DEXCOM INC
Form 10-Q
August 01, 2018
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-Q

ý QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended June 30, 2018

¨ 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, California	92121
(Address of Principal Executive Offices)	(Zip Code)

Registrant's Telephone Number, including area code: (858) 200-0200
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 ý No ¨
Indicate by check mark whether the registrant has submitted electronically and posted on its corporate website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ý No ¨
Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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 (Check one):

Large Accelerated Filer	ý	Accelerated Filer	o
Non-Accelerated Filer	o (Do not check if a smaller reporting company)	Smaller Reporting Company	o
Emerging Growth Company	o		

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. o
Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ¨ No ý
As of July 26, 2018, 88,355,733 shares of the Registrant's common stock were outstanding.

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DexCom, Inc.
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PART I - FINANCIAL INFORMATION
ITEM 1. FINANCIAL STATEMENTS

DexCom, Inc.
Consolidated Balance Sheets
(In millions—except par value data)

	June 30, 2018 (Unaudited)	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 300.2	$ 441.5
Short-term marketable securities	305.9	107.1
Accounts receivable, net	162.0	134.3
Inventory	46.2	45.2
Prepaid and other current assets	21.7	16.6
Total current assets	836.0	744.7
Property and equipment, net	156.8	145.6
Goodwill	11.9	12.1
Other assets	2.8	1.7
Total assets	$ 1,007.5	$ 904.1
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued liabilities	$ 117.9	$ 87.2
Accrued payroll and related expenses	46.1	48.5
Deferred revenue	6.8	3.2
Total current liabilities	170.8	138.9
Other liabilities	19.6	18.2
Long term senior convertible notes	335.0	327.6
Total liabilities	525.4	484.7
Commitments and contingencies (Note 6)		
Stockholders' equity:		
Preferred stock, $0.001 par value, 5.0 shares authorized; no shares issued and outstanding at June 30, 2018 and December 31, 2017, respectively	—	—
Common stock, $0.001 par value, 200.0 authorized; 88.7 and 88.4 issued and outstanding, respectively, at June 30, 2018; and 87.3 and 87.0 shares issued and outstanding, respectively, at December 31, 2017	0.1	0.1
Additional paid-in capital	1,149.1	1,093.7
Accumulated other comprehensive loss	(1.3)	(2.6)
Accumulated deficit	(665.8)	(671.8)
Total stockholders' equity	482.1	419.4
Total liabilities and stockholders' equity	$ 1,007.5	$ 904.1

See accompanying notes

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DexCom, Inc.
Consolidated Statements of Operations
(In millions—except per share data)
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Revenues	$242.5	$170.6	$426.9	$312.9
Cost of sales	88.9	53.1	154.4	101.3
Gross profit	153.6	117.5	272.5	211.6
Operating expenses				
Research and development	47.2	45.3	92.0	93.4
Selling, general and administrative	111.3	85.8	216.1	172.2
Total operating expenses	158.5	131.1	308.1	265.6
Operating loss	(4.9)	(13.6)	(35.6)	(54.0)
Income from equity investments	42.7	—	50.1	—
Other income (expense)	(5.6)	1.8	(3.0)	2.2
Interest income	2.2	0.5	3.7	0.7
Interest expense	(4.8)	(3.1)	(9.6)	(3.6)
Income (loss) before income taxes	29.6	(14.4)	5.6	(54.7)
Income tax benefit	(0.6)	(17.3)	(0.4)	(15.9)
Net income (loss)	$30.2	$2.9	$6.0	$(38.8)
Basic net income (loss) per share	$0.34	$0.03	$0.07	$(0.45)
Shares used to compute basic net income (loss) per share	88.2	86.4	87.7	85.8
Diluted net income (loss) per share	$0.34	$0.03	$0.07	$(0.45)
Shares used to compute diluted net income (loss) per share	89.4	87.4	88.8	85.8

See accompanying notes

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Net income (loss)	$30.2	$2.9	$6.0	$(38.8)
Foreign currency translation gain (loss)	3.6	(0.3)	1.3	(0.6)
Comprehensive income (loss)	$33.8	$2.6	$7.3	$(39.4)

See accompanying notes

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DexCom, Inc.
Consolidated Statements of Cash Flows
(In millions)
(Unaudited)

	Six Months Ended June 30,	
	2018	2017
Operating activities		
Net income (loss)	$6.0	$(38.8)
Adjustments to reconcile net income (loss) to cash provided by operating activities:		
Depreciation and amortization	12.7	7.6
Share-based compensation	50.2	55.9
Non-cash interest expense	7.5	2.1
Unrealized income on equity investment	(50.1)	—
Deferred tax	—	(17.1)
Other non-cash income and expenses	4.7	6.1
Changes in operating assets and liabilities:		
Accounts receivable, net	(28.1)	0.5
Inventory	(1.0)	2.8
Prepaid and other assets	(5.0)	(6.2)
Accounts payable and accrued liabilities	32.9	1.8
Accrued payroll and related expenses	(2.0)	(2.1)
Deferred revenue	3.6	0.5
Deferred rent and other liabilities	1.3	1.5
Net cash provided by operating activities	32.7	14.6
Investing activities		
Purchase of available-for-sale marketable securities	(224.1)	(91.4)
Proceeds from the maturity of available-for-sale marketable securities	75.4	19.6
Purchase of other equity investments	(1.0)	—
Purchase of property and equipment	(25.6)	(34.9)
Net cash used in investing activities	(175.3)	(106.7)
Financing activities		
Net proceeds from issuance of common stock	5.2	5.7
Payments on acquisition related contingent consideration liability	(1.8)	—
Proceeds from issuance of convertible debt, net of issuance costs	—	389.0
Proceeds from short-term borrowings	—	75.0
Repayment of short-term borrowings	—	(75.0)
Net cash provided by financing activities	3.4	394.7
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(1.8)	(1.2)
Increase (decrease) in cash, cash equivalents and restricted cash	(141.0)	301.4
Cash, cash equivalents and restricted cash, beginning of period	441.5	94.5
Cash, cash equivalents and restricted cash, end of period	$300.5	$395.9
Reconciliation of cash and restricted cash:		
Cash	$300.2	$395.9
Restricted cash	0.3	—
Total cash and restricted cash	$300.5	$395.9
Supplemental disclosure of non-cash investing and financing transactions:		
Acquisition of property and equipment included in accounts payable and accrued liabilities	$6.3	$4.9

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See accompanying notes

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DexCom, Inc.
Notes to Consolidated Financial Statements
(Unaudited)

1. Organization and Summary of Significant Accounting Policies

Organization and Business

DexCom, Inc. is a medical device company focused on the design, development and commercialization of continuous glucose monitoring ("CGM") systems for ambulatory use by people with diabetes and by healthcare providers for the treatment of people with diabetes. 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

We have incurred operating losses since our inception and have an accumulated deficit of $665.8 million at June 30, 2018. As of June 30, 2018, we had available cash, cash equivalents and marketable securities totaling $606.1 million and working capital of $665.2 million. Our ability to transition to, and maintain, profitable operations is dependent upon achieving a level of revenues adequate to support our cost structure. If events or circumstances occur such that we do not meet our operating plan as expected, we may be required to reduce planned increases in compensation expenses and other operating expenses needed to support the growth of our business which could have an adverse impact on our ability to achieve our intended business objectives. We believe our working capital resources will be sufficient to fund our operations through at least August 1, 2019.

We have prepared the accompanying unaudited consolidated financial statements in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and disclosures required by U.S. GAAP for complete financial statements. In the opinion of management, all adjustments, which include only normal recurring adjustments considered necessary for a fair presentation, have been included. Operating results for the three and six months ended June 30, 2018 are not necessarily indicative of the results that may be expected for the year ending December 31, 2018. These unaudited consolidated financial statements should be read in conjunction with the audited financial statements and related notes thereto for the year ended December 31, 2017 included in the Annual Report on Form 10-K filed by us with the Securities and Exchange Commission on February 27, 2018.

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.

Use of Estimates

The preparation of consolidated financial statements in conformity with U.S. GAAP requires us to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. Actual results could differ from these estimates. Significant estimates include excess or obsolete inventories, valuation of inventory, warranty accruals, convertible debt, employee bonus, clinical trial expenses, allowance for bad debt, refunds, rebates, including pharmacy rebates and self-funded insurance liabilities.

Share-Based Compensation

On March 8, 2018, the Compensation Committee of the Board of Directors of the Company approved a grant of 43,370 performance restricted stock units (PSUs) to our CEO, Kevin Sayer, that vest based on a performance condition, 2018 sensor unit sales, and a market condition, our 3-year relative Total Shareholder Return ("TSR") performance versus the Nasdaq Composite Index from January 1, 2018 to December 31, 2020 (the "Performance Period"). This grant of PSUs is also subject to continuing employment requirements. The actual number of shares that vest can range from 0% to 200% of target shares awarded depending upon the level of achievement of the respective market and performance conditions during the Performance Period. The fair value of the PSUs is estimated on the grant date using a Monte Carlo simulation model due to the market condition for the TSR component. This pricing model uses multiple simulations to evaluate the probability of achieving the market condition to calculate the fair value of the PSUs. The maximum share-based compensation expense related to this grant over the Performance Period is approximately $4.5 million. Share-based compensation expense is updated based on the expected achievement of the related performance conditions at the end of each reporting period.

We recorded $25.6 million and $50.2 million in share-based compensation expense during the three and six months ended June 30, 2018, compared to $25.3 million and $55.9 million during the three and six months ended June 30, 2017. At June 30,

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2018, unrecognized estimated compensation costs related to unvested restricted stock units and PSUs totaled $172.6 million and is expected to be recognized through 2021.

Revenue Recognition

We adopted ASC Topic 606, effective January 1, 2018 using the modified retrospective method. Our revenue policy prior to the adoption of ASC Topic 606 is stated in Note 1 of the audited financial statements and related notes thereto for the year ended December 31, 2017 included in the Annual Report on Form 10-K filed by us with the Securities and Exchange Commission on February 27, 2018.

Revenue for periods after January 1, 2018

We generate our revenue from the sale of our durable systems and disposable units (the "Components"). Our durable system includes a reusable transmitter, a receiver, a power cord and a USB cable. Disposable sensors for use with the durable system are sold separately. We also provide free of charge software and mobile applications for use with our durable systems and disposable sensors. The initial durable system price is generally not dependent upon the subsequent purchase of any amount of disposable sensors.

We sell our durable systems and disposable units through two main sales channels: 1) directly to customers who use our products or organizations (the "Direct Channel") and 2) to distribution partners who resell our products (the "Distributor Channel").

Under the Direct Channel, we sell our durable systems and disposable units to customers who use our products and we receive payment directly from customers who use our products, organizations and third-party payors. Third-party payors primarily include commercial insurance companies and federal and state agencies (under Medicare and Medicaid programs). With respect to customers who directly pay for products, the products are generally paid for at the time of shipment using a customer’s credit card. We also receive a prescription or statement of medical necessity and, for insurance reimbursement customers, an assignment of benefits prior to shipment.

Under our Distributor Channel, we have entered into distribution agreements with Byram Healthcare and its subsidiaries (“Byram”), Cardinal Health and affiliates (including Edgepark Medical Supplies) and other distributors that allow the distributors to sell our durable systems and disposable units. The majority of our distributors stock our products, and we refer to these distributors as Stocking Distributors, whereby the Stocking Distributors fulfill orders for our product from their inventory. We also have contracts with certain distributors that do not stock our products, but rather products are shipped directly to the customer by us on behalf of our distributor, and we refer to these distributors as Drop-Ship Distributors.

