

DEXCOM INC  
Form 10-Q  
November 04, 2015  
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UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549  
FORM 10-Q

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

For the quarterly period ended September 30, 2015

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 (I.R.S. Employer  
Incorporation or Organization) Identification No.)

6340 Sequence Drive 92121  
San Diego, California (Zip Code)  
(Address of Principal Executive Offices)

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  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  No

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

Large Accelerated Filer  Accelerated Filer

Non-Accelerated Filer  (Do not check if a smaller reporting company) Smaller Reporting Company

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

As of November 2, 2015, 81,294,938 shares of the Registrant's common stock were outstanding.

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ITEM 1. FINANCIAL STATEMENTS

DexCom, Inc.

Consolidated Balance Sheets

(In millions—except par value data)

	September 30, 2015 (Unaudited)	December 31, 2014
Assets		
Current assets:		
Cash and cash equivalents	\$85.3	\$71.8
Short-term marketable securities, available-for-sale	28.0	11.8
Accounts receivable, net	55.8	42.4
Inventory	30.6	16.0
Prepaid and other current assets	4.0	3.9
Total current assets	203.7	145.9
Restricted cash	—	1.0
Property and equipment, net	46.6	31.2
Intangible assets, net	2.4	2.7
Goodwill	3.7	3.2
Other assets	0.3	0.6
Total assets	\$256.7	\$184.6
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued liabilities	\$34.3	\$20.4
Accrued payroll and related expenses	20.4	17.2
Current portion of long-term debt	2.5	2.3
Current portion of deferred revenue	1.6	0.7
Total current liabilities	58.8	40.6
Other liabilities	4.2	1.5
Long-term debt, net of current portion	0.4	2.3
Total liabilities	63.4	44.4
Commitments and contingencies (Note 4)		
Stockholders' equity:		
Preferred stock, \$0.001 par value, 5.0 shares authorized; no shares issued and outstanding at September 30, 2015 and December 31, 2014, respectively	—	—
Common stock, \$0.001 par value, 100.0 authorized; 81.5 and 81.3 issued and outstanding, respectively, at September 30, 2015; and 77.6 and 77.3 shares issued and outstanding, respectively, at December 31, 2014	0.1	0.1
Additional paid-in capital	750.4	638.0
Accumulated other comprehensive loss	(0.3)	) (0.1 )
Accumulated deficit	(556.9)	) (497.8 )
Total stockholders' equity	193.3	140.2
Total liabilities and stockholders' equity	\$256.7	\$184.6
See accompanying notes		



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

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2015	2014	2015	2014
Product revenue	\$104.2	\$67.9	\$269.9	\$172.8
Development grant and other revenue	1.0	1.1	1.3	2.1
Total revenue	105.2	69.0	271.2	174.9
Product cost of sales	30.5	21.8	84.0	57.4
Development and other cost of sales	—	—	—	0.6
Total cost of sales	30.5	21.8	84.0	58.0
Gross profit	74.7	47.2	187.2	116.9
Operating expenses				
Research and development	64.8	18.5	109.0	47.8
Selling, general and administrative	52.3	33.7	136.9	92.2
Total operating expenses	117.1	52.2	245.9	140.0
Operating loss	(42.4	) (5.0	) (58.7	) (23.1
Interest expense	(0.1	) (0.2	) (0.4	) (0.6
Net loss	\$(42.5	) \$(5.2	) \$(59.1	) \$(23.7
Basic net loss per share	\$(0.53	) \$(0.07	) \$(0.75	) \$(0.32
Shares used to compute basic net loss per share	80.5	75.8	79.2	74.7
Diluted net loss per share	\$(0.53	) \$(0.08	) \$(0.75	) \$(0.33
Shares used to compute diluted net loss per share	80.5	76.1	79.2	75.0
See accompanying notes				

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

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2015	2014	2015	2014
Net loss	\$ (42.5	) \$ (5.2	) \$ (59.1	) \$ (23.7
Unrealized gain (loss) on short-term available-for-sale marketable securities	—	—	—	—
Foreign currency translation loss	—	0.1	(0.2	) —
Comprehensive loss	\$ (42.5	) \$ (5.1	) \$ (59.3	) \$ (23.7
See accompanying notes				

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DexCom, Inc.

Consolidated Statements of Cash Flows

(In millions)

(Unaudited)

	Nine Months Ended September 30,	
	2015	2014
Operating activities		
Net loss	\$(59.1	) \$(23.7
Adjustments to reconcile net loss to cash provided by operating activities:		
Depreciation and amortization	7.7	6.0
Share-based compensation	59.2	35.7
Non-cash research and development charge through issuance of common stock	36.5	—
Accretion and amortization related to marketable securities, net	0.3	0.1
Amortization of debt issuance costs	0.2	0.3
Change in fair value of contingent consideration	—	(0.7
Loss on disposal of equipment	0.3	—
Changes in operating assets and liabilities:		
Accounts receivable, net	(13.4	) (5.3
Inventory	(14.6	) (5.3
Prepaid and other assets	—	0.7
Restricted cash	1.0	—
Accounts payable and accrued liabilities	12.8	6.1
Accrued payroll and related expenses	3.1	1.7
Deferred revenue	0.9	(0.1
Deferred rent and other liabilities	2.8	(0.3
Net cash provided by operating activities	37.7	15.2
Investing activities		
Purchase of available-for-sale marketable securities	(35.4	) (10.3
Proceeds from the maturity of available-for-sale marketable securities	18.8	9.8
Purchase of property and equipment	(21.7	) (11.6
Acquisitions, net of cash acquired	(0.5	) —
Net cash used in investing activities	(38.8	) (12.1
Financing activities		
Net proceeds from issuance of common stock	16.3	18.5
Repayment of long-term debt	(1.7	) (1.6
Net cash provided by financing activities	14.6	16.9
Increase in cash and cash equivalents	13.5	20.0
Cash and cash equivalents, beginning of period	71.8	43.2
Cash and cash equivalents, end of period	\$85.3	\$63.2
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 in the hospital for the treatment of people with and without 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

We have incurred operating losses since our inception and have an accumulated deficit of \$556.9 million at September 30, 2015. As of September 30, 2015, we had available cash, cash equivalents and marketable securities totaling \$113.3 million and working capital of \$144.9 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 September 30, 2016.

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 nine months ended September 30, 2015 are not necessarily indicative of the results that may be expected for the year ending December 31, 2015. 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, 2014 included in the Annual Report on Form 10-K filed by us with the Securities and Exchange Commission on February 25, 2015.

Principles of Consolidation

The consolidated financial statements include the accounts of DexCom and our wholly owned subsidiaries, DexCom AB and SweetSpot Diabetes Care, Inc. (“SweetSpot”). All significant intercompany balances and transactions have been eliminated in consolidation.

Segment Reporting

An operating segment is identified as a component of a business that has discrete financial information available, and one for which the chief operating decision maker must decide the level of resource allocation. In addition, the guidance for segment reporting indicates certain quantitative thresholds. The operations of SweetSpot, our subsidiary, does not meet the definition of an operating segment and are currently not material, but may become material in the future.

We currently consider our operations to be, and manage our business globally within, one reportable segment, which is consistent with how our President and Chief Executive Officer, who is our chief operating decision maker, reviews our business, makes investment and resource allocation decisions and assesses operating performance.

We sell our products through a direct sales force in the United States and through distribution arrangements in the United States, Canada, Australia, New Zealand, and in portions of Europe, Asia, the Middle East, Latin America and Africa. DexCom, Inc. is domiciled in the United States.

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, employee bonus, clinical trial expenses, allowance for bad debt, refunds and rebates,



including pharmacy rebates and share-based compensation expense.

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### Share-Based Compensation

Share-based compensation expense is measured at the grant date based on the estimated fair value of the award and is recognized, for awards that are ultimately expected to vest, primarily on a straight-line basis over the requisite service period of the individual grants, which typically equals the vesting period.

The fair value of our Restricted Stock Units (“RSUs”) is based on the market price of our common stock on the date of grant. We estimate the fair value of stock options granted and stock purchase rights under our Employee Stock Purchase Plan (“ESPP”) using the Black-Scholes-Merton (“BSM”) option-pricing model. Inherent in this model are assumptions related to our expected stock price volatility over the expected term of the awards, risk-free interest rate and any expected dividends. We determine our expected stock price volatility based on our historical stock price volatility over the most recent period equivalent to the expected life of the award. We determine the expected life of an award by considering various relevant factors, including the vesting period and contractual term of the award, our employees’ historical exercise patterns and length of service and employee characteristics. For stock purchase rights under our ESPP, the expected life is equal to the current offering period. The risk-free interest rate assumption is based upon observed interest rates appropriate for the expected life of our employee stock options and stock purchase plan. As we have not paid any cash dividends since our inception and do not anticipate paying dividends in the foreseeable future, we assume a dividend yield of zero.

We are also required to estimate at grant the likelihood that the award will ultimately vest (the “pre-vesting forfeiture rate”), and to revise the estimate, if necessary, in future periods if the actual forfeiture rate differs. We determine the pre-vesting forfeiture rate of an award based on our historical pre-vesting award forfeiture experience, giving consideration to company-specific events impacting historical pre-vesting award forfeiture experience that are unlikely to occur in the future as well as anticipated future events that may impact forfeiture rates. We use our historical data to estimate pre-vesting forfeitures and record stock-based compensation expense only for those awards that are expected to vest.

We recorded \$22.6 million and \$59.2 million in share-based compensation expense during the three and nine months ended September 30, 2015, respectively, compared to \$13.8 million and \$35.7 million during the three and nine months ended September 30, 2014 respectively. At September 30, 2015, unrecognized estimated compensation costs related to unvested stock options and restricted stock units totaled \$166.2 million and is expected to be recognized through 2019.

### Revenue Recognition

We sell our durable systems and disposable units through a direct sales force in the United States and through distribution arrangements in the United States, Canada, Australia, New Zealand, and in portions of Europe, Asia, the Middle East, Latin America and Africa. Components are individually priced and can be purchased separately or together. We receive payment directly from customers who use our products, as well as from distributors, organizations and third-party payors. 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 in packages of four. We 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 purchase of any amount of disposable sensors.

Revenue is recognized when persuasive evidence of an arrangement exists, delivery has occurred or services have been rendered, the price is fixed or determinable, and collectability is reasonably assured. Revenue on product sales is generally recognized upon shipment, which is when title and the risk of loss have been transferred to the customer and there are no other post shipment obligations. 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 and do not include customer acceptance provisions. We recognize revenue from contracted insurance payors based on the contracted rate. For non-contracted insurance payors, we obtain prior authorization from the payor and recognize revenue based on the estimated collectible amount and historical experience. We also receive a prescription or statement of medical necessity and, for insurance reimbursement customers, an assignment of benefits prior to shipment.

We provide a “30-day money back guarantee” program whereby customers 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. We accrue for estimated returns, refunds and rebates,

including pharmacy rebates, by reducing revenues and establishing a liability account at the time of shipment based on historical experience. Returns have historically been immaterial.

We have entered into distribution agreements with Byram Healthcare and its subsidiaries ("Byram"), RGH Enterprises, Inc. ("Edgepark") and other distributors that allow the distributors to sell our durable systems and disposable units. We have contracts with certain distributors who 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

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refer to these distributors as Drop-Ship Distributors. Revenue is recognized based on contracted prices and invoices are either paid by check following the issuance of a purchase order or letter of credit, or they are paid by wire at the time of placing the order. Terms of distributor orders are generally Freight on Board (“FOB”) shipping point (or Free Carrier (“FCA”) shipping point for international orders). Distributors do not have rights of return per their distribution agreement outside of our standard 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 have had collaborative license and development arrangements with strategic partners for the development and commercialization of products utilizing our technologies. The terms of these agreements typically include the license of certain intellectual property rights and the provision of multiple deliverables by us (for example, research and development services, product prototypes and products for use in clinical trials) in exchange for consideration to us of some combination of non-refundable license fees, funding of research and development activities, payments based upon achievement of development milestones and royalties in the form of a designated percentage of product sales or profits. With the exception of royalties, these types of consideration are classified as development grant and other revenue in our consolidated statements of operations and are generally recognized over the service period except for substantive milestone payments, which are generally recognized when the milestone is achieved. In determining whether each milestone is substantive, we considered whether the consideration earned by achieving the milestone should (i) be commensurate with either (a) our performance to achieve the milestone or (b) the enhancement of value of the item delivered as a result of a specific outcome resulting from our performance to achieve the milestone, (ii) relate solely to past performance and (iii) be reasonable relative to all deliverables and payment terms in the arrangement. We recognize royalties in the period in which we obtain the royalty report, which is necessary to determine the amount of royalties we are entitled to receive.

