
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, 2021

☐ **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

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DEXCOM, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation or organization)

33-0857544
(I.R.S. Employer Identification No.)

6340 Sequence Drive, San Diego, CA 92121
(Address of principal executive offices)

(858) 200-0200

(Registrant's telephone number, including area code)

(Former name, former address and former fiscal year, if changed since last report)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.001 Par Value Per Share	DXCM	Nasdaq Global Select Market

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

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

Large accelerated filer	<input checked="" type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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

As of October 21, 2021, there were 96,922,034 shares of the registrant's common stock outstanding

DexCom, Inc.
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PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

DexCom, Inc. Consolidated Balance Sheets (Unaudited)

(In millions, except par value data)

	September 30, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	\$ 1,444.3	\$ 817.6
Short-term marketable securities	1,253.6	1,890.1
Accounts receivable, net	529.1	428.5
Inventory	351.3	234.7
Prepaid and other current assets	77.9	53.9
Total current assets	3,656.2	3,424.8
Property and equipment, net	742.2	515.3
Operating lease right-of-use assets	91.3	93.3
Goodwill	23.9	19.3
Deferred tax assets	216.3	216.4
Intangibles and other assets, net	46.0	21.4
Total assets	\$ 4,775.9	\$ 4,290.5
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 598.0	\$ 481.1
Accrued payroll and related expenses	115.3	114.3
Short-term operating lease liabilities	19.3	16.5
Deferred revenue	2.3	2.2
Total current liabilities	734.9	614.1
Long-term senior convertible notes	1,703.5	1,667.2
Long-term operating lease liabilities	102.9	101.8
Other long-term liabilities	98.5	80.9
Total liabilities	2,639.8	2,464.0
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.001 par value, 5.0 million shares authorized; no shares issued and outstanding at September 30, 2021 and December 31, 2020	—	—
Common stock, \$0.001 par value, 200.0 million shares authorized; 97.8 million and 96.9 million shares issued and outstanding, respectively, at September 30, 2021; and 96.9 million and 96.1 million shares issued and outstanding, respectively, at December 31, 2020	0.1	0.1
Additional paid-in capital	2,322.1	2,125.3
Accumulated other comprehensive income	1.4	3.2
Accumulated deficit	(28.0)	(202.1)
Treasury stock, at cost; 0.9 million shares at September 30, 2021 and 0.8 million shares at December 31, 2020	(159.5)	(100.0)
Total stockholders' equity	2,136.1	1,826.5
Total liabilities and stockholders' equity	\$ 4,775.9	\$ 4,290.5

See accompanying notes

DexCom, Inc.
Consolidated Statements of Operations
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
<i>(In millions, except per share data)</i>				
Revenues	\$ 650.2	\$ 500.9	\$ 1,750.3	\$ 1,357.8
Cost of sales	203.3	160.5	542.4	476.8
Gross profit	446.9	340.4	1,207.9	881.0
Operating expenses:				
Research and development	128.8	87.7	367.3	240.7
Selling, general and administrative	199.8	158.6	575.4	444.8
Total operating expenses	328.6	246.3	942.7	685.5
Operating income	118.3	94.1	265.2	195.5
Interest expense	(25.1)	(24.4)	(75.1)	(60.1)
Loss on extinguishment of debt	(0.8)	(0.5)	(0.8)	(5.9)
Interest and other income (expense), net	(1.7)	5.9	(0.7)	14.2
Income before income taxes	90.7	75.1	188.6	143.7
Income tax expense	19.8	2.9	14.5	5.3
Net income	\$ 70.9	\$ 72.2	\$ 174.1	\$ 138.4
Basic net income per share	\$ 0.73	\$ 0.75	\$ 1.80	\$ 1.48
Shares used to compute basic net income per share	96.9	95.8	96.6	93.8
Diluted net income per share	\$ 0.71	\$ 0.73	\$ 1.74	\$ 1.43
Shares used to compute diluted net income per share	100.5	99.5	99.8	96.9

See accompanying notes

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

<i>(In millions)</i>	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Net income	\$ 70.9	\$ 72.2	\$ 174.1	\$ 138.4
Other comprehensive income (loss), net of tax:				
Translation adjustments and other	(1.3)	0.4	(1.4)	0.2
Unrealized gain (loss) on marketable debt securities	(0.1)	(1.1)	(0.4)	0.3
Total other comprehensive income (loss), net of tax	(1.4)	(0.7)	(1.8)	0.5
Comprehensive income	<u>\$ 69.5</u>	<u>\$ 71.5</u>	<u>\$ 172.3</u>	<u>\$ 138.9</u>

See accompanying notes

DexCom, Inc.
Consolidated Statements of Stockholders' Equity
(Unaudited)

	Three Months Ended September 30, 2021						
	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Treasury Stock	Total Stockholders' Equity
	Shares	Amount					
<i>(In millions)</i>							
Balance at June 30, 2021	96.7	\$ 0.1	\$ 2,193.6	\$ 2.8	\$ (98.9)	\$ (100.0)	\$ 1,997.6
Issuance of common stock under equity incentive plans	0.1	—	—	—	—	—	—
Issuance of common stock for Employee Stock Purchase Plan	—	—	11.6	—	—	—	11.6
Conversions of 2023 Notes	0.2	—	24.3	—	—	5.6	29.9
Benefit of note hedge upon conversions of 2023 Notes	(0.1)	—	65.1	—	—	(65.1)	—
Share-based compensation expense	—	—	27.5	—	—	—	27.5
Net income	—	—	—	—	70.9	—	70.9
Other comprehensive loss, net of tax	—	—	—	(1.4)	—	—	(1.4)
Balance at September 30, 2021	<u>96.9</u>	<u>\$ 0.1</u>	<u>\$ 2,322.1</u>	<u>\$ 1.4</u>	<u>\$ (28.0)</u>	<u>\$ (159.5)</u>	<u>\$ 2,136.1</u>

	Three Months Ended September 30, 2020						
	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Treasury Stock	Total Stockholders' Equity
	Shares	Amount					
<i>(In millions)</i>							
Balance at June 30, 2020	95.4	\$ 0.1	\$ 2,079.8	\$ 3.5	\$ (629.5)	\$ (100.0)	\$ 1,353.9
Issuance of common stock under equity incentive plans	0.2	—	—	—	—	—	—
Issuance of common stock for Employee Stock Purchase Plan	—	—	8.6	—	—	—	8.6
Repurchase and conversions of 2022 Notes	0.4	—	34.6	—	—	—	34.6
Share-based compensation expense	—	—	30.7	—	—	—	30.7
Net income	—	—	—	—	72.2	—	72.2
Other comprehensive loss, net of tax	—	—	—	(0.7)	—	—	(0.7)
Balance at September 30, 2020	<u>96.0</u>	<u>\$ 0.1</u>	<u>\$ 2,153.7</u>	<u>\$ 2.8</u>	<u>\$ (557.3)</u>	<u>\$ (100.0)</u>	<u>\$ 1,499.3</u>

See accompanying notes

DexCom, Inc.
Consolidated Statements of Stockholders' Equity
(Unaudited)

Nine Months Ended September 30, 2021

(In millions)	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Treasury Stock	Total Stockholders' Equity
	Shares	Amount					
Balance at December 31, 2020	96.1	\$ 0.1	\$ 2,125.3	\$ 3.2	\$ (202.1)	\$ (100.0)	\$ 1,826.5
Issuance of common stock under equity incentive plans	0.7	—	—	—	—	—	—
Issuance of common stock for Employee Stock Purchase Plan	—	—	20.3	—	—	—	20.3
Conversions of 2023 Notes	0.2	—	24.3	—	—	5.6	29.9
Benefit of note hedge upon conversions of 2023 Notes	(0.1)	—	65.1	—	—	(65.1)	—
Share-based compensation expense	—	—	87.1	—	—	—	87.1
Net income	—	—	—	—	174.1	—	174.1
Other comprehensive loss, net of tax	—	—	—	(1.8)	—	—	(1.8)
Balance at September 30, 2021	<u>96.9</u>	<u>\$ 0.1</u>	<u>\$ 2,322.1</u>	<u>\$ 1.4</u>	<u>\$ (28.0)</u>	<u>\$ (159.5)</u>	<u>\$ 2,136.1</u>

Nine Months Ended September 30, 2020

(In millions)	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Treasury Stock	Total Stockholders' Equity
	Shares	Amount					
Balance at December 31, 2019	91.6	\$ 0.1	\$ 1,675.9	\$ 2.3	\$ (695.7)	\$ (100.0)	\$ 882.6
Issuance of common stock under equity incentive plans	1.0	—	0.3	—	—	—	0.3
Issuance of common stock for Employee Stock Purchase Plan	—	—	15.0	—	—	—	15.0
Equity component of 2025 Notes issuance, net of issuance costs	—	—	289.4	—	—	—	289.4
Repurchase and conversions of 2022 Notes	3.4	—	87.8	—	—	—	87.8
Share-based compensation expense	—	—	85.3	—	—	—	85.3
Net income	—	—	—	—	138.4	—	138.4
Other comprehensive income, net of tax	—	—	—	0.5	—	—	0.5
Balance at September 30, 2020	<u>96.0</u>	<u>\$ 0.1</u>	<u>\$ 2,153.7</u>	<u>\$ 2.8</u>	<u>\$ (557.3)</u>	<u>\$ (100.0)</u>	<u>\$ 1,499.3</u>

See accompanying notes

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

	Nine Months Ended September 30,	
	2021	2020
<i>(In millions)</i>		
Operating activities		
Net income	\$ 174.1	\$ 138.4
Adjustments to reconcile net income to cash provided by operating activities:		
Depreciation and amortization	69.9	46.7
Share-based compensation	87.1	85.3
Loss on extinguishment of debt	0.8	5.9
Non-cash interest expense	66.7	52.0
Deferred income taxes	0.2	—
Other non-cash income and expenses	30.5	5.5
Changes in operating assets and liabilities:		
Accounts receivable, net	(90.6)	(83.8)
Inventory	(106.2)	(80.9)
Prepaid and other assets	(18.2)	(11.8)
Operating lease right-of-use assets and liabilities, net	(0.1)	(1.3)
Accounts payable and accrued liabilities	115.3	126.6
Accrued payroll and related expenses	0.5	4.3
Deferred revenue and other liabilities	6.7	16.7
Net cash provided by operating activities	336.7	303.6
Investing activities		
Purchases of marketable securities	(1,540.2)	(2,143.1)
Proceeds from sale and maturity of marketable securities	2,165.3	1,298.5
Purchases of property and equipment	(309.0)	(138.8)
Acquisitions, net of cash acquired	(31.6)	—
Other investing activities	(4.5)	(10.6)
Net cash provided by (used in) investing activities	280.0	(994.0)
Financing activities		
Proceeds from issuance of convertible notes, net of issuance costs	—	1,188.8
Repurchase of convertible notes	—	(282.6)
Net proceeds from issuance of common stock	20.3	15.3
Other financing activities	(9.1)	(4.5)
Net cash provided by financing activities	11.2	917.0
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(0.9)	0.8
Increase in cash, cash equivalents and restricted cash	627.0	227.4
Cash, cash equivalents and restricted cash, beginning of period	818.2	446.4
Cash, cash equivalents and restricted cash, end of period	\$ 1,445.2	\$ 673.8
Reconciliation of cash, cash equivalents and restricted cash, end of period:		
Cash and cash equivalents	\$ 1,444.3	\$ 673.5
Restricted cash	0.9	0.3
Total cash, cash equivalents and restricted cash	\$ 1,445.2	\$ 673.8
Supplemental disclosure of non-cash investing and financing transactions:		
Shares issued for repurchase and conversions of senior convertible notes	\$ 94.5	\$ 1,350.9
Shares received under note hedge upon conversions of 2023 Notes	\$ (65.1)	\$ —
Acquisition of property and equipment included in accounts payable and accrued liabilities	\$ 30.2	\$ 27.8
Right-of-use assets obtained in exchange for operating lease liabilities	\$ 12.2	\$ 34.8
Right-of-use assets obtained in exchange for finance lease liabilities	\$ 6.3	\$ 33.4

See accompanying notes

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

1. Organization and Significant Accounting Policies

Organization and Business

DexCom, Inc. is a medical device company that develops and markets continuous glucose monitoring, or CGM, systems for the management of diabetes by patients, caregivers, and clinicians around the world. Unless the context requires otherwise, the terms “we,” “us,” “our,” the “company,” or “Dexcom” refer to DexCom, Inc. and its subsidiaries.

Basis of Presentation and Principles of Consolidation

We have prepared the accompanying unaudited consolidated financial statements in accordance with U.S. generally accepted accounting principles, or GAAP, for interim financial information and with the instructions to Form 10-Q and Article 10 of Securities and Exchange Commission, or SEC, Regulation S-X. Accordingly, they do not include all of the information and disclosures required by 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, 2021 are not necessarily indicative of the results that may be expected for the year ending December 31, 2021. We expect that revenues we generate from the sales of our products will fluctuate from quarter to quarter. We experience seasonality that is typical in our industry, with lower sales in the first quarter of each year compared to the fourth quarter of the previous year.

These consolidated financial statements should be read in conjunction with the audited consolidated financial statements and related notes thereto for the year ended December 31, 2020 included in the Annual Report on Form 10-K that we filed with the SEC on February 11, 2021.

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

We determine the functional currencies of our international subsidiaries by reviewing the environment where each subsidiary primarily generates and expends cash. For international subsidiaries whose functional currencies are the local currencies, we translate the financial statements into U.S. dollars using period-end exchange rates for assets and liabilities and average exchange rates for each period for revenue, costs and expenses. We include translation-related adjustments in comprehensive income and in accumulated other comprehensive income in the equity section of our consolidated balance sheets. We record gains and losses resulting from transactions with customers and vendors that are denominated in currencies other than the functional currency and from certain intercompany transactions in interest and other income (expense), net in our consolidated statements of operations.

Use of Estimates

The preparation of consolidated financial statements in conformity with GAAP requires us to make certain estimates and assumptions that affect the amounts reported in our consolidated financial statements and the disclosures made in the accompanying notes. Areas requiring significant estimates include rebates, transaction price, the collectibility of accounts receivable, excess or obsolete inventories and the valuation of inventory, accruals for litigation contingencies, and the amount of our worldwide tax provision and the realizability of deferred tax assets. Despite our intention to establish accurate estimates and use reasonable assumptions, actual results may differ from our estimates.

Accounts Receivable and Allowance for Doubtful Accounts

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

Concentration of Credit Risk

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

Revenue Recognition

We generate our revenue from the sale of disposable sensors and our reusable transmitter and receiver, collectively referred to as Reusable Hardware. We also refer to Reusable Hardware in this section as Components. We generally recognize revenue when control is transferred to our customers in an amount that reflects the net consideration to which we expect to be entitled.

In determining how revenue should be recognized, a five-step process is used, which includes identifying performance obligations in the contract, determining whether the performance obligations are separate, allocating the transaction price to each separate performance obligation, estimating the amount of variable consideration to include in the transaction price and determining the timing of revenue recognition for separate performance obligations.

Contracts and Performance Obligations

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

Transaction Price

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

Variable Consideration

We include an estimate of variable consideration in the calculation of the transaction price at the time of sale, when control of the Components transfers to the customer. Variable consideration includes, but is not limited to: rebates, chargebacks, consideration payable to customers such as specialty distributor and wholesaler fees, product returns provision, prompt payment discounts, and various other promotional or incentive arrangements. We classify our provisions related to variable consideration as a reduction of accounts receivable when we are not required to make a payment or as a liability when we are required to make a payment.

Rebates

We are subject to rebates on pricing programs with managed care organizations, such as pharmacy benefit managers, governmental and third-party commercial payors, primarily in the U.S. We estimate provisions for rebates based on contractual arrangements, estimates of products sold subject to rebate, known events or trends and channel inventory data.

Chargebacks

We participate in chargeback programs, primarily with government entities in the U.S., under which pricing on products below negotiated list prices is provided to participating entities and equal to the difference between their acquisition cost and the lower negotiated price. We estimate provisions for chargebacks primarily based on historical experience on a product and program basis, current contract prices under the chargeback programs and channel inventory data.

Consideration Payable to the Customer

We pay administrative and service fees to certain of our distributors based on a fixed percentage of the product price. These fees are not in exchange for a distinct good or service and therefore are recognized as a reduction of the transaction price. We accrue for these fees based on actual net sales and contractual fee rates negotiated with the customer.

Product Returns

In accordance with the terms of their distribution agreements, most distributors do not have rights of return. The distributors typically have a limited time frame to notify us of any missing, damaged, defective or non-conforming products. We generally provide a “30-day money back guarantee” program whereby first-time end-user customers may return Reusable Hardware. We estimate our product returns provision principally based on historical experience by applying a historical return rate to the amounts of revenue estimated to be subject to returns. Additionally, we consider other specific factors such as estimated shelf life of inventory in the distribution channel and changes to customer terms.

Prompt Payment Discounts

We provide customers with prompt payment discounts which may result in adjustments to the price that is invoiced for the product transferred, in the case that payments are made within a defined period. We estimate prompt payment discount accruals based on actual net sales and contractual discount rates.

Various Other Promotional or Incentive Arrangements

Other promotional or incentive arrangements are periodically offered to customers, including but not limited to co-payment assistance we provide to patients with commercial insurance, promotional programs related to the launch of products or other targeted promotions. We record a provision for the incentive earned based on the number of estimated claims and our estimate of the cost per claim related to product sales that we have recognized as revenue.

Revenue Recognition

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

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

Our sales of Components include an assurance-type warranty.

Contract Balances

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

Accounts receivable as of September 30, 2021 included unbilled accounts receivable of \$9.2 million. We expect to invoice and collect all unbilled accounts receivable within 12 months.

We record deferred revenue when we have entered into a contract with a customer and cash payments are received or due prior to transfer of control or satisfaction of the related performance obligation.

Our performance obligations are generally satisfied within 12 months of the initial contract date. The deferred revenue balance related to performance obligations that will be satisfied after 12 months was \$13.8 million as of September 30, 2021 and \$8.2 million as of December 31, 2020. These balances are included in other long-term liabilities in our consolidated balance sheets. Revenue recognized in the period from performance obligations satisfied in previous periods was not material for the periods presented.

Deferred Cost of Sales

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

Incentive Compensation Costs

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

Net Income Per Share

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

Potentially dilutive common shares consist of shares issuable from restricted stock units, warrants, and our senior convertible notes. Potentially dilutive common shares issuable upon vesting of restricted stock units and exercise of warrants are determined using the average share price for each period under the treasury stock method. Potentially dilutive common shares issuable upon conversion of our senior convertible notes are determined using the if-converted method. In periods of net losses, we exclude all potentially dilutive common shares from the computation of the diluted net loss per share for those periods as the effect would be anti-dilutive.

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

(In millions)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Net income	\$ 70.9	\$ 72.2	\$ 174.1	\$ 138.4
Net income per common share				
Basic	\$ 0.73	\$ 0.75	\$ 1.80	\$ 1.48
Diluted	\$ 0.71	\$ 0.73	\$ 1.74	\$ 1.43
Basic weighted average shares outstanding	96.9	95.8	96.6	93.8
Dilutive potential common stock outstanding:				
Restricted stock units	0.5	1.0	0.5	1.1
Warrants	3.1	2.7	2.7	2.0
Senior convertible notes	—	—	—	—
Diluted weighted average shares outstanding	100.5	99.5	99.8	96.9

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

(In millions)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Restricted stock units	—	—	—	—
Warrants	—	—	—	—
Senior convertible notes	7.0	7.2	7.0	8.8
Total	7.0	7.2	7.0	8.8

Recent Accounting Guidance

Recently Adopted Accounting Pronouncements

In December 2019, the FASB issued ASU No. 2019-12, *Simplifying the Accounting for Income Taxes*, which is intended to simplify various aspects of the income tax accounting guidance, including requirements such as tax basis step-up in goodwill obtained in a transaction that is not a business combination, ownership changes in investments, and interim-period accounting for enacted changes in tax law. ASU 2019-12 is effective for public business entities for fiscal years beginning after December 15, 2020, including interim periods within those fiscal years, and early adoption is permitted. Our adoption of ASU 2019-12 at the beginning of the first quarter of 2021 did not have a significant impact on our consolidated financial statements.

Recently Issued Accounting Pronouncements Not Yet Adopted

In August 2020, the FASB issued ASU No. 2020-06, *Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40)*. This new guidance is intended to reduce

the complexity of accounting for convertible instruments. The guidance also addresses how convertible instruments are accounted for in the diluted earnings per share calculation and requires enhanced disclosures about the terms of convertible instruments. Entities may adopt ASU 2020-06 using either a partial retrospective or fully retrospective method of transition. This ASU is effective for public business entities for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. Early adoption is permitted for fiscal years beginning after December 15, 2020, including interim periods within those fiscal years. We will adopt ASU 2020-06 in the first quarter of 2022, and expect to use the full retrospective method, reflecting the application of the new standard in each prior reporting period. We have started the process of evaluating the impact of the full retrospective adoption of ASU 2020-06 on our consolidated financial statements. We expect the adoption of ASU 2020-06 will lead to an increase in the carrying value of the senior convertible notes on our Consolidated Balance Sheets.