We determine revenue recognition through the following steps:

- Identification of the contract, or contracts, with a customer
- Identification of the performance obligations in the contract
- Determination of the transaction price
- Allocation of the transaction price to the performance obligations in the contract
- Recognition of revenue when, or as, we satisfy a performance obligation

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Contracts and performance obligations

We account for a contract with a customer when there is an approval and commitment from both parties, the rights of the parties are identified, payment terms are identified, the contract has commercial substance and collectability of the consideration is probable.

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 performance obligations. Components are individually priced and can be purchased separately or bundled in a contract. For bundled contracts, we account for individual components as a separate performance obligation as the components are separately identifiable from each other and the customer can benefit from each component on its own or with other resources that are readily available to the customer. We also provide free-of-charge software, mobile applications and updates for our DexCom Share® remote monitoring system.

Transaction price

Transaction prices of the Components are typically based on contracted rates. In determining the transaction price, we evaluate whether the price is subject to variable consideration such as sales incentives, rebates, price adjustments or return provisions, to determine the consideration to which we expect to be entitled. To the extent the transaction price includes variable consideration, we estimate the amount of variable consideration that should be included in the transaction price utilizing either the expected value method or the most likely amount method depending on the nature of the variable consideration. Variable consideration is estimated at contract inception and updated at each reporting period as additional information becomes available if, in our judgment, it is probable that a significant future reversal of cumulative revenue under the contract will not occur. Standalone selling price of our free-of-charge software, mobile applications and updates are based on an expected cost plus a margin approach. 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. We report revenue net of taxes collected from customers, which are subsequently remitted to governmental authorities. We account for shipping and handling charges billed to customers as costs to fulfill our promise to transfer the products to the customer and as such, shipping and handling costs billed to customers are included in revenue while related costs are included as cost of sales.

We generally provide a “30-day money back guarantee” program whereby first-time end-user customers in most of our sales channels who purchase a durable system and a package of four disposable sensors may return the durable system for any reason within thirty days of purchase and receive a full refund of the purchase price of the durable system. Our returns have historically been immaterial.

Most distributors do not have rights of return per their distribution agreement 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. For any such products, we shall either, at our option, replace the portion of defective or non-conforming product at no additional cost to the distributor or cancel the order and refund any portion of the price paid to us at that time for the sale in question.

We contract with various pharmacy benefit managers and private payor organizations, primarily insurance companies, for the payment of rebates based on contracted discounts after the final dispensing of the product by a distributor or retail pharmacy to a pharmacy benefit plan participant based upon contractual agreements with private sector benefit providers. We estimate these pharmacy rebates using the expected value method and record such estimates in the same period the related revenue is recognized, resulting in a reduction of revenue and the establishment of a current liability. The pharmacy rebate liability is based on contractual discount rates, expected utilization under each contract and our estimate of the amount of inventory in the distribution channel that will become subject to such rebates. Our estimates for expected utilization for rebates are based on historical rebate claims and to a lesser extent third party market research data. Pharmacy rebates are generally invoiced and paid monthly or quarterly in arrears so that our accrual consists of an estimate of the amount expected to be incurred for the current month's or quarter’s activity, plus an accrual for unpaid rebates from prior periods, and an accrual for inventory in the distribution channel. Refer to Note 2 for additional revenue related disclosures.

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Revenue recognition

Revenue is recognized when control is transferred to our customers, in an amount that reflects the net consideration we expect to be entitled. The timing of revenue recognition is based on the satisfaction of performance obligations, which can be satisfied at a point in time or over time, depending on the nature of the performance obligation. Substantially all of our performance obligations associated with our durable systems and disposable units 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 (or Free Carrier ("FCA") shipping point for international orders. For certain of our distributors, control transfers at delivery of the product to the customer.

We recognize revenue from contracted insurance payors and distributors based on the contracted rate and estimate of any variable consideration. For non-contracted insurance payors, we obtain prior authorization from the payor and recognize revenue based on the estimated collectible amount and historical experience.

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 product component.

Our sales of receiver and transmitter components of our CGM system include an assurance-type warranty which is accounted for based on the cost accrual method recognized as expense when the products are sold and is not considered a separate performance obligation.

Self-Funded Health Insurance

Effective January 1, 2018, we are self-insured for claims under our U.S. health benefit plans subject to stop loss policies. We established an accrual for this self-insured program with the assistance of outside actuaries based on claims experience and an estimate of claims incurred but not yet reported ("IBNR") and other relevant factors. The projections involved in this process are subject to uncertainty related to the timing and amount of claims filed, levels of IBNR, fluctuations in health care costs and changes to regulatory requirements. Actual claims may differ from the estimate and any difference could be significant. The accrued obligation for our self-insured program is included in "Accounts payable and accrued liabilities" in the consolidated balance sheets was $2.7 million as of June 30, 2018. We also have a restricted cash account for claim payments associated with our self-insured program, included in the "Prepaid and other current assets" line item in the consolidated balance sheets.

Recent Accounting Guidance

Recently adopted accounting pronouncements

In May 2014, the Financial Accounting Standards Board ("FASB") issued authoritative guidance for Revenue from Contracts with Customers ASC Topic 606 ("ASU 2014-09"), to supersede nearly all existing revenue recognition guidance under U.S. GAAP. The core principle of the guidance is to recognize revenue when promised goods or services are transferred to customers in an amount that reflects the consideration that is expected to be received for those goods or services. The guidance defines a five step process to achieve this core principle and it is possible when the five step process is applied, more judgment and estimates may be required within the revenue recognition process than required under existing U.S. GAAP, including identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligation. We have applied this standard electing the modified retrospective method. The company applied the practical expedient permitted under ASC Topic 606 to those contracts that were not completed, as of January 1, 2018. Our analysis of open contracts as of January 1, 2018, resulted in no material cumulative effect from applying ASU 2014-09.

In October 2016, the FASB issued ASU No. 2016-16, Accounting for Income Taxes - Intra-Entity Asset Transfer other than Inventory (Topic 740) ("ASU 2016-16"), which would require the recognition of the tax expense from the sale of an asset other than inventory when the transfer occurs, rather than when the asset is sold to a third party or otherwise recovered through use. The new guidance is effective for public business entities for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years. Early adoption is permitted. The amendment should be applied on a modified retrospective basis through a cumulative-effect adjustment directly to retained earnings as of the beginning period of adoption. Due to the full valuation allowance on the U.S. deferred tax assets, we have determined that none of the provisions of ASU 2016-16 have a significant impact on our consolidated

financial statements.

In January 2016, the FASB issued ASU No. 2016-01 to amend the guidance on the classification and measurement of financial instruments, which was further amended in February 2018 by ASU No. 2018-03. The new guidance requires entities to measure equity investments that do not result in consolidation and are not accounted for under the equity method at fair value and recognize any changes in fair value in net income. The new guidance also amends certain disclosure requirements associated with the fair value of financial instruments. The new guidance is effective for public business entities for fiscal years

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beginning after December 15, 2017, including interim periods within those fiscal years. The adoption of this guidance did not have a significant impact on our financial statements.

In December 2016, the FASB issued Accounting Standards Update No. 2016-18, Restricted Cash (ASU 2016-18). This update requires additional disclosure and that the Statement of Cash Flow explain the change during the period in the total cash, cash equivalents and amounts generally described as restricted cash. Therefore, amounts generally described as restricted cash should be included with cash & cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the Statement of Cash Flows. The new guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2017 with early adoption permitted. The adoption of this ASU impacted the presentation of cash flows with inclusion of restricted cash flows for each of the presented periods.

Recently issued accounting pronouncements not yet adopted

In June 2018, the FASB issued ASU 2018-07, Compensation-Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting ("ASU 2018-07"), which simplifies the accounting for share-based payments made to nonemployees so the accounting for such payments is substantially the same as those made to employees. Under ASU 2018-07, share based awards to nonemployees will be measured at fair value on the grant date of the awards, entities will need to assess the probability of satisfying performance conditions if any are present, and awards will continue to be classified according to Accounting Standards Codification 718 upon vesting which eliminates the need to reassess classification upon vesting, consistent with awards granted to employees. ASU 2018-07 is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years, and early adoption is permitted. We are in the process of evaluating the impact of adoption of ASU 2018-07 on our consolidated financial statements.

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842) ("ASU 2016-02"), which require a lessee to recognize a lease payment liability and a corresponding right of use asset on their balance sheet for all lease terms longer than 12 months, lessor accounting remains largely unchanged. ASU 2016-02 is effective for fiscal years, and interim periods within those years, beginning on or after December 15, 2018 and early adoption is permitted. We will adopt ASU 2016-02 in the first quarter of 2019. We have started the process of gathering and assessing our lease contracts and implementing changes to our systems. We expect the adoption will lead to an increase in the assets and liabilities recorded on our Consolidated Balance Sheets.

2. Revenue

Adoption of ASU 2014-09 (ASC Topic 606), Revenue from Contracts with Customers

On January 1, 2018 we adopted ASC Topic 606 electing the modified retrospective method. We applied the practical expedient permitted under ASC Topic 606 to those contracts which were not completed as of the date of initial adoption. Results for reporting periods after January 1, 2018 are presented under ASC Topic 606, while prior period amounts are not adjusted and continue to be reported in accordance with legacy accounting guidance under ASC Topic 605. The impact of applying ASC Topic 606 was not material, as such we did not record a cumulative adjustment to retained earnings.

Practical expedients and exemptions

Under the practical expedients in ASC Topic 606, we generally expense incentive compensation associated with our internal sales force when incurred because the amortization period is less than one year. These costs are recorded within selling, general and administrative expense.

Disaggregation of Revenue

We sell our durable systems and disposable units through a direct sales force in the United States, Canada and some countries of Europe, and through distribution arrangements in the United States, Canada, Australia, New Zealand, and in some countries of Europe, Asia, Latin America, the Middle East and Africa. During the three and six months ended June 30, 2018, no individual country, outside the United States, generated revenue that represented more than 10% of our total revenue. We disaggregate our revenue from contracts by major sales channel and geography as we believe they best depict how the nature, amount and timing of revenues and cash flows are affected by economic factors.

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Revenues by geographic region

The following table sets forth revenues by our two primary geographical markets, United States and outside of the United States, based on the geographic location to which we deliver the product (in millions):

	Three Months Ended June 30, 2018	Six Months Ended June 30, 2018
Revenues:		
United States	$ 189.6	$ 335.0
Outside of the United States	52.9	91.9
Total	$ 242.5	$ 426.9

Revenues by customer sales channel

The following table sets forth revenues disaggregated by customer sales channel (in millions):

	Three Months Ended June 30, 2018	Six Months Ended June 30, 2018
Revenues:		
Distributor	$ 158.4	$ 276.7
Direct	84.1	150.2
Total	$ 242.5	$ 426.9

Contract Balances

The timing of revenue recognition, billing and cash collections results in trade receivables and deferred revenue on the consolidated balance sheet. A receivable is recognized in the period our right to the consideration is unconditional. We generally do not have any contracts or performance obligations with a term of more than one year.

Our contracts with customers do not typically include extended payment terms. Payment terms vary by contract type and type of customer and generally range from 30 to 60 days.