Non-refundable license fees are recognized as revenue when we have a contractual right to receive such payment, the contract price is fixed or determinable, the collection of the resulting receivable is reasonably assured and we have no further performance obligations under the license agreement. Multiple element arrangements, such as license, development and other multiple element service arrangements are analyzed to determine how the arrangement consideration should be allocated among the separate units of accounting, or whether they must be accounted for as a single unit of accounting.

For transactions containing multiple element arrangements, we consider deliverables as separate units of accounting and recognize deliverables as revenue upon delivery only if (i) the deliverable has standalone value and (ii) if the arrangement includes a general right of return relative to the delivered item(s), delivery or performance of the undelivered item(s) is probable and substantially controlled by us. We allocate consideration to the separate units of accounting using the relative selling price method, in which allocation of consideration is based on vendor-specific objective evidence (“VSOE”) if available, third-party evidence (“TPE”), or if VSOE and TPE are not available, management’s best estimate of a standalone selling price for elements.

We use judgment in estimating the value allocable to the deliverables in a transaction based on our estimate of the fair value or relative selling price attributable to the related deliverables and the consideration from such transactions is typically recognized as product revenue or development grant and other revenue. For arrangements that are accounted for as a single unit of accounting, total payments under the arrangement are recognized as revenue on a straight-line basis over the period we expect to complete our performance obligations. We review the estimated period of our performance obligations on a periodic basis and update the recognition period as appropriate. The cumulative amount of revenue earned is limited to the cumulative amount of payments we are entitled to as of the period ending date. If we cannot reasonably estimate when our performance obligation either ceases or becomes inconsequential, then revenue is deferred until we can reasonably estimate when the performance obligation ceases or becomes inconsequential. Revenue is then recognized over the remaining estimated period of performance. Deferred revenue amounts are classified as current liabilities to the extent that revenue is expected to be recognized within one year. Significant management judgment is required in determining the level of effort required under an arrangement and the period over which we are expected to complete our performance obligations under an arrangement.

Warranty Accrual

Estimated warranty costs associated with a product are recorded at the time of shipment. We estimate future warranty costs by analyzing historical warranty experience for the timing and amount of returned product, and these estimates are evaluated on at least a quarterly basis to determine the continued appropriateness of such assumptions.

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### Foreign Currency

The financial statements of our non-U.S. subsidiary, whose functional currency is the Swedish Krona, are translated into U.S. dollars for financial reporting purposes. Assets and liabilities are translated at period-end exchange rates, and revenue and expense transactions are translated at average exchange rates for the period. Cumulative translation adjustments are recognized as part of comprehensive income and are included in accumulated other comprehensive loss in the consolidated balance sheet. Gains and losses on transactions denominated in other than the functional currency are reflected in operations. To date the results of operations of this subsidiary and related translation adjustments have not been material in our consolidated results.

### Comprehensive Loss

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

### Inventory

Inventory is valued at the lower of cost or market value on a part-by-part basis that approximates first in, first out. We make adjustments to reduce the cost of inventory to its net realizable value, if required, for estimated excess, obsolete and potential scrapped inventories. Factors influencing these adjustments include inventories on hand and on order compared to estimated future usage and sales for existing and new products, as well as judgments regarding quality control testing data, and assumptions about the likelihood of scrap and obsolescence. Once written down the adjustments are considered permanent and are not reversed until the related inventory is sold or disposed. We recorded charges of approximately \$2.0 million in cost of goods sold for the nine months ended September 30, 2015 related to excess and obsolete inventory due to the approval and launch of our DexCom G4 PLATINUM with Share System. Our products require customized products and components that currently are available from a limited number of sources. We purchase certain components and materials from single sources due to quality considerations, costs or constraints resulting from regulatory requirements.

### Marketable Securities

We have classified our marketable securities with remaining maturity at purchase of more than three months and remaining maturities of one year or less as short-term available-for-sale marketable securities. Marketable securities with remaining maturities of greater than one year are also classified as short-term available-for-sale marketable securities as such marketable securities represent the investment of cash that is available for current operations. We carry our marketable securities at fair value with unrealized gains and losses, if any, reported as a separate component of stockholders' equity and included in comprehensive loss. Realized gains and losses are calculated using the specific identification method and recorded as interest income. We invest in various types of securities, including debt securities in government-sponsored entities, corporate debt securities, U.S. Treasury securities and commercial paper. We do not generally intend to sell 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 maturity.

### Fair Value Measurements

The fair value hierarchy described by the authoritative guidance for fair value measurements is based on three levels of inputs, of which the first two are considered observable and the last unobservable, that may be used to measure fair value and include the following:

Level 1—Quoted prices in active markets for identical assets or liabilities.

Level 2—Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

We carry our marketable securities at fair value. The carrying amounts of financial instruments, such as cash and cash equivalents, accounts receivable, prepaid expenses and other current assets, accounts payable and accrued liabilities,

are carried at cost, which approximate the related fair values due to the short-term maturities of these instruments. For additional detail see Note 6 "Fair Value Measurements."

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### Property and Equipment

Property and equipment is stated at cost and depreciated over the estimated useful lives of the assets, generally three years for computer equipment, four years for machinery and equipment, and five years for furniture and fixtures, using the straight-line method. Leasehold improvements are stated at cost and amortized over the shorter of the estimated useful lives of the assets or the remaining lease term.

### Goodwill and Intangible Assets

Goodwill, which has an indefinite useful life, represents the excess of cost over fair value of net assets acquired. The change in the carrying value of goodwill during the nine months ended September 30, 2015 resulted from an acquisition of a small privately held engineering consulting company with 10 full time employees to complement our research and development activities, which closed in April 2015.

Our identifiable intangible assets are comprised of acquired core technologies, customer relationships, covenants not-to-compete, in-process research and development and trade names. The cost of identifiable intangible assets with finite lives is generally amortized on a straight-line basis over the assets' respective estimated useful lives.

We test goodwill and intangible assets with indefinite lives for impairment on an annual basis. Also, between annual tests we test for impairment if events and circumstances indicate it is more likely than not that the fair value is less than the carrying value. Events that would indicate impairment and trigger an interim impairment assessment include, but are not limited to, current economic and market conditions, including a decline in market capitalization, a significant adverse change in legal factors, business climate or operational performance of the business and an adverse action or assessment by a regulator.

### Recent Accounting Guidance

In May 2014, the Financial Accounting Standards Board ("FASB") issued authoritative guidance for Revenue from Contracts with Customers, to supersede nearly all existing revenue recognition guidance under U.S. GAAP. The core principle of the guidance is to recognize revenues 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. The updated standard permits the use of either the retrospective or cumulative effect transition method and is effective for us in our first quarter of fiscal 2018. Early adoption is not permitted. We have not yet selected a transition method and we are currently evaluating the effect that the updated standard will have on our consolidated financial statements and related disclosures.

In July 2015, the FASB issued guidance to change the subsequent measurement of inventory from lower of cost or market to lower of cost and net realizable value. The guidance requires that inventory accounted for under the first-in, first-out (FIFO) or average cost methods be measured at the lower of cost and net realizable value, where net realizable value represents the estimated selling price of inventory in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. The guidance is effective for us beginning in the first quarter of fiscal 2018. Earlier application is permitted as of the beginning of an interim or annual reporting period. We are currently evaluating the effect this guidance will have on our consolidated financial statements.



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## 2. Net Loss Per Common Share

Basic net loss per share attributable to common stockholders is calculated by dividing the net 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 loss per share attributable to common stockholders is computed by dividing the net loss attributable to common stockholders by the weighted-average number of common share equivalents outstanding for the period determined using the treasury-stock method. For purposes of this calculation, outstanding options and unvested RSUs settleable in shares of common stock are considered to be common stock equivalents and are only included in the calculation of diluted net loss per share when their effect is dilutive.

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

	Three Months Ended September 30,		Nine Months Ended September 30,		
	2015	2014	2015	2014	
Numerator for basic and diluted net loss per share:					
Net loss for basic	\$ (42.5	) \$ (5.2	) \$ (59.1	) \$ (23.7	)
Impact of income related to mark-to-market on contingent consideration obligation settleable in shares	—	(0.9	) —	(0.7	)
Net loss for diluted	\$ (42.5	) \$ (6.1	) \$ (59.1	) \$ (24.4	)
Denominator for basic and diluted net loss per share:					
Weighted average common shares outstanding for basic	80.5	75.8	79.2	74.7	
Dilutive potential common stock outstanding:					
Contingently issuable shares related to contingent consideration obligation settleable in shares	—	0.3	—	0.3	
Weighted average common shares outstanding for diluted	80.5	76.1	79.2	75.0	
Basic net loss per share	\$ (0.53	) \$ (0.07	) \$ (0.75	) \$ (0.32	)
Diluted net loss per share	\$ (0.53	) \$ (0.08	) \$ (0.75	) \$ (0.33	)

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Options outstanding to purchase common stock	1.6	3.8	1.6	3.8
Unvested restricted stock units	4.2	4.3	4.2	4.3
Total	5.8	8.1	5.8	8.1

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## 3. Financial Statement Details (in millions)

## Short- Term Marketable Securities, Available-for-Sale

Short-term Marketable securities, consisting solely of debt securities, were as follows:

	September 30, 2015			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Market Value
U.S. government agencies	\$22.1	\$—	\$—	\$22.1
Corporate debt	4.4	—	—	4.4
Commercial paper	1.5	—	—	1.5
Total	\$28.0	\$—	\$—	\$28.0

	December 31, 2014			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Market Value
U.S. government agencies	\$9.1	\$—	\$—	\$9.1
Corporate debt	2.3	—	—	2.3
Commercial paper	0.4	—	—	0.4
Total	\$11.8	\$—	\$—	\$11.8

	September 30, 2015	December 31, 2014
Raw materials	\$10.7	\$7.6
Work-in-process	2.5	1.0
Finished goods	17.4	7.4
Total	\$30.6	\$16.0

	September 30, 2015	December 31, 2014
Accounts Payable and Accrued Liabilities		
Accounts payable trade	\$16.7	\$9.9
Accrued tax, audit, and legal fees	2.5	1.6
Clinical trials	0.4	0.4
Accrued other including warranty	14.7	8.5
Total	\$34.3	\$20.4

## 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 nine months ended September 30, 2015 and 2014 were as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Beginning balance	\$1.2	\$0.9	\$1.3	\$0.9
Charges to costs and expenses	1.9	1.6	4.9	3.8
Costs incurred	(1.8	) (1.3	) (4.9	) (3.5
Ending balance	\$1.3	\$1.2	\$1.3	\$1.2



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## 4. Commitments and Contingencies

## Long-Term Debt

In November 2012, we entered into a loan and security agreement (the "Loan Agreement") that provides for (i) a \$15.0 million revolving line of credit and (ii) a total term loan of up to \$20.0 million (the "Term Loan"), in both cases, to be used for general corporate purposes. The borrowings under the Loan Agreement are collateralized by a first priority security interest in substantially all of our assets with a negative pledge on our intellectual property.

The revolving line of credit is an interest-only financing that bears an interest rate equal to the prime rate plus 0.5% and requires repayment of principal at the maturity date of November 2015. Under the revolving line of credit, available funds, which were up to \$15.0 million as of September 30, 2015 can be drawn at any time, and repaid funds can be redrawn. No amounts have been drawn against the revolving line of credit.

In accordance with the Loan Agreement, \$7.0 million was advanced under the Term Loan at the funding date in November 2012 and up to \$13.0 million in additional funds was available upon our request until September 30, 2013 (the "Draw Period"). In August 2013, the Loan Agreement was amended to change the Draw Period for the additional funds under the Term Loan to January 1, 2014 through March 31, 2014. We did not borrow any additional funds and the Draw Period expired unused. The Term Loan bears a fixed interest rate equal to the three-year treasury rate at the time of advance plus 6.94% and requires payment of interest only for the first year and amortized payments of interest and principal thereafter through the maturity date of November 2016.

