

DEXCOM INC  
Form 10-Q  
November 01, 2016  
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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, 2016

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number 000-51222

DEXCOM, INC.

(Exact name of Registrant as specified in its charter)

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

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

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ 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 <input checked="" type="checkbox"/>	Accelerated Filer <input type="checkbox"/>	Non-Accelerated Filer <input type="checkbox"/>
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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 October 27, 2016, 84,524,171 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, 2016	December 31, 2015
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	\$ 97.7	\$ 86.1
Short-term marketable securities, available-for-sale	29.6	29.1
Accounts receivable, net	76.8	74.1
Inventory	44.7	35.2
Prepaid and other current assets	9.8	6.8
Total current assets	258.6	231.3
Property and equipment, net	88.4	54.7
Intangible assets, net	1.6	2.2
Goodwill	11.8	3.7
Other assets	1.5	0.1
Total assets	\$ 361.9	\$ 292.0
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 58.6	\$ 38.9
Accrued payroll and related expenses	27.0	24.9
Current portion of long-term debt	—	2.3
Current portion of deferred revenue	0.5	0.8
Total current liabilities	86.1	66.9
Other liabilities	14.0	3.9
Total liabilities	100.1	70.8
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, 2016 and December 31, 2015, respectively	—	—
Common stock, \$0.001 par value, 100.0 authorized; 84.8 and 84.5 issued and outstanding, respectively, at September 30, 2016; and 82.0 and 81.7 shares issued and outstanding, respectively, at December 31, 2015	0.1	0.1
Additional paid-in capital	876.0	776.8
Accumulated other comprehensive loss	(0.7	) (0.3 )
Accumulated deficit	(613.6	) (555.4 )
Total stockholders' equity	261.8	221.2
Total liabilities and stockholders' equity	\$ 361.9	\$ 292.0
See accompanying notes		

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DexCom, Inc.

Consolidated Statements of Operations

(In millions—except per share data)

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Product revenue	\$148.6	\$104.2	\$402.1	\$269.9
Development grant and other revenue	—	1.0	—	1.3
Total revenue	148.6	105.2	402.1	271.2
Cost of sales	47.5	30.5	140.4	84.0
Gross profit	101.1	74.7	261.7	187.2
Operating expenses				
Research and development	43.9	64.8	112.4	109.0
Selling, general and administrative	75.7	52.3	207.1	136.9
Total operating expenses	119.6	117.1	319.5	245.9
Operating loss	(18.5 )	(42.4 )	(57.8 )	(58.7 )
Interest income	0.1	—	0.3	—
Interest expense	(0.2 )	(0.1 )	(0.4 )	(0.4 )
Loss before income taxes	(18.6 )	(42.5 )	(57.9 )	(59.1 )
Income tax expense	0.2	—	0.3	—
Net loss	\$(18.8 )	\$(42.5 )	\$(58.2 )	\$(59.1 )
Basic and diluted net loss per share	\$(0.22 )	\$(0.53 )	\$(0.70 )	\$(0.75 )
Shares used to compute basic and diluted net loss per share	84.1	80.5	83.3	79.2
See accompanying notes				

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DexCom, Inc.

Consolidated Statements of Comprehensive Loss

(In millions)

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Net loss	\$(18.8)	\$(42.5)	\$(58.2)	\$(59.1)
Unrealized gain (loss) on short-term available-for-sale marketable securities	—	—	—	—
Foreign currency translation loss	—	—	(0.4 )	(0.2 )
Comprehensive loss	\$(18.8)	\$(42.5)	\$(58.6)	\$(59.3)
See accompanying notes				

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DexCom, Inc.

Consolidated Statements of Cash Flows

(In millions)

(Unaudited)

	Nine Months Ended September 30, 2016    2015	
Operating activities		
Net loss	\$(58.2)	\$(59.1)
Adjustments to reconcile net loss to cash provided by operating activities:		
Depreciation and amortization	11.4	7.7
Share-based compensation	81.7	59.2
Non-cash research and development charge through issuance of common stock	—	36.5
Accretion and amortization related to marketable securities, net	0.2	0.3
Amortization of debt issuance costs	0.1	0.2
Loss on disposal of equipment	0.4	0.3
Changes in operating assets and liabilities:		
Accounts receivable, net	(2.2 )	(13.4 )
Inventory	(8.9 )	(14.6 )
Prepaid and other assets	(4.1 )	—
Restricted cash	—	1.0
Accounts payable and accrued liabilities	18.6	12.8
Accrued payroll and related expenses	2.0	3.1
Deferred revenue	(0.3 )	0.9
Deferred rent and other liabilities	2.2	2.8
Net cash provided by operating activities	42.9	37.7
Investing activities		
Purchase of available-for-sale marketable securities	(30.1 )	(35.4 )
Proceeds from the maturity of available-for-sale marketable securities	29.2	18.8
Purchase of property and equipment	(38.1 )	(21.7 )
Acquisitions, net of cash acquired	0.4	(0.5 )
Net cash used in investing activities	(38.6 )	(38.8 )
Financing activities		
Net proceeds from issuance of common stock	9.9	16.3
Repayment of long-term debt	(2.3 )	(1.7 )
Net cash provided by financing activities	7.6	14.6
Effect of exchange rate changes on cash and cash equivalents	(0.3 )	—
Increase in cash and cash equivalents	11.6	13.5
Cash and cash equivalents, beginning of period	86.1	71.8
Cash and cash equivalents, end of period	\$97.7	\$85.3
Supplemental disclosure of non-cash investing and financing transactions:		
Issuance of common stock in connection with acquisition	\$7.2	\$—
Acquisition-related holdback liability	\$1.8	\$—
Assets acquired and financing obligation under build-to-suit leasing arrangement	\$6.0	\$—
See accompanying notes		



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DexCom, Inc.

