goodwill impairment charge. Instead, entities will record an impairment charge based on the excess of a reporting unit's carrying amount over its fair value. ASU 2017-04 is effective for public business entities for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years, and early adoption is permitted. We do not expect the adoption to have a material financial impact on our consolidated financial statements.

In August 2018, the FASB issued ASU No. 2018-13, *Fair Value Measurement: Disclosure Framework – Changes to the Disclosure Requirements for Fair Value Measurement* (ASU 2018-13), which adds and modifies certain disclosure requirements for fair value measurements. Under the new guidance, entities will no longer be required to disclose the amount of and reasons for transfers between Level 1 and Level 2 of the fair value hierarchy, or valuation processes for Level 3 fair value measurements. However, public business entities will be required to disclose the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements, and related changes in unrealized gains and losses included in other comprehensive income. ASU 2018-13 is effective for public business entities for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years, and early adoption is permitted. We do not expect the adoption to have a material financial impact on our consolidated financial statements.

In August 2018, the FASB issued ASU No. 2018-15, *Intangibles - Goodwill and Other – Internal-Use Software: Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement that is a Service Contract* (ASU 2018-15). This new guidance requires a customer in a cloud computing arrangement to determine which implementation costs to capitalize as assets or expense as incurred. Capitalized implementation costs related to a hosting arrangement that is a service contract will be amortized over the term of the hosting arrangement, beginning when the module or component of the hosting arrangement is ready for its intended use. ASU 2018-15 is effective for public business entities for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years, and early adoption is permitted. Application of this guidance can be applied either prospectively or retrospectively. We will adopt the new standard on January 1, 2020 on a prospective basis. We do not expect the adoption to have a material financial impact on our consolidated financial statements, however, the adoption of this standard will result in an increase in capitalized assets related to qualifying cloud computing arrangement implementation costs incurred after the adoption date.

In December 2019, the FASB issued ASU No. 2019-12, *Simplifying the Accounting for Income Taxes,* which is intended to simplify various aspects of the income tax accounting guidance, including requirements such as tax basis step-up in goodwill obtained in a transaction that is not a business combination, ownership changes in investments, and interim-period accounting for enacted changes in tax law. ASU 2019-12 is effective for public business entities for fiscal years beginning after December 15, 2020, including interim periods within those fiscal years, and early adoption is permitted. We are currently evaluating the impact that this guidance will have on our consolidated financial statements.

2. Development and Other Agreements

Collaboration with Verily Life Sciences

On November 20, 2018, we entered into an Amended and Restated Collaboration and License Agreement with Verily Life Sciences LLC (an Alphabet Company) and Verily Ireland Limited (collectively, Verily), which we refer to as the Restated Collaboration Agreement. This replaced our original Collaboration and License Agreement with Verily dated August 10, 2015, as amended in October 2016, including the royalty obligations provisions under that original agreement. Pursuant to the Restated Collaboration Agreement, we and Verily have agreed to continue to jointly develop a certain next-generation CGM product, and potentially one or more additional CGM products, for which we will have exclusive commercialization rights.

The Restated Collaboration Agreement also provides us with an exclusive license to use intellectual property of Verily resulting from the collaboration, and certain Verily patents, in the development, manufacture and commercialization of blood-based or interstitial glucose monitoring products more generally (subject to certain exclusions, which are outside of the CGM field as it is commonly understood). It also provides us with non-exclusive license rights under Verily's other intellectual property rights to develop, manufacture and commercialize those kinds of glucose monitoring products and certain CGM-product companion software functionalities. The Restated Collaboration Agreement requires us to use commercially reasonable efforts to develop, launch and commercialize the CGM product(s) that are the subject of the collaboration according to certain timing and other objectives, and provides for one executive sponsor from each of DexCom and Verily to meet periodically and make decisions related to the collaboration (within a limited scope of authority) by consensus.

In consideration of Verily's performance of its obligations under the joint development plan of the Restated Collaboration Agreement, the licenses granted to us and the amendment of the original agreement, we have made upfront and incentive payments and we will make potential future milestone payments upon the achievement of certain goals. In the fourth quarter of 2018, we made an initial payment of $250.0 million through the issuance of 1,840,943 shares of our common stock. We recorded a $217.7 million charge in our consolidated statement of operations during 2018 relating to the issuance of this common stock because this milestone payment did not meet the capitalization criteria. The amount of the charge was based on our closing stock price of $118.28 per share on December 28, 2018, the date on which we obtained the necessary regulatory approvals and the transaction closed. During 2019, we made an incentive payment of $3.2 million due to the completion of certain development obligations and recorded as research and development in the consolidated statement of operations. Additional milestone payments of up to a total of $275.0 million may become due and payable by us upon the achievement of future development, product regulatory approval and revenue milestones. These payments may be paid in cash or shares of our common stock, at our election. If we elect to make all $275.0 million of these payments in shares, we will issue a total of 2,025,036 shares of our common stock, based on the volume weighted average trading price during the 15 consecutive days ending on the date of the Restated Collaboration Agreement. Alternatively, if we elect to make all $275.0 million of these payments in cash, any such cash payment would be equal to the number of shares that would otherwise be issued for the given milestone payment multiplied by the value of our stock on the date the relevant milestone is achieved, adjusted for stock splits, dividends, and the like.

The Restated Collaboration Agreement will continue until December 31, 2028, unless terminated by either party upon uncured material breach of the Restated Collaboration Agreement by the other party. Upon achievement of the first revenue milestone event and payment of the corresponding milestone fee by us, the term of the Restated Collaboration Agreement will be extended until December 31, 2033.

3. Fair Value Measurements

Assets and Liabilities Measured at Fair Value on a Recurring Basis

We estimate the fair value of our Level 1 financial instruments, which are in active markets, using unadjusted quoted market prices for identical instruments.

We obtain the fair values for our Level 2 financial instruments, which are not in active markets, from a primary professional pricing source that uses quoted market prices for identical or comparable instruments, rather than direct observations of quoted prices in active markets. Fair values obtained from this professional pricing source can also be based on pricing models whereby all significant observable inputs, including maturity dates, issue dates, settlement date, benchmark yields, reported trades, broker-dealer quotes, issue spreads, benchmark securities, bids, offers or other market related data, are observable or can be derived from, or corroborated by, observable market data for substantially the full term of the asset. We validate the quoted market prices provided by our primary pricing service by comparing the fair values of our Level 2 marketable securities portfolio balance provided by our primary pricing service against the fair values of our Level 2 marketable securities portfolio balance provided by our investment managers.

The following table summarizes financial assets that we measured at fair value on a recurring basis as of December 31, 2019, classified in accordance with the fair value hierarchy:

	Fair Value Measurements Using			
(In millions)	Level 1	Level 2	Level 3	Total
Cash equivalents	$ 110.1	$ 144.9	$ —	$ 255.0
Debt securities, available for sale:				
U.S. government agencies	—	676.0	—	676.0
Commercial paper	—	248.2	—	248.2
Corporate debt	—	162.9	—	162.9
Total debt securities, available for sale	—	1,087.1	—	1,087.1
Other assets [1]	0.7	—	—	0.7
Total assets measured at fair value on a recurring basis	$ 110.8	$ 1,232.0	$ —	$ 1,342.8

[1] Includes assets which are held pursuant to a deferred compensation plan for our executives, which consist mainly of mutual funds.