The aggregate debt issuance costs and fees incurred with respect to the issuance of the Loan Agreement were \$1.1 million. These costs have been capitalized as debt issuance costs on our consolidated balance sheet as other assets. Fees related to the revolving line of credit are being amortized through the maturity date of November 2015. Issuance costs and fees related to the term loan are being amortized through the maturity date of November 2016 using the effective interest method. As of September 30, 2015, the remaining unamortized issuance costs and fees totaled \$0.1 million. Principal repayment obligations under the Loan Agreement as of September 30, 2015 were as follows (in millions):

Fiscal Year Ending	
Remainder of 2015	\$0.6
2016	2.3
Total	\$2.9

## Leases

In April 2006, we entered into an office lease agreement for facilities located in San Diego, California. In August 2010, we entered into a First Amendment to Office Lease (the "First Lease Amendment") with Kilroy Realty, L.P. (the "Landlord") with respect to facilities in the buildings at 6340 Sequence Drive and 6310 Sequence Drive, each in San Diego, California, and on October 1, 2014, we entered into a Second Amendment to Office Lease (the "Second Lease Amendment"), which added the building at 6290 Sequence Drive in San Diego, California to our lease and extended the lease term related to the buildings at 6340 Sequence Drive, 6310 Sequence Drive, and 6290 Sequence Drive, each in San Diego, California.

Under the Second Lease Amendment, we will continue to lease approximately 129,000 square feet in the current locations at 6340 Sequence Drive and 6310 Sequence Drive, and leased an additional 45,000 square feet at 6290 Sequence Drive, for a total of approximately 174,000 square feet of space. We also retain the right and obligation to lease an additional 45,000 square feet in the 6290 Sequence Drive location (the "Additional Space"), of which we leased approximately 15,000 square feet on April 1, 2015, and have agreed to lease the remaining 30,000 square feet beginning on October 1, 2015. The amended 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 Second Lease Amendment and the Second Lease Amendment is still in effect, we generally have the right to terminate the lease starting at the 55<sup>th</sup> month of the Second Lease Amendment. In September 2015, we received \$1.8 million of tenant improvement allowance associated with the Second Lease Amendment, which was recorded as a

deferred rent obligation and will be 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 sheet.

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. We have also entered into

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other operating lease agreements, primarily for office and warehouse space, that expire at various times through September 2017.

Rental obligations, excluding real estate taxes, operating costs, and tenant improvement allowances, under all lease agreements as of September 30, 2015 were as follows (in millions):

Fiscal Year Ending	
Remainder of 2015	\$ 1.2
2016	4.7
2017	4.3
2018	5.2
2019	5.3
Thereafter	11.9
Total	\$32.6

Total rent expense for the three and nine months ended September 30, 2015 was \$1.4 million and \$4.2 million, respectively, compared to \$0.8 million and \$2.3 million, respectively, for the same periods of 2014.

Litigation

From time to time, we are subject to various claims and suits arising out of the ordinary course of business, including commercial 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 September 30, 2015, we had purchase commitments with vendors totaling \$43.2 million due within one year. There are no material purchase commitments due beyond one year.

5. Development and Other AgreementsCollaboration with Google Life Sciences

On August 10, 2015, we entered into a Collaboration and License Agreement (the “GLS Collaboration Agreement”) with Google Life Sciences LLC (“GLS”). Pursuant to the GLS Collaboration Agreement, we and GLS have agreed to jointly develop a series of next-generation continuous glucose monitoring products. The GLS Collaboration Agreement provides us with an exclusive license to use certain intellectual property of GLS related to the development, manufacture and commercialization of the products contemplated under the GLS Collaboration Agreement. The GLS 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 GLS have agreed to make committee decisions by consensus.

The terms of GLS Collaboration Agreement required that we pay an upfront fee of \$35.0 million in either cash or shares of our common stock at our sole election, with the number of shares calculated based on the volume weighted average trading price during a period of twenty consecutive trading days ending prior to the date of the GLS Collaboration Agreement. In addition, we will pay GLS up to \$65.0 million 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.

On August 27, 2015, we filed a Registration Statement on Form S-3 with the SEC and issued 404,591 shares of our common stock to GLS in connection with the \$35.0 million upfront payment. We recorded \$36.5 million in research and development expense in our consolidated statement of operations for the three and nine months ended September 30, 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 GLS Collaboration Agreement.



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In addition, GLS is eligible to receive tiered royalty payments associated with the commercialization of the products contemplated under the GLS Collaboration Agreement, which are subject to regulatory approval. Unless we attain annual product sales subject to the GLS Collaboration Agreement in excess of \$750 million, there will be no royalty paid by us to GLS. Above this range, and upon marketing approval of the initial product contemplated by the GLS Collaboration Agreement, or upon commercialization of any other DexCom product that incorporates GLS intellectual property, we will pay to GLS a royalty percentage starting in the high single digits and declining to the mid-single digits based on our annual aggregate product sales.

The GLS Collaboration Agreement shall be terminable by either party (a) upon uncured material breach of the GLS Collaboration Agreement by the other party, (b) if the second product contemplated by the GLS 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 GLS under the GLS Collaboration Agreement are less than a specified aggregate dollar amount. Additionally, we have the right to terminate the GLS Collaboration Agreement upon the expiration of the last to expire patent that covers a product developed under the GLS Collaboration Agreement.

Edwards Lifesciences LLC

On November 10, 2008, we entered into a Collaboration Agreement with Edwards Lifesciences LLC (“Edwards”). The Collaboration Agreement was amended by the parties on May 5, 2009 (as amended, the “Collaboration Agreement”). In accordance with the Collaboration Agreement, the parties also entered into a Manufacturing and Supply Agreement and Quality Agreement, each dated as of November 10, 2008 (the “Manufacturing and Supply Agreement” and “Quality Agreement,” respectively). Pursuant to the Collaboration Agreement, the parties agreed to develop jointly and to market an in-hospital automatic blood glucose monitoring system (“In-Hospital Product”). On September 3, 2015, we and Edwards entered into a Restatement of License, Termination of Collaboration & Release Agreement (the “Restated Agreement”) terminating each of the Manufacturing and Supply Agreement and Quality Agreement, and amending in part the Collaboration Agreement. Pursuant to the Restated Agreement, we and Edwards agreed to a mutual release of claims, including any activities related to further development obligations or milestone payments. In addition, the Restated Agreement provides Edwards with a fully paid-up, royalty-free license to use certain of our intellectual property solely in the field of blood-based glucose monitoring within the hospital environment. Under the Restated Agreement, we reserve the right to market and sell our interstitial continuous glucose monitoring technology in all settings, including within the hospital market. No payments are required by either party in connection with the Restated Agreement.

Tandem Diabetes Care, Inc.

On February 1, 2012, we entered into a non-exclusive Development and Commercialization Agreement (the “Tandem Agreement”) with Tandem Diabetes Care, Inc. (“Tandem”) to integrate a future generation of our continuous glucose monitoring technology with Tandem’s t:slim<sup>®</sup> insulin delivery system in the United States. On January 4, 2013, the Tandem Agreement was amended to allow for the integration of our G4 PLATINUM systems with Tandem’s t:slim insulin delivery system in the United States.

We received an initial payment of \$1.0 million as a result of the execution of the Tandem Agreement, which was fully recognized in development grant and other revenue as of December 31, 2014. In July 2014, we received an additional \$1.0 million milestone payment related to the regulatory submission by Tandem of their CGM enabled insulin pump. We recorded \$1.0 million and \$1.2 million during the three and nine months ended September 30, 2014, respectively, in development grant and other revenue related to this initial consideration received and the July 2014 milestone payment.

In September 2015, we received the final \$1.0 million milestone payment related to the regulatory approval of Tandem’s CGM enabled insulin pump, which was recognized in development grant and other revenue for the three and nine months ended September 30, 2015. Under the terms of the Tandem Agreement, we are entitled to receive up to \$1.0 million to offset certain development, clinical and regulatory expenses. Each of the milestones related to the Tandem Agreement is considered to be substantive.

In September 2015, the Tandem Agreement was amended to eliminate Tandem’s obligation to pay DexCom a royalty of \$100 for each Tandem t:slim G4 integrated pump system sold and instead to reallocate \$100 for each Tandem t:slim G4 integrated pump system to incremental marketing activities for such pump systems, or marketing activities



to support other jointly funded development projects.

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## The Leona M. and Harry B Helmsley Charitable Trust

In July 2013, we were awarded a \$4.0 million grant (the "Helmsley Grant") from the Leona M. and Harry B. Helmsley Charitable Trust (the "Helmsley Trust") to accelerate the development of the sixth generation of our advanced glucose-sensing technologies (the "Gen 6 Sensor"). The funding is milestone-based and is contingent upon our meeting specific development milestones related to the development of the Gen 6 Sensor over a period of several years. Upon successful commercialization of our Gen 6 Sensor, we are obligated to either (1) make royalty payments based on a percentage of product sales of up to \$2.0 million per year for four years, or (2) at our sole election, make a one-time \$6.0 million royalty payment. The Helmsley Grant funds will offset research and development expense as incurred and earned. During 2013, \$0.5 million of the Helmsley Grant was received and \$0.5 million was earned. During 2014, \$2.5 million of the Helmsley Grant was received and \$2.5 million was earned. During the three months ended September 30, 2015 we did not receive or earn any funds from the Helmsley Trust. During the nine months ended September 30, 2015, \$1.0 million of the Helmsley Grant was received and \$1.0 million was earned. As of September 30, 2015, we have received the full \$4.0 million grant funds from the Helmsley Trust.

## 6. 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.

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 September 30, 2015 (in millions):

	Fair Value Measurements Using			Total
	Level 1	Level 2	Level 3	
Cash equivalents	\$—	\$33.1	\$—	\$33.1
Marketable securities, available for sale				
U.S. government agencies	—	22.1	—	22.1
Corporate debt	—	4.4	—	4.4
Commercial paper	—	1.5	—	1.5
Total marketable securities, available for sale	\$—	\$28.0	\$—	\$28.0

The following table represents our fair value hierarchy for our financial assets (cash equivalents, marketable securities and restricted cash) measured at fair value on a recurring basis as of December 31, 2014 (in millions):

	Fair Value Measurements Using			Total
	Level 1	Level 2	Level 3	
Cash equivalents	\$—	\$54.3	\$—	\$54.3
Marketable securities, available for sale				
U.S. government agencies	—	9.1	—	9.1
Corporate debt	—	2.3	—	2.3
Commercial paper	—	0.4	—	0.4
Total marketable securities, available for sale	\$—	\$11.8	\$—	\$11.8
Restricted cash	\$1.0	\$—	\$—	\$1.0

Our restricted cash balance as of December 31, 2014 included certificates of deposit.



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There were no transfers between Level 1 and Level 2 securities during three and nine months ended September 30, 2015 and 2014.

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

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

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 Form 10-K for the period ended December 31, 2014, as filed with the SEC on February 25, 2015, and 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 systems ("CGM") for ambulatory use by people with diabetes and for use by healthcare providers for the treatment of people with and without diabetes. Unless the context requires otherwise, the terms "we," "us," "our," the "company," or "DexCom" refer to DexCom, Inc. and its subsidiaries.

Background

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 ambulatory continuous glucose monitoring systems, including the SEVEN PLUS, G4 PLATINUM and G5 Mobile, as well as the continued research and clinical development of our technology platform.

The International Diabetes Federation ("IDF") estimates that in 2014, 387 million people around the world had diabetes, and the Centers for Disease Control ("CDC") estimates that in 2012, diabetes affected 29.1 million people in the United States, of which 8.1 million were undiagnosed. IDF estimates that by 2035, the worldwide incidence of people suffering from diabetes will reach 592 million. According to the CDC's National Vital Statistics Reports for 2010, diabetes was the seventh leading cause of death by disease in the United States. According to the Congressional Diabetes Caucus, diabetes is the leading cause of kidney failure, adult-onset blindness, lower-limb amputations, and significant cause of heart disease and stroke, high blood pressure and nerve damage. According to the IDF, there were an estimated 4.9 million deaths attributable to diabetes globally in 2014. The American Diabetes Association ("ADA") Fast Facts, revised in July 2014, states that diabetes is the primary cause of death for more than 69,000 Americans each year, and contributes to the death of more than 234,000 Americans annually. According to an article published in The New England Journal of Medicine in November 2014, excess mortality for people with diabetes younger than 30 years of age is largely explained by acute complications of diabetes.