2. Fair Value Measurements

Assets and Liabilities Measured at Fair Value on a Recurring Basis

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

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

The following table summarizes financial assets that we measured at fair value on a recurring basis as of September 30, 2021, classified in accordance with the fair value hierarchy:

(In millions)	Fair Value Measurements Using			
	Level 1	Level 2	Level 3	Total
Cash equivalents	\$ 782.8	\$ 250.0	\$ —	\$ 1,032.8
Debt securities, available for sale:				
U.S. government agencies	—	898.8	—	898.8
Commercial paper	—	254.8	—	254.8
Corporate debt	—	100.0	—	100.0
Total debt securities, available for sale	—	1,253.6	—	1,253.6
Other assets ⁽¹⁾	6.3	—	—	6.3
Total assets measured at fair value on a recurring basis	\$ 789.1	\$ 1,503.6	\$ —	\$ 2,292.7

⁽¹⁾ Includes assets which are held pursuant to a deferred compensation plan for senior management, which consist mainly of mutual funds.

The following table summarizes financial assets that we measured at fair value on a recurring basis as of December 31, 2020, classified in accordance with the fair value hierarchy:

(In millions)	Fair Value Measurements Using			
	Level 1	Level 2	Level 3	Total
Cash equivalents	\$ 491.5	\$ 150.0	\$ —	\$ 641.5
Debt securities, available for sale:				
U.S. government agencies	—	1,570.4	—	1,570.4
Commercial paper	—	258.8	—	258.8
Corporate debt	—	60.9	—	60.9
Total debt securities, available for sale	—	1,890.1	—	1,890.1
Other assets ⁽¹⁾	3.4	—	—	3.4
Total assets measured at fair value on a recurring basis	\$ 494.9	\$ 2,040.1	\$ —	\$ 2,535.0

⁽¹⁾ Includes assets which are held pursuant to a deferred compensation plan for senior management, which consist mainly of mutual funds.

There were no transfers into or out of Level 3 securities during the three and nine months ended September 30, 2021.

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

Fair Value of Senior Convertible Notes

The fair value, based on trading prices (Level 1), of our senior convertible notes were as follows as of the dates indicated:

(In millions)	Fair Value Measurements Using Level 1	
	September 30, 2021	December 31, 2020
Senior Convertible Notes due 2023	\$ 2,719.0	\$ 1,936.4
Senior Convertible Notes due 2025	1,432.2	1,219.2
Total fair value of outstanding senior convertible notes	\$ 4,151.2	\$ 3,155.6

For more information on the carrying values of our senior convertible notes, see Note 4, "Debt."

Foreign Currency and Derivative Financial Instruments

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

As of September 30, 2021 and December 31, 2020, notional amounts of \$48.0 million and \$48.0 million, respectively, were outstanding to hedge certain foreign currency risk. The resulting impact on our consolidated financial statements from currency hedging activities was not significant for the three and nine months ended September 30, 2021 or 2020.

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

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

In accordance with authoritative guidance, we measure certain non-financial assets and liabilities at fair value on a non-recurring basis. These measurements are usually performed using the discounted cash flow method or cost method and Level 3 inputs. These include items such as non-financial assets and liabilities initially measured at fair value in a business combination and non-financial long-lived assets measured at fair value for an impairment assessment. In general, non-financial assets, including goodwill, intangible assets, and property and equipment, are measured at fair value when there are indicators of impairment and are recorded at fair value only when any impairment is recognized. We recorded no significant impairment losses during the three and nine months ended September 30, 2021 and 2020.

3. Balance Sheet Details

Short-Term Marketable Securities

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

	September 30, 2021			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Market Value
(In millions)				
Debt securities, available for sale:				
U.S. government agencies	\$ 898.9	\$ —	\$ (0.1)	\$ 898.8
Commercial paper	254.8	—	—	254.8
Corporate debt	100.1	—	(0.1)	100.0
Total debt securities, available for sale	\$ 1,253.8	\$ —	\$ (0.2)	\$ 1,253.6
	December 31, 2020			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Market Value
(In millions)				
Debt securities, available for sale:				
U.S. government agencies	\$ 1,570.4	\$ 0.1	\$ (0.1)	\$ 1,570.4
Commercial paper	258.7	0.1	—	258.8
Corporate debt	60.9	—	—	60.9
Total debt securities, available for sale	\$ 1,890.0	\$ 0.2	\$ (0.1)	\$ 1,890.1

As of September 30, 2021, the estimated market value of available-for-sale securities with contractual maturities up to 12 months and up to 18 months were \$1,083.7 million and \$169.9 million, respectively. As of December 31, 2020, all of our debt securities had contractual maturities of less than 12 months. Gross realized gains and losses on sales of our debt securities for the three and nine months ended September 30, 2021 and September 30, 2020 were not significant.

We periodically review our portfolio of debt securities to determine if any investment is impaired due to credit loss or other potential valuation concerns. For debt securities where the fair value of the investment is less than the amortized cost basis, we have assessed at the individual security level for various quantitative factors including, but not limited to, the nature of the investments, changes in credit ratings, interest rate fluctuations, industry analyst reports, and the severity of impairment. Unrealized losses on available-for-sale debt securities at September 30, 2021 were not significant and were primarily due to changes in interest rates, including market credit spreads, and not due to increased credit risks associated with specific securities. Accordingly, we have not recorded an allowance for credit losses. We do not intend to sell these investments and it is not more likely than not that we will be required to sell the investments before recovery of their amortized cost bases, which may be at maturity.

Inventory

<i>(In millions)</i>	September 30, 2021	December 31, 2020
Raw materials	\$ 129.1	\$ 69.9
Work-in-process	18.4	14.2
Finished goods	203.8	150.6
Total inventory	<u>\$ 351.3</u>	<u>\$ 234.7</u>

Property and Equipment

<i>(In millions)</i>	September 30, 2021	December 31, 2020
Land ⁽¹⁾	\$ 15.6	\$ 15.6
Building ⁽¹⁾	49.1	49.2
Furniture and fixtures	27.7	15.3
Computer software and hardware	45.5	35.7
Machinery and equipment	241.5	198.9
Leasehold improvements	242.4	135.8
Construction in progress	323.4	219.0
Total cost	945.2	669.5
Less accumulated depreciation and amortization	(203.0)	(154.2)
Total property and equipment, net	<u>\$ 742.2</u>	<u>\$ 515.3</u>

⁽¹⁾ Represents finance lease right-of-use assets.

Intangibles and Other Assets, Net

We recorded net intangible assets of \$23.4 million, consisting primarily of customer-related relationship, as result of an acquisition in the third quarter of 2021.

Accounts Payable and Accrued Liabilities

<i>(In millions)</i>	September 30, 2021	December 31, 2020
Accounts payable trade	\$ 210.0	\$ 163.3
Accrued tax, audit, and legal fees	34.0	15.3
Accrued rebates	293.4	247.0
Accrued warranty	12.5	11.7
Other accrued liabilities	48.1	43.8
Total accounts payable and accrued liabilities	<u>\$ 598.0</u>	<u>\$ 481.1</u>

Accrued Payroll and Related Expenses

<i>(In millions)</i>	September 30, 2021	December 31, 2020
Accrued wages, bonus and taxes	\$ 88.4	\$ 87.7
Other accrued employee benefits	26.9	26.6
Total accrued payroll and related expenses	<u>\$ 115.3</u>	<u>\$ 114.3</u>

Other Long-Term Liabilities

<i>(In millions)</i>	September 30, 2021	December 31, 2020
Finance lease obligations	\$ 57.8	\$ 54.0
Contractual obligations	12.6	12.6
Other liabilities	28.1	14.3
Total other long-term liabilities	<u>\$ 98.5</u>	<u>\$ 80.9</u>

4. Debt

Senior Convertible Notes

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

<i>(Dollars in millions)</i>	September 30, 2021	December 31, 2020
Principal amount:		
Senior Convertible Notes due 2023	\$ 817.4	\$ 850.0
Senior Convertible Notes due 2025	1,207.5	1,207.5
Total principal amount	2,024.9	2,057.5
Unamortized debt discount	(305.7)	(371.1)
Unamortized debt issuance costs	(15.7)	(19.2)
Carrying amount of liability component	<u>\$ 1,703.5</u>	<u>\$ 1,667.2</u>
Carrying amount of equity component	<u>\$ 454.5</u>	<u>\$ 461.0</u>
Remaining amortization period of debt discount on the liability component:		
Senior Convertible Notes due 2023	2.2 years	2.9 years
Senior Convertible Notes due 2025	4.1 years	4.9 years

For our senior convertible notes for which the if-converted value exceeded the principal amount, the amount in excess of principal was as follows as of the dates indicated:

<i>(In millions)</i>	September 30, 2021	December 31, 2020
Senior Convertible Notes due 2023	\$ 1,903.6	\$ 1,077.5
Senior Convertible Notes due 2025	163.9	—
Total by which the notes' if-converted value exceeds their principal amount	<u>\$ 2,067.5</u>	<u>\$ 1,077.5</u>

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

(Dollars in millions)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Cash interest expense:				
Contractual coupon interest ^{(1),(2)}	\$ 2.4	\$ 2.4	\$ 7.0	\$ 7.1
Non-cash interest expense:				
Accretion of debt discount	20.8	20.0	62.1	48.3
Amortization of debt issuance costs	1.1	1.1	3.3	3.1
Total interest expense recognized on senior notes	<u>\$ 24.3</u>	<u>\$ 23.5</u>	<u>\$ 72.4</u>	<u>\$ 58.5</u>
Effective interest rates:				
Senior Convertible Notes due 2022 ⁽²⁾	*	5.1 %	*	5.1 %
Senior Convertible Notes due 2023	5.6 %	5.6 %	5.6 %	5.6 %
Senior Convertible Notes due 2025	5.5 %	5.5 %	5.5 %	5.5 %

⁽¹⁾ Interest on the 2022 Notes began accruing upon issuance and was payable semi-annually on May 15 and November 15 of each year. Interest on the 2023 Notes began accruing upon issuance and is payable semi-annually on June 1 and December 1 of each year. Interest on the 2025 Notes began accruing upon issuance and is payable semi-annually on May 15 and November 15 of each year.

⁽²⁾ Our \$400.0 million aggregate principal amount of unsecured senior convertible notes issued in June 2017 with a stated interest rate of 0.75% and maturity date of May 15, 2022 (the 2022 Notes) were repurchased and converted by August 2020.

* Not applicable as no notes were outstanding at this date.

Repurchase, Conversion, and Redemption of 2022 Notes

In May 2020, we used approximately \$282.6 million of the net proceeds from the 2025 Notes offering described below and issued 1,953,067 shares of Dexcom common stock to repurchase \$260.0 million principal amount outstanding of the 2022 Notes and the associated conversion feature of the repurchased notes (which was recorded in additional paid-in capital). Holders of \$37.2 million in aggregate principal amount of the 2022 Notes elected conversion at their option during the three months ended September 30, 2020, for a total of \$140.0 million aggregate principal amount of the 2022 Notes converted at the holders' option during the nine months ended September 30, 2020. We settled these conversions by issuing 375,178 and 1,412,497 shares of our common stock during the three and nine months ended September 30, 2020, respectively.

As a result of the repurchase and conversions of the 2022 Notes, we recorded losses on extinguishment of debt of \$0.5 million and \$5.9 million for the three and nine months ended September 30, 2020, respectively. The losses on extinguishment of debt included the unamortized debt issuance costs for the 2022 Notes.

0.75% Senior Convertible Notes due 2023

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

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

Since upon conversion by the holders we may elect to settle such conversion in shares of our common stock, cash, or a combination thereof, we accounted for the cash conversion option as an equity instrument classified to stockholders' equity. As a result, we recognized \$171.6 million in additional paid-in capital, net of debt issuance costs, during 2018.

Holders of \$32.6 million in aggregate principal amount of the 2023 Notes elected conversion at their option during the three months ended September 30, 2021. We settled these conversions by issuing a combination of common stock and treasury stock. We issued 197,816 shares and 197,876 shares to settle the converted 2023 Notes during the three and nine months ended September 30, 2021, respectively, of which 45,745 shares were issued out of treasury stock. As a result of the elected conversions, we recorded a loss on extinguishment of debt of \$0.8 million. We received 122,209 shares of common stock from the exercise of a portion of the 2023 Note Hedge we purchased concurrently with the issuance of the 2023 Notes, as described below.

Conversion Rights at the Option of the Holders

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

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

- (1) during any calendar quarter commencing after March 31, 2019 (and only during such calendar quarter), if the last reported sale price of Dexcom's common stock for at least 20 trading days (whether or not consecutive) during the period of 30 consecutive trading days ending on the last trading day of the immediately preceding calendar quarter is greater than or equal to 130% of the applicable conversion price of the 2023 Notes on each such trading day;
- (2) during the five business day period after any five consecutive trading day period in which the trading price per \$1,000 principal amount of the 2023 Notes for each day of that five-day consecutive trading day period was less than 98% of the product of the last reported sale price of Dexcom's common stock and the applicable conversion rate of the 2023 Notes on such trading day;
- (3) if we call any or all of the 2023 Notes for redemption, at any time prior to the close of business on the scheduled trading day immediately preceding the redemption date; or
- (4) upon the occurrence of specified corporate transactions.

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

Circumstance (1) listed above occurred during the quarters ended December 31, 2020, March 31, 2021, and June 30, 2021. As a result, the 2023 Notes were convertible at the option of the holder from January 1, 2021 through September 30, 2021. Circumstance (1) listed above also occurred during the quarter ended September 30, 2021 and as a result, the 2023 Notes will remain convertible at the option of the holder from October 1, 2021 through December 31, 2021.

Conversion Rights at Our Option

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

2023 Note Hedge

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

with respect to the calculation of diluted earnings per share. See above for conversion activity related to the 2023 Notes and shares received as the result of exercising a portion of the 2023 Note Hedge.

2023 Warrants

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

0.25% Senior Convertible Notes due 2025

In May 2020, we completed an offering of \$1.21 billion aggregate principal amount of unsecured senior convertible notes with a stated interest rate of 0.25% and a maturity date of November 15, 2025 (the 2025 Notes). The net proceeds from the offering, after deducting initial purchasers' discounts and estimated costs directly related to the offering, were approximately \$1.19 billion. The initial conversion rate of the 2025 Notes is 1.6655 shares per \$1,000 principal amount of notes, which is equivalent to a conversion price of approximately \$600.42 per share, subject to adjustments, with a maximum conversion rate of 2.3732. The 2025 Notes may be settled in cash, stock, or a combination thereof, solely at our discretion. We use the if-converted method for assumed conversion of the 2025 Notes to compute the weighted average shares of common stock outstanding for diluted earnings per share.

No principal payments are due on the 2025 Notes prior to maturity. Other than restrictions relating to certain fundamental changes and consolidations, mergers or asset sales and customary anti-dilution adjustments, the indenture relating to the 2025 Notes includes customary terms and covenants, including certain events of default after which the 2025 Notes may be due and payable immediately.

Since upon conversion by the holders we may elect to settle such conversion in shares of our common stock, cash, or a combination thereof, we accounted for the cash conversion option as an equity instrument classified to stockholders' equity. As a result, we recognized \$289.4 million in additional paid-in-capital, net of debt issuance costs, during 2020.

Conversion Rights at the Option of the Holders

In the event of a fundamental change (as defined in the indenture related to the 2025 Notes), holders of the 2025 Notes have the right to require us to repurchase for cash all or a portion of their notes at a price equal to 100% of the principal amount of the 2025 Notes, plus any accrued and unpaid interest. Holders of the 2025 Notes who convert their notes in connection with a make-whole fundamental change (as defined in the indenture) or following the delivery by Dexcom of a notice of redemption are, under certain circumstances, entitled to an increase in the conversion rate.

Prior to 5:00 p.m., New York City time, on the business day immediately preceding August 15, 2025, holders of the 2025 Notes may convert all or a portion of their notes, in multiples of \$1,000 principal amount, only under the following circumstances:

- (1) during any calendar quarter commencing after September 30, 2020 (and only during such calendar quarter), if the last reported sale price of Dexcom's common stock for at least 20 trading days (whether or not consecutive) during the period of 30 consecutive trading days ending on the last trading day of the immediately preceding calendar quarter is greater than or equal to 130% of the applicable conversion price of the Notes on each such trading day;
- (2) during the five business day period after any five consecutive trading day period in which the trading price per \$1,000 principal amount of the Notes for each day of that five day consecutive trading day period was less than 98% of the product of the last reported sale price of Dexcom's common stock and the applicable conversion rate of the Notes on such trading day;
- (3) if we call any or all of the Notes for redemption, at any time prior to the close of business on the scheduled trading day immediately preceding the redemption date; or
- (4) upon the occurrence of specified corporate transactions.

On or after August 15, 2025, until 5:00 p.m., New York City time, on the business day immediately preceding the maturity date, holders of the 2025 Notes may convert all or a portion of their notes regardless of the foregoing circumstances.

Conversion Rights at Our Option

Dexcom may not redeem the 2025 Notes prior to May 20, 2023. On or after May 20, 2023 and prior to August 15, 2025, Dexcom may redeem for cash all or part of the 2025 Notes, at its option, if the last reported sale price of our common stock has been at least 130% of the conversion price then in effect for at least 20 trading days (whether or not consecutive) during any 30 consecutive trading day period ending on, and including, the trading day immediately preceding the date on which Dexcom provides notice of redemption. The redemption price will be equal to 100% of the principal amount of the 2025 Notes to be redeemed plus accrued and unpaid interest to, but excluding, the redemption date.

Revolving Credit Agreement

Terms of the Revolving Credit Agreement

On December 19, 2018, we entered into an amended and restated revolving credit agreement which was subsequently amended on May 11, 2020 (as amended, the Credit Agreement). The Credit Agreement provides for available principal amount of \$200.0 million which can be increased up to \$500.0 million at our option subject to customary conditions and approval of our lenders. Borrowings under the Credit Agreement are available for general corporate purposes, including working capital and capital expenditures.

Information related to availability and outstanding borrowings on our Credit Agreement is as follows as of the date indicated:

<i>(In millions)</i>	September 30, 2021
Available principal amount	\$ 200.0
Letters of credit sub-facility	10.0
Outstanding borrowings	—
Outstanding letters of credit	6.4
Total available balance	\$ 193.6

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

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

Our obligations under the Credit Agreement are guaranteed by our existing and future wholly-owned domestic subsidiaries, and are secured by a first-priority security interest in substantially all of the assets of Dexcom and the guarantors, including all or a portion of the equity interests of our domestic subsidiaries and first-tier foreign subsidiaries but excluding real property and intellectual property (which is subject to a negative pledge). The Credit Agreement contains covenants that limit certain indebtedness, liens, investments, transactions with affiliates, dividends and other restricted payments, subordinated indebtedness and amendments to subordinated indebtedness documents, and sale and leaseback transactions of Dexcom or any of its domestic subsidiaries. The Credit Agreement also requires us to maintain a maximum leverage ratio and a minimum fixed charge coverage ratio. We were in compliance with these covenants as of September 30, 2021.

5. Contingencies

Litigation

We are subject to various claims, complaints and legal actions that arise from time to time in the normal course of business, including commercial insurance, product liability, intellectual property 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.

During the quarters ended June 30, 2021 and September 30, 2021, we and certain Abbott entities served complaints for patent infringement against each other in multiple jurisdictions, inside and outside the United States. We intend to vigorously pursue our claims and defenses in these cases to protect our intellectual property and to defend against Abbott's infringement allegations.

We do not believe we are party to any other currently pending legal proceedings, the outcome of which could have a material adverse effect on our business, financial condition or results of operations. There can be no assurance that existing or future legal proceedings arising in the ordinary course of business or otherwise will not have a material adverse effect on our business, financial condition or results of operations.

6. Income Taxes

We estimate our annual effective tax rate to be 27.8% for the full year 2021, which differed from the U.S. federal statutory rate due to state and foreign income taxes, nondeductible executive compensation, and increases to unrecognized tax benefits offset by federal research tax credits generated. Our positive effective tax rate of 7.7% for the nine months ended September 30, 2021 was due to excess tax benefits recognized for employee share-based compensation and a one-time tax benefit related to the revaluation of our U.K. net operating loss deferred tax asset resulting from the increase in the U.K. corporate tax rate from 19% to 25% effective April 2023.

We operate in various jurisdictions outside of the U.S., many of which are enacting Anti-Tax Avoidance Directive (ATAD) laws that may impact our ability to deduct certain costs, which could potentially affect our estimated annual effective tax rate. We have made certain estimations and assumptions in determining the estimated annual effective tax rate, including the impact of these laws, the final application of which may differ from our estimates.

7. Stockholders' Equity

Share-Based Compensation

Our share-based compensation expense is associated with restricted stock units, or RSUs, performance stock units, or PSUs, and our Employee Stock Purchase Plan, or ESPP. The following table summarizes our share-based compensation expense included in our consolidated statements of operations for the periods shown.