The following table summarizes financial assets that we measured at fair value on a recurring basis as of December 31, 2018, classified in accordance with the fair value hierarchy:

	Fair Value Measurements Using			
(In millions)	Level 1	Level 2	Level 3	Total
Cash equivalents	$ 199.3	$ 66.7	$ —	$ 266.0
Equity investment in Tandem Diabetes Care, Inc.	38.0	—	—	38.0
Debt securities, available for sale:				
U.S. government agencies	—	173.1	—	173.1
Commercial paper	—	36.2	—	36.2
Corporate debt	—	1.3	—	1.3
Total debt securities, available for sale	—	210.6	—	210.6
Total assets measured at fair value on a recurring basis	$ 237.3	$ 277.3	$ —	$ 514.6

There were no transfers between Level 1 and Level 2 securities during the years ended December 31, 2019 and December 31, 2018. There were no transfers into or out of Level 3 securities during the years ended December 31, 2019 and 2018.

We hold certain other investments that we do not measure at fair value on a recurring basis. The carrying values of these investments are not significant and we include them in other assets in our consolidated balance sheets. It is impracticable for us to estimate the fair value of these investments on a recurring basis due to the fact that these entities are often privately held and limited information is available. We monitor the information that becomes available from time to time and adjust the carrying values of these investments if there are identified events or changes in circumstances that have a significant adverse effect on the fair values.

Fair Value of Senior Convertible Notes

The fair value, based on trading prices (Level 1), of our Senior Convertible Notes were as follows as of the dates indicated:

	Fair Value Measurements Using Level 1	
(In millions)	December 31, 2019	December 31, 2018
0.75% Senior Convertible Notes due 2022	$ 890.8	$ 540.2
0.75% Senior Convertible Notes due 2023	1,260.0	859.6
Total fair value of outstanding senior convertible notes	$ 2,150.8	$ 1,399.8

For more information on the carrying values of our 2022 Notes and 2023 Notes, see Note 5, "Debt."

Foreign Currency and Derivative Financial Instruments

From time to time we engage in limited hedging transactions to reduce foreign currency risks. The fair values of these derivatives are based on quoted market prices, which are Level 1 inputs, and the derivative instruments are recorded in current assets or current liabilities in our balance sheets consistent with the nature of the instrument at period end. Derivative gains and losses are included in interest and other income, net in our consolidated statement of operations.

As of December 31, 2019, a notional amount of $8.0 million was outstanding to hedge currency risk relating to certain intercompany balances. The resulting impact from the hedging activity on our consolidated financial statements was not significant for the year ended December 31, 2019.

As of December 31, 2018, a notional amount of $60.0 million was outstanding to hedge currency risk relating to certain intercompany balances. Derivative instrument gains on forward exchange contracts were $0.4 million for the twelve months ended December 31, 2018. The fair value of the forward contract exchange derivative instrument liability was $0.2 million as of December 31, 2018. We entered into no foreign currency forward contracts during 2017.

Our foreign currency exposures vary but are primarily concentrated in the British Pound, the Euro, and the Canadian Dollar. We monitor the costs and the impact of foreign currency risks upon our financial results as part of our risk management program. We do not use derivative financial instruments for speculation or trading purposes or for activities other than risk management. We do not require and are not required to pledge collateral for these financial instruments and we do not carry any master netting arrangements to mitigate the credit risk.

Assets and Liabilities Measured at Fair Value on a Non-Recurring Basis

In accordance with authoritative guidance, we measure certain non-financial assets and liabilities at fair value on a non-recurring basis. These measurements are usually performed using the discounted cash flow method and Level 3 inputs. These include items such as non-financial assets and liabilities initially measured at fair value in a business combination and non-financial long-lived assets measured at fair value for an impairment assessment. In general, non-financial assets, including goodwill, intangible assets, and property and equipment, are measured at fair value when there are indicators of impairment and are recorded at fair value only when any impairment is recognized. We recorded no significant impairment losses during the twelve months ended December 31, 2019, 2018 and 2017.

4. Balance Sheet Details

Short-Term Marketable Securities

Short-term marketable securities, consisting of equity securities and debt securities, were as follows as of the dates indicated:

	December 31, 2019			
(In millions)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Market Value
Debt securities, available for sale:				
U.S. government agencies	$ 675.6	$ 0.4	$ —	$ 676.0
Commercial paper	248.1	0.1	—	248.2
Corporate debt	163.0	—	(0.1)	162.9
Total debt securities, available for sale	$ 1,086.7	$ 0.5	$ (0.1)	$ 1,087.1

	December 31, 2018			
(In millions)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Market Value
Equity investment in Tandem Diabetes Care, Inc	$ 2.0	$ 36.0	$ —	$ 38.0
Debt securities, available for sale:				
U.S. government agencies	$ 173.2	$ —	$ (0.1)	$ 173.1
Commercial paper	36.2	—	—	36.2
Corporate debt	1.3	—	—	1.3
Total debt securities, available for sale	$ 210.7	$ —	$ (0.1)	$ 210.6
Total marketable securities	$ 212.7	$ 36.0	$ (0.1)	$ 248.6

As of December 31, 2019 and 2018, all of our debt securities had contractual maturities of less than twelve months. Gross realized gains and losses on our debt securities for the twelve months ended December 31, 2019, 2018 and 2017 were not significant.

We periodically review our portfolio of debt securities to determine if any investment is other-than-temporarily impaired due to changes in credit risk or other potential valuation concerns. We believe that the investments we held at December 31, 2019 were not other-than-temporarily impaired. Unrealized losses on available-for-sale debt securities at that date were not significant and were due to changes in interest rates, including market credit spreads, and not due to increased credit risks associated with specific securities. We do not intend to sell these investments and it is not more likely than not that we will be required to sell the investments before recovery of their amortized cost bases, which may be at maturity.

The following table reconciles the net gain recognized on equity securities during the twelve months ended December 31, 2019, 2018 and 2017 to the unrealized gain recognized during those periods on equity securities still held at the reporting dates.

	Twelve Months Ended December 31,		
(In millions)	2019	2018	2017
Net gains and losses recognized during the period on equity securities	$ (4.2)	$ 80.1	$ —
Less: Net gains and losses recognized during the period on equity securities sold during the period	4.2	(44.1)	—
Unrealized gains recognized during the reporting period on equity securities still held at the reporting date	$ —	$ 36.0	$ —

Accounts Receivable

(In millions)	December 31, 2019	2018
Accounts receivable	$ 292.1	$ 233.9
Less allowance for doubtful accounts	(5.8)	(7.2)
Total accounts receivable, net	$ 286.3	$ 226.7

Inventory

(In millions)	December 31, 2019	2018
Raw materials	$ 64.9	$ 30.8
Work-in-process	11.1	11.2
Finished goods	43.8	28.7
Total inventory	$ 119.8	$ 70.7

During the twelve months ended December 31, 2019, we recorded excess and obsolete inventory charges of $14.1 million in cost of sales as a result of our ongoing assessment of sales demand, inventory on hand for each product and the continuous improvement and innovation of our products. During the twelve months ended December 31, 2018, we recorded excess and obsolete inventory charges of $7.3 million in cost of sales primarily as a result of the approval and launch of our G6 system and our ongoing assessment of sales demand and the continuous improvement and innovation of our products.

Property and Equipment

(In millions)	December 31, 2019	2018
Building and land	$ 15.5	$ 6.0
Furniture and fixtures	12.8	9.0
Computer software and hardware	32.7	29.2
Machinery and equipment	130.2	80.7
Leasehold improvements	102.5	80.7
Construction in progress	132.6	57.3
Total cost	426.3	262.9
Less accumulated depreciation and amortization	(105.0)	(79.8)
Total property and equipment, net	$ 321.3	$ 183.1

Building and Land. Although we do not legally own these premises, under previous lease accounting standards we were deemed the owner of the construction project during the construction period of our manufacturing facility in Mesa, Arizona under a build-to-suit lease arrangement. As a result of our adoption of ASC 842, we de-recognized the estimated fair value of the building shell that was included in "building and land" in our consolidated balance sheets as of December 31, 2018 and the related lease liability and recorded the difference between the asset and liability as an adjustment to retained earnings at the beginning of the first quarter of 2019. The December 31, 2019 balance in "building and land" represents our finance lease right-of-use assets as a result of our adoption of ASC 842.