According to the CDC 2011 National Diabetes Fact Sheet, in the United States, another individual is diagnosed with diabetes every 17 seconds. As reported by the Congressional Diabetes Caucus website as of August 6, 2014, each day approximately 5,082 people are diagnosed with diabetes, and about 1.7 million people 20 years or older were diagnosed in 2012. In addition to those newly diagnosed, the Congressional Diabetes Caucus website reports that every 24 hours there are: 238 amputations in people with diabetes, 120 people who enter end-stage kidney disease programs, and 48 people who go blind.

According to the ADA, one in every five healthcare dollars was spent on treating diabetes in 2012, and the direct medical costs and indirect expenditures attributable to diabetes in the United States were an estimated \$245 billion, an increase of \$71 billion, or approximately 41%, since 2007. Of the \$245 billion in overall expenses, the ADA estimated that approximately \$176 billion were direct costs associated with diabetes care, chronic complications and excess general medical costs, and \$69 billion were indirect medical costs. The ADA also found that average medical expenditures among people with diagnosed diabetes were 2.3 times higher than for people without diabetes in 2012. According to the IDF, expenditures attributable to diabetes were

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an estimated \$612 billion globally in 2014. The IDF estimates that expenditures attributable to diabetes will grow to \$678 billion globally by 2035.

We believe continuous glucose monitoring has the potential to enable more people with diabetes to achieve and sustain tight glycemic control. The Diabetes Control and Complications Trial demonstrated that improving blood glucose control lowers the risk of developing diabetes-related complications by up to 50%. The study also demonstrated that people with Type 1 diabetes achieved sustained benefits with intensive management. Yet, according to an article published in the Journal of the American Medical Association in 2004, less than 50% of diabetes patients were meeting ADA standards for glucose control (A1c), and only 37% of people with diabetes were achieving their glycemic targets. According to an article published in The New England Journal of Medicine in November 2014, in two national registries, only 13% to 15% of people with diabetes met treatment guidelines for good glycemic control, and more than 20% had very poor glycemic control. The CDC estimated that as of 2006, 63.4% of all adults with diabetes were monitoring their blood glucose levels on a daily basis, and that 86.7% of insulin-requiring patients with diabetes monitored daily.

Various clinical studies also demonstrate the benefits of continuous glucose monitoring and that continuous glucose monitoring is equally effective in patients who administer insulin through multiple daily injections or through use of continuous subcutaneous insulin infusion pumps. Results of a Juvenile Diabetes Research Foundation study published in the New England Journal of Medicine in 2008, and the extension phase of the study, published in Diabetes Care in 2009, demonstrated that continuous glucose monitoring improved A1c levels and reduced incidence of hypoglycemia for patients over the age of 25 and for all patients of all ages who utilized continuous glucose monitoring regularly. Our initial target market in the United States consists of the estimated 30% of people with Type 1 diabetes who utilize insulin pump therapy and the estimated 50% of people with Type 1 diabetes who utilize multiple daily insulin injections. Our broader target market in the United States consists of our initial target market plus an estimated 20% of people with Type 1 diabetes using conventional insulin therapy and the estimated 27% of people with Type 2 diabetes who require insulin. Although our initial focus was within the United States, we have expanded our operations to include Canada, Australia, New Zealand, and portions of Europe, Asia, the Middle East, Latin America and Africa.

**Products**

Ambulatory Product Line: SEVEN® PLUS, DexCom G4®, DexCom G4® PLATINUM, DexCom Share™ System and DexCom G5® Mobile

We received approval from the FDA and commercialized our first product in 2006. In 2007, we received approval and began commercializing our second generation system, the DexCom SEVEN. In 2009 we received approval and began commercializing our third generation system, the DexCom SEVEN PLUS. We no longer market or provide support for the DexCom SEVEN or SEVEN PLUS systems. On June 14, 2012, we received Conformité Européenne Marking (“CE Mark”) approval for our fourth generation continuous glucose monitoring system, the DexCom G4 system, enabling commercialization of the DexCom G4 system in the European Union, Australia, New Zealand and the countries in Asia and Latin America that recognize the CE Mark. The DexCom G4 system was approved for use by adults at home and in healthcare facilities. On October 5, 2012, we received approval from the FDA for the DexCom G4 PLATINUM, which is designed for up to seven days of continuous use by adults with diabetes, and we began commercializing this product in the United States in the fourth quarter of 2012. On February 14, 2013, we received CE Mark approval for a pediatric indication for our DexCom G4 system, enabling us to market and sell this system in the European Union, Australia, New Zealand and the countries in Asia and Latin America that recognize the CE Mark to persons two years old and older who have diabetes (hereinafter referred to as the "Pediatric Indication"), and we initiated a limited commercial launch in the second quarter of 2013. In connection with our receipt of CE Mark approval for the Pediatric Indication, we changed the name of the DexCom G4 system to the DexCom G4 PLATINUM system. On February 3, 2014, we received approval from the FDA for a Pediatric Indication for the DexCom G4 PLATINUM system in the United States. On June 3, 2014, we received approval from the FDA for an expanded indication for the DexCom G4 PLATINUM for professional use. This expanded indication allows healthcare professionals to purchase the DexCom G4 PLATINUM system for use with multiple patients. Healthcare professionals can use the insights gained from a DexCom G4 PLATINUM professional session to adjust therapy and to educate and motivate patients to modify their behavior after viewing the effects that specific foods, exercise, stress,

and medications have on their glucose levels. On January 23, 2015, we received approval from the FDA for the DexCom G4 PLATINUM with Share, which is designed for up to seven days of continuous use, and we began commercializing this product in the United States in the first quarter of 2015. The DexCom G4 PLATINUM with Share remote monitoring system uses a secure wireless connection between a patient's receiver and an app on the patient's iPhone®, iPod touch®, or iPad® mobile digital device to transmit glucose information to apps on the mobile devices of up to five designated recipients, or "followers," who can remotely monitor a patient's glucose information and receive alert notifications anywhere they have an Internet or cellular connection. Unless the context requires otherwise, the term "G4 PLATINUM" shall refer to the DexCom G4 and DexCom G4 PLATINUM systems (and all associated indications of use for such systems,

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including without limitation, associated DexCom Share System functionalities) that are commercialized by us in and outside of the United States.

As compared to the SEVEN PLUS, the G4 PLATINUM offers:

- an improved sensor wire design that allows more scalable manufacturing,
- a smaller, sleeker receiver that is capable of displaying data in color,
- a new transmitter design that offers improved communication range with the receiver which allows for improved data capture,
- additional user interface and algorithm enhancements that are intended to make the user experience more customizable and to make its glucose monitoring function more accurate especially in the hypoglycemic range,
- the ability to market and sell to an expanded customer population due to the approval by the FDA of, and our obtaining a CE Mark for, a Pediatric Indication, and
- DexCom Share remote monitoring capabilities.

### DexCom SHARE™

On October 17, 2014, we received approval from the FDA for the DexCom SHARE remote monitoring system.

DexCom SHARE enables users of our G4 PLATINUM System to have their sensor glucose information remotely monitored by their family or friends. To use DexCom SHARE, the G4 PLATINUM user docks their G4 PLATINUM Receiver in the DexCom SHARE Cradle and their sensor glucose information is wirelessly transmitted to, and viewed by, such patient's friends or family through the DexCom SHARE mobile application. DexCom SHARE provides secondary notifications to individuals designated by a G4 PLATINUM System user and does not replace real time continuous glucose monitoring or standard home blood glucose monitoring.

On January 23, 2015, the FDA approved a version of the G4 PLATINUM Receiver that includes the DexCom Share System. The G4 PLATINUM Receiver with Share remote monitoring system uses a secure wireless connection via Bluetooth Low Energy ("BLE") between a patient's receiver and a mobile application on the patient's iPhone, iPod touch, or iPad mobile digital device to transmit glucose information to mobile applications on the mobile devices of up to five designated recipients, or "followers," without the need to use the DexCom SHARE Cradle component. The mobile applications that comprise the DexCom Share System were classified by the FDA as Class II, exempt, due to the fact that these mobile applications were secondary displays of the associated G4 PLATINUM Receiver. With the mobile applications classified as Class II, exempt, DexCom must comply with certain general and special controls required by the FDA but does not need prior FDA approval to commercialize changes to the DexCom Share System. We began commercialization of the G4 PLATINUM with Share in the first quarter of 2015 and discontinued the DexCom SHARE Cradle. Effective April 24, 2015, our DexCom Share System also supports the Apple Watch™, allowing the Apple Watch to utilize DexCom Share System functionality. Effective June 2, 2015, the mobile application for the Share System followers became available for Android devices.

### DexCom G5 Mobile

On August 19, 2015, we received approval from the FDA for the DexCom G5 Mobile Continuous Glucose Monitoring System (the "G5 Mobile"). The G5 Mobile is designed to allow our transmitter to run the algorithm that has historically operated on the receiver, and to communicate directly to a patient's iPhone, iPod touch, or iPad mobile digital device to utilize DexCom Share System functionality. The G5 Mobile transmitter has a labeled useful life of three months.

We previously received CE Mark approval for, and in September, 2015, we launched the G5 Mobile in certain countries in Europe. In the countries and regions outside of the United States that recognize the CE Mark, the G5 Mobile does not require confirmatory finger sticks when making treatment decisions, although a minimum of two finger sticks a day remain necessary for calibration of the G5 Mobile.

Data from the G5 Mobile can be integrated with DexCom CLARITY™, our next generation cloud-based reporting software, for personalized, easy-to-understand analysis of trends that may improve diabetes management.

Except with respect to the foregoing, the G5 Mobile is equivalent to the G4 PLATINUM System in technical and regulatory respects.

In-Hospital Product Line: GlucoClear®



To address the in-hospital critical care patient population, on November 10, 2008 we entered into a “Manufacturing and Supply Agreement,” a “Quality Agreement,” and a “Collaboration Agreement,” with Edwards to develop jointly and market a specific glucose monitoring product platform for the in-hospital critical care market. On October 30, 2009, the first generation

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blood-based in-vivo automated glucose monitoring system, which was branded the GlucoClear, received CE Mark approval for use by healthcare providers in the hospital. In January 2013, Edwards received CE Mark approval for the second generation system. In 2014, Edwards announced that it was likely to cease the commercialization of the GlucoClear system. On September 3, 2015, we and Edwards entered into a Restatement of License, Termination of Collaboration & Release Agreement (the “Restated Agreement”), terminating each of the “Manufacturing and Supply Agreement” and “Quality Agreement,” and amending in part the “Collaboration Agreement.” Pursuant to the Restated Agreement, DexCom and Edwards agreed to a mutual release of claims, including any activities related to further development obligations or milestone payments. In addition, the Restated Agreement provides Edwards with a fully paid-up, royalty-free license to use certain of DexCom’s intellectual property solely in the field of blood-based glucose monitoring within the hospital environment. Under the Restated Agreement, DexCom reserves the right to market and sell its interstitial continuous glucose monitoring technology in all settings, including within the hospital market. No payments are required by either party in connection with the Restated Agreement.

**SweetSpot**

Through our acquisition of SweetSpot in 2012, we have a software platform that enables our customers to aggregate and analyze data from certain diabetes devices and to share it with their healthcare providers. In November 2011, SweetSpot received 510(k) clearance from the FDA to market to clinics its initial cloud based data management service, which helps healthcare providers and patients see, understand and use blood glucose meter data to diagnose and manage diabetes. SweetSpot has also developed a data transfer service that is registered with the FDA as a Medical Device Data System. This data transfer service allows researchers to control the transfer of data from certain diabetes devices to research tools and databases according to their own research workflows.