Substantially all of our deferred revenue as of June 30, 2018 is associated with an upgrade promotional program related to our G6 system and certain of our free of charge software and mobile applications which will be recognized during 2018. During the three months ended June 30, 2018, we recognized revenue of $2.0 million that was recorded as deferred revenue as of March 31, 2018. During the six months ended June 30, 2018, we recognized revenue of $1.9 million that was recorded as deferred revenue as of December 31, 2017.

3. Net Income (Loss) Per Common 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 for the period, without consideration for common stock equivalents. Diluted net income (loss) per share is computed using the weighted average number of common shares outstanding and, when dilutive, potential common share equivalents from outstanding options and unvested RSUs settleable in shares of common stock (using the treasury-stock method), and potential common shares from convertible securities (using the if-converted method).

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The following table sets forth the computation of basic and diluted net income (loss) per share (in millions, except per share data):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Net income (loss)	$30.2	$2.9	$6.0	$(38.8)
Net income (loss) per common share:				
Basic	$0.34	$0.03	$0.07	$(0.45)
Diluted	$0.34	$0.03	$0.07	$(0.45)
Basic weighted average shares outstanding	88.2	86.4	87.7	85.8
Effect of potentially dilutive stock options	0.2	0.4	0.3	—
Effect of potentially dilutive share-based awards	1.0	0.6	0.8	—
Diluted weighted average shares outstanding	89.4	87.4	88.8	85.8

Outstanding anti-dilutive securities not included in diluted net income (loss) per share attributable to common stockholders calculation (in millions):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Options outstanding to purchase common stock	—	—	—	0.4
Unvested restricted stock units	—	0.1	0.4	3.0
Senior convertible notes	4.0	4.0	4.0	4.0
Total	4.0	4.1	4.4	7.4

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4. Financial Statement Details (in millions)

Short-Term Marketable Securities

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

	June 30, 2018			
	Cost or Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Market Value
Equity investment in Tandem Diabetes Care, Inc	$5.0	$ 50.1	$ —	$ 55.1
Debt securities, available for sale				
U.S. government agencies	$199.6	$ —	$ (0.2)	$ 199.4
Commercial paper	49.3	—	—	49.3
Corporate debt	2.1	—	—	2.1
Total available-for-sale debt securities	$251.0	$ —	$ (0.2)	$ 250.8
Total marketable securities	$256.0	$ 50.1	$ (0.2)	$ 305.9

Gross unrealized gain on our equity investment in Tandem Diabetes Care, Inc. of $42.7 million and $50.1 million for three and six months ended June 30, 2018, respectively is included in our Consolidated Statements of Operations under "Income from equity investments."

	December 31, 2017			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Market Value
U.S. government agencies	$87.5	$ —	$ (0.2)	$ 87.3
Corporate debt	14.7	—	—	14.7
Commercial paper	5.1	—	—	5.1
Total marketable securities	$107.3	$ —	$ (0.2)	$ 107.1

As of June 30, 2018, the estimated market value of available-for-sale marketable securities with contractual maturities of up to one year and up to 13 months were $249.8 million and $1.0 million, respectively. We do not generally intend to sell the 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.

Inventory

	June 30, 2018	December 31, 2017
Raw materials	$21.7	$ 20.0
Work-in-process	9.7	8.2
Finished goods	14.8	17.0
Total	$46.2	$ 45.2

During the three and six months ended June 30, 2018 we recorded excess and obsolete inventory charges of $3.5 million and $5.5 million, respectively, in cost of goods sold primarily related to the approval and launch of our G6 System and the continuous improvement and innovation of our products.

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Property and Equipment

	June 30, 2018	December 31, 2017
Building [1]	$6.0	$ 6.0
Furniture and fixtures	8.4	5.7
Computer equipment	27.7	25.6
Machinery and equipment	61.9	33.8
Leasehold improvements	79.1	41.7
Construction in progress	39.2	87.6
Total	222.3	200.4
Accumulated depreciation and amortization	(65.5)	(54.8)
Property and equipment, net	$156.8	$ 145.6

(1) As described in Footnote 6 “Commitments and Contingencies,” although we do not legally own these premises, we were deemed the owner of the construction project during the construction period of our new manufacturing facility in Mesa, Arizona under a build-to-suit lease arrangement.

Accounts Payable and Accrued Liabilities

	June 30, 2018	December 31, 2017
Accounts payable trade	$59.9	$ 46.7
Accrued tax, audit, and legal fees	15.4	7.1
Accrued rebates	19.9	13.9
Accrued warranty	7.5	8.8
Accrued other	15.2	10.7
Total	$117.9	$ 87.2

Accrued Warranty

Warranty costs are reflected in the consolidated statements of operations as product cost of sales. A reconciliation of our accrued warranty costs for the three and six months ended June 30, 2018 and 2017 were as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Beginning balance	$8.9	$9.9	$8.8	$9.8
Charges to costs and expenses	3.4	3.4	7.9	8.4
Costs incurred	(4.8)	(5.0)	(9.2)	(9.9)
Ending balance	$7.5	$8.3	$7.5	$8.3

Other Liabilities

	June 30, 2018	December 31, 2017
Financing lease obligations	$7.3	$ 6.7
Deferred rent	8.1	8.7
Other	4.2	2.8
Total	$19.6	$ 18.2

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5. Debt

0.75% Senior Convertible Notes due 2022

(in millions)	June 30, 2018	December 31, 2017
0.75% Senior convertible notes due 2022:		
Principal amount	$400.0	$ 400.0
Unamortized debt discount	(57.8)	(64.4)
Unamortized debt issuance costs	(7.2)	(8.0)
Net carrying amount of senior convertible notes	$335.0	$ 327.6
Fair value of outstanding notes	$465.8	$ 381.3
Amount by which the notes' if-converted value exceeds their principal amount	$55.4	$ —

In May 2017, we completed an offering of $350.0 million aggregate principal amount of 0.75% convertible senior notes due 2022 (the "2022 Notes") and, in June 2017 the initial purchasers exercised their option to purchase an additional $50.0 million aggregate principal amount of 2022 Notes. The 2022 Notes have a stated interest rate of 0.75% and a maturity date of May 15, 2022. The net proceeds from the offering, after deducting initial purchasers' discounts and costs directly related to the offering, were approximately $389.0 million. The 2022 Notes may be settled in cash, stock, or a combination thereof, solely at our discretion. The initial conversion rate of the 2022 Notes is 10.0918 shares per $1,000 principal amount, which is equivalent to a conversion price of approximately $99.09 per share, subject to adjustments. 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.

As 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, which resulted in recognizing $72.6 million in additional paid-in-capital during 2017.

The interest expense recognized on the 2022 Notes during the three months ended June 30, 2018 includes $0.7 million, $3.3 million and $0.4 million for the contractual coupon interest, the accretion of the debt discount and the amortization of the debt issuance costs, respectively. The interest expense recognized on the 2022 Notes during the six months ended June 30, 2018 includes $1.5 million, $6.6 million and $0.8 million for the contractual coupon interest, the accretion of the debt discount and the amortization of the debt issuance costs, respectively.

The interest expense recognized on the 2022 Notes during the three and six months ended June 30, 2017 includes $0.4 million, $1.8 million and $0.2 million for the contractual coupon interest, the accretion of the debt discount and the amortization of the debt issuance costs, respectively.

The effective interest rate on the 2022 Notes is 5.1%, which includes the interest on the notes, amortization of the debt discount and debt issuance costs. The discount on the 2022 Notes is 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.

Holders of the 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.

Additionally, in the event of a fundamental change (as defined in the Indenture), holders of the Notes may require us to repurchase all or a portion of their Notes at a price equal to 100% of the principal amount of Notes, plus any accrued and unpaid interest, including any additional interest, to, but excluding, the repurchase date.

Holders of the 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 February 15, 2022, in multiples of $1,000 principal amount, only under the following circumstances:

- 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;
- 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;

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- 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
- 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 Notes may convert all or a portion of their Notes regardless of the foregoing circumstances.

The redemption price will be equal to 100% of the principal amount of such 2022 Notes to be redeemed plus accrued and unpaid interest to, but excluding, the redemption date. 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 includes customary terms and covenants, including certain events of default after which the Notes may be due and payable immediately. We are unaware of any current events or market conditions that would allow holders to convert the 2022 Notes as of June 30, 2018.

Revolving Credit Agreement

In June 2016, we entered into a $200.0 million revolving credit agreement (the “Credit Agreement”), as amended in May 2017, with JPMorgan Chase Bank, NA, as administrative agent, Bank of America, Silicon Valley Bank, Union Bank and Bank of the West. In addition to allowing borrowings in US dollars, the Credit Agreement provides a $25.0 million sublimit for borrowings in Canadian Dollars, Euros, British Pounds, Swedish Krona, Japanese Yen and any other currency that is subsequently approved by JPMorgan Chase and each lender. The Credit Agreement also provides a sub-facility of up to $10.0 million for letters of credit, of which $5.6 million is still available. The interest rate under the Credit Agreement ranges from 0.75% to 2.75% plus our choice of one of two base rates, LIBOR or a rate based on the publicly announced JPMorgan Chase prime rate, the federal funds rate or the overnight bank funding rate. We will also pay a commitment fee of between 0.25% and 0.45%, payable quarterly in arrears, on the average daily unused amount of the revolving facility based on our leverage ratio. The aggregate debt issuance costs and fees incurred with respect to entering into the Credit Agreement were $0.7 million, which have been capitalized on our Consolidated Balance Sheet within “Other Assets” and will be amortized through the maturity date of June 2021 on a straight line basis. 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).

Short-term borrowings

In March 2017 we drew $75.0 million on the Credit Agreement under a six month term. We repaid the entire principal balance in May 2017. As of June 30, 2018 we had no outstanding borrowings under the Credit Agreement, and $195.6 million under the Credit Agreement remains available, which is reduced by outstanding letters of credit.

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6. Commitments and Contingencies

Leases

Under the office lease agreement, as amended (the "Office Lease"), with John Hancock Life Insurance Company (U.S.A.) (the "Landlord") we lease approximately 219,000 square feet of space in the buildings at 6340 Sequence Drive, 6310 Sequence Drive and 6290 Sequence Drive. The amended Office Lease term extends through March 2022 and we have an option to renew the lease upon the expiration of the initial term for two additional five-year terms by giving notice to the Landlord prior to the end of the initial term of the lease and any extension period, if applicable. Provided we are not in default under the Office Lease and the Office Lease is still in effect, we generally have the right to terminate the lease starting at the 55th month of the Office Lease. We have received $3.6 million of tenant improvement allowance associated with the Office Lease, which is recorded as a deferred rent obligation and amortized over the term of the lease and reflected as a reduction to rent expense. Leasehold improvements associated with the tenant improvement allowance are included in Property and equipment, net in our consolidated balance sheets. On February 1, 2016, we entered into a Sublease (the "Sublease") with Entropic Communications, LLC with respect to the building at 6350 Sequence Drive in San Diego, California (the "6350 Building"). Under the Sublease, we have leased approximately 132,600 square feet of space in the 6350 Building. The Sublease term extends through January 2022.