Depreciation expense related to property and equipment for the twelve months ended December 31, 2019, 2018 and 2017 was $46.9 million, $28.6 million, and $16.1 million, respectively.

Loss on disposal of property and equipment during the twelve months ended December 31, 2019, 2018 and 2017 recorded in operating expenses was $10.5 million, $5.4 million and $11.0 million, respectively.

Accounts Payable and Accrued Liabilities

(In millions)	December 31, 2019	December 31, 2018
Accounts payable trade	$ 102.3	$ 75.5
Accrued tax, audit, and legal fees	14.0	11.7
Accrued rebates	93.3	36.1
Accrued warranty	7.4	6.8
Other accrued liabilities	39.4	17.0
Total accounts payable and accrued liabilities	$ 256.4	$ 147.1

Restructuring Plan. In February 2019, our Board of Directors approved a restructuring plan that resulted in the transition of certain of our operations to the Philippines. We incurred total pre-tax charges and costs of approximately $8.0 million, primarily for employee severance benefits under both ongoing and one-time benefit arrangements. We incurred most of these costs in the first half of 2019 and the restructuring activities have been substantially completed as of December 31, 2019.

Accrued Warranty

Warranty costs are reflected in our statements of operations as cost of sales. Reconciliations of our accrued warranty costs for the twelve months ended December 31, 2019 and 2018 were as follows:

(In millions)	Twelve Months Ended December 31, 2019	Twelve Months Ended December 31, 2018
Beginning balance	$ 6.8	$ 8.8
Charges to costs and expenses	32.7	17.4
Costs incurred	(32.1)	(19.4)
Ending balance	$ 7.4	$ 6.8

Other Long-Term Liabilities

(In millions)	December 31, 2019	December 31, 2018
Finance lease obligations	$ 14.4	$ 7.3
Deferred rent	—	9.4
Other liabilities	5.7	3.3
Total other liabilities	$ 20.1	$ 20.0

Our adoption of ASC 842 during the first quarter of 2019 affected the balances of finance lease liabilities and deferred rent. See Note 6, “Leases And Other Commitments” for more information on leases.

5. Debt

Senior Convertible Notes

The carrying amounts of our senior convertible notes were as follows as of the dates indicated:

	December 31,	
(Dollars in millions)	2019	2018
0.75% Senior Convertible Notes due 2022:		
Principal amount	$ 400.0	$ 400.0
Unamortized debt discount	(37.2)	(51.1)
Unamortized debt issuance costs	(4.6)	(6.3)
Net carrying amount of Senior Convertible Notes due 2022	358.2	342.6
0.75% Senior Convertible Notes due 2023:		
Principal amount	850.0	850.0
Unamortized debt discount	(140.0)	(171.8)
Unamortized debt issuance costs	(8.5)	(10.5)
Net carrying amount of Senior Convertible Notes due 2023	701.5	667.7
Total net carrying amount of senior convertible notes	$ 1,059.7	$ 1,010.3
Carrying value of equity component of convertible senior notes, net of debt issuance costs		
Senior Convertible Notes due 2022	$ 70.6	$ 70.6
Senior Convertible Notes due 2023	$ 171.6	$ 171.6
Remaining amortization period of debt discount on the liability component		
Senior Convertible Notes due 2022	2.5 years	3.5 years
Senior Convertible Notes due 2023	4.0 years	5.0 years

The amount by which the notes' if-converted value exceeds their principal amount is as of the dates indicated:

	December 31,	
(In millions)	2019	2018
Senior Convertible Notes due 2022	$ 486.2	$ 125.4
Senior Convertible Notes due 2023	372.4	—
Total by which the notes' if-converted value exceeds their principal amount	$ 858.6	$ 125.4

The following table summarizes the components of interest expense and the effective interest rates for each of our senior convertible notes for the periods shown.

(Dollars in millions)	Twelve Months Ended December 31,		
	2019	2018	2017
Interest expense recognized:			
0.75% Senior Convertible Notes due 2022:			
Contractual coupon interest	$ 3.0	$ 3.0	$ 1.9
Accretion of debt discount [1]	13.9	13.4	8.2
Amortization of debt issuance costs	1.7	1.6	1.0
Interest expense recognized on 2022 Notes	18.6	18.0	11.1
0.75% Senior Convertible Notes due 2023:			
Contractual coupon interest	6.3	0.5	—
Accretion of debt discount [2]	31.9	2.6	—
Amortization of debt issuance costs	2.0	0.2	—
Interest expense recognized on 2023 Notes	40.2	3.3	—
Total interest expense recognized on senior notes	$ 58.8	$ 21.3	$ 11.1
Effective interest rates:			
0.75% Senior Convertible Notes due 2022	5.1%	5.1%	5.1%
0.75% Senior Convertible Notes due 2023	5.6%	5.6%	—

[1] The discount on the 2022 Notes is being amortized through May 15, 2022. Interest on the 2022 Notes began accruing upon issuance and is payable semi-annually on May 15 and November 15 of each year.

[2] The discount on the 2023 Notes is being amortized through December 1, 2023. Interest on the 2023 Notes began accruing upon issuance and is payable semi-annually on June 1 and December 1 of each year.

0.75% *Senior Convertible Notes due 2022*

In June 2017, we completed an offering of $400.0 million aggregate principal amount of unsecured senior convertible notes with a stated interest rate of 0.75% and a maturity date of May 15, 2022 (the 2022 Notes). The net proceeds from the offering, after deducting initial purchasers' discounts and costs directly related to the offering, were approximately $389.0 million. The initial conversion rate of the 2022 Notes is 10.0918 shares per $1,000 principal amount of notes, which is equivalent to a conversion price of approximately $99.09 per share, subject to adjustments. The 2022 Notes may be settled in cash, stock, or a combination thereof, solely at our discretion. We use the if-converted method for assumed conversion of the 2022 Notes to compute the weighted average shares of common stock outstanding for diluted earnings per share.

Since upon conversion by the holders we may elect to settle such conversion in shares of our common stock, cash, or a combination thereof, we accounted for the cash conversion option as an equity instrument classified to stockholders' equity. As a result, we recognized $72.6 million in additional paid-in-capital during 2017.

No principal payments are due on the 2022 Notes prior to maturity. Other than restrictions relating to certain fundamental changes and consolidations, mergers or asset sales and customary anti-dilution adjustments, the indenture relating to the 2022 Notes includes customary terms and covenants, including certain events of default after which the 2022 Notes may be due and payable immediately.

Conversion Rights at the Option of the Holders

In the event of a fundamental change (as defined in the indenture related to the 2022 Notes), holders of the 2022 Notes have the right to require us to repurchase for cash all or a portion of their notes at a price equal to 100% of the principal amount of the 2022 Notes, plus any accrued and unpaid interest. Holders of the 2022 Notes who convert their notes in connection with a make-whole fundamental change (as defined in the indenture) or following the delivery by DexCom of a notice of redemption are, under certain circumstances, entitled to an increase in the conversion rate.

Prior to 5:00 p.m., New York City time, on the business day immediately preceding February 15, 2022, holders of the 2022 Notes may convert all or a portion of their notes, in multiples of $1,000 principal amount, only under the following circumstances:

(1) during any calendar quarter commencing after September 30, 2017 (and only during such calendar quarter), if the last reported sale price of common stock for at least 20 trading days (whether or not consecutive) during the period of 30 consecutive trading days ending on the last trading day of the immediately preceding calendar quarter is greater than or equal to 130% of the applicable conversion price of the Notes on each such trading day;

(2) during the five business day period after any five consecutive trading day period in which the trading price per $1,000 principal amount of the Notes for each day of that five day consecutive trading day period was less than 98% of the product of the last reported sale price of common stock and the applicable conversion rate of the Notes on such trading day;

(3) if we call any or all of the Notes for redemption, at any time prior to the close on business on the scheduled trading day immediately preceding the redemption date; or

(4) upon the occurrence of specified corporate transactions.

