

**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, 2024

OR

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 001-36189

Tandem Diabetes Care, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)
12400 High Bluff Drive
San Diego, California
(Address of principal executive offices)

20-4327508
(I.R.S. Employer
Identification No.)
92130
(Zip Code)

(858) 366-6900

(Registrant's telephone number, including area code)

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

<u>Title of Each Class</u>	<u>Trading Symbol(s)</u>	<u>Name of Exchange on Which Registered</u>
Common Stock, par value \$0.001 per share	TNDM	Nasdaq Global 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 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 November 1, 2024, there were 65,676,532 shares of the registrant's Common Stock outstanding.

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements.

TANDEM DIABETES CARE, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except par value)

	September 30, 2024 (Unaudited)	December 31, 2023 (Note 1)
Assets		
Current assets:		
Cash and cash equivalents	\$ 49,039	\$ 58,868
Short-term investments	424,266	409,044
Accounts receivable, net	107,188	105,555
Inventories	152,441	157,937
Prepaid and other current assets	19,892	16,585
Total current assets	752,826	747,989
Property and equipment, net	81,064	76,542
Operating lease right-of-use assets	87,393	87,791
Other long-term assets	36,447	40,336
Total assets	\$ 957,730	\$ 952,658
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 48,754	\$ 49,586
Accrued expenses	12,280	12,726
Employee-related liabilities	58,718	43,430
Current portion of convertible senior notes, net	40,605	—
Operating lease liabilities	18,033	17,060
Deferred revenue	42,567	43,994
Other current liabilities	38,319	28,462
Total current liabilities	259,276	195,258
Convertible senior notes, net - long-term	307,829	285,035
Operating lease liabilities - long-term	109,479	113,572
Deferred revenue - long-term	11,196	13,331
Other long-term liabilities	32,240	31,830
Total liabilities	720,020	639,026
Commitments and contingencies (Note 13)	—	—
Stockholders' equity:		
Common stock, \$0.001 par value; 200,000 shares authorized, 65,646 and 65,552 shares issued and outstanding at September 30, 2024 and December 31, 2023, respectively.	66	66
Additional paid-in capital	1,282,354	1,263,997
Accumulated other comprehensive income	3,870	1,369
Accumulated deficit	(1,048,580)	(951,800)
Total stockholders' equity	237,710	313,632
Total liabilities and stockholders' equity	\$ 957,730	\$ 952,658

See accompanying notes to unaudited condensed consolidated financial statements.

TANDEM DIABETES CARE, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME (LOSS)
(Unaudited)
(In thousands, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Sales	\$ 243,971	\$ 185,622	\$ 657,555	\$ 550,922
Cost of sales	119,318	95,869	325,436	276,527
Gross profit	124,653	89,753	332,119	274,395
Operating expenses:				
Selling, general and administrative	99,639	79,328	283,987	266,752
Research and development	51,107	41,970	146,677	127,063
Acquired in-process research and development expenses	—	—	—	78,750
Total operating expenses	150,746	121,298	430,664	472,565
Operating loss	(26,093)	(31,545)	(98,545)	(198,170)
Other income (expense), net:				
Interest income and other, net	5,344	5,656	13,482	17,305
Interest expense	(1,865)	(4,840)	(5,555)	(8,079)
Loss on extinguishment of debt	—	—	(1,268)	—
Total other income (expense), net	3,479	816	6,659	9,226
Loss before income taxes	(22,614)	(30,729)	(91,886)	(188,944)
Income tax expense	637	2,232	4,894	3,665
Net loss	\$ (23,251)	\$ (32,961)	\$ (96,780)	\$ (192,609)
Other comprehensive income (loss):				
Unrealized gain on short-term investments	\$ 3,948	\$ 349	\$ 2,189	\$ 1,800
Foreign currency translation gains (losses)	1,175	(1,362)	312	(2,189)
Comprehensive loss	\$ (18,128)	\$ (33,974)	\$ (94,279)	\$ (192,998)
Net loss per share - basic and diluted	\$ (0.35)	\$ (0.51)	\$ (1.48)	\$ (2.97)
Weighted average shares used to compute basic and diluted net loss per share	65,538	65,117	65,287	64,834

See accompanying notes to unaudited condensed consolidated financial statements.

TANDEM DIABETES CARE, INC.
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(Unaudited)
(In thousands)

Three Months Ended September 30, 2024

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at June 30, 2024	65,435	\$ 65	\$ 1,260,392	\$ (1,253)	\$ (1,025,329)	\$ 233,875
Exercise of stock options	24	—	409	—	—	409
Vesting of restricted stock units, net of shares withheld for taxes	187	1	(4,928)	—	—	(4,927)
Stock-based compensation expense	—	—	26,481	—	—	26,481
Unrealized gain on short-term investments	—	—	—	3,948	—	3,948
Foreign currency translation gains	—	—	—	1,175	—	1,175
Net loss	—	—	—	—	(23,251)	(23,251)
Balance at September 30, 2024	65,646	\$ 66	\$ 1,282,354	\$ 3,870	\$ (1,048,580)	\$ 237,710

Nine Months Ended September 30, 2024

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2023	65,552	\$ 66	\$ 1,263,997	\$ 1,369	\$ (951,800)	\$ 313,632
Stock repurchase and retirement of shares	(1,107)	(1)	(29,999)	—	—	(30,000)
Exercise of stock options	94	—	1,806	—	—	1,806
Vesting of restricted stock units, net of shares withheld for taxes	705	1	(17,125)	—	—	(17,124)
Issuance of common stock under Employee Stock Purchase Plan	402	—	6,286	—	—	6,286
Stock-based compensation expense	—	—	73,018	—	—	73,018
Purchase of capped call options related to convertible notes due 2029	—	—	(15,813)	—	—	(15,813)
Unwind of capped call options related to convertible notes due 2025	—	—	184	—	—	184
Unrealized gain on short-term investments	—	—	—	2,189	—	2,189
Foreign currency translation gains	—	—	—	312	—	312
Net loss	—	—	—	—	(96,780)	(96,780)
Balance at September 30, 2024	65,646	\$ 66	\$ 1,282,354	\$ 3,870	\$ (1,048,580)	\$ 237,710

See accompanying notes to unaudited condensed consolidated financial statements.