On April 28, 2016, we entered into a certain Industrial Net Lease (the "Mesa Lease") with PRA/LB, L.L.C. with respect to facilities in the building at 232 South Dobson Road in Mesa, Arizona (the "Mesa Building"). Under the Mesa Lease, we have leased approximately 148,797 square feet of space in the Mesa Building, of which approximately 78,000 square feet was available to us on May 1, 2016 and the remaining portion of the Mesa Building became available to us in January 2018. The term of the Mesa Lease extends through March 2028 with four options to extend the Mesa Lease term, each for five-year periods. The Mesa Lease arrangement involves the construction of our new manufacturing facility where we are involved in the design and construction of the leased space, including non-standard tenant improvements paid for by us. This arrangement is referred to as a build-to suit lease and for accounting purposes, we were considered the owner of the construction project during the construction period. During the second quarter of 2016, we capitalized the fair value of the Mesa Building of $6.0 million within "Property and Equipment, net," and recorded a corresponding financing lease obligation liability of $6.0 million within "Other Liabilities" in the Consolidated Balance Sheet. We have concluded that the Mesa Lease does not qualify for "sale-leaseback" treatment due to prohibited continuing involvement, accordingly the Mesa Lease will be treated as a financing arrangement.

We have also entered into other operating lease agreements, primarily for office and warehouse space, that expire at various times through July 2026. These facility leases have annual rental increases ranging from approximately 2.5% to 4%. The difference between the straight-line expense over the term of the lease and actual amounts paid are recorded as deferred rent.

Rental obligations, excluding real estate taxes, operating costs, and tenant improvement allowances, under all lease agreements as of June 30, 2018 were as follows (in millions):

Fiscal Year Ending	
Remainder of 2018	$5.1
2019	11.1
2020	11.5
2021	11.7
2022	3.7
Thereafter	9.4
Total	$52.5

Total rent expense for the three and six months ended June 30, 2018 was $2.9 million and $5.7 million, compared to $2.8 million and $5.6 million for the same periods in 2017.

Litigation

On March 28, 2016, AgaMatrix, Inc. filed a patent infringement lawsuit against us in the United States District Court for the District of Oregon, asserting that certain of our products infringe certain patents held by AgaMatrix. On June 6,

2016, AgaMatrix filed a First Amended Complaint asserting the same three patents. On February 24, 2017, the Court granted AgaMatrix’s motion to substitute WaveForm Technologies, Inc. (“WaveForm”) as the new plaintiff following AgaMatrix’s transfer of the three patents to its newly formed entity. On August 25, 2016, we filed petitions for inter partes review with the Patent Trial and Appeal Board ("PTAB") of the U.S. Patent and Trademark Office seeking a determination that two of the three

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asserted patents are invalid under U.S. patent law and those petitions were granted on March 6, 2017. On March 8, 2017, we filed a petition for inter partes review with the PTAB seeking a determination that the third of the three asserted patents is invalid under U.S. patent law. This petition was granted on September 15, 2017. Based on the PTAB's orders granting these petitions, most activity in the patent infringement lawsuit against us in the District of Oregon has been stayed until the inter partes review by the PTAB is completed. 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. We believe the PTAB erred in finding any claims of the first two patents not unpatentable, and appealed the PTAB's decision to the United States Court of Appeals for the Federal Circuit ("Federal Circuit") on March 30, 2018. The inter partes review of the third patent is ongoing. It is our position that Waveform's assertions of infringement have no merit.

DexCom has also filed several lawsuits against AgaMatrix. DexCom filed a patent infringement lawsuit against Agamatrix in the United States District Court for the Central District of California ("C.D. Cal."), which is currently on appeal to the Federal Circuit based on a Final Judgment of non-infringement entered by the C.D. Cal. judge on February 23, 2018. On September 15, 2017, DexCom 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 DexCom. In addition, on September 18, 2017, Dexcom filed a Complaint against AgaMatrix in the International Trade Commission ("ITC") requesting 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.

On January 19, 2018, Arbmetrics, LLC filed a patent infringement lawsuit against us in the United States Southern District of California. On April 4, 2018, Arbmetrics filed a First Amended Complaint asserting the same patent. It is our position that Arbmetric's assertions of infringement have no merit.

Neither the outcome of these lawsuits nor the amount and range of potential fees associated with the lawsuits can be assessed at this time. As of June 30, 2018, no amounts have been accrued in respect of 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 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 consolidated financial position.

Purchase Commitments

We are party to various purchase arrangements related to our manufacturing and development activities including materials used in our CGM systems. As of June 30, 2018, we had purchase commitments with vendors totaling $87.2 million due within one year. There are no material purchase commitments due beyond one year.

7. Development and Other Agreements

Collaboration with Verily Life Sciences

On August 10, 2015, we entered into a Collaboration and License Agreement (the "Verily Collaboration Agreement") with Google Life Sciences LLC, now renamed Verily Life Sciences ("Verily"). Pursuant to the Verily Collaboration Agreement, we and Verily have agreed to jointly develop a series of next-generation CGM products. The Verily Collaboration Agreement provides us with an exclusive license to use certain intellectual property of Verily related to the development, manufacture and commercialization of the products contemplated under the Verily Collaboration Agreement. The Verily Collaboration Agreement provides for the establishment of a joint steering committee, joint development committee and joint commercialization committee to oversee and coordinate the parties' activities under the collaboration. We and Verily have agreed to make committee decisions by consensus. Certain aspects of this

collaboration were clarified and amended on October 25, 2016.

Under the terms of Verily Collaboration Agreement we paid an upfront fee of $35.0 million through the issuance of 404,591 shares of our common stock. We recorded $36.5 million in research and development expense in our consolidated statement of operations during 2015 related to the issuance of the 404,591 shares of our common stock, based on our stock price of $90.29 per share as of the date of Verily Collaboration Agreement. In addition, we will pay Verily up to $65.0 million

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in additional milestones upon achievement of various development and regulatory objectives, which payments may be paid in cash or shares of our common stock at our sole election, calculated based on the volume weighted average trading price during a period of twenty consecutive trading days ending on the trading day prior to the date on which the applicable objective has been achieved.

In addition, Verily is eligible to receive tiered royalty payments associated with the commercialization of the products contemplated under the Verily Collaboration Agreement, which are subject to regulatory approval. Unless we attain annual product sales subject to the Verily Collaboration Agreement in excess of $750.0 million, there will be no royalty paid by us to Verily. Above this range, and upon marketing approval of the initial product contemplated by the Verily Collaboration Agreement, or upon commercialization of any other DexCom product that incorporates Verily intellectual property, we will pay to Verily a royalty percentage starting in the high single digits and declining to the mid-single digits based on our annual aggregate product sales.

The Verily Collaboration Agreement shall be terminable by either party (a) upon uncured material breach of the Verily Collaboration Agreement by the other party, (b) if the second product contemplated by the Verily Collaboration Agreement has not been submitted to the FDA for approval by a specified date and (c) if the annual net sales for the products developed with Verily under the Verily Collaboration Agreement are less than a specified aggregate dollar amount. Additionally, we have the right to terminate the Verily Collaboration Agreement upon the expiration of the last to expire patent that covers a product developed under the Verily Collaboration Agreement.

8. Fair Value Measurements

We base the fair value of our Level 1 financial instruments that are in active markets using quoted market prices for identical instruments.

We obtain the fair value of our Level 2 financial instruments, which are not in active markets, from a primary professional pricing source using quoted market prices for identical or comparable instruments, rather than direct observations of quoted prices in active markets. Fair value 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.

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The following table represents our fair value hierarchy for our financial assets (cash equivalents and marketable securities) measured at fair value on a recurring basis as of June 30, 2018 (in millions):

	Fair Value Measurements Using			
	Level 1	Level 2	Level 3	Total
Cash equivalents	$149.0	$24.9	$—	$173.9
Equity investment in Tandem Diabetes Care, Inc.	55.1	—	—	55.1
Debt securities, available for sale				
U.S. government agencies	—	199.4	—	199.4
Commercial paper	—	49.3	—	49.3
Corporate debt	—	2.1	—	2.1
Total debt securities, available for sale	$—	$250.8	$—	$250.8

The following table represents our fair value hierarchy for our financial assets (cash equivalents and marketable securities) measured at fair value on a recurring basis as of December 31, 2017 (in millions):

	Fair Value Measurements Using			
	Level 1	Level 2	Level 3	Total
Cash equivalents	$306.6	$38.0	$—	$344.6
Marketable securities, available for sale				
U.S. government agencies	—	87.3	—	87.3
Corporate debt	—	5.1	—	5.1
Commercial paper	—	14.7	—	14.7
Total marketable securities, available for sale	$—	$107.1	$—	$107.1

There were no transfers between Level 1 and Level 2 securities during the three and six months ended June 30, 2018 and 2017. There were no transfers into or out of Level 3 securities during the three and six months ended June 30, 2018 and 2017.

The fair value of our outstanding 2022 Note was $465.8 million at June 30, 2018 and is a Level 2 measurement. See Note 5 to the Unaudited Consolidated Financial Statements for further discussion on the carrying value of our 2022 Notes.

Any additional investments are included in “Other Assets” in the 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 if there are no identified events or changes in circumstances that may have a significant adverse effect on the fair value.

9. Income Taxes

Our effective tax rate for the three and six months ended June 30, 2018 was a negative of 2% and 7% compared to 120% and 29% for the same periods of 2017. Our effective tax rate was impacted primarily by a $1.2 million tax benefit for refunds of foreign withholding tax, partially offset by state and foreign tax expense.

We maintain a full valuation allowance against our net deferred tax assets as of June 30, 2018 based on our assessment that it is not more likely than not these future benefits will be realized before expiration.

We made provisional estimates related to certain provisions of the Tax Cuts and Jobs Act of 2017 in the fourth quarter of 2017, including a reduction in our net deferred tax assets by $105.7 million offset by an increase in the valuation allowance related to the revaluation of our net deferred tax assets from 35% to 21%, and a zero transition tax on the mandatory deemed repatriation of foreign earnings due to our estimated net deficit in foreign earnings of $41.2 million at December 31, 2017. Additional work is necessary to finalize the calculation of our gross balances of U.S. deferred tax assets and liabilities, as well as the analysis of our net deficit in foreign earnings in connection with the transition tax. Any subsequent adjustment to these amounts is expected to have no tax effect due to our valuation allowance against net deferred tax assets. This analysis will be completed by the fourth quarter of 2018.

ITEM 2. MANAGEMENT’S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

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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.

Overview

We are a medical device company primarily focused on the design, development and commercialization of continuous glucose monitoring ("CGM") systems for use by people with diabetes and by healthcare providers for the treatment of people with diabetes. Unless the context requires otherwise, the terms "we," "us," "our," the "company," or "DexCom" refer to DexCom, Inc. and its subsidiaries.

From inception to 2006, we devoted substantially all of our resources to start-up activities, raising capital and research and development, including product design, testing, manufacturing and clinical trials. Since 2006, we have devoted considerable resources to the commercialization of our continuous glucose monitoring systems, including the G4 PLATINUM, G5 Mobile and G6, as well as the continued research and clinical development of our technology platform.

From inception through June 30, 2018, we have generated $2.8 billion of product, development grant and other (non-product) revenue, and we have incurred operating losses in each year since our inception in May 1999. As of June 30, 2018, we had an accumulated deficit of $665.8 million.

We expect our losses to continue as we proceed with our commercialization and research and development activities. We have financed our operations primarily through offerings of equity securities and debt, and the sales of our products.

Financial Operations

Revenue

We sell our durable systems and disposable units through a direct sales force in the United States, Canada and portions of Europe, and through distribution arrangements in the United States, Australia, New Zealand, and in portions of Europe, Asia, Latin America, the Middle East and Africa. We have contracts with certain distributors, the majority of whom stock our products, and we refer to these distributors as Stocking Distributors, whereby the Stocking Distributors fulfill orders for our product from their inventory. We also have contracts with certain distributors that do not stock our products, but rather products are shipped directly to the customer by us on behalf of our distributor, and we refer to these distributors as Drop-Ship Distributors. 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 previous fourth quarter, related to annual insurance deductible resets and unfunded flexible spending accounts.