On or after February 15, 2022, until 5:00 p.m., New York City time, on the business day immediately preceding the maturity date, holders of the 2022 Notes may convert all or a portion of their notes regardless of the foregoing circumstances.

Circumstance (1) listed above occurred during the quarters ended March 31, 2019, September 30, 2019 and December 31, 2019. As a result, the 2022 Notes became convertible at the option of the holders from April 1, 2019 through June 30, 2019, October 1, 2019 through December 31, 2019 and will remain convertible at the option of the holder from January 1, 2020 through March 31, 2020.

Holders of 2022 Notes with an insignificant principal amount exercised their option to convert their 2022 Notes during the second and fourth quarters of 2019 and we settled these conversions with shares of our common stock. We continue to classify the carrying value of the liability component of the 2022 Notes as long-term debt, and the equity component of the 2022 Notes as permanent equity in our consolidated balance sheets as of December 31, 2019.

Conversion Rights at Our Option

DexCom may not redeem the 2022 Notes prior to May 15, 2020. On or after May 15, 2020, DexCom may redeem for cash all or part of the 2022 Notes, at its option, if the last reported sale price of our common stock has been at least 140% of the conversion price then in effect for at least 20 trading days (whether or not consecutive) during any 30 consecutive trading day period ending on, and including, the trading day immediately preceding the date on which DexCom provides notice of redemption. The redemption price will be equal to 100% of the principal amount of the 2022 Notes to be redeemed plus accrued and unpaid interest to, but excluding, the redemption date.

0.75% Senior Convertible Notes due 2023

In November 2018, we completed an offering of $850.0 million aggregate principal amount of unsecured senior convertible notes with a stated interest rate of 0.75% and a maturity date of December 1, 2023 (the 2023 Notes). The net proceeds from the offering, after deducting initial purchasers' discounts and costs directly related to the offering, were approximately $836.6 million. The initial conversion rate of the 2023 Notes is 6.0869 shares per $1,000 principal amount of notes, which is equivalent to a conversion price of approximately $164.29 per share, subject to adjustments. We entered into transactions for a convertible note hedge (the 2023 Note Hedge) and warrants (the 2023 Warrants) concurrently with the issuance of the 2023 Notes. The 2023 Notes may be settled in cash, stock, or a combination thereof, solely at our discretion. We use the if-converted method for assumed conversion of the 2023 Notes to compute the weighted average shares of common stock outstanding for diluted earnings per share.

Since upon conversion by the holders we may elect to settle such conversion in shares of our common stock, cash, or a combination thereof, we accounted for the cash conversion option as an equity instrument classified to stockholders' equity. As a result, we recognized $174.4 million in additional paid-in capital during 2018.

No principal payments are due on the 2023 Notes prior to maturity. Other than restrictions relating to certain fundamental changes and consolidations, mergers or asset sales and customary anti-dilution adjustments, the indenture relating to the 2023 Notes includes customary terms and covenants, including certain events of default after which the 2023 Notes may be due and payable immediately.

Conversion Rights at the Option of the Holders

Holders of the 2023 Notes have the right to require us to repurchase for cash all or a portion of their notes at 100% of their principal amount, plus any accrued and unpaid interest, upon the occurrence of a fundamental change (as defined in the indenture relating to the notes). We will also be required to increase the conversion rate for holders who convert their 2023 Notes in connection with certain fundamental changes occurring prior to the maturity date or following the delivery by DexCom of a notice of redemption.

Holders of the 2023 Notes may convert all or a portion of their notes at their option prior to 5:00 p.m., New York City time, on the business day immediately preceding September 1, 2023, in multiples of $1,000 principal amount, only under the following circumstances:

(1) during any calendar quarter commencing after March 31, 2019 (and only during such calendar quarter), if the last reported sale price of common stock for at least 20 trading days (whether or not consecutive) during the period of 30 consecutive trading days ending on the last trading day of the immediately preceding calendar quarter is greater than or equal to 130% of the applicable conversion price of the 2023 Notes on each such trading day;

(2) during the five business day period after any five consecutive trading day period in which the trading price per $1,000 principal amount of the 2023 Notes for each day of that five-day consecutive trading day period was less than 98% of the product of the last reported sale price of common stock and the applicable conversion rate of the 2023 Notes on such trading day;

(3) if we call any or all of the 2023 Notes for redemption, at any time prior to the close of business on the scheduled trading day immediately preceding the redemption date; or

(4) upon the occurrence of specified corporate transactions.

On or after September 1, 2023, until 5:00 p.m., New York City time, on the second scheduled trading day immediately preceding the maturity date, holders of the 2023 Notes may convert all or a portion of their notes regardless of the foregoing circumstances.

Circumstance (1) listed above occurred during the quarter ended December 31, 2019. As a result, the 2023 Notes are convertible at the option of the holders from January 1, 2020 and will remain convertible until March 31, 2020. We continue to classify the carrying value of the liability component of the 2023 Notes as long-term debt, and the equity component of the 2023 Notes as permanent equity in our consolidated balance sheets as of December 31, 2019.

Conversion Rights at Our Option

DexCom may not redeem the 2023 Notes prior to December 1, 2021. On or after December 1, 2021 and prior to September 1, 2023, DexCom may redeem for cash all or part of the 2023 Notes, at its option, if the last reported sale price of our common stock has been at least 130% of the conversion price then in effect for at least 20 trading days (whether or not consecutive) during any 30 consecutive trading day period ending on, and including, the trading day immediately preceding the date on which DexCom provides notice of redemption. The redemption price will be equal to 100% of the principal amount of the 2023 Notes to be redeemed plus accrued and unpaid interest to, but excluding, the redemption date.

2023 Note Hedge

In connection with the offering of the 2023 Notes, in November 2018 we entered into convertible note hedge transactions with two of the initial purchasers of the 2023 Notes (the 2023 Counterparties) entitling us to purchase up to 5.2 million shares of our common stock at an initial price of $164.29 per share, each of which is subject to adjustment. The cost of the 2023 Note Hedge was $218.9 million and we accounted for it as an equity instrument by recognizing $218.9 million in additional paid-in capital during 2018. The 2023 Note Hedge will expire on December 1, 2023. The 2023 Note Hedge is expected to reduce the potential equity dilution upon any conversion of the 2023 Notes and/or offset any cash payments we are required to make in excess of the principal amount of converted 2023 Notes if the daily volume-weighted average price per share of our common stock exceeds the strike price of the 2023 Note Hedge. The strike price of the 2023 Note Hedge initially corresponds to the conversion price of the 2023 Notes and is subject to certain adjustments under the terms of the 2023 Note Hedge. An assumed exercise of the 2023 Note Hedge by us is considered anti-dilutive since the effect of the inclusion would always be anti-dilutive with respect to the calculation of diluted earnings per share.

2023 Warrants

In November 2018, we also sold warrants to the 2023 Counterparties to acquire up to 5.2 million shares of our common stock. The 2023 Warrants require net share settlement and a pro rated number of warrants will expire on each of the 60 scheduled trading days starting on March 1, 2024. We received $183.8 million in cash proceeds from the sale of the 2023 Warrants, which we recorded in additional paid-in capital during 2018. The 2023 Warrants could have a dilutive effect on our earnings per share to the extent that the price of our common stock during a given measurement period exceeds the strike price of the 2023 Warrants. The strike price of the 2023 Warrants is initially $198.38 per share and is subject to certain adjustments under the terms of the warrant agreements. We use the treasury share method for assumed conversion of the 2023 Warrants when computing the weighted average common shares outstanding for diluted earnings per share.