(In millions)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Cost of sales	\$ 2.0	\$ 4.8	\$ 6.6	\$ 10.8
Research and development	9.8	9.9	31.3	27.9
Selling, general and administrative	15.7	16.0	49.2	46.6
Total share-based compensation expense	\$ 27.5	\$ 30.7	\$ 87.1	\$ 85.3

At September 30, 2021, unrecognized estimated compensation costs related to RSUs, PSUs and ESPP totaled \$178.2 million and is expected to be recognized through 2024.

Equity Award Activity

The total vest date fair value of RSUs and PSUs that vested during the nine months ended September 30, 2021 was \$240.4 million and \$29.5 million, respectively.

8. Business Segment and Geographic Information

Reportable Segments

An operating segment is identified as a component of a business that has discrete financial information available and for which the chief operating decision maker must decide the level of resource allocation. In addition, the guidance for segment reporting indicates certain quantitative materiality thresholds. None of the components of our business meet the definition of an operating segment.

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

Disaggregation of Revenue

We disaggregate revenue by geographic region and by major sales channel. We have determined that disaggregating revenue into these categories achieves the ASC Topic 606 disclosure objectives of depicting how the nature, amount, timing and uncertainty of revenue and cash flows are affected by economic factors.

Dexcom is domiciled in the United States. We sell our CGM systems through a direct sales force in the United States, Australia, Canada, New Zealand, and some countries in Europe, and through distribution arrangements in the United States, and certain countries in Africa, Asia, Europe, Latin America, and the Middle East, as well as Australia, Canada, and New Zealand.

Revenues by geographic region

During the three and nine months ended September 30, 2021 and 2020, no individual country outside the United States generated revenue that represented more than 10% of our total revenue. The table below sets forth revenues by our two primary geographical markets, the United States and outside of the United States, based on the geographic location to which we deliver the components. The majority of our long-lived assets are located in the United States.

(Dollars in millions)	Three Months Ended September 30, 2021		Three Months Ended September 30, 2020	
	Amount	% of Total	Amount	% of Total
United States	\$ 489.6	75 %	\$ 398.6	80 %
Outside of the United States	160.6	25 %	102.3	20 %
Total revenues	\$ 650.2	100 %	\$ 500.9	100 %

(Dollars in millions)	Nine Months Ended September 30, 2021		Nine Months Ended September 30, 2020	
	Amount	% of Total	Amount	% of Total
United States	\$ 1,332.3	76 %	\$ 1,058.0	78 %
Outside of the United States	418.0	24 %	299.8	22 %
Total revenues	\$ 1,750.3	100 %	\$ 1,357.8	100 %

Revenues by customer sales channel

The following table sets forth revenues by major sales channel for the periods shown:

(Dollars in millions)	Three Months Ended September 30, 2021		Three Months Ended September 30, 2020	
	Amount	% of Total	Amount	% of Total
Distributor	\$ 552.3	85 %	\$ 382.4	76 %
Direct	97.9	15 %	118.5	24 %
Total revenues	\$ 650.2	100 %	\$ 500.9	100 %

(Dollars in millions)	Nine Months Ended September 30, 2021		Nine Months Ended September 30, 2020	
	Amount	% of Total	Amount	% of Total
Distributor	\$ 1,438.9	82 %	\$ 1,000.2	74 %
Direct	311.4	18 %	357.6	26 %
Total revenues	\$ 1,750.3	100 %	\$ 1,357.8	100 %

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 include, among other things, impacts on our business due to health pandemics or other contagious outbreaks, such as the current COVID-19 pandemic. The risks and uncertainties that could cause actual results to differ materially are more fully described under "Risk Factors" in Part II, Item 1A of this Quarterly Report, elsewhere in this Quarterly Report, and in our other reports filed with the SEC. We assume no obligation to update any of the forward-looking statements after the date of this report or to conform these forward-looking statements to actual results. You should read the following discussion and analysis together with our consolidated financial statements and related notes in Part I, Item 1 of this Quarterly Report.

Overview

WHO WE ARE

We are a medical device company primarily focused on the design, development and commercialization of continuous glucose monitoring, or CGM, systems for the management of diabetes by patients, caregivers, and clinicians around the world.

We received approval from the Food and Drug Administration, or FDA, and commercialized our first product in 2006. We launched our latest generation system, the Dexcom G6[®] integrated Continuous Glucose Monitoring System, or G6, in 2018.

Unless the context requires otherwise, the terms "we," "us," "our," the "company," or "Dexcom" refer to DexCom, Inc. and its subsidiaries.

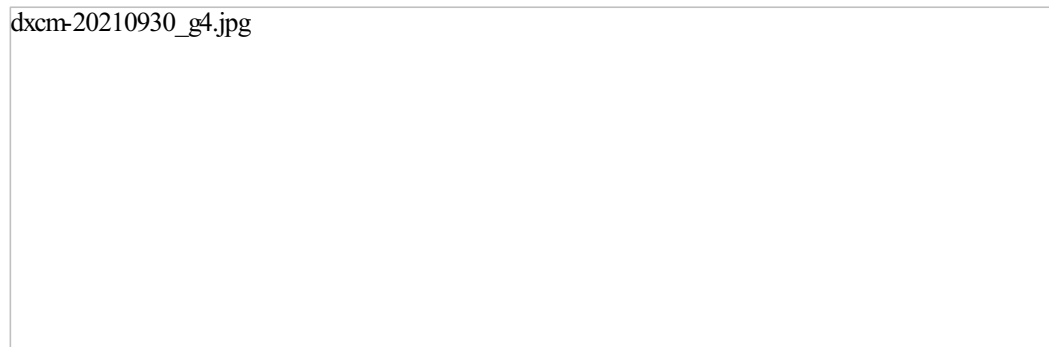
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Global Presence

We have built a direct sales organization in the United States, Australia, Canada, New Zealand, and certain countries in Europe to call on health care professionals, such as endocrinologists, physicians and diabetes educators, who can educate and influence patient adoption of continuous glucose monitoring. To complement our direct sales efforts, we have entered into distribution arrangements in the United States, and certain countries in Africa, Asia, Europe, Latin America, and the Middle East, as well as Australia, Canada, and New Zealand that allow distributors to sell our products.

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Future Developments

Product Development: We plan to develop future generations of technologies that are focused on improved performance and convenience and that will enable intelligent insulin administration. Over the longer term, we plan to continue to develop and improve networked platforms with open architecture, connectivity and transmitters capable of communicating with other devices. We also intend to expand our efforts to accumulate CGM patient data and metrics and apply predictive modeling and machine learning to generate interactive CGM insights that can inform patient behavior.

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

New Opportunities: We are also exploring how to extend our offerings to other opportunities, including for people with Type 2 diabetes that are non-insulin using, people with pre-diabetes, people who are obese, people who are pregnant, and people in the hospital setting. Eventually, we may apply our technological expertise to products beyond glucose monitoring.

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Impact of COVID-19 Pandemic

During 2020 and 2021, we have been subject to challenging social and economic conditions created as a result of the novel strain of coronavirus, SARS-CoV-2 (COVID-19). These conditions continue to create various financial impacts to our operations by necessitating precautions for our personnel to operate safely both in person as well as remotely. Costs incurred include items like incremental payroll costs, consulting support, IT infrastructure and facilities-related costs.

As the result of the COVID-19 pandemic, we made Dexcom CGM systems available for use in hospital settings and other healthcare facilities to assist frontline workers. The extent of the impact of the COVID-19 outbreak on our operational and financial performance will depend on certain developments, including the duration and spread of the outbreak, impact on our customers and our sales cycles, employee or industry events, and effect on our vendors, all of which are uncertain and cannot be predicted. The COVID-19 pandemic and its adverse effects have become more prevalent in the locations where we, our customers, suppliers or third-party business partners conduct business and as a result, we have experienced moderate disruptions in our global operations. We have experienced and may experience constrained supply or curtailed customer demand, including due to customer loss of private health insurance coverage for our products, that could materially adversely impact our business, results of operations and overall financial performance in future periods. We currently utilize third parties to, among other things, manufacture components and materials for our devices, and to provide services such as sterilization services and we purchase these materials and services from numerous suppliers worldwide.

The global COVID-19 pandemic has and may continue to have an adverse impact on our manufacturing and distribution capabilities. Disruptions relating to the COVID-19 pandemic, including shelter-in-place orders in the U.S. and other countries, could prevent employees, suppliers, distributors, and others from accessing manufacturing facilities and from transporting our products or the components required to manufacture our products. For example, we have experienced some supply chain disruption due to the global restrictions resulting from the COVID-19 pandemic in the manufacturing of our next-generation CGM product. Further, worldwide supply chain disruption relating to the COVID-19 pandemic has resulted in product shortages that has and may continue to impact our ability to manufacture our devices. As of the filing date of this Form 10-Q, the extent to which COVID-19 may impact our financial condition or results of operations or guidance is uncertain. The effect of the COVID-19 pandemic will not be fully reflected in our results of operations and overall financial performance until future periods. See “Risk Factors” in Part II, Item 1A of this Quarterly Report for further discussion of the possible impact of the COVID-19 pandemic on our business.

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 described in Note 1 to the consolidated financial statements included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2020. The accounting policies and estimates that are most critical to a full understanding and evaluation of our reported financial results are described in 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, 2020. There were no material changes to our critical accounting policies during the nine months ended September 30, 2021.

Results of Operations

Key Highlights for the Three Months Ended September 30, 2021

Revenues	Gross Profit	Operating Income
\$650.2 million	\$446.9 million	\$118.3 million
up 30% from the same period 2020	up 31% from the same period 2020	up 26% from the same period 2020
Net Income	Operating Cash Flow	Cash, Cash Equivalents, & Short-Term Marketable Securities
\$70.9 million	\$247.3 million	\$2.70 billion
down 2% from the same period 2020	up 68% from the same period 2020	down .4% from fiscal year 2020

Financial Overview

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Financial Overview

	Three Months Ended September 30,		2021 - 2020	
	2021	2020	\$ Change	% Change
<i>(In millions, except per share amounts)</i>				
Revenues	\$ 650.2	\$ 500.9	\$ 149.3	30 %
Cost of sales	203.3	160.5	42.8	27 %
Gross profit	\$ 446.9	\$ 340.4	\$ 106.5	31 %
Gross profit as a percent of total revenue	68.7 %	68.0 %		
Operating income	\$ 118.3	\$ 94.1	\$ 24.2	26 %
Net income	70.9	72.2	(1.3)	(2) %
Basic net income per share	0.73	0.75	(0.02)	(3) %
Diluted net income per share	\$ 0.71	\$ 0.73	\$ (0.02)	(3) %

	Nine Months Ended September 30,		2021 - 2020	
	2021	2020	\$ Change	% Change
<i>(In millions, except per share amounts)</i>				
Revenues	\$ 1,750.3	\$ 1,357.8	\$ 392.5	29 %
Cost of sales	542.4	476.8	65.6	14 %
Gross profit	\$ 1,207.9	\$ 881.0	\$ 326.9	37 %
Gross profit as a percent of total revenue	69.0 %	64.9 %		
Operating income	\$ 265.2	\$ 195.5	\$ 69.7	36 %
Net income	174.1	138.4	35.7	26 %
Basic net income per share	1.80	1.48	0.32	22 %
Diluted net income per share	\$ 1.74	\$ 1.43	\$ 0.31	22 %

Revenue, Cost of Sales and Gross Profit

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

Three Months Ended September 30, 2021 Compared to Three Months Ended September 30, 2020

The revenue increase was primarily driven by increased sales volume of our disposable sensors due to the continued growth of our worldwide customer base, partially offset by increased volumes in the U.S. pharmacy channel at a lower price aligned with the evolution of our U.S. channel strategy. Disposable sensor and other revenue comprised approximately 84% of total revenue and Reusable Hardware revenue comprised approximately 16% of total revenue for the three months ended September 30, 2021. Disposable sensor and other revenue comprised approximately 81% of total revenue and Reusable Hardware revenue comprised approximately 19% of total revenue for the three months ended September 30, 2020.

Cost of sales increased primarily due to increased sales volume. The increase in gross profit and gross profit margin in the third quarter of 2021 compared to the third quarter of 2020 were primarily driven by increased revenues and cost savings associated with incremental improvements to product design and manufacturing efficiencies.

Nine Months Ended September 30, 2021 Compared to Nine Months Ended September 30, 2020

The revenue increase was primarily driven by increased sales volume of our disposable sensors due to the continued growth of our worldwide customer base, partially offset by increased volumes in the U.S. pharmacy channel at a lower price aligned with the evolution of our U.S. channel strategy. Disposable sensor and other revenue comprised approximately 84% of total revenue and Reusable Hardware revenue comprised approximately 16% of total revenue for the nine months ended

September 30, 2021. Disposable sensor and other revenue comprised approximately 81% of total revenue and Reusable Hardware revenue comprised approximately 19% of total revenue for the nine months ended September 30, 2020.

Cost of sales increased primarily due to increased sales volume. The increase in gross profit and gross profit margin in the first nine months of 2021 compared to the first nine months of 2020 were primarily driven by increased revenues and cost savings associated with incremental improvements to product design and manufacturing efficiencies.

Operating Expenses

Quarter Ended September 30, 2021 Compared to Quarter Ended September 30, 2020

(In millions)	Three Months Ended September 30,		2021 - 2020	
	2021	2020	\$ Change	% Change
Research and development	\$ 128.8	\$ 87.7	\$ 41.1	47 %
as a % of total revenue	20 %	18 %		
Selling, general and administrative	199.8	158.6	41.2	26 %
as a % of total revenue	31 %	32 %		
Total operating expenses	\$ 328.6	\$ 246.3	\$ 82.3	33 %
as a % of total revenue ⁽¹⁾	51 %	49 %		

⁽¹⁾ The sum of the individual percentages may not equal the total due to rounding.

Research and Development Expense

Research and development expense increased primarily due to \$20.0 million in additional third party and consulting fees primarily related to software, \$14.1 million in additional salaries, bonuses, and payroll-related costs, and \$2.6 million in additional clinical trials costs. We continue to believe that focused investments in research and development are critical to our future growth and competitive position in the marketplace, and to the development of new and updated products and services that are central to our core business strategy.

Selling, General and Administrative Expense

Selling, general and administrative expense increased primarily due to \$13.4 million in additional salaries, bonuses, and payroll-related costs, \$12.1 million in additional advertising and marketing costs, and \$5.2 million in additional legal costs partially offset by \$4.7 million in lower third party service provider fees.

Nine Months Ended September 30, 2021 Compared to Nine Months Ended September 30, 2020

(In millions)	Nine Months Ended September 30,		2021 - 2020	
	2021	2020	\$ Change	% Change
Research and development	\$ 367.3	\$ 240.7	\$ 126.6	53 %
as a % of total revenue	21 %	18 %		
Selling, general and administrative	575.4	444.8	130.6	29 %
as a % of total revenue	33 %	33 %		
Total operating expenses	\$ 942.7	\$ 685.5	\$ 257.2	38 %
as a % of total revenue	54 %	50 %		

⁽¹⁾ The sum of the individual percentages may not equal the total due to rounding.

Research and Development Expense

Research and development expense increased primarily due to \$51.3 million in additional third party and consulting fees primarily related to software, \$42.1 million in additional salaries, bonuses, and payroll-related costs, and \$11.7 million in additional clinical trials costs. We continue to believe that focused investments in research and development are critical to our future growth and competitive position in the marketplace, and to the development of new and updated products and services that are central to our core business strategy.

Selling, General and Administrative Expense

Selling, general and administrative expense increased primarily due to \$56.5 million in additional advertising and marketing costs, \$46.7 million in additional salaries, bonuses, and payroll-related costs, \$8.7 million of investments in customer experience, partially offset by \$9.2 million in lower third party service provider fees.

Non-Operating Income and Expenses

Interest Expense

Interest expense is comprised primarily of costs related to our senior convertible notes. Interest expense increased \$0.7 million to \$25.1 million for the three months ended September 30, 2021 compared to \$24.4 million for the same period of 2020. Interest expense increased \$15.0 million to \$75.1 million for the nine months ended September 30, 2021 compared to \$60.1 million for the nine months ended September 30, 2020. The increase in interest expense for the periods presented is primarily due to the May 2020 issuance of our 2025 Notes.

Loss on Extinguishment of Debt

We recorded a \$0.8 million loss on extinguishment of debt during the three and nine months ended September 30, 2021 in connection with the conversions of a portion of our 2023 Notes. We recorded losses on extinguishment of debt of \$0.5 million and \$5.9 million during the three and nine months ended September 30, 2020, respectively, in connection with the repurchase and conversions of our 2022 Notes. See Note 4 to the consolidated financial statements in Part I, Item 1 of this Quarterly Report for more information about these transactions.

Interest and Other Income (Expense), Net

Interest and other income (expense), net consists primarily of interest income on our marketable debt securities portfolio and foreign currency transaction gains and losses due to the effects of foreign currency fluctuations. Interest income was \$0.3 million and \$1.2 million for the three and nine months ended September 30, 2021, respectively, compared to \$2.4 million and \$12.0 million for the three and nine months ended September 30, 2020, respectively. The decrease in interest income for the three months ended September 30, 2021 was primarily related to a decrease in average invested balances compared to the same period in 2020. The decrease in interest income for the nine months ended September 30, 2021 was primarily related to a decline in market interest rates, partially offset by an increase in average invested balances compared to the same period in 2020.

Income Tax Expense

We recorded income tax expense of \$19.8 million on pre-tax income of \$90.7 million for the three months ended September 30, 2021 compared to income tax expense of \$2.9 million on pre-tax income of \$75.1 million for the three months ended September 30, 2020.

We recorded income tax expense of \$14.5 million on pre-tax income of \$188.6 million for the nine months ended September 30, 2021 and income tax expense of \$5.3 million on pre-tax income of \$143.7 million for the nine months ended September 30, 2020.

Our estimated annual effective tax rate from normal, recurring operations did not change materially during the three months ended September 30, 2021. Our income tax expense for the three months ended September 30, 2021 also includes the discrete impact of excess tax benefits from stock compensation. Our income tax expense for the prior period is attributable to foreign and state income tax expense in taxable jurisdictions with no net operating losses. We maintained a valuation allowance on our deferred tax assets during the prior period, most of which was released in the fourth quarter of 2020.

Our income tax expense for the nine months ended September 30, 2021 is primarily attributable to income tax expense from normal, recurring operations at an estimated annual effective tax rate of 27.8%, offset by excess tax benefits from stock compensation net of disallowed executive compensation and a one-time tax benefit related to the revaluation of our U.K. net operating loss deferred tax asset resulting from the increase in the U.K. corporate tax rate from 19% to 25%, effective April 2023. Income tax expense in the prior period is primarily related to foreign income taxes in jurisdictions with current taxable income. We maintained a valuation allowance on our deferred tax assets during the prior period, most of which was released in the fourth quarter of 2020.

Liquidity and Capital Resources

Overview, Capital Resources, and Capital Requirements

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

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

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

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

The evolution of the international expansion of our business.

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

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

program. Our cash, cash equivalents and short-term marketable securities totaled \$2.70 billion as of September 30, 2021. None of those funds were restricted and approximately 95% of those funds were located in the United States.

Our cash, cash equivalents and short-term marketable securities as of September 30, 2021 decreased by \$9.8 million from December 31, 2020 due to the factors described in “Cash Flows” below. We believe that our cash, cash equivalents, and marketable securities balances, projected cash contributions from our commercial operations, and our \$200.0 million revolving line of credit, of which \$193.6 million remains available, will be sufficient to meet our anticipated seasonal working capital needs, capital expenditure requirements, contractual obligations, commitments, debt service requirements, and other liquidity requirements associated with our operations for at least the next 12 months.

Revolving Credit Agreement

On December 19, 2018, we entered into an amended and restated revolving credit agreement which was subsequently amended on May 11, 2020 (as amended, the Credit Agreement). The Credit Agreement provides for available principal amount of \$200.0 million which can be increased up to \$500.0 million at our option subject to customary conditions and approval of our lenders.

As of September 30, 2021, we had no outstanding borrowings, \$6.4 million in outstanding letters of credit, and a total available balance of \$193.6 million under the Credit Agreement.

On October 13, 2021, we amended and restated the Credit Agreement (as amended and restated, the Amended Credit Agreement). The Amended Credit Agreement also includes a subfacility of up to \$25.0 million for letters of credit. Subject to customary conditions and the approval of any lender whose commitment would be increased, we have the option to increase the maximum principal amount available under the Amended Credit Agreement by up to an additional \$300.0 million, resulting in a maximum available principal amount of \$500.0 million. However, at this time none of the lenders have committed to provide any such increase in their commitments. Revolving loans under the Amended Credit Agreement will be available for general corporate purposes, including working capital and capital expenditures.

We monitor counterparty risk associated with the institutional lenders that are providing this credit facility. We currently believe that this credit facility will be available to us should we choose to borrow under it.