Cost of Sales

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. A portion of our costs are currently fixed due to our moderate level of production volumes compared to our potential capacity. All of our manufacturing costs are included in cost of sales.

Research and Development

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.

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Selling, General and Administrative

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.

Results of Operations

Quarter Ended June 30, 2018 Compared to June 30, 2017

Revenue, Cost of Sales and Gross Profit

Revenues increased $71.9 million to $242.5 million for the three months ended June 30, 2018 compared to $170.6 million for the three months ended June 30, 2017 based primarily on increased sales volume of our disposable sensors due to the continued growth of our installed base of customers using our G4 PLATINUM, G5 Mobile and G6 systems, and durable systems to both new and existing customers. Revenue attributable to our disposable sensors and durable systems was approximately 70% and 30%, respectively, of revenue, for each of the three months ended June 30, 2018 and June 30, 2017. Revenue from products shipped to our distributors, which are primarily Stocking Distributors, for the three months ended June 30, 2018 was approximately $158.4 million or 65% of our revenue compared to $125.6 million or 74% of our total revenue for the three months ended June 30, 2017.

Cost of sales increased $35.8 million to $88.9 million for the three months ended June 30, 2018 compared to $53.1 million for the three months ended June 30, 2017, primarily due to increased sales volume. The gross profit of $153.6 million, or 63% for the three months ended June 30, 2018 increased $36.1 million compared to $117.5 million, or 69%, for the same period in 2017, primarily due to increased revenue and decreased warranty costs, partially offset by a $3.5 million excess and obsolete inventory charge primarily related to the approval and launch of our G6 System and the continuous improvement and innovation of our products, scrap and royalty related charges.

Research and Development. Research and development expense increased $1.9 million to $47.2 million for the three months ended June 30, 2018, compared to $45.3 million for the three months ended June 30, 2017. The increase was primarily due to an increase of $5.1 million in additional salaries, bonus, and payroll related costs, $0.5 million in additional facilities costs, $0.5 million in additional software license costs, $0.4 million in additional supplies costs, offset by a decrease of $4.5 million of expensed equipment and a $0.7 million reduction in share-based compensation expense.

Selling, General and Administrative. Selling, general and administrative expense increased $25.5 million to $111.3 million for the three months ended June 30, 2018 compared to $85.8 million for the three months ended June 30, 2017. The increase was primarily due to higher sales related costs primarily due to increased headcount and higher marketing costs to support revenue growth and the continued commercialization of our products in both the United States and Europe. Significant elements of the increase in selling, general, and administrative expenses included $11.5 million in additional salaries, bonus, payroll related costs, $4.8 million of additional legal fees, $2.9 million in additional incentive compensation paid to our sales personnel, $2.3 million in additional marketing costs, $2.0 million in additional temporary labor costs, $1.2 million in additional consulting expenses, and $1.0 million in additional share-based compensation expense.

Income from Equity Investments. Income from equity investments of $42.7 million for the three months ended June 30, 2018 represents unrealized gain on our equity investment in Tandem Diabetes Care, Inc.

Other Income/(expense). Other income/(expense) decreased $7.4 million to $(5.6) million for the three months ended June 30, 2018 compared to $1.8 million for the three months ended June 30, 2017 and is primarily related to foreign currency transaction gains and losses.

Interest Income. Interest income was $2.2 million for the three months ended June 30, 2018 compared to $0.5 million for the three months ended June 30, 2017 and is related to our marketable securities portfolio.

Interest Expense. Interest expense increased $1.7 million to $4.8 million for the three months ended June 30, 2018 compared to $3.1 million for the three months ended June 30, 2017. The increase was primarily due to an additional $2.0 million of interest expense related to the 2022 Notes.

Income Tax Expense. Our income tax benefit was $0.6 million on a pre-tax income of $29.6 million, resulting in a negative effective tax rate of 2% for the three months ended June 30, 2018, compared to income tax benefit of $17.3 million on a pre-tax loss of $14.4 million and an effective tax rate of 120% for the three months ended June 30, 2017. The current period

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benefit is primarily attributable to a refund of foreign withholding tax, partially offset by state and foreign income tax expense. The income tax benefit from the same period in 2017 resulted from the one-time accounting for issuance of convertible debt.

We maintain a full valuation allowance against our net deferred tax assets as of June 30, 2018 based on our assessment that it is not more likely than not these future benefits will be realized before expiration. The Company analyzes its ability to realize its deferred tax assets quarterly weighing all available positive and negative evidence of future taxable income. As of June 30, 2018, the Company is in a three-year cumulative loss position.

If adequate positive evidence exists in future periods, including the existence of three-year cumulative income, then we will determine what portion, if any, of the valuation allowance will be released. A release of some or all of our valuation allowance will result in a material income tax benefit on our financial statements.

Six Months Ended June 30, 2018 Compared to June 30, 2017

Revenue, Cost of Sales and Gross Profit

Revenues increased $114.0 million to $426.9 million for the six months ended June 30, 2018 compared to $312.9 million for the six months ended June 30, 2017 based primarily on increased sales volume of our disposable sensors due to the continued growth of our installed base of customers using our G4 PLATINUM, G5 Mobile and G6 systems and durable systems to both new and existing customers. Revenue attributable to our disposable sensors and durable systems was approximately 70% and 30%, respectively, of total revenue, for each of the six months ended June 30, 2018 and 2017. Revenue from products shipped to our distributors, which are primarily Stocking Distributors, for the six months ended June 30, 2018 was approximately $276.7 million or 65% of our revenue compared to $235.4 million or 75% of our total revenue for the six months ended June 30, 2017.

Cost of sales increased $53.1 million to $154.4 million for the six months ended June 30, 2018 compared to $101.3 million for the six months ended June 30, 2017, primarily due to increased sales volume. The gross profit of $272.5 million, or 64% for the six months ended June 30, 2018 increased $60.9 million compared to $211.6 million, or 68% for the same period in 2017, primarily due to increased revenue and a decrease in warranty costs, partially offset by $5.5 million excess and obsolete inventory charge primarily related to the approval and launch of our G6 System and the continuous improvement and innovation of our products, scrap and royalty related charges.

Research and Development. Research and development expense decreased $1.4 million to $92.0 million for the six months ended June 30, 2018, compared to $93.4 million for the six months ended June 30, 2017. The decrease was primarily due to $4.0 million less stock compensation costs and $3.7 million less expensed equipment costs, offset by $5.2 million in additional salaries, bonus, and payroll related costs and $1.1 million in additional depreciation.

Selling, General and Administrative. Selling, general and administrative expense increased $43.9 million to $216.1 million for the six months ended June 30, 2018, compared to $172.2 million for the six months ended June 30, 2017. The increase was primarily due to higher headcount related selling, and marketingcosts to support revenue growth and the continued commercialization of our products. Significant elements of the increase in selling, general, and administrative expenses included $16.4 million in additional salaries, bonus, and payroll related costs, $5.6 million of additional legal fees, $5.3 million of additional marketing costs, $4.4 million in additional temporary labor costs, $4.3 million in additional incentive compensation paid to our sales personnel, $3.7 million in additional consulting fees, and $2.0 million of additional software license costs.

Income from Equity Investments. Income from equity investments of $50.1 million for the six months ended June 30, 2018 represents unrealized gain on our equity investment in Tandem Diabetes Care, Inc.

Other Income/(expense). Other income/(expense) decreased $5.2 million to $(3.0) million for the six months ended June 30, 2018 compared to $2.2 million for the six months ended June 30, 2017 and is primarily related to foreign currency transaction gains and losses.

Interest Expense. Interest expense was $9.6 million for the six months ended June 30, 2018 compared to $3.6 million for the six months ended June 30, 2017 and is related to our 2022 Notes and Revolving Credit Agreement. The increase was primarily due to an additional $6.5 million of interest expense related to the 2022 Notes.

Income Tax Benefit. Income tax benefit was $0.4 million on a pre-tax income of $5.6 million, resulting in a negative effective tax rate of 7% for the six months ended June 30, 2018, compared to income tax benefit of $15.9 million on a pre-tax loss of $54.7 million and an effective tax rate of 29% for the six months ended June 30, 2017. The current

period benefit is primarily attributable to a refund of foreign withholding tax, partially offset by state and foreign income tax expense. The income tax benefit from the same period in 2017 resulted from the one-time accounting for issuance of convertible debt.

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We maintain a full valuation allowance against our net deferred tax assets as of June 30, 2018 based on our assessment that it is not more likely than not these future benefits will be realized before expiration. The Company analyzes its ability to realize its deferred tax assets quarterly weighing all available positive and negative evidence of future taxable income. As of June 30, 2018, the Company is in a three-year cumulative loss position.
If adequate positive evidence exists in future periods, including the existence of three-year cumulative income, then we will determine what portion, if any, of the valuation allowance will be released. A release of some or all of our valuation allowance will result in a material income tax benefit on our financial statements.

Liquidity and Capital Resources
We have incurred losses since our inception in May 1999. As of June 30, 2018, we had an accumulated deficit of $665.8 million and had working capital of $665.2 million. To date, we have funded our operations primarily through offerings of equity securities and debt, and the sales of our products.
In June 2016, we entered into a $200.0 million Credit Agreement, including a subfacility of up to $10.0 million for letters of credit, of which $5.6 million is still available. The revolving loans under the Credit Agreement will be available for general corporate purposes, including working capital and capital expenditures. In March 2017 we drew $75.0 million on the Credit Agreement under a six month term and we repaid the entire principal balance in May 2017. As of June 30, 2018 we had no outstanding borrowings under the Credit Agreement, and $195.6 million under the Credit Agreement remains available, which is reduced by outstanding letters of credit.
In May 2017, we completed an offering of $350.0 million aggregate principal amount of 0.75% convertible senior notes due 2022 (the "2022 Notes") and, in June 2017 the initial purchasers exercised their option to purchase an additional $50.0 million aggregate principal amount. The 2022 Notes have a stated interest rate of 0.75% and a maturity date of May 15, 2022. Holders may elect to convert any time after February 15, 2022 for shares. The 2022 Notes may be settled in cash, stock, or a combination thereof, solely at our discretion. We used a portion of the net proceeds of the offering of the 2022 Notes to repay $75 million of borrowings under our existing credit facility. The remainder of the proceeds are available for general corporate purposes and capital expenditures, including working capital needs and buildout of our manufacturing facility in Arizona. 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 commitments with respect to any such acquisitions or investments at this time.
Our cash, cash equivalents and marketable securities totaled $606.1 million as of June 30, 2018. Our cash, cash equivalents, and marketable securities portfolio is primarily denominated in U.S. dollars and consists of investment grade, highly liquid securities of various holdings including obligations of U.S. government sponsored enterprises, commercial paper, corporate debt, money market funds and equity investments. The change in our cash, cash equivalents and marketable securities during the six months ended June 30, 2018 was due to the factors described in the “Cash Flow Summary” below.
Cash Flow Summary
The following table sets forth a summary of our cash flows for the periods indicated (in millions):

	Six Months Ended June 30,		Change
	2018	2017	
Net cash provided by operating activities	$32.7	$14.6	$18.1
Net cash used in investing activities	$(175.3)	$(106.7)	$(68.6)
Net cash provided by financing activities	$3.4	$394.7	$(391.3)

As of June 30, 2018, we had $300.5 million of cash, cash equivalents and restricted cash compared to $441.5 million as of December 31, 2017, a decrease of $141.0 million. The cash flows during the six months ended June 30, 2018 were related primarily to the following items:

Cash inflows:

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Net cash provided by operating activities of $32.7 million comprised of net income of $6.0 million, $1.7 million changes in operating assets and liabilities, offset by $25.0 million of net non-cash expenses. Non-cash expenses of $75.1 million were primarily related to share-based compensation, depreciation and amortization, and non-cash

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interest expense related to our senior convertible notes, partially offset by $50.1 million of unrealized gain on our equity investments.