**Sensor Augmented Insulin Pumps**

We are leveraging our technology platform to enhance the capabilities of our current products and to develop additional continuous glucose monitoring products. In 2008 and 2015 we entered into a development agreement with Animas Corporation (“Animas”), a subsidiary of Johnson & Johnson, and in 2012 and 2015 we entered into development agreements with Tandem. The purpose of each of these development relationships is to integrate our technology into the insulin pump product offerings of the respective partner, enabling the partner's insulin pump to receive glucose readings from our transmitter and display this information on the pump's screen. The initial Animas insulin pump product augmented with our sensor technology has been branded the Vibe®, and received CE Mark approval in May 2011, which allows Animas to market the Vibe in the countries that recognize CE Mark approvals. In December 2014, Animas received FDA approval for the VIBE system in the United States and began commercializing this product in the first quarter of 2015. On September 9, 2015 Tandem announced it had received FDA approval of its t:slim G4™ Insulin Pump, a touch-screen pump that is integrated with our G4 PLATINUM system and is indicated for use by people 12 years of age or older who use insulin. Tandem began commercializing this product on September 23, 2015.

**Future Products**

We plan to develop future generations of technologies focused on improved performance and convenience and that will enable intelligent insulin administration. Over the longer term, we plan to develop networked platforms with open architecture, connectivity and transmitters capable of communicating with other devices and software systems. Our product development timelines are highly dependent on our ability to achieve clinical endpoints and regulatory and legal requirements and to overcome technology challenges, and our product development timelines may be delayed due to extended regulatory approval timelines, scheduling issues with patients and investigators, requests from institutional review boards, sensor 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 are successful, the FDA may not approve our products, and even if approved, we may not achieve acceptance in the marketplace by physicians and people with diabetes. On August 10, 2015, we entered into a Collaboration and License Agreement (the “GLS Collaboration Agreement”) with Google Life Sciences LLC (“GLS”). Pursuant to the GLS Collaboration Agreement, we and GLS have agreed to jointly develop a series of next-generation continuous glucose monitoring products. The GLS Collaboration

Agreement provides us with an exclusive license to use certain intellectual property of GLS related to the development, manufacture and commercialization of the products contemplated under the GLS Collaboration Agreement. The GLS 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 GLS have agreed to make committee decisions by consensus.

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## Commercial Operations

We have built a direct sales organization in the United States to call on endocrinologists, physicians and diabetes educators who can educate and influence patient adoption of continuous glucose monitoring. The approval by the FDA of a Pediatric Indication for our G4 PLATINUM system in February 2014 allows our sales organization to call on pediatric endocrinologists and pediatricians who can educate and influence adoption of continuous glucose monitoring by parents who have children aged two years or older with diabetes. We believe that focusing efforts on these participants is important given the instrumental role they each play in the decision-making process for diabetes therapy. To complement our direct sales efforts, we have entered into U.S. and international distribution arrangements that allow distributors to sell our products. We believe our direct, highly specialized and focused sales organization and our domestic and international distribution agreements are sufficient for us to support our sales efforts for at least the next twelve months.

As a medical device company, reimbursement from Medicare and private third-party healthcare payors is an important element of our success. Although the Centers for Medicare and Medicaid (“CMS”) released 2008 Alpha-Numeric Healthcare Common Procedure Coding System (“HCPCS”) codes applicable to each of the three components of our continuous glucose monitoring systems, to date, our approved products are not reimbursed by virtue of a national coverage decision by Medicare. It is not known when, if ever, Medicare will adopt a national coverage decision with respect to continuous glucose monitoring devices. Until any such coverage decision is adopted by Medicare, reimbursement of our products will generally be limited to those customers covered by third-party payors that have adopted coverage policies for continuous glucose monitoring devices that include our products. As of November 4, 2015, the seven largest private third-party payors, in terms of the number of covered lives, have issued coverage policies for the category of continuous glucose monitoring devices. In addition, we have negotiated contracted rates with all seven of those third-party payors for the purchase of our G4 PLATINUM and G5 Mobile systems by their members. Many of these coverage policies reimburse for our products under durable medical equipment benefits, are restrictive in nature and require the patient to comply with extensive documentation and other requirements to demonstrate medical necessity under the policy. In addition, customers who are insured by payors that do not offer coverage for our devices will have to bear the financial cost of the products. We currently employ in-house reimbursement expertise to assist customers in obtaining reimbursement from private third-party payors. We also maintain a field-based reimbursement team charged with calling on third-party private payors to obtain coverage decisions and contracts. We have had formal meetings and have increased our efforts to create and liberalize coverage policies with third-party payors, including obtaining reimbursement for our products under pharmacy benefits, and expect to continue to do so in fiscal 2015. However, unless government and other third-party payors provide adequate coverage and reimbursement for our products, people with diabetes may not use them on a widespread basis. We currently manufacture our products at our headquarters in San Diego, California. At September 30, 2015, these facilities had more than 8,000 square feet of laboratory space and approximately 18,000 square feet of controlled environment rooms. In July 2012, the FDA completed an inspection of our facilities, and did not identify any observations or require any other types of corrective action. During a routine FDA post-approval facility inspection ending on November 7, 2013, the FDA issued a Form 483 with several observations regarding DexCom Medical Device Reporting (“MDR”) procedures and complaint reportability determinations. DexCom responded to the observations on November 26, 2013. On March 14, 2014, we received the 2014 Warning Letter from the FDA related to administrative deficiencies in filing MDRs. On April 2, 2014, we responded to the 2014 Warning Letter. On April 16, 2015, the FDA initiated an on-site inspection intended to both close out the 2014 Warning Letter and conduct our normal biennial quality system inspection. The FDA completed its inspection with no observations. On May 21, 2015, the FDA issued a letter closing the 2014 Warning Letter.

There are technical challenges to increasing manufacturing capacity, including FDA qualification of new manufacturing facilities, equipment design and automation, material procurement, problems with production yields, and quality control and assurance. We have focused significant effort on continual improvement programs in our manufacturing operations intended to improve quality, yields and throughput. We have made progress in manufacturing to enable us to supply adequate amounts of product to support our commercialization efforts, however we cannot guarantee that supply will not be constrained going forward. Additionally, the production of our continuous

glucose monitoring systems must occur in a highly controlled and clean environment to minimize particles and other yield- and quality-limiting contaminants. Developing commercial-scale manufacturing facilities has and will continue to require the investment of substantial additional funds and the hiring and retaining of additional management, quality assurance, quality control and technical personnel who have the necessary manufacturing experience. Manufacturing is subject to numerous risks and uncertainties described in detail in “Risk Factors” below.

We manufacture our G4 PLATINUM and G5 Mobile systems with certain components supplied by outside vendors and other components that we manufacture internally. Key components that we manufacture internally include our wire-based sensors for the G4 PLATINUM and G5 Mobile systems. The remaining components and assemblies are purchased from outside vendors. We then assemble, test, package and ship the finished G4 PLATINUM and G5 Mobile systems, which include a reusable transmitter, a receiver, disposable sensors and our mobile applications including functionality related to the DexCom Share System.

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Product revenues are generated from the sale of durable continuous glucose monitoring systems (receivers and transmitters) and disposable sensors through a direct sales force in the United States as well as through distribution arrangements in the United States, Canada, Australia, New Zealand, and in portions of Europe, Asia, the Middle East, Latin America and Africa. The sensor is inserted by the user and is intended to be used continuously for up to seven days, after which it may be replaced with a new disposable sensor. Our transmitter is reusable until it reaches the end of its battery life.

The receiver is reusable. As we establish an installed base of customers using our products, we expect to generate an increasing portion of our revenues through recurring sales of our disposable sensors. We recognize product revenue generally upon shipment and our sales terms provide for customer payment at the time of order, payment due within negotiated contractual terms with insurance payors, or with the issuance of a purchase order or letter of credit for certain distributors and institutions.

As of September 30, 2015, we had an accumulated deficit of \$556.9 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. In November 2012, we entered into our Loan Agreement that provides for (i) a \$15.0 million revolving line of credit and (ii) initially provided a total term loan of up to \$20.0 million (the "Term Loan"). In accordance with the Loan Agreement, \$7.0 million was advanced under the Term Loan at the funding date in November 2012, and up to \$13.0 million in additional funds was initially available upon our request from June 1, 2013 to September 30, 2013 (the "Draw Period"). In August 2013, the Loan Agreement was amended to change the Draw Period for the additional funds under the Term Loan to January 1, 2014 through March 31, 2014. We did not borrow any additional funds and the Draw Period expired unused. There is currently \$15.0 million available under the Loan Agreement. In July 2013, we were awarded a \$4.0 million grant from the Helmsley Trust to accelerate the development of our Gen 6 Sensor. As of September 30, 2015, we have received the full \$4.0 million grant funds from the Helmsley Trust.

### Financial Operations

#### Revenue

We sell our durable systems and disposable units through a direct sales force in the United States and through distribution arrangements in the United States, Canada, Australia, New Zealand, and in portions of Europe, Asia, the Middle East, Latin America and Africa. We have contracts with Stocking Distributors and Drop-Ship Distributors. We expect that revenues we generate from the sales of our products will fluctuate from quarter to quarter. Between 2008 and 2012, we entered into joint development and collaboration agreements with Animas and Tandem, as well as other third parties under agreements that have since expired or been terminated, under which we recognized development grant and other revenue received pursuant to each agreement ratably over the term of the development period. We recognize development milestones associated with each agreement as revenue upon achievement of each milestone if the milestone is considered substantive.

#### Cost of Sales

Product 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 product cost of sales. Development and other cost of sales consists primarily of salaries, fringe benefits, facility expense, and supplies directly attributable to our development or service contracts.

#### 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.

**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 and administrative functions. Other significant expenses include trade show expenses, sales samples, insurance, professional fees for our outside legal counsel and independent auditors, litigation expenses, patent application expenses and consulting expenses.

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## Results of Operations

## Quarter Ended September 30, 2015 Compared to September 30, 2014

## Revenue, Cost of Sales and Gross Profit

Product revenues increased \$36.3 million to \$104.2 million for the three months ended September 30, 2015 compared to \$67.9 million for the three months ended September 30, 2014 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 and G5 Mobile 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 product revenue, for each of the three months ended September 30, 2015 and 2014. There were no sales of the SEVEN PLUS during the three months ended September 30, 2015. Sales of the SEVEN PLUS represented less than 1% of our revenues for the three months ended September 30, 2014. In conjunction with the FDA approval and launch of the G5 Mobile during the third quarter of 2015, the product gross profit for the three months ended September 30, 2015 included a revenue deferral of \$0.8 million and additional cost of goods sold of \$0.6 million related to an upgrade program.

Product cost of sales increased \$8.7 million to \$30.5 million for the three months ended September 30, 2015 compared to \$21.8 million for the three months ended September 30, 2014, primarily due to increased sales volume. The product gross profit increased \$27.6 million to \$73.7 million for the three months ended September 30, 2015 compared to \$46.1 million for the same period in 2014, primarily due to increased revenue.

Revenue from products shipped to our Drop-Ship Distributors' customers was \$9.3 million, or 9%, of our total revenues for the three months ended September 30, 2015 compared to \$6.5 million, or 9%, of our total revenues for the three months ended September 30, 2014. Revenue from products shipped to Stocking Distributors was \$68.1 million, or 65%, of our total revenues for the three months ended September 30, 2015 compared to \$40.0 million, or 58%, of our total revenues for the three months ended September 30, 2014.

Development grant and other revenues were \$1.0 million and \$1.1 million for the three months ended September 30, 2015 and 2014, respectively, primarily attributable to milestone payments related to our development agreement with Tandem. We did not incur any development and other cost of sales during the three months ended September 30, 2015 and 2014.

Research and Development. Research and development expense increased \$46.3 million to \$64.8 million for the three months ended September 30, 2015 compared to \$18.5 million for the three months ended September 30, 2014. The increase was primarily due to the upfront fee related to GLS Collaboration Agreement, as well as additional headcount and costs to support development of future products. Significant elements of the increase in research and development costs included \$36.5 million in non-cash expense associated with the issuance of 404,591 shares in August 2015 related to the GLS Collaboration Agreement, \$3.3 million in additional share-based compensation driven by higher grant date fair value of awards as a result of our increasing stock price, and \$2.0 million in additional salaries, bonus and payroll related costs.

Selling, General and Administrative. Selling, general and administrative expense increased \$18.6 million to \$52.3 million for the three months ended September 30, 2015 compared to \$33.7 million for the three months ended September 30, 2014. The increase was primarily due to higher headcount related selling costs and marketing costs to support revenue growth and the continued commercialization of our products. Significant elements of the increase in selling, general, and administrative expenses included \$4.6 million in additional share-based compensation costs driven by higher grant date fair value of awards as a result of our increasing stock price, \$3.6 million in additional salaries, bonus, and payroll related costs, and \$3.3 million in additional marketing costs.