Notes to Consolidated Financial Statements

(Unaudited)

### 1. Organization and Summary of Significant Accounting Policies

#### Organization and Business

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

#### Basis of Presentation

We have incurred operating losses since our inception and have an accumulated deficit of \$613.6 million at September 30, 2016. As of September 30, 2016, we had available cash, cash equivalents and marketable securities totaling \$127.3 million and working capital of \$172.5 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, 2017.

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, 2016 are not necessarily indicative of the results that may be expected for the year ending December 31, 2016. 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, 2015 included in the Annual Report on Form 10-K filed by us with the Securities and Exchange Commission on February 23, 2016.

#### Principles of Consolidation

The consolidated financial statements include the accounts of DexCom, Inc. and our wholly owned subsidiaries. All significant intercompany balances and transactions have been eliminated in consolidation.

#### 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. None of the operations of our subsidiaries 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 portions of Europe, and through distribution arrangements in the United States, Canada, Australia, New Zealand, and in portions of Europe, Asia, Latin America, the Middle East 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 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 \$29.0 million and \$81.7 million in share-based compensation expense during the three and nine months ended September 30, 2016, compared to \$22.6 million and \$59.2 million during the three and nine months ended September 30, 2015. At September 30, 2016, unrecognized estimated compensation costs related to unvested restricted stock units totaled \$184.5 million and is expected to be recognized through 2020.

### Revenue Recognition

We sell our durable systems and disposable units through a direct sales force in the United States and portions of Europe, and through distribution arrangements in the United States, Canada, Australia, New Zealand, and in portions of Europe, Asia, Latin America the Middle East 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. Allowances for rebates include contracted discounts with commercial payors and are amounts owed after the final dispensing of the product by a distributor or retail pharmacy to a pharmacy benefit plan participant and are based upon contractual agreements with private sector benefit providers. The allowance for rebates is based on contractual discount rates, expected utilization under each contract and our estimate of the amount of inventory in the distribution channel that will become subject to such rebates. Our estimates for expected utilization for rebates are based on historical rebate claims and to a lesser extent third party market research data. Rebates are generally invoiced and paid monthly or quarterly in arrears so that our accrual consists of an estimate of the amount expected to be incurred for the current month's or quarter's activity, plus an accrual for unpaid rebates from prior periods, and an accrual for inventory in the distribution channel.

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

contracts with certain distributors, including and pharmacy wholesalers, 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 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 shipping point (or Free Carrier shipping point for international orders). Distributors do not have rights of return per their distribution

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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.

### 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.

### Foreign Currency

The financial statements of our foreign subsidiaries 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. Translation related adjustments are recognized as part of comprehensive income and are included in accumulated other comprehensive loss in the consolidated balance sheet. Gains and losses resulting from certain intercompany transactions as well as transactions with customers and vendors that are denominated in currencies other than the functional currency of each subsidiary give rise to foreign exchange gains or losses reflected in operations. To date the results of operations of these subsidiaries and related translation adjustments and foreign exchange gains or losses 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. During the first quarter of 2015, we recorded charges of approximately \$2.0 million in cost of goods sold related to excess and obsolete inventory due to the approval and launch of our DexCom G4 PLATINUM with Share System. During the nine months ended September 30, 2016, we recorded charges of \$3.5 million in cost of goods sold related to excess and obsolete receiver inventory primarily related to the February 23, 2016 customer notification regarding the audible alarms and alerts associated with our receivers which was classified as a voluntary Class 1 recall by the FDA. 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 at maturity.



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### 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.”

### 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

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. The change in goodwill for the three and nine months ended September 30, 2016 compared to December 31, 2015 was primarily due to the acquisition of Nintamed, our distributor in Germany, Switzerland and Austria, based on our preliminary purchase price allocation. The acquisition is part of our strategy to expand our international operations. In connection with the acquisition, we issued 110,993 shares of our common stock with an aggregate value of \$7.2 million as of May 2, 2016 and recorded a \$1.8 million holdback liability within “Other Liabilities” in the Consolidated Balance Sheets, which represents a portion of the purchase price withheld and payable in May 2018, in either cash or common stock at our election, to the extent that certain breaches of the representations and warranties have not occurred. We have determined that the acquisition of Nintamed was a non-material business combination.

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 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

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(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. Early adoption 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.

In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842) (“ASU 2016-02”), which require a lessee to recognize a lease payment liability and a corresponding right of use asset on their balance sheet for all lease terms longer than 12 months, lessor accounting remains largely unchanged. ASU 2016-02 is effective for fiscal years, and interim periods within those years, beginning on or after December 15, 2018 and early adoption is permitted. We are currently evaluating the effect this guidance will have on our consolidated financial statements.

In February 2016, the FASB issued ASU 2016-09, Compensation - Stock Compensation (Topic 718) (“ASU 2016-09”), which is intended to simplify several areas of accounting for share-based payment arrangements. The amendments in this update cover such areas as the recognition of excess tax benefits and deficiencies, the classification of those excess benefits on the statement of cash flows, an accounting policy election for forfeitures, the amount an employer can withhold to cover income taxes and still qualify for equity classification and the classification of those taxes paid on the statement of cash flows. ASU 2016-09 is effective for fiscal years beginning after December 15, 2016, and interim periods within those annual periods, with early adoption permitted. We are currently evaluating the effect this guidance will have on our consolidated financial statements.