- Proceeds from issuance of common stock of $5.2 million under our employee stock purchase plan and pursuant to the exercise of then-outstanding stock options.

Cash outflows:

- Capital expenditures of $25.6 million primarily related to purchase of facility related build-outs, office equipment and machinery and equipment.
- Net cash outflow of $149.7 million as a result of debt and equity securities transactions.

Net Cash Provided by Operating Activities. The increase in cash provided by operating activities was primarily due to a $2.9 million change in operating assets and liabilities, and by an $29.6 million decrease in non-cash expenses, offset by a $44.8 million decrease in net loss. The decrease in non-cash expenses was primarily associated with a $50.1 million unrealized gain on our equity investments decrease in non-cash share-based compensation.

Net Cash Used in Investing Activities. The change in cash used in investing activities was primarily related to a $77.9 million net change in debt and equity investments, offset by a decrease of $9.3 million to purchase equipment to support facility related build-outs, manufacturing equipment and information technology infrastructure.

Net Cash Provided by Financing Activities. The decrease in cash provided by financing activities was primarily due to $389.0 million proceeds from the issuance of convertible debt in the second quarter of fiscal 2017.

Operating Capital and Capital Expenditure Requirements

We anticipate that we will continue to incur operating losses as we incur expenses and expand the commercialization of our approved products domestically and internationally, develop additional continuous glucose monitoring products, and expand our marketing, manufacturing and corporate infrastructure.

We believe that our cash, cash equivalents, marketable securities balances, projected cash contributions from our commercial operations and $200.0 million available under our Credit Agreement, of which $195.6 million remains available, will be sufficient to meet our anticipated cash requirements with respect to the continued scale-up of our commercialization activities, research and development activities, including clinical trials, the expansion of our marketing, manufacturing and corporate infrastructure, and to meet our other anticipated cash needs through at least August 1, 2019. If our available cash, cash equivalents and marketable securities are insufficient to satisfy our liquidity requirements, or if we develop additional products or new markets for our existing products, we may seek to sell additional equity or debt securities or obtain an additional credit facility. The sale of additional equity and debt securities may result in additional dilution to our stockholders. If we raise additional funds through the issuance of debt securities or preferred stock, these securities could have rights senior to those of our common stock and could contain covenants that would restrict our operations. We may require additional capital beyond our currently forecasted amounts. Any such required additional capital may not be available on reasonable terms, if at all. Additionally, we cannot guarantee that we will be successful in obtaining additional cash contributions from future partnership arrangements. Our ability to transition to, and maintain profitable operations is dependent upon achieving a level of revenues adequate to support our cost structure. If events or circumstances occur such that we do not meet our operating plan as expected, or if we are unable to obtain additional financing, we may be required to reduce planned increases in compensation related expenses or other operating expenses related to research, development, and commercialization activities, which could have an adverse impact on our ability to achieve our intended business objectives.

Because of the numerous risks and uncertainties associated with the development of continuous glucose monitoring technologies, we are unable to estimate the exact amounts of capital outlays and operating expenditures associated with our current and anticipated clinical trials. Our future funding 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 manufacturing 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;

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- 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; and
- the acquisition of businesses, products and technologies and our ability to integrate and manage any acquired businesses, products and technologies.

Contractual Obligations

We are party to various purchase arrangements related to components used in manufacturing and research and development activities. As of June 30, 2018, we had firm purchase commitments with certain vendors totaling approximately $87.2 million due within one year. There are no material purchase commitments due beyond one year. We are party to various leasing arrangements as described in the Management's Discussion and Analysis of Financial Condition and Results of Operations in Item 7 of our Annual Report on Form 10-K for the fiscal year ended December 31, 2017 and Note 6 to our Consolidated Financial Statements in this Form 10-Q. We have not entered into any significant new leasing arrangements during the three and six months ended June 30, 2018.

Off-Balance Sheet Arrangements

We have not engaged in any off-balance sheet activities.

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.

Our significant accounting policies are more fully described in Note 1 to our consolidated financial statements included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2017. Our accounting policies and estimates which are most critical to a full understanding and evaluation of our reported financial results are described in the Management's Discussion and Analysis of Financial Condition and Results of Operations in Item 7 of our Annual Report on Form 10-K for the fiscal year ended December 31, 2017. There were no material changes to our critical accounting policies during the six months ended June 30, 2018.

Recent Accounting Guidance

Recently adopted accounting pronouncements

In May 2014, the Financial Accounting Standards Board ("FASB") issued authoritative guidance for Revenue from Contracts with Customers ASC Topic 606 ("ASU 2014-09"), to supersede nearly all existing revenue recognition guidance under U.S. GAAP. The core principle of the guidance is to recognize revenue when promised goods or services are transferred to customers in an amount that reflects the consideration that is expected to be received for those goods or services. The guidance defines a five step process to achieve this core principle and it is possible when the five step process is applied, more judgment and estimates may be required within the revenue recognition process than required under existing U.S. GAAP, including identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligation. We have applied this standard electing the modified retrospective method. The

company applied the practical expedient permitted under ASC Topic 606 to t

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hose contracts that were not completed, as of January 1, 2018. Our analysis of open contracts as of January 1, 2018, resulted in no material cumulative effect from applying ASU 2014-09.

In October 2016, the FASB issued ASU No. 2016-16, Accounting for Income Taxes - Intra-Entity Asset Transfer other than Inventory (Topic 740) ("ASU 2016-16"), which would require the recognition of the tax expense from the sale of an asset other than inventory when the transfer occurs, rather than when the asset is sold to a third party or otherwise recovered through use. The new guidance is effective for public business entities for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years. Early adoption is permitted. The amendment should be applied on a modified retrospective basis through a cumulative-effect adjustment directly to retained earnings as of the beginning period of adoption. Due to the full valuation allowance on the U.S. deferred tax assets, we have determined that none of the provisions of ASU 2016-16 have a significant impact on our consolidated financial statements.

In January 2016, the FASB issued ASU No. 2016-01 to amend the guidance on the classification and measurement of financial instruments, which was further amended in February 2018 by ASU No. 2018-03. The new guidance requires entities to measure equity investments that do not result in consolidation and are not accounted for under the equity method at fair value and recognize any changes in fair value in net income. The new guidance also amends certain disclosure requirements associated with the fair value of financial instruments. The new guidance is effective for public business entities for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years. The adoption of this guidance did not have a significant impact on our financial statements.

Recently issued accounting pronouncements not yet adopted

In June 2018, the FASB issued ASU 2018-07, Compensation-Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting ("ASU 2018-07"), which simplifies the accounting for share-based payments made to nonemployees so the accounting for such payments is substantially the same as those made to employees. Under ASU 2018-07, share based awards to nonemployees will be measured at fair value on the grant date of the awards, entities will need to assess the probability of satisfying performance conditions if any are present, and awards will continue to be classified according to Accounting Standards Codification 718 upon vesting which eliminates the need to reassess classification upon vesting, consistent with awards granted to employees. ASU 2018-07 is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years, and early adoption is permitted. We are in the process of evaluating the impact of adoption of ASU 2018-07 on our consolidated financial statements.

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842) ("ASU 2016-02"), which require a lessee to recognize a lease payment liability and a corresponding right of use asset on their balance sheet for all lease terms longer than 12 months, lessor accounting remains largely unchanged. ASU 2016-02 is effective for fiscal years, and interim periods within those years, beginning on or after December 15, 2018 and early adoption is permitted. We will adopt ASU 2016-02 in the first quarter of 2019. We have started the process of gathering and assessing our lease contracts and implementing changes to our systems. We expect the adoption will lead to an increase in the assets and liabilities recorded on our Consolidated Balance Sheets.

ITEM 3. 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.

Foreign Currency 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 United States dollars. Accordingly, we have assessed that we do not have any 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 United States dollar and foreign currencies, primarily the British Pound, the Euro, the Canadian Dollar, the Swiss Franc and the Swedish Krona, could adversely affect our financial results, including our revenues, revenue growth rates, gross margins, income and losses as well as assets and liabilities.

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We do not currently engage in hedging or similar transactions to reduce our foreign currency risks. We will continue to monitor and evaluate our internal processes relating to foreign currency exchange, including the potential use of hedging strategies.

ITEM 4. 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, our Chief Executive Officer and our Chief Financial Officer concluded that our disclosure controls and procedures were effective 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.

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, there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions, regardless of how remote.

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PART II OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

On March 28, 2016, AgaMatrix, Inc. filed a patent infringement lawsuit against us in the United States District Court for the District of Oregon, asserting that certain of our products infringe certain patents held by AgaMatrix. On June 6, 2016, AgaMatrix filed a First Amended Complaint asserting the same three patents. On February 24, 2017, the Court granted AgaMatrix's motion to substitute WaveForm Technologies, Inc. ("WaveForm") as the new plaintiff following AgaMatrix's transfer of the three patents to its newly formed entity. On August 25, 2016, we filed petitions for inter partes review with the Patent Trial and Appeal Board ("PTAB") of the U.S. Patent and Trademark Office seeking a determination that two of the three asserted patents are invalid under U.S. patent law and those petitions were granted on March 6, 2017. On March 8, 2017, we filed a petition for inter partes review with the PTAB seeking a determination that the third of the three asserted patents is invalid under U.S. patent law. This petition was granted on September 15, 2017. Based on the PTAB's orders granting these petitions, most activity in the patent infringement lawsuit against us in the District of Oregon has been stayed until the inter partes review by the PTAB is completed. 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. We believe the PTAB erred in finding any claims of the first two patents not unpatentable, and appealed the PTAB's decision to the United States Court of Appeals for the Federal Circuit ("Federal Circuit") on March 30, 2018. The inter partes review of the third patent is ongoing. It is our position that Waveform's assertions of infringement have no merit.

DexCom has also filed several lawsuits against AgaMatrix. DexCom filed a patent infringement lawsuit against Agamatrix in the United States District Court for the Central District of California ("C.D. Cal."), which is currently on appeal to the Federal Circuit based on a Final Judgment of non-infringement entered by the C.D. Cal. judge on February 23, 2018. On September 15, 2017, DexCom 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 DexCom. In addition, on September 18, 2017, Dexcom filed a Complaint against AgaMatrix in the International Trade Commission ("ITC") requesting 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.

On January 19, 2018, Arbmetrics, LLC filed a patent infringement lawsuit against us in the United States Southern District of California. On April 4, 2018, Arbmetrics filed a First Amended Complaint asserting the same patent. It is our position that Arbmetric's assertions of infringement have no merit.

Neither the outcome of these lawsuits nor the amount and range of potential fees associated with the lawsuits can be assessed at this time. As of June 30, 2018, no amounts have been accrued in respect of 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 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 Quarterly Report on Form 10-Q,

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.