Revolving Credit Agreement

Terms of the Revolving Credit Agreement

On December 19, 2018, we entered into an amended and restated revolving credit agreement (the Credit Agreement) which provides for available principal amount of $200.0 million which can be increased up to $500.0 million at our option subject to customary conditions and approval of our lenders. Borrowings under the Credit Agreement are available for general corporate purposes, including working capital and capital expenditures.

Information related to availability and outstanding borrowings on our Credit Agreement is as follows:

(In millions)	December 31, 2019
Available principal amount	$ 200.0
Letters of credit sub-facility	10.0
Outstanding borrowings	—
Outstanding letters of credit	4.4
Total available balance	195.6

Revolving loans under the Credit Agreement bear interest at our choice of one of two base rates plus a range of applicable margin rates that are based on our leverage ratio. The first base rate is the highest of (a) the publicly announced JPMorgan Chase prime rate, (b) the federal funds rate, or (c) the overnight bank funding rate, and the applicable margin rate ranges from 0.375% to 1.000%. The second base rate is a LIBOR-based rate, and the applicable margin rate ranges from 1.375% to 2.000%. We will also pay a commitment fee of between 0.2% and 0.3%, payable quarterly in arrears, on the average daily unused amount of the revolving facility based on our leverage ratio.

The Credit Agreement will mature on the earlier to occur of (i) December 19, 2023 or (ii) 91 days prior to the maturity date of the 2022 Notes or (iii) 91 days prior to the maturity date of the 2023 Notes if both (a) the aggregate outstanding principal amount of the 2022 Notes or the 2023 Notes, as applicable, is greater than EBITDA for the period of four consecutive fiscal quarters ending prior to such date and (b) unrestricted domestic cash on hand is less than the aggregate outstanding principal amount of the 2022 Notes or the 2023 Notes, as applicable, plus $100.0 million.

Our obligations under the Credit Agreement are guaranteed by our existing and future wholly-owned domestic subsidiaries, and are secured by a first-priority security interest in substantially all of the assets of DexCom and the guarantors, including all or a portion of the equity interests of our domestic subsidiaries and first-tier foreign subsidiaries but excluding real property and intellectual property (which is subject to a negative pledge). The Credit Agreement contains covenants that limit certain indebtedness, liens, investments, transactions with affiliates, dividends and other restricted payments, subordinated indebtedness and amendments to subordinated indebtedness documents, and sale and leaseback transactions of DexCom or any of its domestic subsidiaries. The Credit Agreement also requires us to maintain a maximum leverage ratio and a minimum fixed charge coverage ratio. We were in compliance with these covenants as of December 31, 2019.

6. Leases And Other Commitments

Leases

We lease office, manufacturing and warehouse space facilities under various domestic and international operating leases that expire at various times through August 2026. Certain of our leases have renewal options which allow us to extend the lease term typically between three and five years per option and some of our leases have multiple options to extend. We have one finance lease for our manufacturing facility in Mesa, Arizona under a lease that expires in March 2028 with options to renew

this lease for four additional five-year terms. Our facility leases generally provide for periodic rent increases and many contain escalation clauses. Certain leases also require us to pay taxes, insurance, and maintenance.

The remaining lease terms of our leases range from less than one year to approximately thirteen years; and represent the non-cancellable periods of the leases, including extension options that we determined are reasonably certain to be exercised.

We adopted ASC 842 utilizing the modified retrospective transition method through a $2.1 million cumulative-effect adjustment to accumulated deficit at the beginning of the first quarter of 2019. We will continue to report financial information for fiscal years prior to 2019 under the previous lease accounting standards and as such prior comparative periods have not been recast. We elected the package of practical expedients permitted under the transition guidance in the new standard, which allowed us to carry forward the historical classification of leases that were in place as of January 1, 2019.

Under the previous lease accounting standards we were deemed the owner of our Mesa, Arizona building during the construction period. As a result of our adoption of ASC 842, we have de-recognized the estimated fair value of the building shell and the related lease liability as of December 31, 2018 and recorded the difference between the asset and liability as an adjustment to retained earnings at the beginning of the first quarter of 2019.

In addition, as a result of our adoption of ASC 842 we recorded operating lease right-of-use assets of $26.7 million, finance lease right-of-use assets of $15.3 million, operating lease liabilities of $40.4 million and finance lease liabilities of $15.9 million in our consolidated balance sheets at the beginning of the first quarter of 2019, with no material impact to our consolidated statement of operations.

Operating lease right-of-use assets and liabilities are presented separately in our consolidated balance sheets. Finance lease right-of-use assets are included in property and equipment and finance lease liabilities are included in accounts payable and accrued liabilities and in other long-term liabilities in our consolidated balance sheets.

As of December 31, 2019, the maturities of our operating and finance lease liabilities were as shown in the table below:

(In millions)	Operating Leases	Finance Leases
2020	$ 17.4	$ 1.3
2021	17.4	1.3
2022	14.6	1.4
2023	14.3	1.4
2024	12.5	1.5
Thereafter	23.9	13.9
Total future lease cost [(1)]	100.1	20.8
Less: Amount representing interest	(14.3)	(5.8)
Present value of future payments	85.8	15.0
Less: Short-term leases not recorded as a liability	0.2	—
Revised present value of future lease payments	86.0	15.0
Less: Current portion	(13.6)	(0.6)
Long-term portion	$ 72.4	$ 14.4

[(1)] Total future lease cost excludes $5.5 million of legally binding minimum lease payments for leases signed but not yet commenced.

The components of lease expense for the twelve months ended December 31, 2019 were as follows:

(In millions)	Twelve Months Ended December 31, 2019
Finance lease cost:	
Amortization of right-of-use assets	$ 1.1
Interest on lease liabilities	0.8
Operating lease cost	12.2
Short-term lease cost [1]	3.5
Variable lease cost [2]	3.9
Total lease cost	$ 21.5

[1] Short-term lease cost is primarily related to temporary office space associated with the transition of certain operations to the Philippines.

[2] Variable lease costs are primarily related to common area maintenance charges and property taxes.

Prior to January 1, 2019, we recorded operating lease rent expense under ASC 840 on a straight-line basis over the non-cancellable lease term. Rent expense for the twelve months ended December 31, 2018 and 2017 was $12.5 million and $11.1 million, respectively.

Other information related to leases was as shown in the table below. All figures include the leases recorded at the beginning of the first quarter of 2019 as a result of our adoption of ASC 842.

(Dollars in millions)	Twelve Months Ended December 31, 2019
Cash paid for amounts included in the measurement of lease liabilities:	
Operating cash flows from operating leases	$ 14.3
Operating cash flows from finance leases	$ 0.8
Financing cash flows from finance leases	$ 0.5
Right-of-use assets obtained in exchange for lease liabilities:	
Operating leases	$ 80.6
Finance leases	$ 15.5
Weighted average remaining lease term in years:	
Operating leases	6.2
Finance leases	13.3
Weighted average discount rate:	
Operating leases	5.0%
Finance leases	5.0%

Amortization of operating lease right-of-use asset included in cash flows from operating activities in the Consolidated Statements of Cash Flows was $9.1 million for the twelve months ended December 31, 2019.

Purchase Commitments

We are party to various purchase arrangements related to our manufacturing and research and development activities. As of December 31, 2019, we had approximately $165.8 million of open purchase orders and contractual obligations in the ordinary course of business, most of which are due within one year.