## 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.

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

	Three Months Ended September 30, 2016		Nine Months Ended September 30, 2015	
Options outstanding to purchase common stock	0.8	1.6	0.8	1.6
Unvested restricted stock units	3.7	4.2	3.7	4.2
Total	4.5	5.8	4.5	5.8



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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, 2016			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Market Value
U.S. government agencies	\$ 22.4	\$ —	\$ —	\$ 22.4
Corporate debt	3.2	—	—	3.2
Commercial paper	4.0	—	—	4.0
Total	\$ 29.6	\$ —	\$ —	\$ 29.6

	December 31, 2015			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Market Value
U.S. government agencies	\$ 22.1	\$ —	\$ —	\$ 22.1
Corporate debt	4.9	—	—	4.9
Commercial paper	2.1	—	—	2.1
Total	\$ 29.1	\$ —	\$ —	\$ 29.1

As of September 30, 2016, the estimated market value of available-for-sale marketable securities with contractual maturities of up to one year and up to 18 months were \$25.1 million and \$4.5 million, respectively.

## Inventory

	September 30, 2016	December 31, 2015
Raw materials	\$ 17.5	\$ 16.0
Work-in-process	2.6	2.6
Finished goods	24.6	16.6
Total	\$ 44.7	\$ 35.2

## Accounts Payable and Accrued Liabilities

	September 30, 2016	December 31, 2015
Accounts payable trade	\$ 26.3	\$ 19.0
Accrued tax, audit, and legal fees	3.7	2.1
Clinical trials	0.6	0.7
Pharmacy rebates	6.9	4.0
Accrued other including warranty	21.1	13.1
Total	\$ 58.6	\$ 38.9

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## 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, 2016 and 2015 were as follows:

	Three Months Ended September 30, 2016		Nine Months Ended September 30, 2015	
Beginning balance	\$7.9	\$1.2	\$3.3	\$1.3
Charges to costs and expenses	5.2	1.9	18.7	4.9
Costs incurred	(4.8 )	(1.8 )	(13.7)	(4.9 )
Ending balance	\$8.3	\$1.3	\$8.3	\$1.3

## Other Liabilities

	September 30, 2016	December 31, 2015
Financing lease obligations	\$ 6.0	\$ —
Deferred rent	5.2	3.8
Other	2.8	0.1
Total	\$ 14.0	\$ 3.9

## 4. Commitments and Contingencies

## Revolving Credit Agreement

In June 2016, we entered into a \$200.0 million revolving credit agreement (the “Credit Agreement”) with JPMorgan Chase Bank, NA, as administrative agent, Bank of America, Silicon Valley Bank and Union Bank. In addition to allowing borrowings in US dollars, the Credit Agreement provides a \$25.0 million sublimit for borrowings in Canadian Dollars, Euros, British Pounds, Swedish Krona, Japanese Yen and any other currency that is subsequently approved by JPMorgan Chase and each lender. The Credit Agreement also provides a sub-facility of up to \$10.0 million for letters of credit. The interest rate under the Credit Agreement ranges from 0.75% to 2.75% plus our choice of one of two base rates, LIBOR or a rate based on the publicly announced JPMorgan Chase prime rate, the federal funds rate or the overnight bank funding rate. We will also pay a commitment fee of between 0.25% and 0.45%, payable quarterly in arrears, on the average daily unused amount of the revolving facility based on our leverage ratio. The aggregate debt issuance costs and fees incurred with respect to entering into the Credit Agreement were \$0.7 million, which have been capitalized on our Consolidated Balance Sheet within “Other Assets” and will be amortized through the maturity date of June 2021 on a straight line basis, which approximates the effective interest method. As of September 30, 2016 we had no outstanding borrowings under the Credit Agreement.

## 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 revolving line of credit expired as of November 2015 with no amounts drawn or outstanding. In accordance with the Loan Agreement, \$7.0 million was advanced under the Term Loan at the funding date in November 2012 and the remaining \$13.0 million in additional funds expired unused. In June 2016, we paid off the remaining principal balance under the Term Loan.

## Leases

Under the office lease agreement, as amended (the “Office Lease”), with John Hancock Life Insurance Company (U.S.A.) (the “Landlord”) we lease approximately 219,000 square feet of space in the buildings at 6340 Sequence Drive, 6310 Sequence Drive and 6290 Sequence Drive. The amended lease term extends through March 2022 and we have an option to renew the lease upon the expiration of the initial term for two additional five-year terms by giving notice

to the Landlord prior to the end of the initial term of the lease and any extension period, if applicable. Provided we are not in default under the Office Lease and the Office Lease is still in effect, we generally have the right to terminate the lease starting at the 55<sup>th</sup> month of the Office Lease. In September 2015, we received \$1.8 million of tenant improvement allowance associated with the Office Lease, which was recorded as a deferred rent obligation and will be amortized over the term of the lease and reflected as a reduction to

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rent expense. Leasehold improvements associated with the tenant improvement allowance are included in Property and equipment, net in our consolidated balance sheet. On February 1, 2016, we entered into a Sublease (the “Sublease”) with Entropic Communications, LLC with respect to the building at 6350 Sequence Drive in San Diego, California (the “6350 Building”). Under the Sublease, we have leased approximately 132,600 square feet of space in the 6350 Building. The lease term extends through January 2022.

On April 28, 2016, we entered into a certain Industrial Net Lease (the “Mesa Lease”) with PRA/LB, L.L.C. with respect to facilities in the building at 232 South Dobson Road in Mesa, Arizona (the “Mesa Building”). Under the Mesa Lease, we have leased approximately 148,797 square feet of space in the Mesa Building, of which approximately 78,000 square feet was available to us on May 1, 2016 and the remaining portion of the Mesa Building will become available to us on or around January 1, 2018. The term of the Mesa Lease extends through March 2028 with four extension options, each with five-year terms. The lease arrangement involves the construction of our new manufacturing facility where we are involved in the design and construction of the leased space, including non-standard tenant improvements paid for by us. This arrangement is referred to as build-to suit lease and for accounting purposes, we are considered the owner of the construction project during the construction period. As of September 30, 2016, we have capitalized the fair value of the Mesa Building of \$6.0 million within “Property and Equipment, net,” and recorded a corresponding financing lease obligation liability of \$6.0 million within “Other Liabilities” in the Consolidated Balance Sheet. At the conclusion of the construction period we will evaluate the Mesa Lease to determine whether or not it meets the criteria for “sale-leaseback” treatment.