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Risks Related to Our Business

We have incurred losses since inception and anticipate that we will incur continued losses in the future.

We have incurred operating losses in each year since our inception in May 1999, including operating losses of $35.6 million for the six months ended June 30, 2018. As of June 30, 2018, we had an accumulated deficit of $665.8 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 sensor augmented insulin pumps, as well as other collaborations. We also expect that our general and administrative expenses will continue to increase due to the additional operational and regulatory burdens applicable to public healthcare and medical device companies. As a result, we expect we may continue to incur operating losses in the future. These losses, among other things, have had and will continue to have an adverse effect on our stockholders' equity.

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

To achieve commercial success for the G4 PLATINUM, G5 Mobile and G6 systems and our future products, we must either continue to develop and grow our sales and marketing organization and enter into partnerships or other arrangements to market and sell our products or collaborate with third parties to market and sell our products. Developing and managing a direct sales organization is a difficult, expensive and time consuming process.

To be successful we must:

- recruit and retain adequate numbers of effective and experienced sales personnel;
- effectively train our sales personnel in the benefits and risks of our products;
- establish and maintain successful sales, marketing and education programs that educate endocrinologists, physicians and diabetes educators so they can appropriately inform their patients about our products; and
- manage geographically dispersed sales and marketing operations.

We currently employ a direct sales force to sell and market our products in the United States, Canada and certain countries in Europe. Our direct sales force calls directly on healthcare providers and people with diabetes throughout the applicable country to initiate sales of our products. Our sales 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.

We have also entered into distribution arrangements to leverage existing distributors already engaged in the diabetes marketplace. Our United States distribution partnerships 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 call directly on healthcare providers and patients to market and sell our products in Australia, New Zealand, and portions of Europe, Asia, Latin America, the Middle East and Africa. 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 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 and Cardinal Health and affiliates (including

Edgepark Medical Supplies), our two most significant distributors, generated approximately 15% and 15%, respectively, of our total revenue during the six months ended June 30, 2018. 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

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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, efficacy, 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, we may not be able to generate adequate product revenue and may not become profitable.

Although many third-party payors have adopted some form of coverage policy on continuous glucose monitoring devices, our products do not yet have simple broad-based contractual coverage with most 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 Medicare, other government, and commercial third-party healthcare payors 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 May 2017, CMS Medicare Administrative Contractors issued a revision to an existing joint Local Coverage Determination, or LCD, which establishes the Medicare conditions of coverage for therapeutic CGM. 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 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 government and commercial 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 or federal 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 August 1, 2018, 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 products 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 require significant medical documentation 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 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.

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In addition, Medicare, Medicaid, health maintenance organizations and other government and commercial 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 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 groups, 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 efficacy of the product, clinical outcomes associated with the product, and any factors that negatively impact the efficacy 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.

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.

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.

We may never receive approval or clearance from the 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.

Our G4 Platinum and G5 Mobile continuous glucose monitoring systems are classified by the FDA as Class III Medical devices that require premarket approval or PMA. The PMA process requires us to prove the safety and efficacy 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 System 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.

A new 510(k) clearance or PMA is required for any modification to a 510(k)-cleared device that could significantly affect its safety or effectiveness, or that constitutes a major change in its intended use, design, or manufacture. FDA may disagree with our assessment of whether a new clearance or approval is required if we modify our products. If we do not seek a new clearance or approval when they believe one was necessary, they could order us to stop marketing or recall the product, and they could seek a seizure, injunction, criminal prosecution, or take other enforcement action.

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The FDA can refuse to grant a 510(k) clearance 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;
- the system may not satisfy the FDA's safety or efficacy requirements;
- the data from pre-clinical studies and clinical trials may be insufficient to support approval;
- 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 continuous glucose monitoring 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 continuous glucose monitoring 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 or 510(k) applications or supplements, we may be unable to commercialize our continuous glucose monitoring systems under development, which could impair our business, financial condition and operating results.

To support current and any future additional PMA or 510(k) applications or supplements, we together with our partners, must successfully complete pre-clinical studies, bench-testing, and 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 a PMA or 510(k) 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 or 510(k) application or supplement, even if the trial's intended safety and efficacy endpoints are achieved. Additionally, since 2009, the FDA has significantly increased the scrutiny applied to its oversight of companies subject to its regulations, including 510(k) and PMA submissions, by hiring new investigators and increasing the frequency and scope of its inspections of manufacturing facilities. The ongoing review by FDA's Center for Devices and Radiological Health of the 510(k) process could complicate the product approval process for certain of our and our partners' products, although 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 could decline substantially. The commencement or completion of any of our clinical trials may be delayed or halted, or be inadequate to support approval of a PMA or 510(k) application or supplement, 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;

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- 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, or IRBs, 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 IRB 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 our trial design is inadequate to demonstrate safety and efficacy.

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 efficacy, 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 efficacy 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 continuous glucose monitoring devices 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 continuous glucose monitoring devices.

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. 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 healthcare regulations. 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.

Other legal, regulatory and commercial policy influences are subjecting our industry to significant changes, and we

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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.

The ACA included an excise tax on the sale of medical devices equal to 2.3% of the selling price of the device in the U.S. beginning in 2013. The excise tax is applicable to sales of our G4 PLATINUM receivers for professional use. The excise tax was suspended from 2016 through 2019.

As of June 30, 2018, we believe that our current CGM products were exempt from the excise tax, except for our G4 PLATINUM system for professional use which is subject to the excise tax. The current tax liability related to our G4 PLATINUM system for professional use is immaterial, but may become material in the future. Notwithstanding our belief, if the IRS were to determine that this tax applies to any of our current or future products, our future operating results could be harmed, which in turn could cause the price of our stock to decline. In addition, because of the uncertainty surrounding these issues, the impact of this tax has not been reflected in our forward guidance.

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 or reduce medical procedure volumes could materially and adversely affect our business, financial condition and results of operations.

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 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:

- the pricing of our products and services;
- the distribution of our products and services;
- billing for 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 reporting;
- prohibitions on kickbacks, also referred to as anti-kickback laws or regulations;
- any scheme to defraud any healthcare benefit program;
- physician payment disclosure requirements;
- personal health information;
- privacy;
- data protection;
- mobile communications;
- false claims; and
- professional licensure.

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These laws and regulations are extremely complex and, in some 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, and their provisions are open to a variety of interpretations.

The FDA, CMS, the Office of Inspector General for the Department of Health and Human Services, 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 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 system 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 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.

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 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 health care program 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 physician self-referral law, or 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. In addition, the federal overpayment statute, as interpreted by CMS, requires the report and return 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. 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

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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.

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 programs administered by CMS. 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 U.S. Department of Health & Human Services Office of Inspector General, or 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 implicate any of the statute's principal policy objectives and, as such, likely do not pose a material risk of program abuse 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 may be brought under the federal Civil Monetary Penalty Law, which requires a lower burden of proof than other fraud and abuse laws, including the Anti-Kickback Statute.

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.

Additionally, 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.

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, and we also perform internal audits and monitoring. 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.

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 (ZPICs), Medicaid integrity contractors (MICs), and unified program integrity contractors (UPICs) - to perform post-payment audits of claims and identify overpayments, and state Medicaid agencies and other contractors have increased their review activities.

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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.

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.

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 commercially 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 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 increase our manufacturing capacity by a significant factor over the current level. In addition, we will have to modify our manufacturing design, reliability and process if and when our next-generation sensor 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 require FDA submission and approval and our facilities may have to undergo additional inspections by the FDA and corresponding state agencies. We may be unable to adequately maintain, develop and expand our manufacturing process and operations or obtain FDA and state agency approval of our facilities in a timely manner or at all. If we are unable to manufacture a sufficient supply of our current products or any future products for which we may receive approval, 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 and our business will suffer.

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.

We also require the suppliers and business partners of components or services for our products to comply with law and certain of our policies regarding sourcing practices, but we do not control them or their practices. If any supplier or business partner violates laws or implements unethical practices, there could be disruptions to our supply chain, cancellation of our orders, terminations of the relationship with the partner or damage to our reputation.

In the future, if our products have material defects or errors, this could result in loss or delay of revenues, delayed market acceptance, damaged reputation, diversion of development resources, legal claims, increased insurance costs or increased

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service and warranty costs, any of which could harm our business. Such defects or errors could also prompt us to amend certain warning labels or narrow the scope of the use of our products, either of which could hinder our success in the market.

Since the first commercial launch of our products in 2006, we have had periodic field failures related to our products, including reports of sensor errors, sensor failures, broken sensors, receiver malfunctions, audible alarms and alert failures, and transmitter failures. To comply with the FDA's medical device reporting requirements, we have filed reports of all such product field failures. Although we believe we have taken and are taking appropriate actions aimed at reducing or eliminating field failures, we cannot guarantee that we will not have additional failures going forward.

We depend upon third-party suppliers, making us vulnerable to supply problems and price fluctuations, which could harm our business.

We rely on OnCore Manufacturing Services to manufacture and supply circuit boards for our receiver and transmitter; we rely on ON Semiconductor Corp. to manufacture and supply the application-specific integrated circuit that is incorporated into the transmitter; we rely on DSM PTG, Inc. to manufacture certain polymers used to synthesize our polymeric biointerface membranes for our products; and we rely on The Tech Group to supply our injection molded components. Each of these suppliers other than OnCore is a single-source supplier. In some cases, our agreements with these and our other suppliers can be terminated by either party upon short notice. Our contract manufacturers also rely on single-source suppliers to manufacture some of the components used in our products. Our manufacturers and suppliers may encounter problems during manufacturing for a variety of reasons, including failure to follow specific protocols and procedures, failure to comply with applicable regulations, failed FDA audit or inspection, equipment malfunction and environmental factors, any of which could delay or impede their ability to meet our demand. If our 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. Our reliance on these outside manufacturers and suppliers also subjects us to other risks that could harm our business, including:

- we may not be able to obtain adequate supply in a timely manner or on commercially reasonable terms;
- 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 efficacy 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 a PMA or 510(k) supplement or possibly a separate PMA of 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 hardships unrelated to our demand for components, including those related to changes in global economic conditions, which could inhibit their ability to fulfill our orders and meet our requirements.

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.

Potential long-term complications from our current or future products or other continuous glucose monitoring 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,

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and with respect to our G6 system, 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.

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 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 (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 attention of our management and have an adverse effect on our reputation, financial condition, and operating results.

As an example of the difficulty of complying with the regulatory requirements associated with the manufacture of our products, on February 23, 2016, we issued a customer notification via the DexCom website and certified mail regarding the audible alarms and alerts associated with our DexCom G4 PLATINUM and DexCom G5 Mobile receivers. This was classified as a voluntary Class 1 recall by the FDA and was closed by the FDA as of August 11, 2017. The issue with the audible alarms and alerts was identified as a result of our continuous review of complaints received from our customers. A failure of the audible alarms and alerts may cause our customers to not detect a severe hypoglycemic (low glucose) or hyperglycemic (high glucose) event. We have implemented a solution for the audible alarms and alerts issue identified in the customer notification. We notified the FDA that we believe all required actions with respect to the customer notification have been completed.