Senior Convertible Notes

The following table summarizes our outstanding senior convertible note obligations as of September 30, 2021:

Issuance Date	Coupon Rate	Aggregate Principal (in millions)	Maturity Date	Initial Conversion Rate per Share of Common Stock	Conversion Price per Share of Common Stock
November 2018	0.75%	\$ 817.4	December 1, 2023	6.0869	\$164.29
May 2020	0.25%	1,207.5	November 15, 2025	1.6655	\$600.42
		<u>\$ 2,024.9</u>			

We used a portion of the net proceeds from the offering of the 2023 Notes to repurchase 0.8 million shares of our common stock for \$100.0 million in 2018. We used \$282.6 million of the net proceeds from the offering of the 2025 Notes to repurchase a portion of our 2022 Notes; the remaining 2022 Notes were converted for shares of our common stock during 2020. We intend to use the remainder of the net proceeds from the Notes offerings for general corporate purposes and capital expenditures, including working capital needs. We may also use the net proceeds to expand our current business through in-licensing or acquisitions of, or investments in, other businesses, products or technologies; however, we do not have any significant commitments with respect to any such acquisitions or investments at this time.

2023 Note Hedge

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

Note 4 to the consolidated financial statements in Part I, Item 1 of this Quarterly Report for conversion activity related to the 2023 Notes and shares received as the result of exercising a portion of the 2023 Note Hedge.

2023 Warrants

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

See Note 4 to the consolidated financial statements in Part I, Item 1 of this Quarterly Report for more information about the terms of the Credit Agreement, our senior convertible notes, the 2023 Note Hedge, and the 2023 Warrants.

Cash Flows



As of September 30, 2021, we had \$2.70 billion in cash, cash equivalents and short-term marketable securities, which is a decrease of \$9.8 million compared to \$2.71 billion as of December 31, 2020.

The primary cash flows during the nine months ended September 30, 2021 and 2020 are described below. See the consolidated financial statements in Part I, Item 1 of this Quarterly Report for complete consolidated statements of cash flows for these periods.

Nine Months Ended		
	September 30, 2021	September 30, 2020
<i>Operating Cash Flows</i>	<p>\$174.1 million of net income and \$255.2 million of net non-cash adjustments, partially offset by \$92.6 million of net changes in working capital balances</p> <p>Net non-cash adjustments were primarily related to share-based compensation, non-cash interest expense for our senior convertible notes, and depreciation and amortization.</p>	<p>\$138.4 million of net income and \$195.4 million of net non-cash adjustments, partially offset by \$30.2 million of net changes in working capital balances</p> <p>Net non-cash adjustments were primarily related to share-based compensation, non-cash interest expense for our senior convertible notes, and depreciation and amortization.</p>
<i>Investing Cash Flows</i>	<p>\$625.1 million net proceeds from marketable securities</p> <p>\$309.0 million capital expenditures</p> <p>\$31.6 million in acquisitions, net of cash acquired</p> <p>\$4.0 million in minority equity investments</p>	<p>\$844.6 million net purchases of marketable securities</p> <p>\$138.8 million capital expenditures</p>
<i>Financing Cash Flows</i>	<p>\$20.3 million in proceeds from the issuance of common stock under our employee stock plans</p> <p>\$9.1 million in payments for financing leases</p>	<p>\$1.19 billion in proceeds from issuance of convertible notes, net of issuance costs</p> <p>\$15.3 million in proceeds from the issuance of common stock under our employee stock plans</p> <p>\$282.6 million cash outflow for repurchase of convertible notes</p>

Contractual Obligations

We presented our contractual obligations as of December 31, 2020 in our Annual Report on Form 10-K for the twelve months then ended. There were no significant changes to our 2025 Notes and lease obligations. See Note 4 to the consolidated financial statements in Part I, Item 1 of this Quarterly Report for conversion activity related to our 2023 Notes. As of September 30, 2021, we had approximately \$503.9 million of open purchase orders and contractual obligations in the ordinary course of business, the majority of which are due within one year.

Off-Balance Sheet Arrangements

As of September 30, 2021, we did not have any significant off-balance sheet arrangements, as defined in Item 303(a)(4)(ii) of Regulation S-K.

Recent Accounting Guidance

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

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.

Market Price Sensitive Instruments

In order to reduce potential equity dilution, in connection with the issuance of the 2023 Notes we entered into the 2023 Hedge which entitles us to purchase shares of our common stock. Upon conversion of the 2023 Notes, the 2023 Hedge is expected to reduce the equity dilution if the daily volume-weighted average price per share of our common stock exceeds the

strike price of the hedge. We also entered into warrant transactions with the counterparties of the 2023 Hedge entitling them to acquire shares of our common stock. The warrant transactions could have a dilutive effect on our earnings per share to the extent that the price of our common stock during a given quarterly or annual measurement period exceeds the strike price of the warrants. See Note 4 to the consolidated financial statements in Part I, Item 1 of this Quarterly Report for more information.

Foreign Currency Exchange Risk

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

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

We record exchange rate fluctuations resulting from the translation of the short-term intercompany balances between domestic entities and our international subsidiaries as foreign currency transaction gains or losses and include them in interest and other income (expense), net in our consolidated statements of operations. We occasionally enter into foreign currency forward contracts in order to partially offset the impact from fluctuation of the foreign currency rates. As of September 30, 2021, we had foreign currency forward contracts outstanding with a notional amount of \$48.0 million.

The fair values of these derivatives are based on quoted market prices, which are Level 1 inputs, and the derivative instruments are recorded in other current assets or other current liabilities in our consolidated balance sheets consistent with the nature of the instrument at period end. Derivative gains and losses are included in interest and other income (expense), net in our consolidated statements of operations.

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

ITEM 4 - CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Regulations under the Securities Exchange Act of 1934 require public companies to maintain "disclosure controls and procedures," which are defined to mean a company's controls and other procedures that are designed to ensure that information required to be disclosed in the reports that it files or submits under the Securities Exchange Act of 1934 is accumulated and timely communicated to management, including our Chief Executive Officer and Chief Financial Officer, recorded, processed, summarized, and reported within the time periods specified in the Securities and Exchange Commission's rules and forms. Our management, including our Chief Executive Officer and our Chief Financial Officer, conducted an evaluation as of the end of the period covered by this report of the effectiveness of our disclosure controls and procedures. Based on their evaluation as of September 30, 2021, our Chief Executive Officer and our Chief Financial Officer concluded that our disclosure controls and procedures were effective as of such date for this purpose.

Changes in Internal Control over Financial Reporting

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

As a result of the COVID-19 pandemic, certain employees began working remotely in March 2020. We have not identified any material changes in our internal control over financial reporting as a result of these changes to the working

environment. We are continually monitoring and assessing the COVID-19 situation to determine any potential impacts on the design and operating effectiveness of our internal controls 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, we cannot guarantee that any design will succeed in achieving its stated goals under all potential future conditions, regardless of how remote.

PART II. OTHER INFORMATION

ITEM 1 - LEGAL PROCEEDINGS

We are subject to various claims, complaints and legal actions that arise from time to time in the normal course of business, including commercial insurance, product liability, intellectual property 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.

During the quarters ended June 30, 2021 and September 30, 2021, we and certain Abbott entities served complaints for patent infringement against each other in multiple jurisdictions, inside and outside the United States. We intend to vigorously pursue our claims and defenses in these cases to protect our intellectual property and to defend against Abbott's infringement allegations.

We do not believe we are party to any other currently pending legal proceedings, the outcome of which could have a material adverse effect on our business, financial condition or results of operations. There can be no assurance that existing or future legal proceedings arising in the ordinary course of business or otherwise will not have a material adverse effect on our business, financial condition or results of operations.

ITEM 1A - RISK FACTORS

Our short and long-term success is subject to numerous risks and uncertainties, many of which involve factors that are difficult to predict or beyond our control. Before making a decision to invest in, hold or sell our common stock, stockholders and potential stockholders should carefully consider the risks and uncertainties described below, in addition to the other information contained in or incorporated by reference into this Quarterly Report on Form 10-Q, as well as the other information we file with the Securities and Exchange Commission. If any of the following risks are realized, our business, financial condition, results of operations and prospects could be materially and adversely affected. In that case, the value of our common stock could decline and stockholders may lose all or part of their investment. Furthermore, additional risks and uncertainties of which we are currently unaware, or which we currently consider to be immaterial, could have a material adverse effect on our business, financial condition or results of operations. Refer to our disclaimer regarding forward-looking statements at the beginning of Management's Discussion and Analysis of Financial Condition and Results of Operations in Part I, Item 2 of this Quarterly Report.

Summary of Risk Factors

The below summary of risk factors provides an overview of many of the risks we are exposed to in the normal course of our business activities. As a result, the below summary risks do not contain all of the information that may be important to you, and you should read the summary risks together with the more detailed discussion of risks set forth following this section under the heading "Risk Factors," as well as elsewhere in this Quarterly Report on Form 10-Q. Additional risks, beyond those summarized below or discussed elsewhere in this Quarterly Report on Form 10-Q, may apply to our activities or operations as currently conducted or as we may conduct them in the future or in the markets in which we operate or may in the future operate. Consistent with the foregoing, we are exposed to a variety of risks, including risks associated with the following:

- If we experience decreasing prices for our products and we are unable to reduce our expenses, including the per unit cost of producing our products, there may be a material adverse effect on our business, results of operations, financial condition and cash flows.
- We are subject to cost-containment efforts that could result in reduced product pricing and/or sales of our products and cause a reduction in future revenue.
- If we are unable to obtain adequately broad reimbursement at acceptable prices for our products or any future products from third-party payors, our revenue may be negatively impacted.
- The research and development efforts we undertake independently, and in some instances in connection with our collaborations with third parties, may not result in the development of commercially viable products, the generation of significant future revenues or adequate profitability.
- Our products may not achieve market acceptance.
- If our manufacturing capabilities are insufficient to produce an adequate supply of product at appropriate quality levels, we may not be able to meet market demand or our growth could be limited and our business could be harmed.
- Manufacturing difficulties and/or any disruption at our facilities may adversely affect our manufacturing operations and related product sales and increase our expenses.

- We depend upon third-party suppliers and outsource to other parties, making us vulnerable to supply disruptions, suboptimal quality, non-compliance and/or price fluctuations, which could harm our business.
- If we are unable to continue the development of an adequate sales and marketing organization and/or if our direct sales organization is not successful, or enter into and maintain arrangements with third parties to sell, market or distribute our products, we may have difficulty achieving market awareness and selling our products in the future.
- We operate in a highly competitive market and face competition from large, well-established companies with significant resources, and, as a result, we may not be able to compete effectively.
- The outbreak of the SARS-CoV-2 virus and the COVID-19 disease that it causes, or similar public health crises, could have a material adverse impact on our business, financial condition and results of operations, including our manufacturing, commercial operations and sales.
- We are subject to a variety of risks due to our international operations that could adversely affect our business, our operations or profitability and operating results.
- We have incurred significant losses in the past and may incur losses in the future.
- We are subject to complex and evolving U.S. and foreign laws and regulations regarding privacy, data protection, and other matters. Many of these laws and regulations are subject to change and uncertain interpretation, and could result in claims, changes to our business practices, monetary penalties, increased cost of operations, or declines in user growth or engagement, or otherwise harm our business.
- Cybersecurity risks and cyber incidents could result in the compromise of confidential data or critical data systems and give rise to potential harm to customers, remediation and other expenses, expose us to liability under HIPAA, consumer protection laws, or other common law theories, subject us to litigation and federal and state governmental inquiries, damage our reputation, and otherwise be disruptive to our business and operations.
- We conduct business in a heavily regulated industry and if we fail to comply with applicable laws and government regulations, we could become subject to penalties, be excluded from participation in government programs, and/or be required to make significant changes to our operations.
- Managed care trends, consolidation in the health care industry and health care policy changes, including U.S. health care reform legislation, may have a material adverse effect on our business.
- If we are unable to successfully complete the pre-clinical studies or clinical trials necessary to support additional PMA, de novo, or 510(k) applications or supplements, we may be unable to commercialize our CGM systems under development, which could impair our business, financial condition and operating results.
- We are subject to claims of infringement or misappropriation of the intellectual property rights of others, which could prohibit us from shipping affected products, require us to obtain licenses from third parties or to develop non-infringing alternatives, and subject us to substantial monetary damages and injunctive relief. We may also be subject to other claims or suits.
- Our inability to adequately protect our intellectual property could allow our competitors and others to produce products based on our technology, which could substantially impair our ability to compete.
- We face the risk of product liability claims and may be subject to damages, fines, penalties and injunctions, among other things.
- We could become the subject of governmental investigations, claims and litigation.
- Our stock price is highly volatile and investing in our stock involves a high degree of risk, which could result in substantial losses for investors.
- We have indebtedness in the form of convertible senior notes, which could adversely affect our financial health and our ability to respond to changes in our business.

Risks Related to Our Business and Operations

Risks Related to Pricing and Reimbursement

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

We have experienced, and anticipate that we will continue to experience, decreasing prices for our products due to pricing pressure from managed care organizations and other third-party payors, increased market power of our payors, as the medical device industry consolidates, and increased competition among suppliers, including manufacturing services providers. If the prices for our products and services decrease and we are unable to reduce our expenses, including the cost of sourcing materials, logistics and the cost to manufacture our products, our business, results of operations, financial condition and cash flows will be adversely affected. The global COVID-19 pandemic may result in increased costs for manufacturing and outsourced services while also causing additional pressure to reduce the prices for our products if a recession or depression occurs and people are unable to afford our products. We cannot predict the ultimate impact that the COVID-19 pandemic and its effects could have on our business operations, financial condition and cash flows.

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

In the United States and other countries, government and private sector access to health care products continues to be a subject of focus, and efforts to reduce health care costs are being made by third-party payors. Most of our customers rely on third-party payors, including government programs and private health insurance plans, to cover the cost of our products. We expect that the continuing cost reduction and containment measures may reduce the cost or utilization of health care products and could lead to patients being unable to obtain approval for coverage or payment from these third-party payors. Additionally, as a result of COVID-19, some customers have and others may lose access to their private health insurance plan if they lose their job, and an impact to job status may extend for a prolonged period of time, beyond possible coverage periods through COBRA, or where the cost to maintain coverage may not be affordable to our customer. As most of our customers rely on third-party payors, including government programs and private health insurance plans, to cover the cost of our products, our customers may lose coverage for our products, which may harm our business and results of operations.

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

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

As a medical device company, reimbursement from government and/or commercial third-party healthcare payors, including Medicare and Medicaid, is an important element of our success. In January 2017, the Centers for Medicare & Medicaid Services, or CMS, established a classification of “Therapeutic Continuous Glucose Monitors” as durable medical equipment eligible for coverage under Medicare Part B. Coverage criteria for therapeutic CGMs is determined by CMS under national coverage determinations as well as by local Medicare Administrative Contractors under local coverage determinations. Therefore, Medicare reimbursement for our CGM devices is subject to various coverage conditions and often requires a patient-specific coverage analysis. In May 2017, CMS Medicare Administrative Contractors issued a revision to an existing joint Local Coverage Determination, which establishes the Medicare conditions of coverage for therapeutic CGM, including our G5 Mobile and G6 systems. On October 27, 2020, CMS proposed changes to Medicare Durable Medical Equipment, Prosthetics, Orthotic Devices, and Supplies (DMEPOS) coverage and payment policies that would expand Medicare coverage for CGM devices and supplies by classifying all CGMs (not just therapeutic CGMs) as DME and establishing payment amounts for these items and related supplies. If finalized, beginning April 2021, additional manufacturers would be able to obtain Medicare coverage and payment for their CGM devices and some of the new CGM options may be cheaper for Medicare beneficiaries, potentially resulting in decreased sales and resulting revenues.

Similarly, in September 2016, Germany’s Federal Joint Committee agreed to provide reimbursement for continuous glucose monitoring systems under certain conditions, which we believe are met by our current CGM systems.

A number of regulatory and commercial hurdles remain relating to wide-scale sales where a government or commercial third-party payor provides reimbursement, including sales to Medicare beneficiaries. If we are unable to successfully address

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

As of September 30, 2021, the seven largest private third-party payors, in terms of the number of covered lives, have issued coverage policies for the category of CGM devices. In addition, we have negotiated contracted rates with all seven of those third-party payors for the purchase of our current CGM systems by their members. However, people with diabetes without insurance that covers our products will have to bear the financial cost of them. In the United States, people with diabetes using existing single-point finger stick devices are generally reimbursed all or part of the product cost by Medicare or other third-party payors. The commercial success of our products in both domestic and international markets will substantially depend on whether timely and comprehensive third-party reimbursement is widely available for individuals that use them. While many third-party payors have adopted some form of coverage policy on CGM devices, in a sizeable percentage of cases, under durable medical equipment benefits, those coverage policies frequently are restrictive and require significant medical documentation and other requirements in order for policy holders to obtain reimbursement, and as a result, we have difficulty improving the efficiency of our customer service group. Moreover, it is not uncommon for governmental, including federal and/or state, agencies and their contractors to conduct periodic routine billing and compliance reviews that may entail extensive documentation requests, cooperation with which may require significant time and resources, and may result in identification of overpayments that may need to be refunded.

In addition, Medicare, Medicaid, other governmental health programs, health maintenance organizations and other third-party payors are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement of new and existing medical devices, and, as a result, they may be restrictive, or they may not cover or provide adequate payment for our products. Many of these programs impose documentation and other eligibility requirements that make it more difficult to obtain reimbursement. In order to obtain additional reimbursement arrangements, including under pharmacy benefits, we may have to agree to a net sales price lower than the net sales price we might charge in other sales channels. Our revenue may be limited by the continuing efforts of government and third-party payors to contain or reduce the costs of healthcare through various increasingly sophisticated means, such as leveraging increased competition, increasing eligibility requirements such as second opinions and other documentation, purchasing in a bundle, or redesigning benefits. We are unable to predict what effect the current or any future healthcare reform will have on our business, or the effect these matters will have on our customers. Our dependence on the commercial success of our current CGM 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 our current CGM systems, people without coverage who have diabetes may not use our products. Furthermore, payors are increasingly basing reimbursement rates on factors such as prior approvals and the effectiveness of the product, clinical outcomes associated with the product, and any factors that negatively impact the effectiveness or clinical outcomes (or cause a perception of any such negative impact), such as the results of a clinical trial, a product defect, or a product recall, which could negatively impact the reimbursement rate.

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

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

Risks Related to Product Development

The research and development efforts we undertake independently, and in some instances in connection with our collaborations with third parties, may not result in the development of commercially viable products, the generation of significant future revenues or adequate profitability.

In order to address the anticipated needs of our customers, pursue new markets for our existing products, and remain competitive, we focus our research and development efforts and strategic third-party collaboration activities on the

enhancement of our current CGM products, the development of next-generation products and the development of novel technologies and services.

The development of new products, or novel technologies and services and the enhancement of our current CGM products (including obtaining new indications for use), requires significant investment in research and development, intellectual property protection, clinical trials, regulatory approvals and third party reimbursement. The results of our product development and commercialization efforts may be affected by a range of factors, including our ability to anticipate customer needs, innovate and develop new products, and launch those products cost effectively into multiple markets and geographies. If we are unable to successfully anticipate customer needs, innovate, develop new products and successfully launch them, we may not be able to generate significant future revenues or profits from these efforts. Failing to timely launch our products may cause them to become obsolete and materially and adversely affect our business and financial position.

The development and commercial launch timelines for our products depend a great deal on our ability to achieve clinical endpoints and regulatory requirements and to overcome technology challenges, and may be delayed due to scheduling issues with patients and investigators, requests from institutional review boards, or inquiries from regulators about our independent and collaborative product development activities, product performance and manufacturing supply constraints, among other factors. In addition, support of these clinical trials requires significant resources from employees involved in the production of our products, including research and development, manufacturing, quality assurance, and clinical and regulatory personnel. Even if our development and clinical trial efforts succeed, the FDA may not approve the products or may require additional product testing and clinical trials before approving the products, which would result in product launch delays and additional expense. If approved by the FDA, the products may not be accepted in the marketplace by physicians and people with diabetes.

In the ordinary course of our business, we enter into collaborative arrangements to develop new products and to pursue new markets, such as our agreements with Eli Lilly, Insulet, Novo Nordisk, Tandem Diabetes and The Ypsomed Group, to integrate our CGM technology into their insulin delivery systems, and our amended agreement with Verily to develop one or more next-generation CGM products. Our Eli Lilly, Insulet, Novo Nordisk, Verily and Ypsomed collaborations have not yet resulted in a commercial product. In December 2019, Tandem received FDA approval for its second sensor-augmented insulin delivery system, the t:slim X2™ Insulin Pump with Control-IQ™ technology, which integrates with our G6 system. We have also entered into collaborations with several organizations that are currently using, or are developing, programs for the treatment of Type 2 diabetes that utilize our current CGM systems.

As a result of these relationships, our operating results depend, to some extent, on the ability of our partners to successfully commercialize their insulin delivery systems or monitoring products. Any factors that may limit our partners' ability to achieve widespread adoption of their systems, including competitive pressures, technological breakthroughs for the treatment or prevention of diabetes, adverse regulatory or legal actions relating to insulin pump products, or changes in reimbursement rates or policies of third-party payors relating to insulin pumps or similar products, could have an adverse impact on our operating results.

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

Our products may not achieve market acceptance.

We expect that sales of our current CGM systems will account for substantially all of our product revenue for the foreseeable future. If and when we receive FDA or other regulators' approval for, and begin commercialization of, our next-generation CGM systems, we expect most patients will migrate onto those systems. In the periods leading up to the launch of new or upgraded versions of our CGM systems, however, our customers' anticipation of the release of those products may cause them to cancel, change or delay current period purchases of our current products, which could have a material adverse effect on our business, financial condition and results of operations.