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

Rental obligations, excluding real estate taxes, operating costs, and tenant improvement allowances, under all lease agreements as of September 30, 2016 were as follows (in millions):

Fiscal Year Ending

Remainder of 2016	\$ 1.6
2017	7.4
2018	9.8
2019	10.7
2020	11.1
Thereafter	24.3
Total	\$64.9

Total rent expense for the three and nine months ended September 30, 2016 was \$2.4 million and \$6.6 million, compared to \$1.4 million and \$4.2 million for the same periods of 2015.

Litigation

On March 28, 2016, AgaMatrix, Inc. (“AgaMatrix”) filed a patent infringement lawsuit against us in the United States District Court for the District of Oregon, asserting that certain of our products infringe certain patents held by AgaMatrix. On June 6, 2016, AgaMatrix filed a First Amended Complaint asserting the same three patents. On August 25, 2016, we filed petitions for inter partes review with the Patent Trial and Appeal Board of the United States Patent and Trademark Office seeking a determination that two of the three asserted patents are invalid under the U.S. patent law. It is our position that AgaMatrix’s assertions of infringement have no merit. On August 6, 2016, we filed a patent infringement lawsuit in the United States Central District Court of California, asserting certain AgaMatrix products infringed a patent held by us. On September 30, 2016 we filed a First Amended Complaint asserting the same patent. We believe certain AgaMatrix single-point blood glucose monitoring products infringe the asserted patent. Neither the outcome of the litigation nor the amount and range of potential awards or fees associated with the litigation can be assessed at this time. As of September 30, 2016, no amounts have been accrued in respect of this litigation.

We are subject to various claims, complaints and legal actions that arise from time to time in the normal course of business, including product liability and employment related matters. In addition, from time to time, we may bring claims or initiate lawsuits against various third parties with respect to matters arising out of the ordinary course of our business, including commercial and employment related matters. We do not expect that the resolution of these matters would, or will, have a material adverse effect or material impact on our consolidated financial position.

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### 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, 2016, we had purchase commitments with vendors totaling \$63.2 million due within one year. There are no material purchase commitments due beyond one year.

### Other

On May 2, 2016, we entered into a Standard Form of Agreement (the “Skanska Contract”) with Skanska USA Building Inc. (the “Contractor”), providing for construction and design services to build out our new manufacturing facility in the Mesa Building. The first phase of construction began in the second quarter of 2016 and is expected to be completed in mid-2017. The total expenditures under the Skanska Contract are currently anticipated to be approximately \$30 million. As of September 30, 2016 we have paid \$4.9 million under the Skanska Contract.

### 5. Development and Other Agreements

#### Collaboration with Verily Life Sciences

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

The terms of Verily 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 Verily Collaboration Agreement. In addition, we will pay Verily 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 Verily 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 during 2015 related to the issuance of the 404,591 shares of our common stock, based on our stock price of \$90.29 per share as of the date of Verily Collaboration Agreement.

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

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

#### 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

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Agreement. 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.

In September 2015, we received a 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 twelve months ended December 31, 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.

## 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, 2016 (in millions):

	Fair Value Measurements Using		
	Level 1	Level 2	Level 3 Total
Cash equivalents	\$—\$ 31.8	\$	—\$31.8
Marketable securities, available for sale			
U.S. government agencies	—22.4	—	22.4
Corporate debt	—3.2	—	3.2
Commercial paper	—4.0	—	4.0
Total marketable securities, available for sale	\$—\$ 29.6	\$	—\$29.6

The following table represents our fair value hierarchy for our financial assets (cash equivalents and marketable securities) measured at fair value on a recurring basis as of December 31, 2015 (in millions):

	Fair Value Measurements Using		
	Level 1	Level 2	Level 3 Total
Cash equivalents	\$—\$ 32.1	\$	—\$32.1
Marketable securities, available for sale			
U.S. government agencies	—22.1	—	22.1
Corporate debt	—4.9	—	4.9
Commercial paper	—2.1	—	2.1
Total marketable securities, available for sale	\$—\$ 29.1	\$	—\$29.1



There were no transfers between Level 1 and Level 2 securities during the three and nine months ended September 30, 2016 and 2015. There were no transfers into or out of Level 3 securities during the three and nine months ended September 30, 2016 and 2015.

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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 other reports filed with the SEC. We assume no obligation to update any of the forward-looking statements after the date of this report or to conform these forward-looking statements to actual results.

Overview

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

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 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 2015, 415 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 2040, the worldwide incidence of people suffering from diabetes will reach 642 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 5 million deaths attributable to diabetes globally in 2015 between the ages of 20 and 79 years. 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 with ages of less than 30 years 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, 1.9 million people will be diagnosed with diabetes this year, approximately 5,082 people per day. In 2012 alone there were about 1.7 million people 20 years or older diagnosed. 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 an estimated \$673 to \$1,197 billion globally in 2015. The IDF estimates that expenditures attributable to diabetes will grow to a range of \$802 to \$1,452 billion globally by 2040.

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

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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, Latin America, the Middle East 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 Food and Drug Administration (“FDA”) and commercialized our first product in 2006. 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 PLUS system. 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. 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 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 including without limitation, associated DexCom Share System functionalities) that are commercialized by us in and outside of the United States.