7. Contingencies

Litigation

On March 28, 2016, AgaMatrix, Inc., or AgaMatrix, filed a patent infringement lawsuit against us in the U.S. District Court for the District of Oregon, asserting that certain of our products infringe three patents held by AgaMatrix. (After filing suit, AgaMatrix reorganized its business and the Court granted AgaMatrix's motion to substitute the newly created entity WaveForm Technologies, Inc., as the plaintiff following AgaMatrix's transfer of the three asserted patents to WaveForm.) DexCom filed petitions for *inter partes* review with the Patent Trial and Appeal Board, or PTAB, of the U.S. Patent and Trademark Office, challenging each of the three asserted patents as being unpatentable in view of prior art. The PTAB issued a Final Written Decision for each of the first two patents on February 28, 2018, where the PTAB found the majority of asserted claims from the first patent unpatentable and the remaining claims under review not unpatentable. The PTAB found all claims under review from the second patent not unpatentable. On September 12, 2018, the PTAB found all of the asserted claims in the third patent unpatentable. In October 2018, we filed in the District Court a motion for summary judgment that all remaining asserted claims are invalid. The District Court granted that motion and, on August 23, 2019, entered judgment in our favor. On September 6, 2019, WaveForm appealed the judgment. The appeal is pending and no hearing date has been set.

We have also filed several lawsuits against AgaMatrix. We filed a patent infringement lawsuit against AgaMatrix in the United States District Court for the Central District of California, or C.D. Cal., in which a Final Judgment of non-infringement was entered by the C.D. Cal judge on February 23, 2018 and affirmed on appeal by the Federal Circuit on March 7, 2019. AgaMatrix was awarded attorneys' fees for this lawsuit. As of December 31, 2019, we have accrued an immaterial amount for those fees. The fee decision is currently on appeal to the Federal Circuit. On September 15, 2017, we filed a patent infringement lawsuit against AgaMatrix in the United States District Court for the District of Delaware, asserting certain single-point blood glucose monitoring products of AgaMatrix infringe two patents held by us. In addition, on September 18, 2017, we filed a Complaint against AgaMatrix in the International Trade Commission, referred to as the ITC, requesting that the ITC institute an investigation and issue an order excluding certain products of AgaMatrix from importation into or sale in the United States based on AgaMatrix's infringement of the same two patents asserted in the Delaware litigation. The investigation was terminated by the ITC on April 4, 2019 with a finding of non-infringement. The decision is currently on appeal.

Neither the outcome of these lawsuits nor the amount and range of potential loss associated with the lawsuits can be assessed at this time. Other than the attorneys' fees described above, as of December 31, 2019 we have accrued no amounts for contingent losses associated with these suits.

We are subject to various claims, complaints and legal actions that arise from time to time in the normal course of business, including commercial insurance, product liability and employment related matters. In addition, from time to time we may bring claims or initiate lawsuits against various third parties with respect to matters arising out of the ordinary course of our business, including commercial and employment related matters. We do not expect that the resolution of these matters would, or will, have a material adverse effect or material impact on our financial position or results of operations.

8. Income Taxes

Income (loss) before income taxes subject to taxes in the following jurisdictions is as follows:

	Twelve Months Ended December 31,		
(In millions)	2019	2018	2017
United States	$ 119.1	$ (28.3)	$ 12.4
Outside of the United States	(14.9)	(98.2)	(61.0)
Total	$ 104.2	$ (126.5)	$ (48.6)

Significant components of the provision for income taxes are as follows:

	Twelve Months Ended December 31, 2019		
(In millions)	**2019**	**2018**	**2017**
Current:			
Federal	$ —	$ —	$ —
State	1.0	2.7	0.1
Foreign	1.9	0.1	1.5
Total current income taxes	2.9	2.8	1.6
Deferred:			
Federal	—	(1.7)	—
State	—	(0.5)	—
Foreign	0.2	—	—
Total deferred income taxes	0.2	(2.2)	—
Total	$ 3.1	$ 0.6	$ 1.6

At December 31, 2019, we had federal, state and foreign tax net operating loss carryforwards of approximately $438.8 million, $324.1 million, and $124.1 million, respectively. The federal and state tax loss carryforwards will begin to expire in 2027 and 2020, respectively, unless previously utilized. The foreign net operating losses carry forward indefinitely.

At December 31, 2019, we also had federal and state research and development tax credit carryforwards of approximately $54.4 million and $52.7 million, respectively. $0.1 million of the federal research and development tax credit will begin to expire in 2020, unless previously utilized. The state research and development tax credit will carryforward indefinitely until utilized.

Utilization of net operating losses and credit carryforwards is subject to an annual limitation due to ownership change limitations provided by Section 382 and 383 of the Internal Revenue Code of 1986, as amended, and similar state provisions. An ownership change limitation occurred as a result of the stock offering completed in February 2009. The limitation will likely result in approximately $2.1 million of U.S. income tax credits that will expire unused. The related deferred tax assets have been removed from the components of our deferred tax assets as summarized in the table below. We performed a Section 382 study on the remaining federal and state net operating losses and tax credit carryforwards and have determined that there is no annual limitation on them as of December 31, 2019.

Significant components of our deferred tax assets as of December 31, 2019 and 2018 are shown below. A valuation allowance of approximately $332.2 million has been established as of December 31, 2019 to offset the deferred tax assets, as realization of such assets is uncertain. We maintain a deferred tax liability related to indefinite-lived intangible assets that is not netted against the deferred tax assets. Reversal of the taxable temporary difference for these intangible assets cannot serve as a source of income for realization of the deferred tax assets because the deferred tax liability will not reverse until the intangible assets are sold or written down due to impairment.

(In millions)	December 31, 2019	2018
Deferred tax assets:		
Net operating loss carryforwards	$ 127.4	$ 162.0
Capitalized research and development expenses	57.1	62.1
Tax credits	78.6	59.0
Share-based compensation	10.9	12.5
Fixed and intangible assets	14.0	16.0
Accrued liabilities and reserves	62.0	22.5
Convertible Debt	1.7	—
Total gross deferred tax assets	351.7	334.1
Less: valuation allowance	(332.2)	(330.1)
Total net deferred tax assets	19.5	4.0
Deferred tax liabilities:		
Fixed assets and acquired intangibles assets	(19.6)	(3.8)
Convertible debt discount	—	(0.1)
Total deferred tax liabilities	(19.6)	(3.9)
Net deferred tax assets (liabilities)	$ (0.1)	$ 0.1

Significant judgment is required to evaluate the need for a valuation allowance against deferred tax assets. We review all available positive and negative evidence, including projections of pre-tax book income, earnings history, and reliability of forecasting. A valuation allowance is established when it is more likely than not that some or all of the deferred tax assets will not be realized. As of December 31, 2019, we have maintained a full valuation allowance on our deferred tax assets since inception based on our historical losses and the uncertainty of generating future taxable income to utilize our loss and credit carryforwards. A future release of our valuation allowance will result in a material tax benefit recognized in the quarter of the release.

As of December 31, 2019, deferred tax assets for which any subsequently recognized tax benefits will be credited to additional paid-in capital rather than to income tax benefit totaled $55.7 million.