Notwithstanding our prior experience in marketing and selling our products, we might be unable to successfully expand the commercialization of our existing products or begin commercialization of our next-generation CGM systems on a wide-scale for a number of reasons, including:

- our G6 system prompts the user to replace the sensor no later than the tenth day, which might make it expensive for users;

- widespread market acceptance of our products by physicians and people with diabetes will largely depend on our ability to demonstrate their relative safety, effectiveness, reliability, cost-effectiveness and ease of use;
- the limited size of our sales force;
- we may not have sufficient financial or other resources to adequately expand the commercialization efforts for our products;
- our FDA and other regulatory authority marketing application submissions and reviews may be delayed, or cleared or approved with limited product indications and labeling;
- we may not be able to manufacture our products in commercial quantities commensurate with demand or at an acceptable cost;
- people with Type 2 diabetes do not generally receive broad reimbursement from third-party payors for their purchase of CGM products in the United States, since many payors require that a policy holder meet specific medical criteria to qualify for reimbursement, which may reduce widespread access to or use of our products;
- the uncertainties associated with establishing and qualifying new manufacturing facilities;
- people with diabetes may need to incur the costs of single-point finger stick devices, in addition to our systems;
- the relative immaturity of the CGM market internationally, and limited international reimbursement of CGM systems by third-party payors and government healthcare providers outside the United States;
- the introduction and market acceptance of competing products and technologies, which may have a lower cost or price, allow for a convenience improvement and allow for improved accuracy and reliability;
- greater name or brand recognition and more established medical product distribution channels by some of our competitors;
- our inability to obtain sufficient quantities of supplies at appropriate quality levels from our single- or sole-source and other key suppliers;
- our inability to manufacture products that perform in accordance with expectations of consumers; and
- rapid technological change may make our technology and our products obsolete.

In addition to the risks outlined above, our G6 systems are more invasive than many other self-monitored glucose testing systems, including single-point finger stick devices, and people with diabetes may be unwilling to insert a sensor in their body, especially if their current diabetes management involves no more than two finger sticks per day. Moreover, people with diabetes may not perceive the benefits of CGM and may be unwilling to change their current treatment regimens. Physicians may not recommend or prescribe our products unless and until (i) there is more long-term clinical evidence to convince them to alter their existing treatment methods, (ii) there are additional recommendations from prominent physicians that our products are effective in monitoring glucose levels, and (iii) reimbursement or insurance coverage is more widely available. In addition, market acceptance of our products by physicians and people with diabetes in Europe or other countries will largely depend on our ability to demonstrate their relative safety, effectiveness, reliability, cost-effectiveness and ease of use. If we are unable to do so, we may not be able to generate product revenue from our sales efforts in Europe or other countries. We cannot predict when, if ever, healthcare professionals, including physicians, and people with diabetes may adopt more widespread use of CGM systems, including our systems. If our CGM systems do not achieve and maintain an adequate level of acceptance by people with diabetes, healthcare professionals, including physicians, and third party payors, our future revenue may be reduced and our business may be harmed.

Risks Related to Manufacturing, Commercial Operations and Commercialization

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

Our existing manufacturing facilities are designed to manufacture current and next-generation sensors and transmitters, but may not be scaled quickly enough to permit us to manufacture one or more of our CGM systems in quantities sufficient to meet market demand. In the past, we have had difficulty scaling our manufacturing operations to provide a sufficient supply of product to support market demand and our commercialization efforts. From time to time, we have also experienced brief periods of backorder and, at times, have had to limit the efforts of our sales force to introduce our products to new customers. We have focused significant effort on continual improvement programs in our manufacturing operations intended to improve quality, yields and throughput. We have made progress in manufacturing to enable us to supply adequate amounts of product to support our commercialization efforts; however, we cannot guarantee that supply will not be constrained in the future. We may not adequately predict the market demand for our products, in order to produce our products in the quantities we anticipate will be necessary to meet market demand. We will need to adequately predict the market demand for our products and increase our manufacturing capacity by a significant factor over the current level to meet or exceed the anticipated market demand. In

addition, we will have to modify our manufacturing design, reliability and process if and when our next-generation CGM, technologies are approved, cleared or otherwise authorized by the applicable regulatory body and commercialized.

There are technical challenges to increasing manufacturing capacity, including equipment design, automation, validation and installation, contractor issues and delays, licensing and permitting delays or rejections, materials procurement, manufacturing site expansion, problems with production yields and quality control and assurance. Continuing to develop commercial-scale manufacturing facilities will require the investment of substantial additional funds and the hiring and retention of additional management, quality assurance, quality control and technical personnel who have the necessary manufacturing experience. Delays in the launch of next-generation products may result in unanticipated continuing increases in demand for current-generation products (to substitute for the unavailability of the next-generation products) which, if not adequately prepared for, may result in deficits in our ability to produce adequate amounts of the prior-generation products to meet demand at appropriate prices.

The scaling of manufacturing capacity is subject to numerous risks and uncertainties, and may lead to variability in product quality or reliability, increased construction timelines, as well as resources required to design, install and maintain manufacturing equipment, among others, all of which can lead to unexpected delays in manufacturing output. In addition, any changes to our manufacturing processes may trigger the need for submissions or notifications to, and in some cases advance approval from, the FDA or other regulatory authorities because of the potential impact of changes on our previously cleared, approved and/or authorized devices. Our facilities are subject to inspections by the FDA and corresponding state agencies on an ongoing basis, and we must comply with Good Manufacturing Practices and FDA Quality Systems Regulations, as well as certain state requirements. We may be unable to adequately maintain, develop and expand our manufacturing process and operations or maintain compliance with FDA and state agency requirements, and manufacturing issues could impact our cleared and approved products. If we are unable to manufacture a sufficient supply of our current products or any future products for which we may receive approval or clearance, maintain control over expenses or otherwise adapt to anticipated growth, or if we underestimate growth, we may not have the capability to satisfy market demand, contractual obligations, and our business will suffer.

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

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

Additionally, the majority of our operations are conducted at facilities located in San Diego, California and Mesa, Arizona. We take precautions to safeguard our facilities, which include manufacturing protocols, insurance, health and safety protocols, and off-site storage of data. However, a natural or man-made disaster, such as fire, flood, earthquake, act of terrorism, cyber-attack or other disruptive event, such as the COVID-19 pandemic or another public health emergency, could cause substantial delays in our operations, damage, destroy or limit our manufacturing equipment, inventory, or records and cause us to incur additional expenses. Earthquakes are of particular significance since our manufacturing facilities in California are located in an earthquake-prone area. In the event our existing manufacturing facilities or equipment are affected by man-made or natural disasters, we may be unable to manufacture products for sale or meet customer demands or sales projections. If our manufacturing operations were curtailed or ceased, it would seriously harm our business. The insurance we maintain against fires, floods, earthquakes and other natural disasters and similar events may not be adequate to cover our losses in any particular case. Further, insurance coverage may not be available or successfully secured for loss profits or business interruption relating to the COVID-19 pandemic and its impacts.

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

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

Although we work with our suppliers to try to ensure continuity of supply while maintaining quality, timeliness and reliability, the supply of these components, materials and services may be impacted, interrupted or insufficient. Our

manufacturers and suppliers may also encounter problems during manufacturing for a variety of reasons. They may fail to follow specific protocols and procedures, fail to comply with applicable regulations, or be the subject of FDA or other regulatory authority audits or inspections that result in allegations of non-compliance (for example, resulting in Form 483 Observations, Warning Letters, or other FDA enforcement actions). Our manufacturers and suppliers may also experience or be impacted by equipment malfunction, environmental factors, and public health emergencies including but not limited to the global COVID-19 pandemic, any of which could delay or impede their ability to meet our demand.

Further, if our sole- or single-source suppliers shift their manufacturing and assembly sites to other locations, depending on the circumstances and nature of the item supplied, in addition to quality system activities such as verification and validation, there could be a need for FDA notifications or submissions, and the new locations could be subject to regulatory inspections. If there are regulatory delays or impediments impacting our suppliers or us for any reason, we may not be able to quickly establish additional or replacement suppliers, particularly for our single-source components, in part because of the custom nature of various parts we design. Any interruption or delay in the supply of components or materials, or our inability to obtain components or materials from alternate sources at acceptable prices in a timely manner, could impair our ability to meet the demand of our customers and cause them to cancel orders or switch to competitive products. For supply risks related to COVID-19, see *“The outbreak of the SARS-Cov-2 virus and the COVID-19 disease that it causes, or similar public health crises, could have a material adverse impact on our business, financial condition and results of operations, including our manufacturing, commercial operations and sales.”*

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

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

We also outsource certain services to other parties, including inside sales, certain transaction processing, accounting, information technology, manufacturing, and other areas. Outsourcing of services to third parties could expose us to suboptimal quality of service delivery or deliverables and potentially result in repercussions such as missed deadlines or other timeliness issues, erroneous data, supply disruptions, non-compliance (including with applicable legal or regulatory requirements and industry standards) and/or reputational harm, with potential negative effects on our results. Closure of non-essential businesses and shelter-in-place orders occurring in the U.S. and globally as a result of the COVID-19 pandemic may also adversely impact our outsourced operations. We continue to monitor this situation closely.

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

If we are unable to establish and maintain adequate sales, marketing and distribution capabilities or enter into and maintain arrangements with third parties to sell, market and distribute our products, we may have difficulty achieving market awareness and selling our products in the future.

We must continue to develop and grow our sales and marketing organization and enter into partnerships or other arrangements to market and sell our products and/or collaborate with third parties, including distributors and others, to market and sell our products to maintain the commercial success of our current systems and to achieve commercial success for any of

our future products. If we are unable to establish and maintain adequate sales, marketing and distribution capabilities, independently or with others, our future revenue may be reduced and our business may be harmed.

Developing and managing a direct sales organization is a difficult, expensive and time-consuming process. Although we have shifted our sales and marketing activity to be conducted virtually and remotely, restrictions in connection with the COVID-19 outbreak may have a substantial impact on our customers and sales cycles and have impacted and/or interrupted our sales and marketing activity.

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

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

We currently employ sales and marketing personnel for the direct sale and marketing of our products in the United States, Canada and certain countries in Europe. Our direct sales and marketing team calls on healthcare providers and people with diabetes throughout the applicable country to initiate sales of our products. Our sales and marketing organization competes with the experienced, larger and well-funded marketing and sales operations of our competitors. We may not be able to successfully manage our dispersed sales force or increase our product sales at acceptable rates. COVID-19 restrictions vary by location across the United States and other regions of the world, which may continue to limit or prohibit our sales force from having in-person interactions with healthcare providers and people with diabetes, which may result in decreased sales of our products.

We have also entered into distribution arrangements to leverage existing distributors (including wholesalers) already engaged in the distribution of drugs, devices and/or products in the diabetes marketplace. Some of our U.S distributors are focused on accessing underrepresented regions and or third-party payors that contract exclusively with distributors in the United States, while some of our international distributors call directly on healthcare providers and patients to market and sell our products. 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.

Our distribution agreements with Byram and affiliates, Cardinal Health and affiliates (including Edgepark Medical Supplies), AmerisourceBergen, and McKesson, our four most significant distributors, each generated 10% or more of our total revenue during the nine months ended September 30, 2021. 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. Moreover our shift of durable medical equipment sales from our direct sales force to distributors could result in negative impacts on the quality or efficacy of our customer sales and support experience. A substantial decrease or loss of these sales could have a material adverse effect on our financial results and operating performance.

To the extent that we enter into additional arrangements with third parties to perform sales, marketing, distribution and billing services, our product margins could be lower than if we directly marketed and sold our products. To the extent that we enter into co-promotion or other marketing and sales arrangements with other companies, any revenue received will depend on the skills and efforts of others, and we cannot predict whether these efforts will be successful.

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

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

The market for glucose monitoring devices is intensely competitive, subject to rapid change and significantly affected by new product introductions and other market activities of industry participants, including enhanced software capabilities, and related data and IT platforms. Our products are based on our proprietary technology, but a number of companies and medical researchers are pursuing new technologies for the monitoring of glucose levels. FDA or other regulatory approval of a

commercially viable continuous glucose monitor or sensor produced by one of our competitors could significantly reduce market acceptance of our systems. In addition, certain development efforts throughout the diabetes industry, including that of the National Institutes of Health and other supporters of diabetes research are continually seeking ways to prevent, cure or improve treatment of diabetes. Therefore, our products may be rendered obsolete by technological breakthroughs in diabetes monitoring, treatment, prevention or cure.

In selling our current CGM systems, we compete directly with the Diabetes Care division of Abbott Laboratories; Medtronic plc's Diabetes Group; Roche Diabetes Care, a division of Roche Diagnostics; privately-held LifeScan, Inc.; and Ascensia Diabetes Care, each of which manufactures and markets products for the single-point finger stick device market. Collectively, these companies currently account for the majority of the worldwide sales of self-monitored glucose testing systems.

Several companies are developing and/or commercializing products for continuous or periodic monitoring of glucose levels in the interstitial fluid under the skin that compete directly with our products. We have competed with Abbott for several years and their Libre family of CGM products. Medtronic markets and sells a standalone glucose monitoring product called Guardian Connect both internationally and in the United States.

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

We also have begun to become aware of companies outside the traditional medical device sector that are attempting to develop competitive products and services, including for the general health and wellness, or population health space. Some of the companies developing or marketing competing devices are large and well-known publicly traded companies, and these companies may possess competitive advantages over us, including:

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

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

The outbreak of the SARS-CoV-2 virus and the COVID-19 disease that it causes, or similar public health crises, could have a material adverse impact on our business, financial condition and results of operations, including our manufacturing, commercial operations and sales.

The outbreak of the SARS-CoV-2 virus and the COVID-19 disease that it causes is a global pandemic. The novel coronavirus, as well as new variants of the coronavirus have spread to most regions of the world, including the United States and Europe. The extent to which this coronavirus impacts our business and operating results will depend on future developments that are highly uncertain and cannot be accurately predicted, including new information that may emerge concerning the virus and the actions to contain it or to mitigate the COVID-19 impact, among others. It is especially difficult to predict the impact on the global economic markets, which have been and will continue to be highly dependent upon the actions of governments, businesses, and other enterprises in response to the pandemic, as well as the effectiveness of those actions, and vaccine availability, distribution and adoption. The COVID-19 pandemic and its adverse effects have become more prevalent in the locations where we, our customers, suppliers or third-party business partners conduct business and as a result, we may begin to experience more pronounced disruptions in our operations.

The spread of COVID-19, which has caused a broad impact globally, including restrictions on travel and quarantine policies put into place by businesses and governments, may have a material economic effect on our business. For example, such restrictions may have a substantial impact on our customers and sales cycles. They have impacted our sales and marketing activity including quite significantly in Europe where more restrictive health protection measures and greater reliance on in-person sales efforts at doctors' offices create a greater impediment to our selling efforts. Furthermore, changes in hospital or physician policies, federal, state or local regulations, prioritization of hospital or medical resources toward pandemic efforts

may negatively affect the demand for our devices. The COVID-19 pandemic has, and may continue to, put pressure on global economic conditions and overall spending for medical device products, and may cause our customers to modify spending priorities or delay or abandon purchasing decisions. Further, if the spread of the coronavirus pandemic continues and our operations are adversely impacted, we risk a delay, default and/or nonperformance under existing agreements.

Severe respiratory symptoms, infections and deaths related to the pandemic may disrupt healthcare delivery in the United States as well as the operations of regulatory bodies with responsibility for oversight of healthcare and health and medical products. Such disruptions could result in the focus and prioritization of regulatory resources on emergent matters, which could divert regulatory resources away from more routine regulatory matters that are not COVID-19 related but that have the potential to impact our business. For example, there could be delays in FDA review of applications for marketing authorization, including those which may be necessary for or in connection with proposed changes to our products or the changes to the processes by which they are manufactured. It is unknown how long these disruptions could continue, were they to occur. Any elongation or de-prioritization or delay in regulatory review resulting from such disruptions could materially affect our ongoing device design, development, and commercialization plans.

Furthermore, the COVID-19 pandemic and associated shelter-in-place orders have and may continue to limit or restrict our ability to initiate, conduct or continue our clinical trials. Delays and disruptions in our clinical trials have and may continue to result in delays for new or expanded marketing authorizations for our products, which could materially affect our development and commercialization plans for our products. For example, we have experienced some delays in certain pivotal clinical trials for our next-generation CGM product.

Additionally, as a result of the impact of the COVID-19 pandemic, some customers have lost, and others may lose, access to their private health insurance plan if they have lost or lose their job. Any prolonged economic downturn or recession as a result of the COVID-19 pandemic could result in layoffs of employees and a significant increase in unemployment in the United States and elsewhere, which may continue even after the COVID-19 pandemic is contained. An impact to job status may extend for a prolonged period of time, beyond possible coverage periods through COBRA, or where the cost to maintain coverage may not be affordable to our customer. As most of our customers rely on third-party payors, including government programs and private health insurance plans, to cover the cost of our products, our customers may lose coverage to our products, which may harm our business and results of operations.

We currently utilize third parties to, among other things, manufacture components and materials for our devices, and to provide services such as sterilization services and we purchase these materials and services from numerous suppliers worldwide. The global COVID-19 pandemic has and may continue to have an adverse impact on our manufacturing and distribution capabilities. Disruptions relating to the COVID-19 pandemic, including current shelter-in-place orders in the U.S. and other countries, could prevent employees, suppliers, distributors, and others from accessing manufacturing facilities and from transporting our products or the components required to manufacture our products. For example, we have experienced some supply chain disruption due to the global restrictions resulting from the COVID-19 pandemic in the manufacture of our next-generation CGM product. Further, worldwide supply chain disruption relating to the COVID-19 pandemic has resulted in product shortages that has and may continue to impact our ability to manufacture our devices. If either we or any third-party parties in the supply chain for materials used in the production of our devices continue to be adversely impacted by, and/or the restrictions resulting from, the COVID-19 pandemic, our supply chain may be continue disrupted, limiting our ability to manufacture our devices. These disruptions may, among other things, impact our ability to produce and supply products in quantities necessary to meet market demand.

Reduction in our manufacturing and shipping capabilities may have a material economic effect on our business and the results of our operations. If either we or any third-parties in the supply chain for components, materials or services used in the production of our devices are adversely impacted by the disruptions caused by, or restrictions resulting from, the COVID-19 pandemic, our supply chain may be disrupted, which may impact and/or limit our ability to manufacture and distribute our devices.

As a medical device manufacturer, we fall within a “critical essential infrastructure” sector, specifically the “Healthcare/Public Health” sector, and is considered exempt under various stay at home/shelter in place orders, including the California Executive Order N-33-20 (Stay at Home Order) dated March 19, 2020, as amended from time to time. Accordingly, our employees in California and other locations may continue to work because of the importance of our operations to the health and well-being of citizens in the states in which we operate. Consistent with these Stay at Home Orders, we have implemented telework policies wherever possible for appropriate categories of “nonessential” employees. “Essential” employees that are unable to telework continue to work at our facilities, and we have implemented appropriate safety measures, including social distancing, face covering, and increased sanitation standards. We have also suspended any requirement for an employee to obtain a doctor’s note to be absent from or return to the workplace, and are following guidance from the Center for Disease Control and the Occupational Safety and Health Administration regarding suspension of nonessential travel, self-isolation recommendations for employees returning from certain geographic areas, confirmed reports of any COVID-19 diagnosis among our employees, and the return of such employees to our workplace. Pursuant to updated guidance from the Equal Employment

Opportunity Commission, we are engaging in limited and appropriate inquiries of employees regarding potential COVID-19 exposure, based on the direct threat that such exposure may present to our workforce. We continue to address other unique situations that arise among our workforce due to the COVID-19 pandemic on a case-by-case basis. While we believe that we have taken appropriate measures to ensure the health and well-being of our “essential” employees, there can be no assurances that our measures will be sufficient to protect our employees in our workplace or that they may otherwise be exposed to COVID-19 outside of our workplace. If a number of our essential employees become ill, incapacitated or are otherwise unable to continue working during the current or any future epidemic, our operations may be adversely impacted.

While the potential economic impact brought by, and the duration of, the pandemic is difficult to assess or predict, it has already caused, and is likely to result in further, significant disruption of global financial markets. The trading prices for our common stock and other medical device companies have been highly volatile as a result of the COVID-19 pandemic, which may reduce our ability to access capital on favorable terms or at all. In addition, a recession, depression or other sustained adverse market event resulting from the impact of the COVID-19 pandemic could materially and adversely affect our business and the value of our common stock.

The ultimate impact of the current pandemic, or any other health epidemic, is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, our clinical trials, our research programs, healthcare systems or the global economy as a whole. However, these effects could have a material impact on our business, and we will continue to monitor the situation closely.