Interest Expense. Interest expense was \$0.1 million for the three months ended September 30, 2015 compared to \$0.2 million for the three months ended September 30, 2014 and is related to our Loan Agreement.

## Nine Months Ended September 30, 2015 Compared to September 30, 2014

## Revenue, Cost of Sales and Gross Profit

Product revenues increased \$97.1 million to \$269.9 million for the nine months ended September 30, 2015 compared to \$172.8 million for the nine months ended September 30, 2014 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 and G5



Mobile 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 product revenue, for each of the nine months ended September 30, 2015 and 2014. There were no sales of the SEVEN PLUS during the nine months ended September 30, 2015. Sales of the SEVEN PLUS represented less than 1% of our revenues for the nine months ended September 30, 2014.

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Product cost of sales increased \$26.6 million to \$84.0 million for the nine months ended September 30, 2015 compared to \$57.4 million for the nine months ended September 30, 2014 primarily due to increased sales volume. The product gross profit of \$185.9 million for the nine months ended September 30, 2015 increased \$70.5 million compared to \$115.4 million for the same period in 2014, primarily due to increased revenue. In conjunction with the FDA approval and launch of the G4 PLATINUM with Share during the first quarter of 2015, the product gross profit for the nine months ended September 30, 2015 included \$2.7 million in additional cost of goods sold, primarily related to \$2.0 million in excess and obsolete inventory and free product delivered as part of our upgrade program. In conjunction with the FDA approval and launch of the G5 Mobile during the third quarter of 2015, the product gross profit for the nine months ended September 30, 2015 included a revenue deferral of \$0.8 million and additional cost of goods sold of \$0.6 million related to an upgrade program.

Revenue from products shipped to our Drop-Ship Distributors' customers was \$26.3 million, or 10%, of our total revenues for the nine months ended September 30, 2015 compared to \$19.9 million, or 11%, of our total revenues for the nine months ended September 30, 2014. Revenue from products shipped to Stocking Distributors was \$169.5 million, or 63%, of our total revenues for the nine months ended September 30, 2015 compared to \$98.6 million, or 56%, of our total revenues for the nine months ended September 30, 2014.

Development grant and other revenues decreased \$0.8 million to \$1.3 million for the nine months ended September 30, 2015 compared to \$2.1 million for the nine months ended September 30, 2014. We did not incur any development and other cost of sales during the nine months ended September 30, 2015. Development and other cost of sales was \$0.6 million during the nine months ended September 30, 2014. The decrease in development grant and other revenues during the nine months ended September 30, 2015 was primarily due to the completion of development activities with Edwards. The decrease in costs associated with development was primarily due to fewer development obligations during the period with respect to our collaboration and development arrangements.

Research and Development. Research and development expense increased \$61.2 million to \$109.0 million for the nine months ended September 30, 2015, compared to \$47.8 million for the nine months ended September 30, 2014. The increase was primarily due to the upfront fee related to GLS Collaboration Agreement, as well as additional headcount and costs to support development of future products. Significant elements of the increase in research and development costs included \$36.5 in non-cash expense associated with the issuance of 404,591 shares in August 2015 related to the GLS Collaboration Agreement, \$8.4 million in additional share-based compensation driven by higher grant date fair value of awards as a result of our increasing stock price, and \$8.1 million in additional salaries, bonus and payroll related costs.

Selling, General and Administrative. Selling, general and administrative expense increased \$44.7 million to \$136.9 million for the nine months ended September 30, 2015, compared to \$92.2 million for the nine months ended September 30, 2014. The increase was primarily due to higher headcount related selling costs and marketing costs to support revenue growth and the continued commercialization of our products. Significant elements of the increase in selling, general, and administrative expenses included \$12.7 million in additional share-based compensation costs driven by higher grant date fair value of awards as a result of our increasing stock price, \$10.6 million in additional salaries, bonus, and payroll related costs, \$6.2 million in additional marketing costs, and \$2.2 million in additional facilities costs.

Interest Expense. Interest expense was \$0.4 million for the nine months ended September 30, 2015 compared to \$0.6 million for the nine months ended September 30, 2014 and is related to our Loan Agreement.

#### Liquidity and Capital Resources

We have incurred losses since our inception in May 1999. As of September 30, 2015, we had an accumulated deficit of \$556.9 million and had working capital of \$144.9 million. Our cash, cash equivalents and marketable securities totaled \$113.3 million. To date, we have funded our operations primarily through offerings of equity securities and debt, and the sales of our products.

In July 2013, we were awarded the Helmsley Grant from the Helmsley Trust to accelerate the development of our Gen 6 Sensor. The funding was milestone based and was contingent upon our meeting specific development milestones related to the Gen 6 Sensor over a period of several years. All such milestones have now been met. Upon the

successful commercialization of the Gen 6 Sensor, we are obligated to either (1) make royalty payments of up to \$2.0 million per year for four years, or (2) at our sole election, make a one-time \$6.0 million royalty payment. As of September 30, 2015, we have received the full \$4.0 million of the Helmsley Grant funds.

Cash Flow Summary

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(In millions)	Nine Months		Change
	Ended	September 30,	
	2015	2014	
Net cash provided by operating activities	\$37.7	\$15.2	\$22.5
Net cash used in investing activities	\$(38.8 )	\$(12.1 )	\$(26.7 )
Net cash provided by financing activities	\$14.6	\$16.9	\$(2.3 )

**Net Cash Provided by Operating Activities.** The increase in cash provided by operations was primarily due to \$62.8 million in higher non-cash charges primarily comprised of non-cash expense associated with the issuance of 404,591 shares in August 2015 related to the GLS Collaboration Agreement, share-based compensation, partially offset by an additional \$4.9 million cash outflow from changes in operating assets and liabilities. The main drivers in the change in operating assets and liabilities included increases in accounts receivable, inventory and accounts payable and accrued liabilities, all as a result of our growth.

**Net Cash Used in Investing Activities.** The change in cash used in investing activities was primarily due to a \$25.1 million increase in cash used to purchase marketable securities, and by the use of \$21.7 million to purchase equipment to support manufacturing improvements and information technology infrastructure for the nine months ended September 30, 2015, compared to \$11.6 million to purchase equipment for the nine months ended September 30, 2014, partially offset by a \$9.0 million increase in proceeds from the maturity of marketable securities.

**Net Cash Provided by Financing Activities.** The decrease in cash provided by financing activities was due to \$2.2 million decrease in proceeds from the issuance of common stock pursuant to the exercise of then-outstanding stock options for the nine months ended September 30, 2015 compared to the nine months ended September 30, 2014.

#### Operating Capital and Capital Expenditure Requirements

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

We believe that our cash, cash equivalents, marketable securities balances, and projected cash contributions from our commercial operations 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 September 30, 2016. 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;

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- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- the rate of progress and cost of our clinical trials and other development activities;
- the success of our research and development efforts;
- the emergence of competing or complementary technological developments;
- the terms and timing of any collaborative, licensing and other arrangements that we may establish; and
- the acquisition of businesses, products and technologies and our ability to integrate and manage any acquired businesses, products and technologies, including without limitation, SweetSpot.

### Contractual Obligations

We are party to various purchase arrangements related to components used in manufacturing and research and development activities. As of September 30, 2015, we had firm purchase commitments with certain vendors totaling approximately \$43.2 million due within one year. There are no material purchase commitments due beyond one year.

### 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, 2014. 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, 2014. There were no material changes to our critical accounting policies during the nine months ended September 30, 2015.

### Recent Accounting Guidance

In May 2014, the FASB issued authoritative guidance for Revenue from Contracts with Customers, to supersede nearly all existing revenue recognition guidance under U.S. GAAP. The core principle of the guidance is to recognize revenues 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. The updated standard permits the use of either the retrospective or cumulative effect transition method and is effective for us in our first quarter of fiscal 2018. Early adoption is not permitted. We have not yet selected a transition method and we are currently evaluating the effect that the updated standard will have on our consolidated financial statements and related disclosures.

In July 2015, the FASB issued guidance to change the subsequent measurement of inventory from lower of cost or market to lower of cost and net realizable value. The guidance requires that inventory accounted for under the first-in, first-out (FIFO) or average cost methods be measured at the lower of cost and net realizable value, where net realizable value represents the estimated selling price of inventory in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. The guidance is effective for us beginning in the first quarter of fiscal 2018. Earlier application is permitted as of the beginning of an interim or annual reporting period. We are currently evaluating the effect this guidance will have on our consolidated financial statements.



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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

We have only limited business transactions in foreign currencies. We do not currently engage in hedging or similar transactions to reduce our foreign currency risks. We believe we have no material exposure to risk from changes in foreign currency exchange rates at this time. 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

We are subject to additional various claims, complaints and legal actions that arise from time to time in the normal course of business. 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. Other than as described above, 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 operations or financial position. 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, consolidated financial position, results of operations or cash flows.

ITEM 1A. RISK FACTORS

Factors that May Affect our Financial Condition and Results of Operations

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 net losses in each year since our inception in May 1999, including a net loss of \$59.1 million for the nine months ended September 30, 2015. As of September 30, 2015, we had an accumulated deficit of \$556.9 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 and G5 Mobile 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 pump and 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 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 and G5 Mobile systems and our future products, we must continue to develop and grow our sales and marketing organization and enter into partnerships or other arrangements to market and sell our products. 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 disbursed sales and marketing operations.

We currently employ a direct sales force to market our products in the United States. In the United States, our sales force calls directly on healthcare providers and people with diabetes throughout the 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 U.S. 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 to market and sell our products in Canada, Europe, Australia, New Zealand, Asia, the Middle East, Latin America and Africa. Because of the competition for their services, we may be unable to partner with or retain

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additional qualified distributors. Further, we may not be able to enter into agreements with distributors on commercially reasonable terms, if at all.

We may require additional funding to continue the commercialization of our G4 PLATINUM and G5 Mobile systems, or the development and commercialization of our future generation and other continuous glucose monitoring systems, including our sensor augmented insulin pump systems developed in collaboration with Animas and Tandem and our collaboration with Google Life Sciences.

Our operations have consumed substantial amounts of cash since inception. We expect to continue to spend substantial amounts on commercializing our products, including growth of our manufacturing capacity, and on research and development, including conducting clinical trials for our next generation ambulatory continuous glucose monitoring sensors and systems. For the nine months ended September 30, 2015, we generated \$37.7 million in net cash from operating activities, compared to \$15.2 million for the same period in 2014, and as of September 30, 2015, we had working capital of \$144.9 million which included \$113.3 million in cash, cash equivalents and short-term marketable securities. We expect that our cash generated by operations will increase in each of the next several years, and, although we have the ability to borrow up to an additional \$15.0 million pursuant to the Loan Agreement we entered into with Silicon Valley Bank and Oxford Finance in November 2012, we may need additional funds to continue the commercialization of our current products and to develop and commercialize our next generation sensors and systems. Additional financing may not be available on a timely basis on terms acceptable to us, or at all. Any additional financing may be dilutive to stockholders or may require us to grant a lender a security interest in our assets. The amount of funding we may need will depend on many factors, including:

- the revenue generated by sales of our products and other future products;
- the costs, timing and risks of delay of additional regulatory approvals;
- the expenses we incur in manufacturing, developing, selling and marketing our products;
- our ability to scale our manufacturing operations to meet demand for our current and any future products;
- the costs to produce our continuous glucose monitoring systems;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- the rate of progress and cost of our clinical trials and other development activities;
- the success of our research and development efforts;
- the emergence of competing or complementary 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, although we currently have no commitments or agreements relating to any of these types of transactions.

If adequate funds are not available, we may not be able to commercialize our products at the rate we desire and we may have to delay development or commercialization of our other products or license to third parties the rights to commercialize products or technologies that we would otherwise seek to commercialize. We also may have to reduce sales, marketing, customer support or other resources devoted to our products. Any of these factors could harm our financial condition.

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. We have entered into distribution agreements with Byram and Edgepark, pursuant to which we generated approximately 19% and 10%, respectively, of our total revenue during the nine months ended September 30, 2015. We cannot guarantee that these relationships will continue or that we will be able to maintain this volume of sales from these relationships in the future. A substantial decrease or loss of these sales could have a material adverse effect on our operating performance. Additionally, 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. Furthermore, 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.