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. We currently manufacture our products at our headquarters facilities in San Diego, California. In these facilities we have more than 28,000 square feet of laboratory space and approximately 18,000 square feet of controlled environment rooms. During a routine FDA post-market inspection ending on March 29, 2016, the FDA issued a Form 483 with one observation regarding the DexCom MDR procedure specific to retrospective MDR filing when a change in complaint reportability is made. On April 19, 2016 DexCom responded to this observation. On June 2, 2016 we received a copy of the final Establishment Inspection Report from the FDA, which we believe reflects the resolution of this observation without further FDA action.

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 continuous glucose monitoring 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;

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- 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 efficacy 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 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 continuous glucose monitoring 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 continuous glucose monitoring systems or the methods we employ in the use of our systems are covered by U.S. or foreign patents held by them. 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 continuous glucose monitoring systems grows, the possibility of inadvertent patent infringement by us or a patent infringement claim against us increases.

On March 28, 2016, AgaMatrix, Inc. filed a patent infringement lawsuit against us in the United States District Court for the District of Oregon, asserting that certain of our products infringe certain patents held by AgaMatrix. On June 6, 2016, AgaMatrix filed a First Amended Complaint asserting the same three patents. On February 24, 2017, the Court granted AgaMatrix's motion to substitute WaveForm Technologies, Inc. ("WaveForm") as the new plaintiff following AgaMatrix's transfer of the three patents to its newly formed entity. On August 25, 2016, we filed petitions for inter partes review with the Patent Trial and Appeal Board ("PTAB") of the U.S. Patent and Trademark Office seeking a determination that two of the three asserted patents are invalid under the U.S. patent law and those petitions were granted on March 6, 2017. On March 8, 2017, we filed a petition for inter partes review with the PTAB seeking a determination that the third of the three asserted patents is invalid under U.S. patent law. This petition was granted on September 15, 2017. Based on the PTAB's orders granting these petitions, most activity in the patent infringement lawsuit against us in the District of Oregon has been stayed until the inter partes review by the PTAB is completed. 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. We believe the PTAB erred in finding any claims of the first two patents not unpatentable, and appealed the PTAB's decision to the United States Court of Appeals for the Federal Circuit ("Federal Circuit") on March 30, 2018. The inter partes review of the third patent is ongoing. It is our position that Waveform’s assertions of infringement have no merit.
DexCom has also filed several lawsuits against AgaMatrix. DexCom filed a patent infringement lawsuit against Agamatrix in the United States District Court for the Central District of California ("C.D. Cal."), which is currently on appeal to the Federal Circuit based on a Final Judgement of non-infringement entered by the C.D. Cal. judge on February 23, 2018. On September 15, 2017, DexCom 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

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DexCom. In addition, on September 18, 2017, Dexcom filed a Complaint against AgaMatrix in the International Trade Commission ("ITC") requesting 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.

On January 19, 2018, Arbmetrics, LLC filed a patent infringement lawsuit against us in the United States Southern District of California. On April 4, 2018, Arbmetrics filed a First Amended Complaint asserting the same patent. It is our position that Arbmetrics' assertions of infringement have no merit.

Neither the outcome of these lawsuits nor the amount and range of potential fees associated with the lawsuits can be assessed at this time. As of June 30, 2018, no amounts have been accrued in respect of 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. If the relevant patents are upheld as valid and enforceable and we are found to infringe such patents, we could be prohibited from selling our product 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. 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. A court could also order us to pay compensatory damages for such infringement, plus prejudgment interest and could, in addition, treble the compensatory damages and award attorney fees. These damages could be substantial and could harm our reputation, business, financial condition and operating results. A court also could enter orders that temporarily, preliminarily or permanently enjoin us and our customers from making, using, selling or offering to sell one or more of our products, or could enter an order mandating that we undertake certain remedial activities. Depending on the nature of the relief ordered by the court, we could become liable for additional damages to third parties.

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. 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/or attorneys' fees for the prevailing party.

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 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.

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.

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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.

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 Roche Diabetes Care, a division of Roche Diagnostics; LifeScan, Inc., a division of Johnson & Johnson; the Diabetes Care division of Abbott Laboratories, and Panasonic Healthcare Holdings' Ascensia Diabetes Care (formerly Bayer 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 short-term continuous or flash glucose monitoring products that compete directly with our products. Medtronic, Inc. received FDA approval to commercialize a standalone continuous glucose monitoring product called Guardian Connect in March 2018. In 2015, Abbott Diabetes Care, Inc. launched a consumer flash glucose monitoring system, FreeStyle Libre, outside the United States. Abbott received FDA approval for a blinded, professional-use version of this system in September 2016 and FDA approval for the consumer flash glucose monitoring system in the United States in September 2017. Senseonics Holdings, Inc. obtained FDA approval for its implantable CGM system, Eversense®, and received CE Mark for its Eversense® XL system in September 2017. In addition, we believe that others are developing invasive and non-invasive continuous glucose monitoring systems. We cannot predict if other competitors will receive approval by the FDA or other regulatory authorities for their products or the timing of such approvals.

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 and bolus insulin dosing. Medtronic received FDA approval for its 670G insulin delivery system in September 2016 and launched this system in 2017.

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

- significantly 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 continuous glucose monitoring; and
- greater financial and human resources for product development, 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.

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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 and Tandem to integrate our continuous glucose monitoring technology into their insulin delivery systems, and our agreement with Verily to develop a series of next-generation continuous glucose monitoring products. Our Eli Lilly, Insulet and Verily collaborations have not yet resulted in a commercial product. In June 2018, Tandem received FDA approval for its latest sensor-augmented insulin delivery system, the t:slim X2™ Insulin Pump Basal-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, and intends to exit 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 will be 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 continuous glucose monitoring 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.

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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 regulators' approval of a commercially viable continuous glucose monitor or sensor produced by one of our competitors could significantly reduce market acceptance of our systems. As discussed above in the risk factor entitled “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,” several of our competitors are in various stages of developing continuous or flash 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 continuous glucose monitoring products, 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.

We face the risk of product liability claims and may not be able to maintain or obtain insurance.

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 for us for harms arising from use of the G6 system. 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 technology in conjunction with only two finger sticks required for calibration of the system and our G6 system requires no finger sticks. 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, as discussed earlier in the risk factor entitled “If we or our suppliers or distributors fail to comply with ongoing regulatory requirements, or if we experience unanticipated problems with our products, the products could be subject to restrictions or withdrawal from the market.” Although we have product liability and clinical trial liability insurance that we believe is appropriate, this insurance is subject to deductibles and coverage limitations. Our current product liability insurance may not continue to be available to us on acceptable terms, if at all, and, if available, 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. 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, but the individual might be able to circumvent the safeguards designed into the systems and use the products for longer than seven 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. The CE Mark and the recent 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 twice 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.

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

Although we believe our promotional materials and training methods are conducted in compliance with FDA and other regulations, if the FDA determines that our promotional materials or training constitutes promotion of an unapproved use, the FDA could request that we modify our training or promotional materials 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 or training materials to constitute 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.

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 foreign, federal and state 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 could be subject to audits in Europe and around the world, particularly in the areas of consumer and data protection, 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 as well as personally identifiable information of our customers, including full names, social security numbers, addresses, and birth dates, in our data centers and on our networks. Our employees 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 and (iii) damage our reputation, 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 ("HIPAA"), as amended, and implementing regulations, 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. 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. 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 ("OCR") and, in certain situations involving large breaches, to the media. Various 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.

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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 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 data breaches.

In May 2018, the General Data Protection Regulation, or GDPR, became effective in the European Union. The GDPR represents a significant change in the data privacy and security laws applicable in the European Union, and in many ways increases the requirements on companies like DexCom in complying with European Union law. It is a complex regulation that imposes additional procedures, documentation and restrictions, and as its provisions are interpreted by European Union agencies, it could negatively impact our business, financial condition and results of operations. Similar issues could arise as a result of the passage of the California Consumer Privacy Act which becomes effective January 1, 2020.

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 our customers. 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 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;

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•litigation, including potential class action litigation, and potential liability under privacy, security and consumer protection laws or other applicable laws;
•reputational damage; 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;
•product development delays;
•disruption of key business operations; and
•diversion of attention of management and key information technology resources.

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, or FCPA, 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 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.

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The majority of our operations are conducted at five facilities in San Diego, California. Any disruption at these facilities could increase our expenses.

We take precautions to safeguard our facilities, which include manufacturing protocols, insurance, health and safety protocols, and off-site storage of computer data. However, a natural 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. Our second manufacturing facility, located in Mesa, Arizona, commenced operations in the second quarter of 2018 and is intended to help mitigate these risks.

Expanded capacity in our new manufacturing facility may not be fully available until the end of 2018, which may impede or delay our ability to manufacture one or more of our continuous glucose monitoring products in quantities sufficient to meet market demand.

Our new manufacturing facility in Mesa, Arizona, designed to manufacture current and next-generation sensors and transmitters, may not be completed or qualified in accordance with our current plans. There are risks associated with expanding our manufacturing capacity by opening such a facility 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 insuring GMP manufacturing. There are many aspects of the project that rely on third-party contractors and subcontractors, and we and they may encounter delays. If the Mesa facility is not completed and qualified during 2018, there initially will be additional personnel costs and production inefficiencies that could potentially impact manufacturing. If completion was delayed significantly into 2019, we may be unable to meet anticipated demand for our CGM systems during the delay.

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Our products may not continue to achieve market acceptance.

We expect that sales of our G4 PLATINUM system, which consists of a handheld receiver, reusable transmitter and disposable sensor, and our G5 Mobile and G6 systems which consist of a handheld receiver, reusable transmitter, disposable sensors and a smartphone application that securely identifies, receives, deciphers and displays information transmitted by the transmitter, 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 continuous glucose monitoring systems and sensors, we expect most patients will migrate onto those systems. Notwithstanding our prior experience in selling our products, we might be unable to successfully expand the commercialization of our products on a wide scale for a number of reasons, including:

- the FDA approval of our G6 system in the United States in March 2018 means that we have limited experience selling our G6 system;
- our G6 system has a shut off at the ten-day mark which might make it more 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, efficacy, 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 submissions may be delayed, or approved with limited product labeling;
- we may not be able to manufacture our products in commercial quantities or at an acceptable cost;
- people with diabetes do not generally receive broad reimbursement from third-party payors for their purchase of our products since many payors require that a policy holder meet specific medical criteria to qualify for reimbursement, which may reduce widespread use of our products;
- the uncertainties associated with establishing and qualifying new manufacturing facilities;
- people with diabetes will need to incur the costs of our systems in addition to single-point finger stick devices;
- the relative immaturity of the continuous glucose monitoring market internationally, and the general absence of international reimbursement of continuous glucose monitoring devices by third-party payors and government healthcare providers outside the United States;
- the introduction and market acceptance of competing products and technologies;
- our inability to obtain sufficient quantities of supplies at appropriate quality levels from our single-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.

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 continuous glucose monitoring 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, physicians and people with diabetes may adopt more widespread use of continuous glucose monitoring systems, including our systems. If our systems do not achieve an adequate level of acceptance by people with diabetes, physicians and healthcare payors, we may not generate significant product revenue and we may not become profitable.

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.

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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 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 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.

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 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.

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

Our operations in countries outside the United States, which accounted for approximately 22% of our revenues for the six months ended June 30, 2018, are accompanied by certain financial and other risks. In addition to opening offices in the United Kingdom, Germany and Canada, in connection with distributor acquisitions and otherwise, we intend to continue to pursue growth opportunities in sales outside the United States, especially in Europe, which could expose us to greater risks associated with international sales and operations. 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;

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- 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;
- 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 Uni