Risks Related to our International Operations

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

Our operations in countries outside the United States, which accounted for approximately 24% of our revenues for the nine months ended September 30, 2021, are accompanied by certain financial and other risks. In addition to opening offices in Austria, Canada, Germany, the Philippines, Switzerland, Lithuania, and the United Kingdom, in connection with distributor acquisitions and otherwise, we intend to continue to pursue growth opportunities in sales outside the United States, especially in Asia (including Japan and Korea) and Europe, and we may increase our use of administrative and support functions from locations outside the United States, which could expose us to greater risks associated with our sales and operations. As we pursue opportunities outside the United States, we may become more exposed to these risks and our ability to scale our operations effectively may be affected. For example, we are building out a manufacturing facility in Malaysia.

Additionally, our international expansion efforts, including our proposed manufacturing facility in Malaysia, may not be successful and we may experience difficulties in scaling these functions from locations outside the United States and may not experience the expected cost efficiencies.

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

- local product preferences and product requirements;
- longer-term receivables than are typical in the United States;
- fluctuations in foreign currency exchange rates;
- less intellectual property protection in some countries outside the United States than exists in the United States;
- trade protection measures and import and export licensing requirements;
- workforce instability;
- fluctuations in trade policy and tariff regulations; and
- political and economic instability.

Moreover, the tax laws in which we and our subsidiaries do business could change on a prospective or retroactive basis, and any such changes could adversely affect our business and financial condition. There is growing pressure in many jurisdictions, including the United States, and from multinational organizations such as the Organization for Economic Cooperation and Development (OECD) and the European Union to amend existing international tax rules in order to render them more responsive to current global business practices. For example, the OECD has published a package of measures for reform of the international tax rules as a product of its Base Erosion and Profit Shifting (BEPS) initiative, which was endorsed by the G20 finance ministers. Many of the initiatives in the BEPS package require amendments to the domestic tax legislation of various jurisdictions. Separately, the European Union is asserting that a number of country-specific favorable tax regimes and rulings in certain member states may violate, or have violated, European Union law, and may require rebates of some or all of the associated tax benefits to be paid by benefited taxpayers in particular cases. In 2016, the European Union adopted the "Anti-Tax Avoidance Directive," which requires European Union member states to implement measures to prohibit tax

avoidance practices, and Germany published the European Union Anti-Tax Avoidance Directive Implementation Law on June 30, 2021. We have a significant presence in the European Union, as well as significant sales in the European Union, such that any changes in tax laws in the European Union will impact our business. The overall impact of such legislation in European Union member states is uncertain, and our business and financial condition could be adversely affected by any laws impacting our tax rate.

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

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

On June 23, 2016, the United Kingdom, or U.K., held a referendum in which voters approved an exit from the European Union, commonly referred to as “Brexit.” On June 23, 2016, the United Kingdom, or U.K., held a referendum in which voters approved an exit from the European Union, commonly referred to as “Brexit.” As a result, the U.K. left the European Union on January 31, 2020, and this began a transition period that ended on December 31, 2020, during which the U.K. government negotiated the terms of the U.K.’s future relationship with the E.U. In December 2020, the U.K. and E.U. agreed on a trade and cooperation agreement that was applied provisionally from January 1, 2021 until it was ratified by the parties to the agreement. On December 31, 2020, the U.K. passed legislation giving effect to the trade and cooperation agreement, and the E.U. formally adopted the agreement on May 1, 2021. The agreement sets out certain procedures for approval and recognition of medical products in each jurisdiction. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of the trade and cooperation agreement or otherwise, could prevent us from marketing our CGM systems in the U.K. and/or the E.U. and restrict our ability to generate revenue and achieve and sustain profitability. Under the trade and cooperation agreement, U.K. service suppliers no longer benefit from automatic access to the entire E.U. single market, U.K. goods no longer benefit from the free movement of goods and there is no longer the free movement of people between the U.K. and the E.U. Depending on the application of the terms of the trade and cooperation agreement, we could face new regulatory costs and challenges which could have a material adverse effect on our business, results of operations, or financial condition.

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

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

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

The outbreak of the SARS-CoV-2 virus and the COVID-19 disease that it causes, as well as new variants of coronavirus, have also led to healthcare equipment shortages in the U.S. and around the world. Certain U.S. federal government orders have limited companies from exporting certain equipment (such as ventilators) to other countries. Currently, no such orders have been issued with respect to CGMs, however, if supply chain disruption causes significant shortages in CGMs or other equipment, it is possible that we could face additional barriers to exporting our devices outside of the United States.

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

The U.S. Foreign Corrupt Practices Act, the UK Bribery Act and similar worldwide anti-bribery laws in non-U.S. jurisdictions generally prohibit companies and their intermediaries from making improper payments to non-U.S. government officials and, in some instances, other persons for the purpose of obtaining or retaining business. Because of the predominance of government-sponsored healthcare systems around the world, most of our customer relationships outside of the United States are with governmental entities and are therefore potentially subject to such anti-bribery laws. Global enforcement of anti-corruption laws has increased substantially in recent years, with more frequent voluntary self-disclosures by companies, aggressive investigations and enforcement proceedings by U.S. and foreign governmental agencies, and assessment of

significant fines and penalties against companies and individuals. Our international operations create the risk of unauthorized payments or offers of payments by one of our employees, consultants, sales agents, or distributors, because these parties are not always subject to our direct oversight and control. It is our policy to implement safeguards to educate our employees and agents on these legal requirements and discourage improper practices. However, our existing safeguards and any future improvements may prove to be less than effective, and our employees, consultants, sales agents, or distributors may engage in conduct for which we might be held responsible. In addition, the government agencies may seek to hold us liable for successor liability for anti-corruption law violations committed by any companies in which we invest or that we acquire. Any alleged or actual violations of these regulations may subject us to government scrutiny, severe criminal or civil sanctions and other liabilities, including exclusion from government contracting, and could disrupt our business, and result in a material adverse effect on our business, financial condition, and results of operations.

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

Our operations and performance depend on worldwide economic and political conditions. These conditions have been adversely impacted by continued global economic uncertainty, political instability and military hostilities in multiple geographies, concerns over the potential downgrade of U.S. sovereign debt and continued sovereign debt, monetary and financial uncertainties in Europe and other foreign countries, and global health pandemics such as the COVID-19 pandemic. These include potential reductions in the overall stability and suitability of the Euro as a single currency, given the economic and political challenges facing individual Eurozone countries. These conditions have made and may continue to make it difficult for our customers and potential customers to afford our products, and could cause our customers to stop using our products or to use them less frequently. If that were to occur, our revenue may decrease and our performance may be negatively impacted. In addition, the pressure on consumers to absorb more of their own health care costs has resulted in some cases in higher deductibles and limits on durable medical equipment, which may cause seasonality in purchasing patterns. Furthermore, during economic uncertainty, our customers have had job losses and may continue to have issues gaining timely access to sufficient health insurance or credit, which could result in their unwillingness to purchase products or impair their ability to make timely payments to us. While the potential economic impact brought by and the duration of the COVID-19 pandemic may be difficult to assess or predict, it has already caused, and is likely to result in further, significant disruption of global financial markets, which may reduce our ability to access capital on favorable terms or at all. In addition, a recession, depression or other sustained adverse market event resulting from the spread of COVID-19 could materially and adversely affect our business and the value of our common stock.

We cannot predict the reoccurrence of any economic slowdown or the strength or sustainability of the economic recovery, worldwide, in the United States, or in our industry. These and other economic factors could have a material adverse effect on our business, financial condition and results of operations.

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

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

Risks Related to Privacy and Security

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

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

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

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

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

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

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

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

also require us to notify affected individuals and state agencies in the event of a data breach involving individually identifiable information.

Violations of the HIPAA privacy and security regulations may result in criminal and civil penalties. The OCR enforces the regulations and performs compliance audits. In addition to enforcement by OCR, state attorneys general are authorized to bring civil actions seeking either injunction or damages in response to violations that threaten the privacy of state residents. We follow and maintain a HIPAA compliance plan, which we believe complies with the HIPAA privacy and security regulations, but there can be no assurance that OCR or other regulators will agree. The HIPAA privacy regulations and security regulations have and will continue to impose significant costs on us in order to comply with these standards.

There are numerous other laws and legislative and regulatory initiatives at the federal and state levels addressing privacy and security concerns. We also remain subject to federal or state privacy-related laws that are more restrictive than the privacy regulations issued under HIPAA. These laws vary and could impose additional penalties. For example, the Federal Trade Commission uses its consumer protection authority to initiate enforcement actions in response to alleged privacy and data security violations. California recently enacted the California Consumer Privacy Act, or CCPA, which came into effect January 1, 2020, was recently amended and expanded by the California Privacy Rights Act (CPRA) passed on November 3, 2020. The CCPA and CPRA, among other things, create new data privacy obligations for covered companies and provide new privacy rights to California residents, including the right to opt out of certain disclosures of their information. The CCPA also creates a private right of action with statutory damages for certain data breaches, thereby potentially increasing risks associated with a data breach. It remains unclear what, if any, additional modifications will be made to this legislation or how it will be interpreted. Therefore the effects of the CCPA and CPRA are significant and will likely require us to modify our data processing practices, and may cause us to incur substantial costs and expenses to comply, particularly given our base of operations in California. There are also a number of other legislative proposals worldwide, including in the United States at both the federal and state level, that could impose additional and potentially conflicting obligations in areas affecting our business.

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

For instance, in the European Union, increasingly stringent data protection and privacy rules that have and will continue to have substantial impact on the use of patient data across the healthcare industry became effective in May 2018. The EU General Data Protection Regulation, or GDPR, applies across the European Union and includes, among other things, a requirement for prompt notice of data breaches to data subjects and supervisory authorities in certain circumstances and significant fines for non-compliance. The GDPR fine framework can be up to 20 million euros, or up to 4 % of the company's total global turnover of the preceding fiscal year, whichever is higher. The GDPR also requires companies processing personal data of individuals residing in the European Union to comply with EU privacy and data protection rules, even if the company itself does not have a physical presence in the European Union. Noncompliance could result in the imposition of fines, penalties, or orders to stop noncompliant activities. Due to the strong consumer protection aspects of the GDPR, companies subject to its purview are allocating substantial legal costs to the development of necessary policies and procedures and overall compliance efforts. For example, following a decision of the Court of Justice of the EU in October 2015, the transfer of personal data to US companies that had certified as members of the US Safe Harbor Scheme was declared invalid. In July 2016, the European Commission adopted the EU-US Privacy Shield Framework, or the Privacy Shield Framework, which replaced the US Safe Harbor Scheme. On July 16, 2020, the Court of Justice of the European Union issued a decision that declared the Privacy Shield Framework invalid, and will also result in additional compliance obligations for companies that implement standard contractual clauses to ensure a valid basis for the transfer of personal data outside of Europe. We expect continued costs associated with maintaining compliance with GDPR into the future, and these provisions as interpreted by EU agencies, could negatively impact our business, financial condition and results of operations.

In addition to the laws discussed above, we may see more stringent state and federal privacy legislation in 2021 and beyond, as the increased cyber attacks during the COVID-19 pandemic have once again put a spotlight on data privacy and security in the U.S. and other jurisdictions. We cannot predict where new legislation might arise, the scope of such legislation, or the potential impact to our business and operations.

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

Cyber incidents can result from deliberate attacks or unintentional events. We collect and store on our networks sensitive information, including intellectual property, proprietary business information and personally identifiable information of individuals, such as our customers and employees. The secure maintenance of this information and technology is critical to our business operations. We have implemented multiple layers of security measures to protect the confidentiality, integrity and

availability of this data and the systems and devices that store and transmit such data. We utilize current security technologies, and our defenses are monitored and routinely tested internally and by external parties. Despite these efforts, threats from malicious persons and groups, new vulnerabilities and advanced new attacks against information systems create risk of cybersecurity incidents. These incidents can include, but are not limited to, gaining unauthorized access to digital systems for purposes of misappropriating assets or sensitive information, corrupting data, or causing operational disruption. Because the techniques used to obtain unauthorized access, disable or degrade service, or sabotage systems change frequently and may not immediately produce signs of intrusion, we may be unable to anticipate these incidents or techniques, timely discover them, or implement adequate preventative measures.

In response to the COVID-19 pandemic, we have modified our business practices and implemented telework policies wherever possible for appropriate categories of “nonessential” employees to minimize the disruption to our operations, to the extent possible. The continuation of these telework policies for “nonessential employees” also introduces additional operational risk, including increased cybersecurity risk. These cyber risks may include, among other risks, greater phishing, malware, and other cybersecurity attacks, vulnerability to or disruptions of our information technology infrastructure and systems to support remote operations, increased risk of unauthorized access, use or dissemination of confidential information, limited ability to restore the systems in the event of a systems failure or interruption, greater risk of a security breach resulting in destruction, alteration or misuse of valuable information, including proprietary business information and personally identifiable information of individuals, all of which could expose us to risks of data or financial loss, litigation and liability.

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

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

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

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

We rely on information technology and telephone networks and systems, including the Internet, to process and transmit sensitive electronic information and to manage or support a variety of business processes and activities, including sales, billing, customer service, procurement and supply chain, manufacturing, and distribution. We use enterprise information technology systems to record, process, and summarize financial information and results of operations for internal reporting purposes and to comply with regulatory financial reporting, legal, and tax requirements. System failures or outages, including any potential disruptions due to significantly increased global demand on certain cloud based systems during or as a result of the COVID-19 pandemic, or failures to adequately scale our data platforms and architectures support patient care could compromise our ability to perform these functions in a timely manner, which could harm our ability to conduct business or delay our financial

reporting. Such failures could materially adversely affect our operating results and financial condition. Our information technology systems, some of which are managed by third-parties, may be susceptible to damage, disruptions or shutdowns due to computer viruses, ransomware or other malware, attacks by computer hackers, failures during the process of upgrading or replacing software, databases or components thereof, power outages, hardware failures, telecommunication failures, user errors or catastrophic events. Although we have developed systems and processes that are designed to protect customer information and prevent data loss and other security breaches, including systems and processes designed to reduce the impact of a security breach at a third-party vendor, such measures cannot provide absolute security. In addition, certain countries have implemented or may implement legislative and technological actions that either do or can effectively regulate access to the internet, including the ability of internet service providers to limit access to specific websites or content. Other countries have attempted or are attempting to change or limit the legal protections available to businesses that depend on the internet for the delivery of their services. If our systems are breached or suffer severe damage, disruption or shutdown and we are unable to effectively resolve the issues in a timely manner, our business and operating results may significantly suffer and we may be subject to litigation, government enforcement actions and other actions for which we could face financial liability and other adverse consequences which may include:

- additional government oversight of our operations;
- loss of existing customers;
- difficulty in attracting new customers;
- problems in determining product cost estimates and establishing appropriate pricing;
- difficulty in preventing, detecting, and controlling fraud;
- disputes with customers, physicians, and other health care professionals;
- increases in operating expenses, incurrence of expenses, including notification and remediation costs;
- regulatory fines or penalties;
- individual actions or class actions for damages;
- loss of revenues (including through loss of coverage or reimbursement);
- product development delays;
- disruption of key business operations; and
- diversion of attention of management and key information technology resources.

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

Medical devices are increasingly connected to the internet, hospital networks, and other medical devices to provide features that improve healthcare and increase the ability of healthcare providers to treat patients and patients to manage their conditions. For example, we are pursuing collaborations to enable the connectivity and interoperability of our current and next-generation sensors and transmitters with third-party patient monitoring products, which may in turn be connected with the internet, hospital networks and in some cases, other medical devices. These same features may also increase cybersecurity risks and the risks of unauthorized access and use by third parties. As such, unauthorized third parties may seek to access our devices or other products and services, or related devices, products, and services, and modify or use them in a way inconsistent with our FDA clearances and approvals, which may create risks to users and potential exposure to the company.

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

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

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

- authorizations necessary for the clinical investigation and commercial marketing of products;
- the pricing of our products and services;
- the distribution of our products and services;
- billing for products and services;
- the obligation to report and return identified overpayments;

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

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

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

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

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

FDA and the Federal Trade Commission, or FTC, share oversight of medical device promotion. FDA has broad authority over device marketing (including assessment and oversight of safety and effectiveness) and over “promotional labeling,” while FTC has authority over “advertising” for most medical devices (i.e., non-“restricted” devices, such as ours).

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

In addition, the laws and regulations impacting or affecting our business may change significantly in the future. Any new laws or regulations may adversely affect our business, including any changes in laws and regulations due to the COVID-19 pandemic. A review of our business by courts or regulatory authorities may result in a determination that could adversely affect our operations. Also, the regulatory environment applicable to our business may change in a way that restricts or adversely impacts our operations.

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

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

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

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

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

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

The potential effect of these events can in some cases be difficult to quantify. If any of these actions were to occur, it would harm our reputation and cause our product sales and profitability to suffer. In addition, we believe events that could be classified as reportable events pursuant to MDR regulations are generally underreported by physicians and users, and any underlying problems could be of a larger magnitude than suggested by the number or types of MDRs filed by us. Furthermore,

our key component suppliers may not currently be or may not continue to be in compliance with applicable regulatory requirements.

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

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

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

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

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

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

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

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

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

Any subsequent modification of our G6 that could significantly affect its safety or effectiveness (for example, a significant change in design or manufacture), or that would constitute a major change in its intended use, will require us to obtain a new 510(k) clearance or could require a new *de novo* submission or a PMA. The FDA requires each manufacturer to make this determination initially, but the FDA may review any such decision and may disagree with a manufacturer's

determination. If the FDA disagrees with a manufacturer's determination, the FDA may require the manufacturer to cease marketing and/or recall the modified device until appropriate clearance or approval is obtained. Under these circumstances, the FDA may also subject a manufacturer to significant regulatory fines or other penalties.

If future product candidates are not deemed by the FDA to meet the criteria for submission under the 510(k) pathway, or for down-classification under the *de novo* process or otherwise, we would need to pursue a PMA. The PMA process requires us to prove the safety and effectiveness of our systems to the FDA's satisfaction. This process can be expensive, prolonged and uncertain, requires detailed and comprehensive scientific and human clinical data, and may never result in the FDA granting a PMA. The FDA's *de novo* classification of our G6 system under the generic name "integrated continuous glucose monitoring system," makes it a predicate device for future 510(k) submissions. Complying with this classification requires ongoing compliance with the general controls required by the federal Food Drug and Cosmetic Act and the special controls specified by the FDA's G6 order as a Class II device. Any future system or expanded indications for use of current generation systems will require approval of the applicable regulatory authorities. In addition, we intend to seek either 510(k) clearances or PMA approvals for certain changes and modifications to our existing software platform, but cannot predict when, if ever, those changes and modifications will be approved.

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

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

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

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

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

Our products are purchased principally by individual patients, who may be eligible for insurance coverage of their devices from various third-party payors, such as governmental programs (*e.g.*, Medicare, Medicaid, TRICARE, other federal and state health benefit plans, and comparable non-U.S. programs), private insurance plans, and managed care plans. The ability of our customers to obtain appropriate reimbursement for products and services from third-party payors is critical because it affects which products customers purchase and the prices they are willing to pay. As a result, our products are subject to regulation regarding quality and cost by the U.S. Department for Health & Human Services, including CMS, as well as comparable state and non-U.S. agencies responsible for reimbursement and regulation of health care goods and services. The principal U.S. federal laws that implicate reimbursement issues include those that prohibit (i) the filing of false or improper claims for federal payment, known as the federal civil False Claims Act, (ii) unlawful inducements for the referral of business reimbursable under federally-funded health care programs, known as the federal Anti-Kickback Statute, and (iii) health care service providers from

seeking reimbursement for providing certain services to a patient who was referred by a physician who has certain types of direct or indirect financial relationships with the service provider, known as the federal Physician Self-Referral law, or commonly referred to as the “Stark Law.” Many states have similar laws that apply to reimbursement by state Medicaid and other government-funded programs, as well as, in some cases, to all payors, including self-pay patients. In addition, the federal civil False Claims Act requires the reporting and returning of identified overpayments received from federal health care programs within 60 days of identification and quantification, and requires the exercise of reasonable diligence to investigate credible information regarding potential overpayments. Failure to timely refund known overpayments from federal healthcare programs, such as Medicare and Medicaid, would subject a company to civil False Claims Act liability. Insurance companies can also bring a private cause of action claiming treble damages against a manufacturer for causing a false claim to be filed under the federal Racketeer Influenced and Corrupt Organizations Act, or RICO. Additionally, as a manufacturer of FDA-approved devices reimbursable by federal healthcare programs, we are subject to the federal Physician Payments Sunshine Act, which requires us to annually report certain payments and other transfers of value we make to U.S.-licensed physicians or U.S. teaching hospitals, and under an expansion of the law we will also need to begin tracking and reporting payments to physician assistants, nurse practitioners, and other mid-level practitioners. Reporting requirements will go into effect in 2022 for payments and transfers of value made to these additional practitioner-types in 2021.

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

We train and educate employees and marketing representatives on the Anti-Kickback Statute and their obligations thereunder, and we endeavor to comply with the applicable safe harbors. However, some of our arrangements, like many other common and non-abusive arrangements, may implicate the Anti-Kickback Statute and are not covered by a safe harbor, but nevertheless do not present a material risk to beneficiaries or federal healthcare programs and, as such, would not likely invite government scrutiny or prosecution or warrant the imposition of sanctions. However, we cannot offer assurance that arrangements that do not squarely meet an exception or safe harbor will not be found to violate the Anti-Kickback Statute. Allegations of violations of the Anti-Kickback Statute can also trigger liability under the federal Civil Monetary Penalty Law and federal civil False Claims Act, thereby increasing the penalty structure for these violations.