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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 and private third-party healthcare payors is an important element of our success. Although CMS in 2008 released HCPCS codes applicable to each of the three components of our continuous glucose monitoring systems to date, our approved products are not reimbursed by virtue of a national coverage decision by Medicare. It is not known when, if ever, Medicare will adopt a national coverage decision with respect to continuous glucose monitoring devices. Until any such coverage decision is adopted by Medicare, reimbursement of our products will generally be limited to those people with diabetes covered by third-party payors that have adopted policies for continuous glucose monitoring devices allowing for coverage of these devices if certain conditions are met. As of November 4, 2015, the seven largest private third-party payors, in terms of the number of covered lives, have issued coverage policies for the category of continuous glucose monitoring devices. In addition, we have negotiated contracted rates with all seven of those third-party payors for the purchase of our 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 continuous glucose monitoring 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. In addition, Medicare, Medicaid, health maintenance organizations and other third-party payors are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement of new medical devices, and, as a result, they may not cover or provide adequate payment for our products. 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 requiring prospective reimbursement and second opinions, purchasing in groups, or redesigning benefits. Furthermore, we are unable to predict what effect the current or any future healthcare reform will have on our business, or the effect these matters will have on our customers. Our dependence on the commercial success of the G4 PLATINUM and G5 Mobile 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 and G5 Mobile systems, people without coverage who have diabetes may not use our products.

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 proposed legislation 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.

We may never receive approval or clearance from the FDA and other governmental agencies to market our next generation ambulatory system, expanded indications for use of current and future generation ambulatory systems, future SweetSpot software platforms, or any other continuous glucose monitoring system or related component under development.

Our continuous glucose monitoring systems are classified by the FDA as premarket approval, or PMA, medical devices. The PMA process requires us to prove the safety and efficacy of our ambulatory system 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. Any future general ambulatory system or

expanded indications for use of current and future generation ambulatory systems will require approval of the applicable regulatory authorities. We intend to seek either 510(k) clearances or PMA approvals for certain changes and modifications to SweetSpot's existing software platform, but cannot predict when, if ever, those changes and modifications will be approved.

The FDA can refuse to grant a 510(k) clearance or 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;

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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 other regulatory agencies, future generations of our ambulatory system, expanded indications for use of current and future generation ambulatory systems, SweetSpot, 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 the next generation of our ambulatory system could prevent us from generating revenue from these products or achieving profitability. The uncertain timing of regulatory approvals for future generations of our ambulatory products could subject our current inventory to excess or obsolescence charges, which could have an adverse effect on our 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 financial position.

To support these 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 (“IDE”) prior to commencing clinical trials for our continuous glucose monitoring systems, 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 FDA's Center for Devices and Radiological Health is contemplating significant changes to the 510(k) process, which could complicate the product approval process for certain of our and our partner's 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. The data contained in our submission, 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;
- 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 (“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;

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DexCom or third-party organizations do not perform data collection, monitoring and analysis in a timely or accurate manner or consistent with the clinical trial protocol or investigational or statistical plans;  
 third-party clinical investigators have significant financial interests related to DexCom or the study that the FDA deems to make the study results unreliable, or DexCom or investigators fail to disclose such interests;  
 regulatory inspections of our clinical trials or manufacturing facilities 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.

We conduct business in a heavily regulated industry and if we fail to comply with these 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;
- 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.

These laws and regulations are extremely complex and, in some cases, still evolving. If our operations are found to violate any of the federal, state or local laws and regulations which govern our activities, we may be subject to litigation, government enforcement actions, the applicable penalty associated with the violation, including civil and criminal penalties,



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damages, fines or curtailment of our operations. The risk of being found in violation of these laws and regulations is 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. Any action against us for 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.

The FDA, the Office of Inspector General for the Department of Health and Human Services, the 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 pharmaceutical products, payments intended to influence the referral of federal or state healthcare business, and submission of false claims for government reimbursement. As part of our compliance program, we have reviewed our sales contracts and marketing materials and practices to reduce the risk of non-compliance with these federal and state laws, and inform employees and marketing representatives of the Anti-Kickback Statute and their obligations thereunder. However, 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.

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.

We are not 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.

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, facilities and experience in 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 guaranty 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. Developing 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. Also, 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.

In the future, if our products experience a material defect or error, 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 service and warranty costs, any of which could harm our business. Such defects or errors could also prompt us to

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

Our manufacturing operations 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 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 requires corrective action, our supply of critical components may be constrained or unavailable. 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 supplement or possibly a separate PMA, 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 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 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. 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.

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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. 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 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. We and our suppliers are also required to comply with the FDA's Quality System Regulation ("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 8,000 square feet of laboratory space and approximately 18,000 square feet of controlled environment rooms. During a routine FDA post-approval facility inspection ending on November 7, 2013, the FDA issued a Form 483 with several observations regarding DexCom MDR procedures and complaint reportability determinations. DexCom responded to the observations on November 26, 2013. On March 14, 2014, we received the 2014 Warning Letter from the FDA related to administrative deficiencies in filing MDRs. On April 2, 2014, we responded to the 2014 Warning Letter. On April 16, 2015, the FDA initiated an on-site inspection intended to both close out the 2014 Warning Letter and conduct our normal biennial quality system inspection. The FDA completed its inspection with no observations. On May 21, 2015, the FDA issued a letter closing the 2014 Warning Letter.

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 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 approval by the FDA or other regulatory bodies;
- product recall or seizure;
- interruption of production;
- interruption of the supply of components from our key component suppliers;
- operating restrictions;
- injunctions; and
- criminal prosecution.

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 or the imposition of civil or criminal penalties. 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.



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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.

We have previously been subject to litigation from third parties alleging patent infringement. Other parties could, in the future, assert infringement or misappropriation claims against us with respect to our current or future products. 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.

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 were upheld as valid and enforceable and we were found to infringe, 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 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 licenses on satisfactory terms. If we do not obtain 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 if at all. Adverse determinations in a judicial or administrative proceeding or failure to obtain necessary 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 the United States 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

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challenging issued patents. These changes could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

To protect our proprietary rights, we may in the future need to assert claims of infringement against third parties. The outcome of litigation to enforce our intellectual property rights in patents, copyrights, trade secrets or trademarks is highly unpredictable, could result in substantial costs and diversion of resources, and could have a material adverse effect on our 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, 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 and G5 Mobile systems, we compete directly with Roche Diabetes Care, a division of Roche Diagnostics, LifeScan, Inc., a division of Johnson & Johnson, the MediSense and TheraSense divisions of Abbott Laboratories, and Bayer Corporation, each of which manufactures and markets products for the single-point finger stick device market.

Collectively, these companies currently account for substantially all of the worldwide sales of self-monitored glucose testing systems. Several companies are developing or marketing short-term continuous glucose monitoring products that will compete directly with our products. To date, in addition to us, two other companies, Medtronic, Inc. ("Medtronic") and Abbott Diabetes Care, Inc. ("Abbott"), have received approval from the FDA to market, and actively market, continuous glucose monitors. Abbott has discontinued selling its Freestyle Navigator glucose monitoring system in the United States; however, Abbott filed a clinical study for home use of the Navigator II system in the United States and in October 2012, Abbott initiated a limited launch of the Navigator II system in Europe. We believe that Abbott is also conducting clinical studies on a new glucose monitoring platform and has conducted a limited commercial launch of this new system in Europe. We also believe Abbott has submitted a professional use version of this new system to the FDA for review. In addition, we believe that Roche and others, are developing invasive and non-invasive continuous glucose monitoring systems. Also, Medtronic, and other third parties, have developed, or are developing, insulin pumps augmented with continuous glucose monitoring systems that provide, among other things, the ability to suspend insulin administration while the user's glucose levels are low. Most of the companies developing or marketing competing devices are publicly traded or divisions of publicly traded companies, and these companies possess several competitive advantages, 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 offer rebates or 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.

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 Animas and Tandem, to integrate our continuous glucose monitoring technology into their respective insulin delivery systems, and our agreement with GLS to develop a series of next-generation continuous

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glucose monitoring products. We have also entered into an OUS Commercialization Agreement, as amended, with Animas pursuant to which Animas retains the right to develop and market outside the United States an ambulatory insulin pump that is combined with our continuous glucose monitoring technology which has been branded the Vibe. In May 2011, we, together with Animas, received CE Mark certification for the Vibe, allowing it to be marketed in the countries that recognize CE Mark approval. Animas received FDA approval for the Vibe system in December 2014. On September 9, 2015 Tandem received FDA approval for its sensor augmented insulin delivery system, the t:slim G4™ Insulin Pump.

We also previously entered into collaborative agreements with Insulet and Roche neither of which resulted in the successful development of a commercially viable product nor is anticipated to result in significant additional future revenues.

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, similar to the agreements with Roche, 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 assure you 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 achieve acceptance in the marketplace by physicians and people with diabetes.

To date, no continuous glucose monitoring system has received FDA clearance as a replacement for single-point finger stick devices, and our current and future generation products may never be approved for that indication. Our products do not eliminate the need for single-point finger stick devices and our future products may not be approved for that indication. No precedent for FDA approval of continuous glucose monitoring systems as a replacement for single-point finger stick devices has been established. Accordingly, there is no established study design or agreement regarding performance requirements or measurements in clinical trials for continuous glucose monitoring systems. If any of our competitors were to obtain replacement claim labeling for a continuous glucose monitoring system, our products may fail to compete effectively against that system and our business would suffer. 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 approval of a commercially viable continuous glucose monitor or sensor produced by one of our competitors could significantly reduce market acceptance of our systems. Several of our competitors are in various stages of developing continuous glucose monitors or sensors, including non-invasive and invasive devices, and the FDA has approved several of these competing products. In addition, 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 operations, financial condition and results of operations in current periods.

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. We may be subject to product liability

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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 if our products obtain approved labeling in the United States that allows for our patients to make diabetes treatment decisions. 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 for our G5 Mobile system includes an indication that allows patients to make diabetes treatment decisions based on the information generated by such systems, although it still requires finger stick calibrations twice per day. In addition, the FDA or other regulatory agencies may in the future approve similar diabetes treatment indications. We expect that such diabetes treatment indications could expose us to additional liability. These liabilities could prevent or interfere with our product commercialization efforts. Defending a suit, regardless of merit, could be costly, could divert management attention and might result in adverse publicity, which could result in the withdrawal of, or inability to recruit, clinical trial volunteers or result in reduced acceptance of our products in the market.

We may be subject to fines, penalties and injunctions if we are determined to be promoting the use of our products for unapproved 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. If we are found to have violated laws protecting the use and confidentiality of patient health information, we could be subject to civil or criminal penalties, which could increase our liabilities and harm our reputation or our business.

There are a number of federal and state laws protecting the use and confidentiality of certain patient health information, including patient records, and restricting the use and disclosure of that protected information. These laws include state medical privacy laws, breach notification laws and federal and state consumer protection laws. The Department of Health and Human Services has promulgated regulations implementing the privacy and electronic security requirements set forth in the Administrative Simplification provisions of the Health Insurance Portability and Accountability Act of 1996, as amended by the American Recovery and Reinvestment Act of 2009, or HIPAA. These privacy rules protect medical records and other personal health information by limiting their use and disclosure, giving individuals the right to access, amend and seek accounting of their own health information and limiting most use and disclosures of health information to the minimum amount reasonably necessary to accomplish the intended purpose. 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. If we are found to be in violation of the privacy rules under HIPAA or other laws, we could be subject to civil or criminal penalties, which could increase our liabilities, harm our reputation and have a material adverse effect on

our business, financial condition and results of operations.

The majority of our operations are conducted at four 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 a fire, flood, earthquake, an act of terrorism, cyber attack or other disruptive event could cause substantial delays in our operations, damage or destroy our



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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.

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, 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 or potential liability. Security breaches could also cause us to incur significant remediation costs, result in product development delays, disrupt key business operations and divert attention of management and key information technology resources.

If our efforts to protect the security of information about our patients are unsuccessful, we could become subject to costly government enforcement actions and private litigation and our sales and reputation could suffer.