The reconciliation between our effective tax rate on income (loss) from continuing operations and the statutory rate is as follows:

(In millions)	Twelve Months Ended December 31, 2019	2018	2017
Income taxes at statutory rates	$ 21.9	$ (26.6)	$ (17.0)
State income tax, net of federal benefit	(2.3)	(5.5)	(0.7)
Permanent items	1.0	1.3	0.7
Research and development credits	(10.8)	(11.7)	(13.3)
Foreign rate differential	5.6	3.7	5.4
Stock and officers compensation	(14.7)	(5.1)	(10.4)
Rate change	—	—	(0.1)
Unrecognized tax benefits	—	—	(15.4)
Impact of adoption of ASU 2016-16	—	(13.3)	—
Impact of Tax Cuts and Jobs Act of 2017	—	(0.4)	105.7
Other	(1.0)	1.3	(2.2)
Change in valuation allowance	3.4	56.9	(51.1)
Income taxes at effective rates	$ 3.1	$ 0.6	$ 1.6

The following table summarizes the activity related to our gross unrecognized tax benefits:

(In millions)		
Balance at January 1, 2017	$	39.8
Decreases related to prior year tax positions		(14.9)
Increases related to current year tax positions		3.3
Decrease related to Tax Cuts and Jobs Act of 2017		(5.4)
Balance at December 31, 2017		22.8
Decreases related to prior year tax positions		(0.3)
Increases related to current year tax positions		3.4
Balance at December 31, 2018		25.9
Decreases related to prior year tax positions		(0.9)
Increases related to current year tax positions		4.5
Balance at December 31, 2019	$	29.5

Due to the valuation allowance recorded against our deferred tax assets, none of the total unrecognized tax benefits as of December 31, 2019 would reduce our annual effective tax rate if recognized. Interest and penalties are classified as a component of income tax expense and were not material for any period presented. Due to net operating losses incurred, tax years from 1999 and forward for federal and state purposes and from 2016 and forward for foreign jurisdictions remain open to examination by the major taxing jurisdictions to which we are subject. The IRS commenced an audit of our 2015 and 2016 federal income tax returns in February 2018. The audit closed in June 2019 with no significant changes to our unrecognized tax benefits.

We operate under a tax holiday in the Philippines, which is effective through December 31, 2023, and may be extended for another three years if certain additional requirements are satisfied. The tax holiday is conditional upon remaining in good standing, committing no violation of PEZA Rules and Regulations, pertinent circulars and directives. The impact of this tax holiday decreased foreign taxes by $0.2 million in 2019.

9. Employee Benefit Plans and Stockholders' Equity

401(k) Plan

We have a defined contribution 401(k) retirement plan (the 401(k) Plan) covering substantially all employees in the United States that meet certain age requirements. Employees who participate in the 401(k) Plan may contribute up to 75% of their compensation each year, subject to Internal Revenue Service limitations and the terms and conditions of the plan. Under the terms of the 401(k) Plan, we may elect to match a discretionary percentage of contributions. In April 2018, we began matching 50% of contributions up to 4% of annual compensation. Total matching contributions were $4.8 million and $2.6 million for the twelve months ended December 31, 2019, and 2018, respectively.

Employee Stock Purchase Plan, or ESPP

Under the 2015 Employee Stock Purchase Plan (the 2015 ESPP) eligible employees can purchase shares of our common stock at semi-annual intervals through periodic payroll deductions during defined Offering Periods. A total of up to 1.5 million shares may be issued under the 2015 ESPP and it expires upon the earliest to occur of (a) termination of the 2015 ESPP by our board of directors, (b) issuance of all of the shares of common stock reserved for issuance under the plan, or (c) May 28, 2025.

Payroll deductions may not exceed 10% of the participant's cash compensation subject to certain limitations, and the purchase price will not be less than 85% of the lower of the fair market value of the common stock at either the beginning of the applicable Offering Period or the Purchase Date.

We issued 150,408 and 189,904 and 122,857 shares of common stock under the 2015 ESPP during the twelve months ended December 31, 2019, 2018 and 2017, respectively.

Equity Incentive Plans

In May 2015, we adopted the Amended and Restated 2015 Equity Incentive Plan (the 2015 Plan), which replaced our 2005 Equity Incentive Plan and provides for the grant of incentive and nonstatutory stock options, restricted stock, stock bonuses, stock appreciation rights, and restricted stock units to employees, directors or consultants of the Company. On May 30, 2019 our stockholders approved an increase to the maximum number of shares that may be issued under the 2015 Plan. We are permitted to issue up to 9.8 million shares under the 2015 Plan.

Treasury Stock

Repurchased shares of our common stock are held as treasury shares until they are reissued or retired. When we reissue treasury stock, if the proceeds from the sale are more than the average price we paid to acquire the shares we record an increase in additional paid-in capital. Conversely, if the proceeds from the sale are less than the average price we paid to acquire the shares, we record a decrease in additional paid-in capital to the extent of increases previously recorded for similar transactions and a decrease in retained earnings for any remaining amount.

We issue new shares of common stock to satisfy option exercises and RSU vesting under our employee equity incentive plans. We have not yet determined the ultimate disposition of the 0.8 million shares that we repurchased in 2018, and consequently we continue to hold them as treasury shares rather than retiring them. No shares of our common stock were repurchased during 2019.

Stock Options

We have not granted any stock options since 2010. As of December 31, 2019 we have 28,385 options outstanding, all of which are in-the-money. The options have a weighted- average remaining contractual term of 0.27 years, a weighted- average exercise price of $10.11 per share, and an aggregate intrinsic value of $5.9 million. The aggregate intrinsic value of options outstanding and exercisable is calculated as the difference between the exercise price of the underlying options and the $218.74 per share market price of our common stock at December 31, 2019.

The total intrinsic value of stock options exercised as of the date of exercise was as follows:

	Twelve Months Ended December 31,		
(In millions)	**2019**	**2018**	**2017**
Intrinsic value of options exercised	$ 7.4	$ 30.0	$ 21.6

Restricted Stock Units (RSUs)

RSU awards typically vest annually over three or four years and vesting is subject to continued services. A summary of our RSU activity for the twelve months ended December 31, 2019, 2018 and 2017 is as follows:

(In millions except weighted average grant date fair value)	**Shares**	**Weighted Average Grant Date Fair Value**	**Aggregate Intrinsic Value**
Nonvested at December 31, 2016	3.7	$ 62.51	
Granted	1.3	75.78	
Vested	(1.9)	58.92	
Forfeited	(0.4)	67.97	
Nonvested at December 31, 2017	2.7	70.68	$ 154.5
Granted	1.7	66.07	
Vested	(1.4)	68.44	
Forfeited	(0.3)	68.56	
Nonvested at December 31, 2018	2.7	69.19	319.0
Granted	0.7	144.37	
Vested	(1.4)	69.45	
Forfeited	(0.2)	83.45	
Nonvested at December 31, 2019	1.8	$ 96.63	$ 392.0

The total vest-date fair value of RSUs vested was $207.2 million, $120.9 million and $144.5 million for the twelve months ended December 31, 2019, 2018 and 2017, respectively.

Common Stock Reserved for Future Issuance

Shares of common stock reserved for future issuance were as follows as of the dated indicated:

	December 31,	
(In millions)	**2019**	**2018**
Stock options and awards under our plans:		
Stock options granted and outstanding	—	0.1
Unvested restricted stock units	1.8	2.7
Reserved for future grant	4.9	3.2
Employee Stock Purchase Plan	0.9	1.1
Total	7.6	7.1

Share-based Compensation

The following table summarizes share-based compensation expense related to restricted stock units and employee stock purchases under the ESPP for the twelve months ended December 31, 2019, 2018 and 2017:

	Twelve Months Ended December 31,		
(In millions)	**2019**	**2018**	**2017**
Cost of sales	$ 9.0	$ 9.2	$ 9.6
Research and development	33.5	33.0	37.5
Selling, general and administrative	60.2	59.7	59.1
Total share-based compensation expense included in net loss	$ 102.7	$ 101.9	$ 106.2

We estimate the fair value of ESPP purchase rights on the date of grant using the Black-Scholes option pricing model and the assumptions below for the specified reporting periods.