During the period in which we directly billed Medicare, our financial relationships with referring physicians and their immediate family members were required to comply with the Stark Law by meeting an applicable exception. Unlike the Anti-Kickback Statute, failure to meet an exception under the Stark Law results in a violation of the Stark Law, even if such violation is technical in nature. Violations of the Stark Law create overpayment liability under the federal civil False Claims Act and can also trigger separate penalties under the Civil Monetary Penalties Law. Knowing violations of the Stark Law carry increased civil monetary penalties and would likely be classified as the knowing submission of a false claim or knowingly making a false statement to the government, triggering liability under the federal civil False Claims Act. Certain Stark Law violations can also trigger exclusion from federal healthcare programs. Historical violations of the Stark Law, if any, could continue to give rise to liability during the statute of limitations period.

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

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

Private third-party payors and other managed care organizations, such as pharmacy benefit managers, continue to take action to manage utilization and control cost. Consolidation among managed care organizations has increased the negotiating power of managed care organizations and other private third-party payors. Private third-party payors, as well as governments, increasingly employ formularies to control costs by taking into account discounts in connection with decisions about formulary inclusion or favorable formulary placement. Failure to obtain or maintain timely adequate pricing or favorable formulary placement for our products, or failure to obtain such formulary placement at favorable pricing, could adversely impact revenue. Private third-party payors, including self-insured employers, often implement formularies with copayment tiers to encourage utilization of certain products and have also been raising co-payments required from beneficiaries, particularly for higher cost products. Private third-party payors also use additional measures such as value-based pricing/contracting to improve their cost containment efforts. Private third-party payors also are increasingly imposing utilization management tools, such as requiring prior authorization or requiring the patient to first fail on a lower cost product before permitting access to a higher cost product. In addition, on November 20, 2020, the OIG released a Final Rule, “Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor for Certain Point of Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees” which revises the federal Anti-Kickback Statute’s Discount Safe Harbor at 42 CFR 1001.952(h) to explicitly exclude reductions in price offered by drug manufacturers to

pharmacy benefit managers (PBMs) and Part D plans from the safe harbor's definition of a "discount." OIG expressed concern that the retroactive rebate framework incentivizes manufacturers to increase list prices and provide larger rebates on the backend, preventing beneficiaries and the Medicare Program from sharing in savings. The new rule goes into effect January 1, 2022 but would likely impact PBM rebate negotiations this year. While the new rule does not impact us since it is narrowly tailored to drug rather than device manufacturers, it may have a larger impact on the PBM industry. Notably, however, the Final Rule may not have followed proper administrative steps and therefore, may face legal challenges. We cannot be certain whether the Final Rule will remain in place but if it does, it is possible that our PBM arrangements may be restructured.

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

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

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

To support current and any future additional PMA, 510(k), *de novo* applications or supplements, we together with our partners, must successfully complete pre-clinical studies, bench-testing, and in some cases clinical trials that will demonstrate that the product is safe and effective. Product development, including pre-clinical studies and clinical trials, is a long, expensive and uncertain process and is subject to delays (including any potential delays due to the ongoing COVID-19 pandemic) and failure at any stage. Furthermore, the data obtained from the studies and trials may be inadequate to support approval of an application and the FDA may request additional clinical data in support of those applications, which may result in significant additional clinical expenses and may delay product approvals. While we have in the past obtained, and may in the future obtain, an investigational device exemption, or IDE, prior to commencing clinical trials for our products, FDA approval of an IDE application permitting us to conduct testing does not mean that the FDA will consider the data gathered in the trial to be sufficient to support approval of a PMA, *de novo* or 510(k) application or supplement, even if the trial's intended safety and effectiveness endpoints are achieved.

Changes to the regulatory landscape may impact our ability to obtain marketing authorization for future product developments.

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

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

- the FDA or other regulatory authorities do not approve a clinical trial protocol or a clinical trial, or place a clinical trial on hold;
- patients do not enroll in clinical trials at the rate we expect;
- patients or study site personnel who do not comply with clinical trial protocols;
- patient follow-up does not occur at the rate we expect;
- patients experience adverse side effects;

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

Further, the COVID-19 pandemic and associated shelter-in-place orders could limit or restrict our ability to initiate, conduct or continue our clinical trials. Delays and disruption in our clinical trials could result in delays for expanded FDA clearance or approval of our products. We are unable to predict the length of such delays or the scope of the impact of COVID-19 on our clinical trials at this time. We are continuing to monitor this situation and to explore methods of remote monitoring, remote clinical assessments and other similar delivery methods to permit continuation of clinical trial activities.

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

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

Our CGM systems currently have regulatory marketing authorization limited to individual patient home-use, and have otherwise not received clearance or approval from the FDA or other regulators for use in hospital or other in-patient facility settings, although the FDA has advised us that it will not object to the use of our CGM systems in such settings during the COVID-19 pandemic. Our potential supply of our CGM systems for use in this environment during the COVID-19 pandemic may present risks to our business.

We have received, and may continue to receive, numerous inquiries from hospitals around the country about the use of our CGM devices to remotely monitor COVID-19 patients admitted into the hospital. Extension of CGM system use to hospitalized patients during the COVID-19 pandemic allows hospital staff to monitor glucose remotely in patients and may reduce patient/provider interactions, which could help limit viral exposure for hospital staff and help conserve personal protective equipment (PPE). In the context of the COVID-19 pandemic, the FDA has permitted for regulatory flexibility in a variety of specific circumstances, to expedite the development and availability of critical medical products that may be helpful in COVID-19-related efforts.

Following direct communication with the FDA regarding the potential use of our CGM devices in a hospital or other in-patient setting, the FDA notified us on April 1, 2020 that in an exercise of its enforcement discretion it will not object, in the context of the COVID-19 pandemic, to Dexcom providing CGM devices and support to users to enable real-time remote patient monitoring in hospitals and other healthcare facilities, to support COVID-19 healthcare related efforts, so long as we provide certain FDA-specified information with respect to the unique challenges that CGM technologies can raise in the hospital environment.

As a condition of its exercise of enforcement discretion, the FDA has advised that we communicate the following information related to implementing the use of CGM systems for remote monitoring of hospitalized patients:

- Hospitals should consider whether they have the resources and expertise necessary to adequately implement CGM use and provide appropriate training to healthcare providers.
- CGM glucose results are less accurate than blood glucose results obtained using traditional testing methods (e.g., lab glucose, blood glucose meters). Users should consider all CGM glucose information (e.g., trend) along with individual glucose values, and interpret CGM results in the context of the full clinical picture.
- CGM systems are subject to interferences that may generate falsely high and falsely low glucose readings. Levels of interference depend on drug concentration; substances that may not significantly interfere in non-hospitalized patients may interfere when used in the hospital setting because of higher dose levels. Most drugs used in hospital or critical care settings have not been evaluated and their interference with CGM systems is unknown. Known interferences vary by CGM brand, and can include Acetaminophen, Ascorbic acid, Hydroxyurea, or other reducing drugs/ compounds.
- Poor peripheral blood perfusion may cause inaccurate sensor readings. CGM results should be interpreted considering accompanying patient conditions and medications. Other clinical conditions may also cause inaccurate readings.

Our provision of our CGM systems to hospitals and other healthcare facilities for use during the COVID-19 pandemic have and will continue to have the above notice.

We are not actively promoting nor do we plan to actively promote our CGM devices (and related support) for inpatient use, but if we supply them to such facilities as currently permitted by the FDA, this supply could present an increased risk of product liability claims and associated damages should an adverse event occur. Given that our CGM devices have not yet been fully evaluated or tested by either us or the FDA to the extent that would be required in standard circumstances for product development and marketing authorization, there could be unknown or unanticipated risks presented by use in this environment.

The FDA can also decide, at any time, to change its position regarding enforcement discretion for our devices, and require that we seek marketing authorization for this additional intended use by submitting a 510(k) premarket notification, or that we seek and obtain Emergency Use Authorization. The FDA may determine this policy has expired if the impact of the COVID-19 pandemic subsides or the federal public health emergency declaration is lifted and there is no longer an urgent need to use our CGM systems for remote patient monitoring during the COVID-19 pandemic.

As we are unable to predict the duration or ultimate impact of the provision of our CGM systems to hospitals and other healthcare facilities for use during the COVID-19 pandemic at this time, we do not yet know the ultimate impact to our business or financial results. We will continue to monitor the situation closely.

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

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

As a result of the COVID-19 pandemic, many healthcare facilities were or remain closed or available on a limited basis for non-emergent and elective services. Accordingly, our clinical investigators may not have an opportunity to recruit and enroll patients in our clinical trials. We cannot predict the length of current shelter-in-place orders or the impact of such orders and the COVID-19 pandemic more generally on the provision of non-emergent health services or the normal operation of our clinical sites, therefore, we cannot predict the ultimate impact that such restrictions may have on our clinical trial enrollment and results.

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

In response to perceived increases in health care costs in recent years, there have been and continue to be proposals by the federal government, state governments, regulators, and third-party payors to control these costs and, more generally, to reform the U.S. health care system. Certain of these proposals could limit the prices we are able to charge for our products or the amounts of reimbursement available for our products and could limit the acceptance and availability of our products. Further, while the United States has begun shifting to pay-for-performance rather than fee-for-service models and has been embracing many shared-risk arrangements, CMS and OIGs specifically excluded medical device manufacturers from utilizing the new, more flexible Stark Law exceptions and Anti-Kickback Statute safe harbors under the Final Rules, part of the U.S. Department of Health and Human Services' Regulatory Sprint to Coordinated Care, which were published on December 2, 2020 in the Federal Register and will be effective January 19, 2021. The exclusion of manufacturers from utilizing these exceptions and safe harbors will not allow us to avail ourselves of immunity from liability laws, potentially inviting greater scrutiny over our shared risk arrangements. Changes under these Final Rules could have a material adverse effect on our business, financial condition and results of operations.

Additionally, on November 16, 2020 the OIG published a Special Fraud Alert addressing manufacturer Speaker Programs signaling both a more narrow government view of AKS compliance with respect to such programs as well as the potential for increased enforcement in this space by government oversight agencies such as the OIG and DOJ. This development may cause us to assess and consider modification to certain aspects of our speaker programs, which may have a detrimental impact on our ability to educate healthcare providers about our products and to promote use of our products, which may lead to decreased product sales and negatively impact our business, financial condition and results of operations.

Comprehensive healthcare legislation, signed into law in the United States in March 2010, titled the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act of 2010, collectively, the ACA, imposes certain stringent compliance, recordkeeping, and reporting requirements on companies in various sectors of the life sciences industry, with which we may need to comply, and enhanced penalties for non-compliance with the new and revised healthcare laws. Despite the ACA going into effect over a decade ago, continuous legal and Congressional challenges to the law's provisions and persisting uncertainty with respect to the scope and effect of certain provisions have made compliance costly. A case challenging the constitutionality of the ACA's individual mandate is currently before the Supreme Court.

We cannot predict whether the ACA will be repealed, replaced, or modified, or how such repeal, replacement or modification may be timed or structured. The change in Presidential Administration may also result in new agency priorities, rulemakings, and legislation, the scope and effect of which cannot be predicted. As a result, we cannot quantify or predict what the effect of such repeal, replacement, or modification might have on our business and results of operations. However, any changes that lower reimbursement for our products could materially and adversely affect our business, financial condition and results of operations.

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

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

Risks Related to Intellectual Property Protection and Use

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

Third parties have asserted, and may assert, infringement or misappropriation claims against us with respect to our current or future products. We are aware of numerous patents issued to third parties that may relate to aspects of our business, including the design and manufacture of CGM sensors and membranes, as well as methods for continuous glucose monitoring. Whether a product infringes a patent involves complex legal and factual issues, the determination of which is often uncertain. Therefore, we cannot be certain that we have not infringed the intellectual property rights of such third parties or others. Our competitors may assert that our CGM systems or the methods we employ in the use of our systems are covered by U.S. or foreign patents held by them. We have in the past settled some such allegations and may need to do so again in the future. This risk is exacerbated by the fact that there are numerous issued patents and pending patent applications relating to self-monitored glucose testing systems in the medical technology field. Because patent applications may take years to issue, there may be applications now pending of which we are unaware that may later result in issued patents that our products infringe. There could also be existing patents of which we are unaware that one or more components of our system may inadvertently infringe. As the number of competitors in the market for CGM systems grows, the possibility of patent infringement by us or a patent infringement claim against us increases. If we are unable to successfully defend any such claims as they may arise or enter into or extend settlement and license agreements on acceptable terms or at all, our business operations may be harmed. We have been involved in various patent infringement actions in the past. For example, in March 2020, we settled certain patent infringement litigation and proceedings between us and AgaMatrix, Inc. and WaveForm Technologies, Inc. In addition, in July 2014, we entered into a Settlement and License Agreement with Abbott to settle all pending patent infringement legal proceedings brought by Abbott against us, which expired on March 31, 2021. Since the expiration of that agreement, we and certain Abbott entities have served complaints for patent infringement against each other in multiple jurisdictions, inside and outside the United States. We intend to vigorously pursue our claims and defenses in these cases to protect our intellectual property and to defend against Abbott's infringement allegations.

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

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

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

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

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

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

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

Litigation Risks

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

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

Although we have insurance at levels that we believe is appropriate, this insurance is subject to deductibles and coverage limitations. Our current product liability insurance may not continue to be available to us on acceptable terms, if at all, and, if available, the coverage may not be adequate to protect us against any future product liability claims. Further, if additional products are approved for marketing, we may seek additional insurance coverage. If we are unable to obtain insurance at an

acceptable cost or on acceptable terms with adequate coverage or otherwise protect against potential product liability claims, we will be exposed to significant liabilities, which may harm our business. A product liability claim, recall or other claim with respect to uninsured liabilities or for amounts in excess of insured liabilities could result in significant costs and significant harm to our business.

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

As a result of the COVID-19 pandemic, we have received and continue to receive, numerous requests from hospitals and healthcare facilities around the country regarding the use of our CGM devices to remotely monitor COVID-19 patients admitted into the hospital. As noted above, the FDA has informed us that they intend to exercise enforcement discretion and will not object to our provision of its G6 CGM systems to such facilities for use in the inpatient setting during the pandemic. However, our CGM devices are currently approved only for in-home use by patients for the purpose of personal diabetes management and have not otherwise been cleared or approved by the FDA for hospital use. Given that the G6 CGM has not yet been fully evaluated or tested (by us or by the FDA) to the extent that would be required in standard circumstances for product development and marketing authorization, there could be unknown or unanticipated risks presented by use in this environment. To the extent that inpatient use of our CGM systems cause or contribute to an adverse event, we may be subjected to additional product liability lawsuits. Defending a suit, regardless of merit, could be costly, could divert management attention and might result in adverse publicity, which could result in reduced acceptance of our products in the market.

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

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

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

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

We are not presently aware of any governmental investigations involving our executives or us. However, any future investigations of our executives, our managers or us could result in significant liabilities or penalties to us, as well as adverse publicity. Even if we are found to have complied with applicable law, the investigation or litigation may pose a considerable

expense and would divert management's attention, and have a potentially negative impact on the public's perception of us, all of which could negatively impact our financial position and results of operations. Further, should we be found out of compliance with any of these laws, regulations or programs, depending on the nature of the findings, our business, our financial position and our results of operations could be negatively impacted.

We may be subject to fines, penalties and injunctions if we are determined to be promoting the use of our products for unapproved or improper off-label uses or determined to have made claims that are untruthful or misleading or not adequately substantiated.

We believe our marketing, promotional and educational materials and practices comply with FDCA, Federal Trade Commission Act, and other applicable laws and regulations, as may be amended from time to time. If the FDA, FTC or other regulatory body with competent jurisdiction over us, our activities or products takes the position that our marketing, promotional or other materials or activities constitute improper promotion or marketing of an unapproved or improper use, or that they contain untruthful, misleading, or inadequately substantiated statements or claims, such regulatory body could request that we modify our materials or practices, or subject us to regulatory enforcement actions, including the issuance, depending on the regulatory body and the nature of the alleged violation, of a warning letter, injunction, seizure, civil fine and criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider promotional, marketing or other materials or activities to constitute improper promotion of an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. Recent court decisions have impacted the FDA's enforcement activity regarding off-label promotion in light of First Amendment considerations; however, there are still significant risks in this area in part due to the potential False Claims Act exposure and the FDA's continued focus on ensuring devices are marketed in a manner consistent with their FDA-required labeling.

We are not actively promoting nor do we plan to actively promote our G6 CGM systems for inpatient use, but if we supply them to such facilities as currently permitted by FDA, this supply could present an increased risk of product liability claims and associated damages should an adverse event occur. Given that the G6 CGM system has not yet been fully evaluated or tested (by us or by the FDA) to the extent that would be required in standard circumstances for product development and marketing authorization, there could be unknown or unanticipated risks presented by use in this environment.

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

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

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

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

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

Other Risks Related to our Business and Financial Condition

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

We have incurred significant operating losses in the past. As of September 30, 2021, we had an accumulated deficit of \$28.0 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 G5 Mobile and G6 systems; and
- expansion of our workforce.

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

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

We depend to a significant degree on our senior management, especially Kevin Sayer, our President and Chief Executive Officer. Our success will depend on our ability to retain our senior management and to attract and retain qualified personnel in the future, including salespersons, scientists, clinicians, engineers and other highly skilled personnel. Competition for senior management personnel, as well as salespersons, scientists, clinicians and engineers, is intense and we may not be able to retain our personnel. The loss of the services of members of our senior management, scientists, clinicians or engineers could prevent the implementation and completion of our objectives, including the commercialization of our current products and the development and introduction of additional products. The loss of a member of our senior management or our professional staff would require the remaining executive officers to divert immediate and substantial attention to seeking a replacement.

Each of our officers may terminate their employment at any time without notice and without cause or good reason. Additionally, volatility or a lack of positive performance in our stock price may adversely affect our ability to retain key employees.

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

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

We may conduct additional financings to continue the development or commercialization of our current or future generation CGM systems.

Our operations have consumed substantial amounts of cash since inception. We expect to continue to spend substantial amounts on commercialization of our products, including growth of our manufacturing capacity, on research and development, and conducting clinical trials for our next-generation ambulatory CGM sensors and systems. Although we raised substantial net proceeds through the private sale of our convertible notes, we could need funds to continue the commercialization of our current products and to develop and commercialize our next-generation sensors and systems or pursue other strategic initiatives. Additional financing may not be available on a timely basis on terms acceptable to us, or at all. Any additional financing may be dilutive to stockholders or may require us to grant a lender a security interest in our assets. The amount of funding we may need will depend on many factors, including:

- the revenue generated by sales of our products and other future products;
- the costs, timing and risks of delay of additional regulatory approvals;
- the expenses we incur in manufacturing, developing, selling and marketing our products;
- our ability to scale our manufacturing operations to meet demand for our current and any future products;
- the costs to produce our continuous glucose monitoring systems;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- the rate of progress and cost of our clinical trials and other development activities;
- the success of our research and development efforts;
- the emergence of competing or complementary technologies;
- the terms and timing of any collaborative, licensing and other arrangements that we may establish;
- the cost of ongoing compliance with legal and regulatory requirements, and third-party payors' policies;

- the cost of obtaining and maintaining regulatory or payor clearance or approval for our current or future products including those integrated with other companies' products; and
- the acquisition of business, products and technologies, although we currently have no commitments or agreements relating to any of these types of transactions.

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

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

The primary collection risks for our accounts receivable relate to the uninsured patient accounts and patient accounts for which the primary insurance carrier has paid the amounts covered by the applicable agreement, but patient responsibility amounts (exclusions, deductibles and copayments) remain outstanding. In addition, as a result of the impact of the COVID-19 pandemic, some customers have, and others may, lose access to their private health insurance plan if they lose their job. As most of our customers rely on third-party payors, including private health insurance plans, to cover the cost of our products, there has been, and may continue to be, a shift in financial responsibility to our customers for the amounts previously covered by their primary insurance carrier.

In the event that we are unsuccessful in collecting payments owed by patients, and/or experience increases in the amount, or deterioration in the collectability, of uninsured and patient due accounts receivable, this could adversely affect our cash flows and results of operations. We may also be adversely affected by the growth in patient responsibility accounts, as a result of increases in the adoption of plan structures, due to evolving health care policy and insurance landscapes that shift greater responsibility for care to individuals through greater exclusions, prior authorizations, and copayment and deductible amounts.

Changes in our business strategy or restructuring of our businesses may increase our costs or otherwise affect the profitability of our businesses or the value of our assets.