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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 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. On July 21, 2016, the Clinical Chemistry and Clinical Toxicology Devices Panel (the "Panel") of the FDA voted to recommend our proposed non-adjunctive indication for the G5 Mobile. This recommendation is non-binding and we remain in discussions with the FDA concerning the formal approval of our PMA for the expanded non-adjunctive indication for 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.

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

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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. SweetSpot's software provides an advanced cloud-based platform for uploading, processing and delivering health data and transforms raw output from certain medical devices into useful information for healthcare providers, individuals and researchers.

### 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 development agreements with Animas Corporation ("Animas"), a subsidiary of Johnson & Johnson, and in 2012 and 2015 we entered into development agreements with Tandem Diabetes Care, Inc. ("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 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 2015. In July 2014, Tandem filed their submission for FDA approval of their CGM-enabled insulin pump in the United States. In September 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 in September 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. 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 "Verily Collaboration Agreement") with Google Life Sciences LLC, now named Verily Life Sciences ("Verily"). Pursuant to the Verily Collaboration Agreement, we and Verily have agreed to jointly develop a series of next-generation continuous glucose monitoring products. The Verily Collaboration Agreement provides us with an exclusive license to use certain intellectual property of Verily related to the development, manufacture and commercialization of the products contemplated under the Verily Collaboration Agreement. The Verily Collaboration Agreement provides for the establishment of a joint steering committee, joint development committee and joint commercialization committee to oversee and coordinate the parties' activities under the collaboration. We and Verily have agreed to make committee decisions by consensus.

### Commercial Operations

We have built a direct sales organization in the United States, and are building a direct sales force in portions of Europe, to call on endocrinologists, pediatric endocrinologists, physicians, pediatricians and diabetes educators who can educate and influence patient adoption of continuous glucose monitoring. We believe that focusing efforts on these participants is important given the instrumental role they each play in the decision-making process for diabetes therapy. To complement our direct sales efforts, we have entered into 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

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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 1, 2016, 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 2016. 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 facilities in San Diego, California. As of September 30, 2016, 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 a warning letter from the FDA related to administrative deficiencies in filing MDRs, also referred to as the 2014 Warning Letter. 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. During a routine FDA post-market inspection ending on March 29, 2016, the FDA issued a Form 483 with one observation regarding the DexCom MDR procedure specific to retrospective MDR filing when a change in complaint reportability is made. On April 19, 2016 DexCom responded to this observation. On June 2, 2016 we received a copy of the final Establishment Inspection Report from the FDA, which we believe reflects the resolution of this observation without further FDA action.

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.

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 and portions of Europe, as well as through distribution arrangements in the United States, Canada, Australia, New Zealand, and in portions of Europe, Asia, Latin America, the Middle East 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. Our 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.

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As of September 30, 2016, we had an accumulated deficit of \$613.6 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 provided 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”). The revolving line of credit expired as of November 2015 with no amounts drawn or outstanding. In accordance with the Loan Agreement, \$7.0 million was advanced under the Term Loan at the funding date in November 2012, and the remaining \$13.0 million in additional funds expired unused. In June 2016, we paid off the remaining principal balance under the Term Loan. In June 2016, we entered into a \$200.0 million Credit Agreement with JPMorgan Chase Bank, NA, as administrative agent, Bank of America, Silicon Valley Bank and Union Bank. The Credit Agreement provides a subfacility of up to \$10.0 million for letters of credit.

### Financial Operations

#### Revenue

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

#### Cost of Sales

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

#### Research and Development

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

#### Selling, General and Administrative

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

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### Results of Operations

#### Quarter Ended September 30, 2016 Compared to September 30, 2015

##### Revenue, Cost of Sales and Gross Profit

Total revenue increased \$43.4 million to \$148.6 million for the three months ended September 30, 2016 compared to \$105.2 million for the three months ended September 30, 2015, primarily due to increased sales volume of our disposable sensors resulting from 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% of total revenue for the three months ended September 30, 2016, and was approximately 70% and 30% of total revenue for the three months ended September 30, 2015, respectively. Total revenue for the three months ended September 30, 2015 also included development grant and other revenues of \$1.0 million attributable to milestone payments related to our development agreement with Tandem.

Revenue from products shipped to our Drop-Ship Distributors' customers was \$2.5 million, or 2%, of our total revenues for the three months ended September 30, 2016 compared to \$9.3 million, or 9%, of our total revenues for the three months ended September 30, 2015. Revenue from products shipped to Stocking Distributors was \$102.4 million, or 69%, of our total revenues for the three months ended September 30, 2016 compared to \$68.1 million, or 65%, of our total revenues for the three months ended September 30, 2015.

Cost of sales increased \$17.0 million to \$47.5 million for the three months ended September 30, 2016 compared to \$30.5 million for the three months ended September 30, 2015, primarily due to increased sales volume. Gross profit increased \$26.4 million to \$101.1 million for the three months ended September 30, 2016 compared to \$74.7 million for the same period in 2015, primarily due to increased revenue, partially offset by the product mix of sales of our lower margin G5 transmitters.

Research and Development. Research and development expense decreased \$20.9 million to \$43.9 million for the three months ended September 30, 2016 compared to \$64.8 million for the three months ended September 30, 2015. The decrease in research and development costs for the three months ended September 30, 2016 compared to the three months ended September 30, 2015 was due to \$36.5 million of noncash expense related to the issuance of the 404,591 shares in August 2015 related to the Verily Collaboration Agreement, partially offset by \$7.0 million in additional salaries, bonus and payroll related costs, \$3.1 million in additional share-based compensation, and \$0.9 million in additional facilities related costs.