	Twelve Months Ended December 31,		
	2019	**2018**	**2017**
Risk free interest rate	1.72 - 2.55	1.55 – 2.25	0.75 – 1.12
Dividend yield	—%	—%	—%
Expected volatility of DexCom common stock	0.40 - 0.51	0.50 – 0.67	0.33 – 0.56
Expected life (in years)	1	1	1

At December 31, 2019, unrecognized estimated compensation costs related to unvested restricted stock units and ESPP shares totaled $119.3 million and are expected to be recognized through 2022.

10. Business Segment and Geographic Information

Reportable Segments

An operating segment is identified as a component of a business that has discrete financial information available and for which the chief operating decision maker must decide the level of resource allocation. In addition, the guidance for segment reporting indicates certain quantitative materiality thresholds. None of the components of our business meet the definition of an operating segment.

We currently consider our operations to be, and manage our business globally within, one reportable segment, which is consistent with how our President and Chief Executive Officer, who is our chief operating decision maker, reviews our business, makes investment and resource allocation decisions, and assesses operating performance.

Disaggregation of Revenue

DexCom is domiciled in the United States. We sell our CGM systems through a direct sales force in the United States, Canada and some countries in Europe, and through distribution arrangements in the United States, and certain countries in Africa, Asia, Europe, Latin America, and the Middle East, as well as Australia, Canada, and New Zealand. We disaggregate our revenue from contracts by geography and by major sales channel as we believe they best depict how the nature, amount and timing of revenues and cash flows are affected by economic factors.

Revenues by geographic region

During the twelve months ended December 31, 2019, 2018 and 2017, no individual country outside the United States generated revenue that represented more than 10% of our total revenue. The following table sets forth revenues by our two primary geographical markets, the United States and outside of the United States, based on the geographic location to which we deliver the product:

	Twelve Months Ended December 31,					
	2019		2018		2017	
(Dollars in millions)	Amount	% of Total	Amount	% of Total	Amount	% of Total
Revenues:						
United States	$ 1,161.5	79%	$ 818.4	79%	$ 596.2	83%
Outside of the United States	314.5	21%	213.2	21%	122.3	17%
Total	$ 1,476.0	100%	$ 1,031.6	100%	$ 718.5	100%

The majority of our long-lived assets are located in the United States.

Revenues by customer sales channel

The following table sets forth revenues by major sales channel for the twelve months ended December 31, 2019, 2018 and 2017:

	Twelve Months Ended December 31,					
	2019		2018		2017	
(Dollars in millions)	Amount	% of Total	Amount	% of Total	Amount	% of Total
Revenues:						
Distributor	$ 1,011.6	69%	$ 652.9	63%	$ 538.0	75%
Direct	464.4	31%	378.7	37%	180.5	25%
Total	$ 1,476.0	100%	$ 1,031.6	100%	$ 718.5	100%

11. Quarterly Financial Information (Unaudited)

The following is a summary of our quarterly results of operations for the years ended December 31, 2019 and 2018:

(In millions except per share data)	For the Three Months Ended			
	December 31	**September 30**	**June 30**	**March 31**
Year ended December 31, 2019				
Revenues	$ 462.8	$ 396.3	$ 336.4	$ 280.5
Gross profit	309.3	246.9	206.5	168.8
Total operating expenses	207.8	190.9	207.3	183.2
Net income (loss)	92.7	45.8	(10.5)	(26.9)
Basic net income (loss) per share [(1)]	$ 1.01	$ 0.50	$ (0.12)	$ (0.30)
Diluted net income (loss) per share [(1)]	$ 1.00	$ 0.50	$ (0.12)	$ (0.30)
Year ended December 31, 2018				
Revenues	$ 338.0	$ 266.7	$ 242.5	$ 184.4
Gross profit	222.8	168.6	153.6	118.9
Total operating expenses	387.4	154.7	158.5	149.6
Net income (loss)	(179.7)	46.6	30.2	(24.2)
Basic net income (loss) per share [(1)]	$ (2.03)	$ 0.53	$ 0.34	$ (0.28)
Diluted net income (loss) per share [(1)]	$ (2.03)	$ 0.52	$ 0.34	$ (0.28)

[(1)] Basic and diluted earnings per share are computed independently for each of the quarters presented. Therefore, the sum of quarterly basic and diluted per share information may not equal annual basic and diluted earnings per share.

DexCom, Inc.
SCHEDULE II – VALUATION AND QUALIFYING ACCOUNTS
(In millions)

Allowance for doubtful accounts		
Balance at December 31, 2016	$	12.4
Provision for doubtful accounts		5.3
Write-offs and adjustments		(7.0)
Recoveries		0.7
Balance at December 31, 2017	$	11.4

Allowance for doubtful accounts		
Balance at December 31, 2017	$	11.4
Provision for doubtful accounts		3.6
Write-offs and adjustments		(8.3)
Recoveries		0.5
Balance at December 31, 2018	$	7.2

Allowance for doubtful accounts		
Balance at December 31, 2018	$	7.2
Provision for doubtful accounts		0.9
Write-offs and adjustments		(3.0)
Recoveries		0.7
Balance at December 31, 2019	$	5.8

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Officers

Kevin Sayer
Chairman, President and Chief Executive Officer

Donald M. Abbey
Executive Vice President, Quality and Regulatory Affairs

Andrew K. Balo
Executive Vice President, Regulatory Strategy, Clinical Affairs and Strategic Partnership Development

Quentin S. Blackford
Chief Operating Officer and Chief Financial Officer

Richard Doubleday
Executive Vice President, Chief Commercial Officer

Jake Leach
Executive Vice President, Chief Technology Officer

Jeffrey C. Moy
Executive Vice President, Operations

Patrick Murphy
Executive Vice President, Chief Legal Officer

Steven R. Pacelli
Executive Vice President, Strategy and Corporate Development

Sumi Shrishrimal
Senior Vice President, Chief Risk Officer

Shelly Selvaraj
Senior Vice President, Information Technology

Jereme Sylvain
Senior Vice President, Finance and Chief Accounting Officer

Board of Directors

Kevin Sayer, Chairman
Mark Foletta, Lead Independent Director
Steven R. Altman, Director
Nicholas Augustinos, Director
Richard Collins, Director
Bridgette Heller, Director
Barbara E. Kahn, Director
Jay Skyler, M.D., Director
Eric J. Topol, M.D., Director

Trading Market
NASDAQ Global Select Market
Symbol: DXCM

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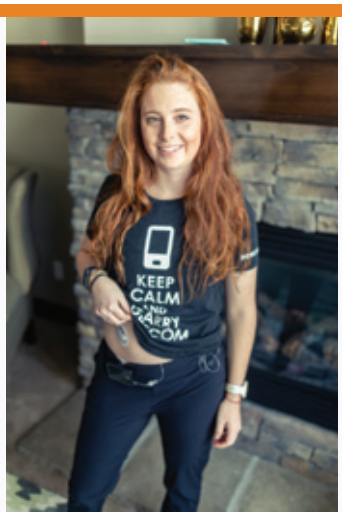
Annual Meeting
May 21, 2020
DexCom, Inc.
6310 Sequence Drive
San Diego, CA 92121
(858) 200-0200

DEXCOM WARRIORS

LAUREN SALKO

Dexcom Warrior since June 2018

Warrior Lauren is a professional skier, Olympic hopeful, and 2019 USASA Champion. Lauren also works to educate others on all things diabetes. With the Share feature, Lauren is able to remain active while her family can monitor her levels.



MAXIM SPEED

Dexcom Warrior since September 2017

After being diagnosed with T1D at seven year old, Dexcom helps Maxim remain healthy and focused on playing soccer. Dexcom has allowed him to travel the world, training and chasing his professional soccer dreams.

Dexcom

www.dexcom.com | 6340 Sequence Drive | San Diego, CA 92121