As changes in our business environment occur we have adjusted, and may further, adjust our business strategies to meet these changes and we may otherwise decide to further restructure our operations or particular businesses or assets. Our new organization and strategies may not produce the anticipated benefits, such as supporting our growth strategies and enhancing shareholder value. Our new organization and strategies could be less successful than our previous organizational structure and strategies. In addition, external events including changing technology, changing consumer patterns, acceptance of our products and changes in macroeconomic conditions may impair the value of our assets. When these changes or events occur, we may incur costs to change our business strategy and may need to write-down the value of assets. For example, current conditions, including COVID-19 and our business decisions, may reduce the value of some of our assets. We also make investments in existing or new businesses, including investments in international expansion of our sales efforts and the build out of our future manufacturing facility in Malaysia. Additionally, we also invest in early to late stage companies for strategic reasons and to support key business initiatives, and we may not realize a return on our equity investments. Many such companies generate net losses and the market for their products, services, or technologies may be slow to develop or never materialize. We are subject to risks associated with our equity investments including partial or complete loss of invested capital, and significant changes in the fair value of this portfolio could adversely impact our financial results. Some of these investments may have returns that are negative or low, the ultimate business prospects of the businesses related to these investments may be uncertain, and these risks may be exacerbated by COVID-19. In any of these events, our costs may increase or returns on new investments may be lower than prior to the change in strategy or restructuring.

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

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

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

stockholders. In addition, our operating results may suffer because of acquisition-related costs or amortization expenses or charges relating to acquired intangible assets.

Compliance with regulations relating to public company corporate governance matters and reporting may strain our resources and divert management's attention.

Many laws and regulations, notably those adopted in connection with the Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, new SEC regulations and The Nasdaq Stock Market listing rules, impose obligations on public companies, such as ours, which have increased the scope, complexity and cost of corporate governance, reporting and disclosure practices. Compliance with these laws and regulations, including enhanced new disclosures, has required and will continue to require substantial management time and oversight and the incurrence of significant accounting and legal costs. The effects of new laws and regulations remain unclear and will likely require substantial management time and oversight and require us to incur significant additional accounting and legal costs. Additionally, changes to existing accounting rules or standards, such as the potential requirement that U.S. registrants prepare financial statements in accordance with International Financial Reporting Standards, may adversely impact our reported financial results and business, and may require us to incur greater accounting fees. These laws, regulations, and standards are subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We intend to continue to invest resources to comply with evolving laws, regulations, and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from revenue-generating activities to compliance activities. If our efforts to comply with new laws, regulations, and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to their application and practice, regulatory authorities may initiate legal proceedings against us and our business may be adversely affected.

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

We are subject to taxes in the United States and numerous foreign jurisdictions, where a number of our subsidiaries are organized. The tax laws in the United States and in other countries in which we and our subsidiaries do business could change on a prospective or retroactive basis, and any such changes could adversely affect our business and financial condition. Further, due to economic and political conditions, tax rates in various jurisdictions may be subject to change. Our effective tax rates could be affected by numerous factors, including changes in the mix of earnings in countries with differing statutory tax rates, changes in the valuation of deferred tax assets and liabilities, and changes in tax laws or their interpretation, both in and outside the United States.

There is growing pressure in many jurisdictions, including the United States, and from multinational organizations such as the Organization for Economic Cooperation and Development (OECD) and the European Union to amend existing international tax rules in order to render them more responsive to current global business practices. For example, the OECD has published a package of measures for reform of the international tax rules as a product of its Base Erosion and Profit Shifting (BEPS) initiative, which was endorsed by the G20 finance ministers. Many of the initiatives in the BEPS package require amendments to the domestic tax legislation of various jurisdictions. Separately, the European Union is asserting that a number of country-specific favorable tax regimes and rulings in certain member states may violate, or have violated, European Union law, and may require rebates of some or all of the associated tax benefits to be paid by benefited taxpayers in particular cases. In 2016, the European Union adopted the "Anti-Tax Avoidance Directive," which requires European Union member states to implement measures to prohibit tax avoidance practices, and Germany published the European Union Anti-Tax Avoidance Directive Implementation Law on June 30, 2021. We have a significant presence in the European Union, as well as significant sales in the European Union, such that any changes in tax laws in the European Union will impact our business. The overall impact of such legislation in European Union member states is uncertain, and our business and financial condition could be adversely affected by any laws impacting our tax rate. The U.S. government has recently enacted comprehensive tax legislation that includes significant changes to the taxation of business entities. These changes include, among others, (i) a permanent reduction to the corporate income tax rate, (ii) a partial limitation on the deductibility of business interest expense, (iii) a shift of the U.S. taxation of multinational corporations from a tax on worldwide income to a territorial system (along with certain rules designed to prevent erosion of the U.S. income tax base) and (iv) a one-time tax on accumulated offshore earnings held in cash and illiquid assets, with the latter taxed at a lower rate. The overall impact of this tax reform is uncertain, and our business and financial condition could be adversely affected. In addition, it is uncertain if and to what extent various states will conform to the newly enacted federal tax law.

Our tax returns and other tax matters also are subject to examination by the U.S. Internal Revenue Service and other tax authorities and governmental bodies. We regularly assess the likelihood of an adverse outcome resulting from these examinations to determine the adequacy of our provision for taxes. We cannot guarantee the outcome of these examinations. If our effective tax rates were to increase, particularly in the United States, or in other countries implementing legislation to reform existing tax legislation, including the European Union and Germany, or if the ultimate determination of our taxes owed

is for an amount in excess of amounts previously accrued, our financial condition, operating results and cash flows could be adversely affected.

Our ability to use our net operating losses to offset future taxable income may be subject to certain limitations which could subject our business to higher tax liability.

Our ability to use our net operating losses, or NOLs, to offset future taxable income may be subject to certain limitations which could subject our business to higher tax liability. We may be limited in the portion of NOL carryforwards that we can use in the future to offset taxable income for U.S. federal and state income tax purposes, and federal tax credits to offset federal tax liabilities. Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, and similar state law provisions, limit the use of NOLs and tax credits after a cumulative change in corporate ownership of more than 50% occurs within a three-year period. The statutes place a formula limit on how much NOLs and tax credits a corporation can use in a tax year after a change in ownership. Avoiding an ownership change is generally beyond our control. Although the ownership changes we experienced in the past have not prevented us from using all NOLs and tax credits accumulated before such ownership changes, we could experience another ownership change that might limit our use of NOLs and tax credits in the future. In addition, realization of deferred tax assets, including net operating loss carryforwards, depends upon our future earnings in applicable tax jurisdictions. If we have insufficient future taxable income in the applicable tax jurisdiction for any reason, including any future corporate reorganization or restructuring activities, we may be limited in our ability to utilize some or all of our net operating losses to offset such income and reduce our tax liability in that jurisdiction. See Note 8 to the consolidated financial statements for the fiscal year ended December 31, 2020 in Part II, Item 8 of our Annual Report on Form 10-K that we filed with the SEC on February 11, 2021 for additional information.

There is also a risk that due to regulatory changes or changes to federal or state law, such as suspensions on the use of NOLs, or other unforeseen reasons, our existing NOLs could expire or otherwise be unavailable either in whole or in part to offset future income tax liabilities. For example, under the Coronavirus Aid, Relief, and Economic Security Act of 2020, or CARES Act, which amended certain provisions of the Tax Cuts and Jobs Act of 2017, or TCJA, NOLs arising in taxable years beginning after December 31, 2017 and before January 1, 2021 may be carried back to each of the five taxable years preceding the tax year of such loss, but NOLs arising in taxable years beginning after December 31, 2020 may not be carried back. The TCJA, as amended by the CARES Act, also provides that NOLs from tax years that began after December 31, 2017 may offset no more than 80% of current taxable income annually for taxable years beginning after December 31, 2020. Accordingly, although we have generated NOLs after the tax year ended December 31, 2017, we might have to pay more federal income taxes in a future tax year as a result of the 80% taxable income limitation than we would have had to pay under the law in effect before the TCJA as amended by the CARES Act.

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

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

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

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

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

Risks Related to Our Common Stock

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

Historically, the market price of our common stock, like the securities of many other medical products companies, fluctuates and could continue to be volatile in the future, especially as our business continues to grow and our business plan continues to evolve. From January 1, 2021 through September 30, 2021, the closing price of our common stock on the Nasdaq Global Select Market was as high as \$572.73 per share and as low as \$323.96 per share. In addition, the trading prices for our common stock and other medical device companies have been highly volatile as a result of the COVID-19 pandemic.

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

- securities analyst coverage or lack of coverage of our common stock or changes in their estimates of our financial performance;
- variations in quarterly operating results;
- future sales of our common stock by our stockholders;
- investor perception of us and our industry;
- announcements by us or our competitors of significant agreements, acquisitions, or capital commitments or product launches or discontinuations;
- changes in market valuation or earnings of our competitors;
- negative business or financial announcements regarding our partners;
- general economic conditions;
- regulatory actions;
- legislation and political conditions;
- global health pandemics, such as COVID-19; and
- terrorist acts.

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

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

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

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

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

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

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

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

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

Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all claims brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. In September 2020, we amended and restated our restated bylaws to provide that the federal district courts of the United States will, to the fullest extent permitted by law, be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, or a Federal Forum Provision. Our decision to adopt a Federal Forum Provision followed a decision by the Supreme Court of the State of Delaware holding that such provisions are facially valid under Delaware law. While there can be no assurance that federal or state courts will follow the holding of the Delaware Supreme Court or determine that the Federal Forum Provision should be enforced in a particular case, application of the Federal Forum Provision means that suits brought by our stockholders to enforce any duty or liability created by the Securities Act must be brought in federal court and cannot be brought in state court. Section 27 of the Exchange Act creates exclusive federal jurisdiction over all claims brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder. Neither the exclusive forum provision nor the Federal Forum Provision applies to suits brought to enforce any duty or liability created by the Exchange Act. Accordingly, actions by our stockholders to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder must be brought in federal court.

Notwithstanding the foregoing, our stockholders will not be deemed to have waived our compliance with the federal securities laws and the regulations promulgated thereunder.

Any person or entity purchasing or otherwise acquiring or holding any interest in any of our securities shall be deemed to have notice of and consented to our exclusive forum provisions, including the Federal Forum Provision. The exclusive forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, or other employees, which may discourage lawsuits with respect to such claims. Alternatively, if a court were to find the choice of forum provisions contained in our restated certificate of incorporation or amended and restated bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, operating results, and financial condition.

Moreover, Section 203 of the Delaware General Corporation Law may discourage, delay, or prevent a change of control of our company. Section 203 imposes certain restrictions on mergers, business combinations, and other transactions between us and holders of 15% or more of our common stock.

Risks Related to Our Debt

Increasing our financial leverage could affect our operations and profitability.

In October 2021, we entered into a Second Amended and Restated Credit Agreement (the Amended Credit Agreement) which amended and restated the credit agreement we had previously entered into in December 2018 as amended in May 2020 (the Credit Agreement). The Amended Credit Agreement is a five-year \$200.0 million revolving credit facility. As of September 30, 2021, we had no outstanding borrowings, \$6.4 million in outstanding letters of credit, and a total available balance of \$193.6 million under our Credit Agreement.

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

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

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

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

We have entered into a revolving credit agreement and a pledge and security agreement with JPMorgan Chase Bank and five other lenders to fund our business operations. These agreements impose numerous financial and other restrictive covenants on our operations, including covenants relating to our general profitability and our liquidity. As of September 30, 2021, we were in compliance with the covenants imposed by the loan and security agreement. If we violate these or any other covenants, any outstanding amounts under these agreements could become due and payable prior to their stated maturity dates, each lender could proceed against any collateral in our operating accounts and our ability to borrow funds in the future may be restricted or eliminated. These restrictions may also limit our ability to borrow additional funds and pursue other business opportunities or strategies that we would otherwise consider to be in our best interests.

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

In November 2018, we completed an offering of \$850.0 million aggregate principal amount of 0.75% convertible senior notes due 2023, or 2023 Notes, which offering we refer to as the 2018 Notes Offering. In May 2020, we completed an offering of approximately \$1.21 billion aggregate principal amount of 0.25% convertible senior notes due 2025, or 2025 notes, which offering we refer to as the 2020 Notes Offering. As of the date hereof, there are no 2022 Notes outstanding. We refer to the 2018 Notes Offering and the 2020 Notes Offering, collectively, as the Notes Offerings, and we refer to the 2023 Notes and the 2025 Notes, collectively, as the Notes. As a result of the Notes Offerings, we incurred \$2.06 billion principal amount of indebtedness, the principal amount of which we may be required to pay at maturity.

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

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

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

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

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

Holders of the Notes will have the right to require us to repurchase their Notes upon the occurrence of a fundamental change at a purchase price equal to 100% of the principal amount of the Notes to be purchased, plus accrued and unpaid interest, if any, to, but not including, the fundamental change purchase date. In addition, each indenture for the Notes provides that we are required to repay amounts due under each indenture in the event that there is an event of default for the Notes that results in the principal, premium, if any, and interest, if any, becoming due prior to maturity date for the Notes. In addition, upon conversion of the Notes, unless we elect to deliver solely shares of our common stock to settle such conversion (other than cash in lieu of any fractional share), we will be required to make cash payments in respect of the Notes being converted. However, we may not have enough available cash or be able to obtain financing at the time we are required to repurchase Notes surrendered upon a fundamental change or repay prior to maturity any accelerated amounts or pay cash for Notes being converted.

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

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

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

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

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

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

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

We do not make any representation or prediction as to the direction or magnitude of any potential effect that the transactions described above may have on the price of the 2023 Notes or our common stock. In addition, we do not make any

representation that the option counterparties will engage in these transactions or that these transactions, once commenced, will not be discontinued without notice.

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

The option counterparties are financial institutions, and we will be subject to the risk that any or all of them may default under the 2023 Note Hedge transactions. Our exposure to the credit risk of the option counterparties will not be secured by any collateral. Recent global economic conditions have resulted in the actual or perceived failure or financial difficulties of many financial institutions. If an option counterparty becomes subject to insolvency proceedings, we will become an unsecured creditor in those proceedings, with a claim equal to our exposure at that time under our transactions with that option counterparty. Our exposure will depend on many factors but, generally, an increase in our exposure will be correlated to an increase in the market price and in the volatility of our common stock. In addition, upon a default by an option counterparty, we may suffer adverse tax consequences and more dilution than we currently anticipate with respect to our common stock. We can provide no assurances as to the financial stability or viability of the option counterparties.

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

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

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

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

Our credit facility contains restrictive covenants relating to our capital raising activities and other financial and operational matters which may make it more difficult for us to obtain additional capital and to pursue business opportunities, including potential acquisitions. In addition, our credit facility and the agreements governing the notes each contain cross-default provisions whereby a default under one agreement would likely result in cross defaults under agreements covering other borrowings. For example, the occurrence of a default with respect to any indebtedness or any failure to repay debt when due in an amount in excess of \$25.0 million, in the case of the 2023 Notes, and \$50.0 million, in the case of the 2025 Notes, that causes such indebtedness to become due prior to its scheduled maturity date would cause a cross default under the indenture governing the Notes. In addition, the occurrence of a default with respect to any indebtedness or any failure to repay debt when due in an amount in excess of \$25.0 million that causes such indebtedness to become due prior to its scheduled maturity date would cause a default under our credit facility. The occurrence of a default under any of these borrowing arrangements would permit the holders of the Notes or the lenders under our credit facility to declare all amounts outstanding under those borrowing arrangements to be immediately due and payable. If the Note holders or the trustee under the indenture governing the Notes or the lenders under our credit facility accelerate the repayment of borrowings, we cannot assure you that we will have sufficient assets to repay those borrowings.

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

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

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

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

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

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

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

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

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

General Risk Factors

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

Our operations and performance depend on worldwide economic and political conditions. These conditions have been adversely impacted by continued global economic uncertainty, political instability and military hostilities in multiple geographies, concerns over the potential downgrade of U.S. sovereign debt and continued sovereign debt, monetary and financial uncertainties in Europe and other foreign countries, and global health pandemics such as the COVID-19 pandemic. These include potential reductions in the overall stability and suitability of the Euro as a single currency, given the economic and political challenges facing individual Eurozone countries. These conditions have made and may continue to make it difficult for our customers and potential customers to afford our products, and could cause our customers to stop using our products or to use them less frequently. If that were to occur, our revenue may decrease and our performance may be negatively impacted. In addition, the pressure on consumers to absorb more of their own health care costs has resulted in some cases in higher deductibles and limits on durable medical equipment, which may cause seasonality in purchasing patterns. Furthermore, during economic uncertainty, our customers have had job losses and may continue to have issues gaining timely access to sufficient health insurance or credit, which could result in their unwillingness to purchase products or impair their ability to make timely payments to us. While the potential economic impact brought by and the duration of the COVID-19 pandemic may be difficult to assess or predict, it has already caused, and is likely to result in further, significant disruption of global financial markets, which may reduce our ability to access capital on favorable terms or at all. In addition, a recession, depression or other

sustained adverse market event resulting from the spread of COVID-19 could materially and adversely affect our business and the value of our common stock.

We cannot predict the reoccurrence of any economic slowdown or the strength or sustainability of the economic recovery, worldwide, in the United States, or in our industry. These and other economic factors could have a material adverse effect on our business, financial condition and results of operations.

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

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

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

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

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

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

- our inability to manufacture an adequate supply of product at appropriate quality levels and acceptable costs;
- possible delays in our research and development programs or in the completion of any clinical trials;
- a lack of acceptance of our products in the marketplace by physicians and people with diabetes;
- the inability of customers to receive reimbursements from third-party payors;
- the purchasing patterns of our customers, including as a result of seasonality;
- failures to comply with regulatory requirements, which could lead to withdrawal of products from the market;
- our failure to continue the commercialization of any of our CGM systems;
- competition;
- inadequate financial and other resources; and
- global and political economic conditions, political instability and military hostilities.

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

Our research and development and clinical processes involve the handling of potentially harmful biological materials as well as hazardous materials. We are subject to international and domestic (including federal, state and local) laws, rules and regulations governing the use, handling, storage and disposal of hazardous and biological materials and we incur expenses relating to compliance with these laws and regulations. If violations of environmental, health and safety laws occur, we could

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

Environmental, social and corporate governance (ESG) regulations, policies and provisions may make our supply chain more complex and may adversely affect our relationships with customers.

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

Our business could be negatively impacted by corporate citizenship and ESG matters and/or our reporting of such matters.

There is an increasing focus from certain investors, customers, consumers, employees, and other stakeholders concerning corporate citizenship and sustainability matters. From time to time, we communicate certain initiatives, including goals, regarding environmental matters, responsible sourcing and social investments, including pursuant to our Sustainability Report. We could fail, or be perceived to fail, in our achievement of such initiatives or goals, or we could fail in fully and accurately reporting our progress on such initiatives and goals. In addition, we could be criticized for the scope of such initiatives or goals or perceived as not acting responsibly in connection with these matters. Our business could be negatively impacted by such matters. Any such matters, or related corporate citizenship and sustainability matters, could have a material adverse effect on our business.

Climate change may have a long-term impact on our business.

While we seek to partner with organizations that mitigate their business risks associated with climate change, we recognize that there are inherent risks related to climate change wherever business is conducted. Access to clean water and reliable energy in the communities where we conduct our business, whether for our offices or for our vendors, is a priority. Our manufacturing sites in California, Arizona and Malaysia and our operations in the Philippines are vulnerable to climate change effects. For example, in California and Arizona, increasing intensity of drought throughout the state and annual periods of wildfire danger increase the probability of planned power outages in the communities where we work and live. While this danger has a low-assessed risk of disrupting normal business operations, it has the potential impact on employees' abilities to commute to work or to work from home and stay connected effectively. Climate-related events, including the increasing frequency of extreme weather events and their impact on U.S., the Philippines, Malaysia and other major regions' critical infrastructure, have the potential to disrupt our business, our third-party suppliers, and/or the business of our customers, and may cause us to experience higher attrition, losses, and additional costs to maintain or resume operations.

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

None.

ITEM 3 - DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4 - MINE SAFETY DISCLOSURES

None.

ITEM 5 - OTHER INFORMATION

None.

ITEM 6 - EXHIBITS

The following exhibits are filed as a part of this Quarterly Report.

Exhibit Number	Exhibit Description	Incorporated by Reference				
		Form	File No.	Date of First Filing	Exhibit Number	Provided Herewith
31.01	Certification of Chief Executive Officer Pursuant to Securities Exchange Act Rule 13a-14(a).	—	—	—	—	X
31.02	Certification of Chief Financial Officer Pursuant to Securities Exchange Act Rule 13a-14(a).	—	—	—	—	X
32.01	Certification of Chief Executive Officer Pursuant to 18 U.S.C. Section 1350 and Securities Exchange Act Rule 13a-14(b).*	—	—	—	—	X
32.02	Certification of Chief Financial Officer Pursuant to 18 U.S.C. Section 1350 and Securities Exchange Act Rule 13a-14(b).*	—	—	—	—	X
101.INS	XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document					X
101.SCH	Inline XBRL Taxonomy Extension Schema Document					X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document					X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document					X
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document					X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document					X
104	Cover Page Interactive Data File - the cover page from the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2021 is formatted in Inline XBRL					X

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

SIGNATURES

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

DEXCOM, INC.
(Registrant)

Dated: October 28, 2021

By: /s/ KEVIN R. SAYER
Kevin R. Sayer,
Chairman of the Board of Directors,
President and Chief Executive Officer
(Principal Executive Officer)

Dated: October 28, 2021

By: /s/ JEREME M. SYLVAIN
Jereme M. Sylvain,
Executive Vice President and Chief Financial Officer
(Principal Financial and Accounting Officer)