The nature of our business involves the receipt and storage of information about our patients. We have implemented programs to detect and alert us to data security incidents. However, because the techniques used to obtain unauthorized access, disable or degrade service, or sabotage systems change frequently and may be difficult to detect for long periods of time, we may be unable to anticipate these techniques or implement adequate preventive measures. We believe that companies have been increasingly subject to a wide variety of security incidents, cyber-attacks and other attempts to gain unauthorized access. 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 year, 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. If we experience significant data security breaches or fail to detect and appropriately respond to significant data security breaches, we could be exposed to government enforcement actions and private litigation. In addition, our patients could further lose confidence in our ability to protect their information, which could cause them to discontinue using our products or purchasing from us altogether.

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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 system which consists 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 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 G5 Mobile system in the United States in August 2015 and the approval to sell our G5 Mobile system in the countries that recognize our CE Mark means that we have relatively limited experience selling our G5 Mobile system;
- the approval for a Pediatric Indication of our G5 Mobile system in the United States, and the countries that recognize our CE Mark means that we have limited experience selling and marketing the G5 Mobile system to persons aged two to 17 years or their legal guardians;
- the approval for a Professional Use Indication of our G4 PLATINUM system in the United States in June 2014 means that we have limited experience selling and marketing the G4 PLATINUM system to healthcare professionals;
- 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;
- except for the G5 Mobile under the CE Mark, our systems are not labeled as a replacement for the information that is obtained from single-point finger stick devices;
- 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 and G5 Mobile systems are more invasive than current 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 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.

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

Our operations and performance depend on worldwide economic and political conditions, which 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 conditions have 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, we may experience a decrease in revenue 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 experienced job losses and may continue to experience issues gaining timely access to sufficient health insurance or credit, which could result in their unwillingness to purchase products or an impairment of 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 financial condition and operating results.

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.

Healthcare reforms, changes in healthcare policies and changes to third-party reimbursements for our products may affect demand for our products.

Comprehensive healthcare legislation, signed into law in March 2010, imposes 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. The impact of this legislation remains unclear, and costs of compliance with this legislation, or any future amendments thereto, could result in certain risks and expenses that we may have to assume.

Other political and regulatory influences are also subjecting our industry to significant changes, and we cannot predict whether new regulations will emerge at the federal or state level, or abroad. The U.S. government 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 U.S. Presidential administration or Congress.

In addition, the comprehensive healthcare reform legislation included an annual excise tax on the sale of medical devices equal to 2.3% of the price of the device starting on January 1, 2013, which does not include, under Internal Revenue Service (“IRS”) guidance, our existing systems as they are medical devices deemed to be generally purchased by the general public at retail under such legislation. As a result, as of September 30, 2015, we believed that our current ambulatory 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,

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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 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.

Failure to obtain regulatory approval in foreign jurisdictions will prevent us from marketing our products abroad. We conduct limited commercial and marketing efforts in Canada, Europe, Australia, New Zealand, the Middle East, Latin America, Asia and Africa with respect to our continuous glucose monitoring systems and may seek to market our products in other regions in the future. Outside the United States, we can market a product only if we receive a marketing authorization and, in some cases, pricing approval, from the appropriate regulatory authorities. The approval procedure varies among countries and can involve additional testing, and the time required to obtain approval may differ from that required to obtain FDA approval. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval in addition to other risks. We may not obtain foreign regulatory approvals on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA. In addition, in order to obtain the approval of our products in certain foreign jurisdictions, we may need to obtain a Certificate to Foreign Government from the FDA. The FDA may refuse to issue a Certificate to Foreign Government in certain instances, including without limitation, during the pendency of any outstanding warning letter. As a result, we may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products in any market outside the United States on a timely basis, or at all.

Our success will depend on our ability to attract and retain our personnel and our ability to successfully transition from Mr. Gregg to Mr. Sayer as our Chief Executive Officer.

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

Effective January 1, 2015, Mr. Gregg assumed his new role as our Executive Chairman. In this role, Mr. Gregg remains an employee and continues to lead our external efforts. Mr. Gregg also chairs our Board of Directors as of January 1, 2015. Mr. Sayer assumed the role of Chief Executive Officer effective on January 1, 2015. If we are unable to successfully transition the role of Chief Executive Officer from Mr. Gregg to Mr. Sayer, it could have an adverse impact on our financial condition and operating results.

We expect to continue to expand our operations and grow our research and development, manufacturing, sales and marketing, product development and administrative operations. We expect this expansion to place a significant strain on our management and it will require hiring a significant number of qualified personnel. Accordingly, recruiting and retaining such personnel will be critical to our success. There is intense competition from other companies and research and academic

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institutions for qualified personnel in the areas of our activities. If we fail to identify, attract, retain and motivate these skilled personnel, we may be unable to continue our development and commercialization activities.

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

If we are presented with appropriate opportunities, we could acquire or make other investments in complementary companies, products or technologies. In March 2012, we acquired SweetSpot. We may not realize the anticipated benefit of the acquisition of SweetSpot or any future acquisition, or the realization of the anticipated benefits may require greater expenditures than anticipated by us. We will likely face risks, uncertainties and disruptions associated with the integration process, including difficulties in the integration of the operations and services of any acquired company, integration of acquired technology with our products, diversion of our management's attention from other business concerns, the potential loss of key employees or customers of the acquired businesses and impairment charges if future acquisitions are not as successful as we originally anticipate. If we fail to successfully integrate other companies, products or technologies that we acquire, our business could be harmed. Furthermore, we may have to incur debt or issue equity securities to pay for any additional future acquisitions or investments, the issuance of which could be dilutive to our existing shareholders. In addition, our operating results may suffer because of acquisition-related costs or amortization expenses or charges relating to acquired intangible assets.

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

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

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

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

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

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



For instance, estimating the fair value of share-based payments is highly dependent on assumptions regarding the future exercise behavior of our employees and changes in our stock price. The actual values realized upon the exercise, expiration, early termination or forfeiture of share-based payments might be significantly different than our estimates of the fair values of those awards as determined at the date of grant. If there are errors in our input assumptions for our valuations models, we may inaccurately calculate actual or estimated compensation expense for share-based payments.

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

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

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

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

The SEC "conflict minerals" rule has caused us to incur additional expenses, could limit the supply and increase the cost of certain metals used in manufacturing our products, and could make us less competitive in our target markets.

We are required to disclose the origin, source and chain of custody of specified minerals, known as conflict minerals, that are necessary to the functionality or production of products manufactured or contracted to be manufactured. The requirement mandates companies to obtain sourcing data from suppliers, engage in supply chain due diligence, and file annually with the SEC a specialized disclosure report on Form SD covering the prior calendar year. The rule could limit our ability to source at competitive prices and to secure sufficient quantities of certain minerals used in the manufacture of our products, specifically tantalum, tin, gold and tungsten, as the number of suppliers that provide conflict-free minerals may be limited. In addition, we have incurred, and may continue to incur, material costs associated with complying with the rule, such as costs related to the determination of the origin, source and chain of custody of the minerals used in our products, the adoption of conflict minerals-related governance policies, processes and controls, and possible changes to products or sources of supply as a result of such activities. Within our supply chain, we may not be able to sufficiently verify the origins of the relevant minerals used in our products through the data collection and due diligence procedures that we implement, which may harm our reputation. Furthermore, we may encounter challenges in satisfying those customers that require that all of the components of our products be certified as conflict free, and if we cannot satisfy these customers, they may choose a competitor's products. We continue to investigate the presence of conflict materials within our supply chain.

### Risks Related to Our Common Stock

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

Historically, the market price of our common stock, like the securities of many other medical products companies, fluctuates and could continue to be volatile in the future. From January 1, 2015 through November 2, 2015, the closing price of our common stock on the NASDAQ Global Select Market was as high as \$101.91 per share and as low as \$54.21 per share.

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

- securities analyst coverage or lack of coverage of our common stock or changes in their estimates of our financial performance;

- variations in quarterly operating results;
- future sales of our common stock by our stockholders;
- investor perception of us and our industry;
- announcements by us or our competitors of significant agreements, acquisitions or capital commitments;
- changes in market valuation or earnings of our competitors;

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general economic conditions;  
regulatory actions;  
legislation and political conditions; and  
terrorist acts.

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

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

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

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

- our inability to manufacture an adequate supply of product at appropriate quality levels and acceptable costs;
- possible delays in our research and development programs or in the completion of any clinical trials;
- a lack of acceptance of our products in the marketplace by physicians and people with diabetes;
- the inability of customers to receive reimbursements from third-party payors;
- failures to comply with regulatory requirements, which could lead to withdrawal of products from the market;
- our failure to continue the commercialization of any of our continuous glucose monitoring systems;
- competition;
- inadequate financial and other resources; and

global and political economic conditions, political instability and military hostilities.

Failure to comply with covenants in our loan agreement with Silicon Valley Bank and Oxford Finance LLC could result in our inability to borrow additional funds and adversely impact our business.

We have entered into a loan and security agreement with the Silicon Valley Bank and Oxford Finance LLC to fund our business operations. This loan and security agreement imposes numerous financial and other restrictive covenants on our operations, including covenants relating to our general profitability and our liquidity. As of September 30, 2015, we were in compliance with the covenants imposed by the loan and security agreement. If we violate these or any other covenants, any outstanding amounts under these agreements could become due and payable prior to their stated maturity dates, each lender could proceed against any collateral in our operating accounts and our ability to borrow funds in the future may be restricted or eliminated. These restrictions may also limit our ability to borrow additional funds and pursue other business opportunities or strategies that we would otherwise consider to be in our best interests.

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

This issuance of shares by us in the future or sales of shares by our stockholders may cause the market price of our common stock to decline, perhaps significantly, even if our business is performing well. The market price of our common stock could also decline if there is a perception that sales of our shares are likely to occur in the future. This might also make it more difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate. Also, we may issue securities in connection with future financings and acquisitions, and those shares could dilute the holdings of other stockholders.

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

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

foreseeable

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future and the terms of our loan and security agreement restrict our ability to declare or pay any dividends. As a result, stockholders may only receive a return on their investment in our common stock if the market price of our common stock increases.

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

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

• our Board of Directors may, without stockholder approval, issue shares of preferred stock with special voting or economic rights;

• our stockholders do not have cumulative voting rights and, therefore, each of our directors can only be elected by holders of a majority of our outstanding common stock;

• a special meeting of stockholders may only be called by a majority of our Board of Directors, the Chairman of our Board of Directors, or our Chief Executive Officer;

• our stockholders may not take action by written consent;

• our Board of Directors is divided into three classes, only one of which is elected each year; and

• we require advance notice for nominations for election to the Board of Directors or for proposing matters that can be acted upon by stockholders at stockholder meetings.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

Not applicable.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

The following exhibits are filed as a part of this report.

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Exhibit Number	Exhibit Description	Incorporated by Reference			Date of First Filing	Exhibit Number	Provided Herewith
		Form	File No.				
10.33	Collaboration and License Agreement between DexCom Inc., and Google Life Sciences, LLC dated August 10, 2015**						X
31.01	Certification of Chief Executive Officer Pursuant to Securities Exchange Act Rule 13a-14(a).	—	—	—	—		X
31.02	Certification of Chief Financial Officer Pursuant to Securities Exchange Act Rule 13a-14(a).	—	—	—	—		X
32.01	Certification of Chief Executive Officer Pursuant to 18 U.S.C. Section 1350 and Securities Exchange Act Rule 13a-14(b).*	—	—	—	—		X
32.02	Certification of Chief Financial Officer Pursuant to 18 U.S.C. Section 1350 and Securities Exchange Act Rule 13a-14(b).*	—	—	—	—		X
101.INS	XBRL Instance Document						X
101.SCH	XBRL Taxonomy Extension Schema Document						X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document						X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document						X
101.LAB	XBRL Taxonomy Extension Label Linkbase Document						X
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document						X

\* This certification is not deemed “filed” for purposes of Section 18 of the Securities Exchange Act, or otherwise subject to the liability of that section. Such certification will not be deemed to be incorporated by reference into

any filing under the Securities Act of 1933 or the Securities Exchange Act of 1934, except to the extent that DexCom specifically incorporates it by reference.

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



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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

DEXCOM, INC.  
(Registrant)

Dated: November 4, 2015

By: /s/ Kevin R. Sayer  
Kevin R. Sayer,  
President & Chief Executive Officer (Principal  
Executive Officer)

Dated: November 4, 2015

By: /s/ JESS ROPER  
Jess Roper,  
Senior Vice President & Chief Financial Officer  
(Principal Financial and Accounting Officer)