Selling, General and Administrative. Selling, general and administrative expense increased \$23.4 million to \$75.7 million for the three months ended September 30, 2016 compared to \$52.3 million for the three months ended September 30, 2015. The increase was primarily due to higher headcount related selling, marketing and information technology infrastructure costs to support revenue growth and the continued commercialization of our products. Significant elements of the increase in selling, general, and administrative expenses included \$8.0 million in additional salaries, bonus, and payroll related costs, \$3.4 million of additional consulting fees, \$2.2 million in additional share-based compensation costs, \$1.6 million in additional marketing costs, \$1.1 million of additional software license costs, and \$0.8 million in additional facilities related costs.

Interest Income. Interest income was \$0.1 million for the three months ended September 30, 2016 and is related to our marketable securities portfolio.

Interest Expense. Interest expense was \$0.2 million for the three months ended September 30, 2016 and \$0.1 million for the three months ended September 30, 2015 and is related to our Loan Agreement and Revolving Credit Agreement.

Income Tax Expense. Income tax expense was \$0.2 million for the three months ended September 30, 2016, and is primarily related to state minimum taxes and foreign income taxes related to our international subsidiaries.

#### Nine Months Ended September 30, 2016 Compared to September 30, 2015

##### Revenue, Cost of Sales and Gross Profit

Total revenues increased \$130.9 million to \$402.1 million for the nine months ended September 30, 2016 compared to \$271.2 million for the nine months ended September 30, 2015 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 revenue, for each of the nine months ended September 30, 2016 and 2015. Total revenue for the nine months ended September 30, 2015 also included development grant and other revenues of \$1.3 million attributable to a \$1.0 million milestone payments related to our development agreement with Tandem and services associated with clinical supply and services agreements.

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Revenue from products shipped to our Drop-Ship Distributors' customers was \$20.8 million, or 5%, of our total revenues for the nine months ended September 30, 2016 compared to \$26.3 million, or 10%, of our total revenues for the nine months ended September 30, 2015. Revenue from products shipped to Stocking Distributors was \$268.3 million, or 67%, of our total revenues for the nine months ended September 30, 2016 compared to \$169.5 million, or 63%, of our total revenues for the nine months ended September 30, 2015.

Cost of sales increased \$56.4 million to \$140.4 million for the nine months ended September 30, 2016 compared to \$84.0 million for the nine months ended September 30, 2015, primarily due to increased sales volume, partially due to increased warranty costs related to receivers, and \$3.5 million in receiver related excess and obsolete inventory charges primarily related to the customer notification as discussed in the Risk Factor entitled "If we or our suppliers or distributors fail to comply with ongoing regulatory requirements, or if we experience unanticipated problems with our products, the products could be subject to restrictions or withdrawal from the market." The gross profit of \$261.7 million for the nine months ended September 30, 2016 increased \$74.5 million compared to \$187.2 million for the same period in 2015, primarily due to increased revenue, partially offset by the product mix of sales of our lower margin G5 transmitters and costs related to the customer notification discussed above.

Research and Development. Research and development expense increased \$3.4 million to \$112.4 million for the nine months ended September 30, 2016, compared to \$109.0 million for the nine months ended September 30, 2015.

Research and development expense for the nine months ended September 30, 2015 included \$36.5 million of noncash expense related to the issuance of 404,591 shares in August 2015 related to the Verily Collaboration Agreement.

Excluding this one-time noncash charge, research and development expense for the nine months ended September 30, 2016 increased \$39.9 million with the significant elements of the increase comprised of \$15.2 million in additional salaries, bonus and payroll related costs, \$8.6 million in additional share-based compensation, \$3.3 million in additional supplies, \$1.9 million of additional facilities related costs, and \$1.6 million in additional consulting expenses.

Selling, General and Administrative. Selling, general and administrative expense increased \$70.2 million to \$207.1 million for the nine months ended September 30, 2016, compared to \$136.9 million for the nine months ended September 30, 2015. The increase was primarily due to higher headcount related selling, marketing and information technology infrastructure costs to support revenue growth and the continued commercialization of our products.

Significant elements of the increase in selling, general, and administrative expenses included \$20.1 million in additional salaries, bonus, and payroll related costs, \$10.5 million in additional share-based compensation costs, \$7.3 million of additional consulting fees, \$6.8 million in additional marketing costs, \$2.8 million of additional software license costs, \$1.8 million of additional facilities related costs, \$1.9 million of additional commissions, and \$1.5 million of additional costs to support our international expansion.

Interest Income. Interest income was \$0.3 million for the nine months ended September 30, 2016 and is related to our marketable securities portfolio.

Interest Expense. Interest expense was \$0.4 million for the nine months ended September 30, 2016 compared to \$0.4 million for the nine months ended September 30, 2015 and is related to our Loan Agreement and Revolving Credit Agreement.

Income Tax Expense. Income tax expense was \$0.3 million for the nine months ended September 30, 2016, and is primarily related to state minimum taxes and foreign income taxes related to our international subsidiaries.

Table of Contents**Liquidity and Capital Resources**

We have incurred losses since our inception in May 1999. As of September 30, 2016, we had an accumulated deficit of \$613.6 million and had working capital of \$172.5 million. To date, we have funded our operations primarily through offerings of equity securities and debt, and the sales of our products. In June 2016, we entered into a \$200.0 million Credit Agreement, including a subfacility of up to \$10.0 million for letters of credit. The revolving loans under the Credit Agreement will be available for general corporate purposes, including working capital and capital expenditures.

Our cash, cash equivalents and marketable securities totaled \$127.3 million as of September 30, 2016. Our cash, cash equivalents, and marketable securities portfolio is denominated in U.S. dollars and consists of investment grade, highly liquid securities of various holdings including obligations of U.S. government sponsored enterprises, commercial paper, corporate debt, and money market funds. The change in our cash, cash equivalents and marketable securities during the nine months ended September 30, 2016 was due to the factors described in the “Cash Flow Summary” below.

**Cash Flow Summary**

The following table sets forth a summary of our cash flows for the periods indicated (in millions)

	Nine Months		
	Ended		Change
	September 30,		
	2016	2015	
Net cash provided by operating activities	\$42.9	\$37.7	\$ 5.2
Net cash used in investing activities	\$(38.6)	\$(38.8)	\$ 0.2
Net cash provided by financing activities	\$7.6	\$14.6	\$(7.0 )

As of September 30, 2016, we had \$97.7 million of cash and cash equivalents compared to \$86.1 million as of December 31, 2015, an increase of \$11.6 million. The cash flows during the nine months ended September 30, 2016 were related primarily to the following items:

**Cash inflows:**

Net cash provided by operations of \$42.9 million comprised of net loss of \$58.2 million, changes in working capital balances of \$7.3 million, offset by \$93.8 million positive adjustments to accrual based net loss for non-cash items primarily related to share-based compensation, depreciation and amortization;

Proceeds from issuance of common stock of \$9.9 million.

**Cash outflows:**

Cash used of \$0.9 million as a result of marketable securities transactions;

Capital expenditures of \$38.1 million primarily related to purchase of manufacturing equipment, facility related build-outs and office equipment;

Repayments of debt of \$2.3 million.

**Net Cash Provided by Operating Activities.** The increase in cash provided by operations was primarily due to \$0.9 million in lower net loss, an additional \$14.7 million cash inflow from changes in operating assets and liabilities, and \$22.5 million of additional non-cash share-based compensation, partially offset by \$36.5 million in lower non-cash charges related to the issuance of 404,591 shares in August 2015 related to the Verily Collaboration Agreement. The main drivers in the change in operating assets and liabilities included increases in inventory, accounts payable, accrued payroll and other 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 \$15.7 million net increase in cash as a result of marketable securities transactions, offset by the use of an additional \$16.4 million to purchase equipment to support facility related build-outs, manufacturing equipment and information technology infrastructure.



Net Cash Provided by Financing Activities. The decrease in cash provided by financing activities was due to \$6.4 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, 2016 compared to the nine months ended September 30, 2015, and \$0.6 million increase in loan payments as a result of the payoff of the remaining principal balance under the Term Loan.

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### 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 domestically and internationally, develop additional continuous glucose monitoring products, and expand our marketing, manufacturing and corporate infrastructure.

We believe that our cash, cash equivalents, marketable securities balances, projected cash contributions from our commercial operations and \$200.0 million available under our Credit Agreement 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, 2017. If our available cash, cash equivalents and marketable securities are insufficient to satisfy our liquidity requirements, or if we develop additional products or new markets for our existing products, we may seek to sell additional equity or debt securities or obtain an additional credit facility. The sale of additional equity and debt securities may result in additional dilution to our stockholders. If we raise additional funds through the issuance of debt securities or preferred stock, these securities could have rights senior to those of our common stock and could contain covenants that would restrict our operations. We may require additional capital beyond our currently forecasted amounts. Any such required additional capital may not be available on reasonable terms, if at all. Additionally, we cannot guarantee that we will be successful in obtaining additional cash contributions from future partnership arrangements. Our ability to transition to, and maintain profitable operations is dependent upon achieving a level of revenues adequate to support our cost structure. If events or circumstances occur such that we do not meet our operating plan as expected, or if we are unable to obtain additional financing, we may be required to reduce planned increases in compensation related expenses or other operating expenses related to research, development, and commercialization activities, which could have an adverse impact on our ability to achieve our intended business objectives.

Because of the numerous risks and uncertainties associated with the development of continuous glucose monitoring technologies, we are unable to estimate the exact amounts of capital outlays and operating expenditures associated with our current and anticipated clinical trials. Our future funding requirements will depend on many factors, including, but not limited to:

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

### Contractual Obligations

We are party to various purchase arrangements related to components used in manufacturing and research and development activities. As of September 30, 2016, we had firm purchase commitments with certain vendors totaling approximately \$63.2 million due within one year. There are no material purchase commitments due beyond one year. We are party to various leasing arrangements as described in the Management's Discussion and Analysis of Financial Condition and Results of Operations in Item 7 of our Annual Report on Form 10-K for the fiscal year ended December 31, 2015. We have entered into the following new leasing arrangements during the nine months ended September 30, 2016:

• On February 1, 2016, we entered into a Sublease (the "Sublease") with Entropic Communications, LLC with respect to the building at 6350 Sequence Drive in San Diego, California (the "6350 Building"). Under the Sublease, we have

leased approximately 132,600 square feet of space in the 6350 Building. The lease term extends through January 2022. The total obligation for rent under the life of the lease is \$14.5 million, excluding real estate taxes and operating costs.

On April 28, 2016, we entered into a certain Industrial Net Lease (the “Mesa Lease”) with PRA/LB, L.L.C. with respect to facilities in the building at 232 South Dobson Road in Mesa, Arizona (the “Mesa Building”). Under the

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Mesa Lease, we have leased approximately 148,797 square feet of space in the Mesa Building, of which approximately 78,000 square feet was available to us on May 1, 2016 and the remaining portion of the Mesa Building will become available to us on or around January 1, 2018. The term of the Mesa Lease extends through March 2028 with four extension options, each with five year terms. The total obligation for rent under the lease term ending March 2028 is approximately \$15.3 million, excluding real estate taxes and operating costs.

The following table summarizes our outstanding contractual obligations as of September 30, 2016 and the effect those obligations are expected to have on our liquidity and cash flows in future periods (in millions):

Contractual Obligations:	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years (1)
Operating leases	\$64.9	\$ 1.6	\$17.2	\$21.8	\$ 24.3
Purchase commitments	63.2	63.2	—	—	—
Total	\$128.1	\$64.8	\$17.2	\$21.8	\$ 24.3

**Other**

On May 2, 2016, we entered into that certain Standard Form of Agreement (the “Skanska Contract”) with Skanska USA Building Inc. (the “Contractor”), providing for construction and design services to build out our new manufacturing facility in the Mesa Building. The first phase of construction began in the second quarter of 2016 and is expected to be completed in mid-2017. The total expenditures under the Skanska Contract are currently anticipated to be approximately \$30 million. As of September 30, 2016 we have paid \$4.9 million under the Skanska Contract.

**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, 2015. 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, 2015. There were no material changes to our critical accounting policies during the nine months ended September 30, 2016.

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### 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 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.

In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842) ("ASU 2016-02"), which require a lessee to recognize a lease payment liability and a corresponding right of use asset on their balance sheet for all lease terms longer than 12 months, lessor accounting remains largely unchanged. ASU 2016-02 is effective for fiscal years, and interim periods within those years, beginning on or after December 15, 2018 and early adoption is permitted. We are currently evaluating the effect this guidance will have on our consolidated financial statements.

In February 2016, the FASB issued ASU 2016-09, Compensation - Stock Compensation (Topic 718) ("ASU 2016-09"), which is intended to simplify several areas of accounting for share-based payment arrangements. The amendments in this update cover such areas as the recognition of excess tax benefits and deficiencies, the classification of those excess benefits on the statement of cash flows, an accounting policy election for forfeitures, the amount an employer can withhold to cover income taxes and still qualify for equity classification and the classification of those taxes paid on the statement of cash flows. ASU 2016-09 is effective for fiscal years beginning after December 15, 2016, and interim periods within those annual periods, with early adoption permitted. We are currently evaluating the effect this guidance will have on our consolidated financial statements.

### 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



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

**Changes in Internal Control Over Financial Reporting**

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

**Limitation on Effectiveness of Controls**

It should be noted that any system of controls, however well designed and operated, can provide only reasonable, and not absolute, assurance that the objectives of the system are met. The design of any control system is based, in part, upon the benefits of the control system relative to its costs. Control systems can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the control. In addition, over time, controls may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate. Because of these and other inherent limitations of control systems, there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions, regardless of how remote.

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### PART II OTHER INFORMATION

#### ITEM 1. LEGAL PROCEEDINGS

On March 28, 2016, AgaMatrix, Inc. (“AgaMatrix”) filed a patent infringement lawsuit against us in the United States District Court for the District of Oregon, asserting that certain of our products infringe certain patents held by AgaMatrix. On June 6, 2016, AgaMatrix filed a First Amended Complaint asserting the same three patents. On August 25, 2016, we filed petitions for inter partes review with the Patent Trial and Appeal Board of the United States Patent and Trademark Office seeking a determination that two of the three asserted patents are invalid under the U.S. patent law. It is our position that AgaMatrix’s assertions of infringement have no merit. On August 6, 2016, we filed a patent infringement lawsuit in the United States Central District Court of California, asserting certain AgaMatrix products infringed a patent held by us. On September 30, 2016 we filed a First Amended Complaint asserting the same patent. We believe certain AgaMatrix single-point blood glucose monitoring products infringe the asserted patent. Neither the outcome of the litigation nor the amount and range of potential awards or fees associated with the litigation can be assessed at this time. As of September 30, 2016, no amounts have been accrued in respect of this litigation.

We are subject to various claims, complaints and legal actions that arise from time to time in the normal course of business, including product liability and employment related matters. In addition, from time to time, we may bring claims or initiate lawsuits against various third parties with respect to matters arising out of the ordinary course of our business, including commercial and employment related matters. We do not believe we are party to any currently pending legal proceedings, the outcome of which could have a material adverse effect on our 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

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

##### 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 \$58.2 million for the nine months ended September 30, 2016. As of September 30, 2016, we had an accumulated deficit of \$613.6 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.

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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 dispersed sales and marketing operations.

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

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

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 Verily (formerly 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, 2016, we generated \$42.9 million in net cash from operating activities, compared to \$37.7 million generated for the same period in 2015, and as of September 30, 2016, we had working capital of \$172.5 million which included \$127.3 million in cash, cash equivalents and short-term marketable securities. Although we expect that our cash generated by operations will increase in each of the next several years, 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;  
the cost of ongoing compliance with legal and regulatory requirements, and third party payors' policies;

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the cost of obtaining and maintaining regulatory or payor clearance or approval for our current or future products including those integrated with other companies' products; and

the acquisition of 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 17% and 11% respectively, of our total revenue during the nine months ended September 30, 2016. 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.

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 1, 2016, 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. We are unable to predict what

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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. Furthermore, payors are increasingly basing reimbursement rates on factors such as the efficacy of the product, and clinical outcomes associated with the product, and any factors that negatively impact the efficacy or clinical outcomes (or cause a perception of any such negative impact), such as the results of a clinical trial, a product defect, or a product recall, could negatively impact the reimbursement rate,

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

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 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. In addition, we intend to seek either 510(k) clearances or PMA approvals for certain changes and modifications to our existing software platform, but cannot predict when, if ever, those changes and modifications will be approved.

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

- the system may not be deemed by the FDA to be substantially equivalent to appropriate predicate devices;
- the system may not satisfy the FDA's safety or efficacy requirements;
- the data from pre-clinical studies and clinical trials may be insufficient to support approval;
- the manufacturing process or facilities used may not meet applicable requirements; and
- changes in FDA approval policies or adoption of new regulations may require additional data.

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

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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 products, FDA approval of an IDE application permitting us to conduct testing does not mean that the FDA will consider the data gathered in the trial to be sufficient to support approval of a