Three Months Ended September 30, 2023

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at June 30, 2023	65,062	\$ 65	\$ 1,219,199	\$ (1,193)	\$ (888,837)	\$ 329,234
Exercise of stock options	8	—	106	—	—	106
Vesting of restricted stock units, net of shares withheld for taxes	121	—	(1,945)	—	—	(1,945)
Issuance of common stock for Employee Stock Purchase Plan	—	—	—	—	—	—
Stock-based compensation expense	—	—	20,579	—	—	20,579
Unrealized gain on short-term investments	—	—	—	349	—	349
Foreign currency translation losses	—	—	—	(1,362)	—	(1,362)
Net loss	—	—	—	—	(32,961)	(32,961)
Balance at September 30, 2023	65,191	\$ 65	\$ 1,237,939	\$ (2,206)	\$ (921,798)	\$ 314,000

Nine Months Ended September 30, 2023

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2022	64,513	\$ 65	\$ 1,170,888	\$ (1,817)	\$ (729,189)	\$ 439,947
Exercise of stock options	71	—	1,267	—	—	1,267
Vesting of restricted stock units, net of shares withheld for taxes	358	—	(6,505)	—	—	(6,505)
Issuance of common stock under Employee Stock Purchase Plan	249	—	6,804	—	—	6,804
Exercise of common stock warrants	—	—	—	—	—	—
Stock-based compensation expense	—	—	65,485	—	—	65,485
Unrealized gain on short-term investments	—	—	—	1,800	—	1,800
Foreign currency translation losses	—	—	—	(2,189)	—	(2,189)
Net loss	—	—	—	—	(192,609)	(192,609)
Balance at September 30, 2023	65,191	\$ 65	\$ 1,237,939	\$ (2,206)	\$ (921,798)	\$ 314,000

See accompanying notes to unaudited condensed consolidated financial statements.

TANDEM DIABETES CARE, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)
(In thousands)

	Nine Months Ended September 30,	
	2024	2023
Operating Activities		
Net loss	\$ (96,780)	\$ (192,609)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation and amortization expense	12,362	11,684
Amortization of debt issuance costs	1,587	1,711
Provision for expected credit losses	7,302	4,066
Operating lease termination and other impairment charges	2,000	14,099
Accretion (amortization) of discount or premium on short-term investments	(595)	3,177
Stock-based compensation expense	73,217	65,335
Loss on extinguishment of debt	1,268	—
Acquired in-process research and development expenses	—	78,750
Other	1,610	(1,437)
Changes in operating assets and liabilities:		
Accounts receivable, net	(8,712)	9,872
Inventories	5,215	(32,714)
Prepaid and other current assets	(3,427)	(7,296)
Other long-term assets	440	(1,216)
Accounts payable and accrued expenses	(952)	(4,574)
Employee-related liabilities	15,300	5,571
Deferred revenue	(3,589)	10,042
Operating leases and other current liabilities	6,898	10,745
Other long-term liabilities	364	200
Net cash used in operating activities	13,508	(24,594)
Investing Activities		
Purchases of short-term investments	(251,361)	(391,025)
Proceeds from maturities and redemptions of short-term investments	239,031	415,485
Purchases of property and equipment	(16,162)	(21,605)
Acquisitions, including in-process research and development, net of cash acquired	—	(69,496)
Purchases of intangible assets and strategic investments	—	(2,515)
Net cash used in investing activities	(28,492)	(69,156)
Financing Activities		
Proceeds from issuance of convertible senior notes due 2029, net of \$9,400 debt issuance costs	306,850	—
Repurchase of \$246,740 principal amount of convertible senior notes due 2025	(246,123)	—
Payment for capped call transactions related to convertible senior notes due 2029	(15,813)	—
Repurchase and retirement of common stock	(30,000)	—
Proceeds from issuance of common stock under Company stock plans, net of cash used to settle withholding taxes on vested restricted stock	(9,032)	1,567
Other financing activities	183	(71)
Net cash provided by (used in) financing activities	6,065	1,496
Effect of foreign exchange rate changes on cash	(910)	(652)
Net increase (decrease) in cash and cash equivalents	(9,829)	(92,906)
Cash and cash equivalents at beginning of period	58,868	172,517
Cash and cash equivalents at end of period	\$ 49,039	\$ 79,611
Supplemental disclosures of cash flow information		
Income taxes paid	\$ 1,298	\$ 1,771
Supplemental schedule of non-cash investing and financing activities		
Operating lease right-of-use assets obtained in exchange for operating lease obligations	\$ 4,659	\$ —
Purchases of property and equipment included in accounts payable	\$ 2,641	\$ 3,224

See accompanying notes to unaudited condensed consolidated financial statements.

TANDEM DIABETES CARE, INC.

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

1. Organization and Basis of Presentation

The Company

Tandem Diabetes Care, Inc. is a medical device company focused on the design, development and commercialization of technology solutions for people living with diabetes. Tandem Diabetes Care, Inc. is incorporated in the state of Delaware. Unless the context requires otherwise, the terms the “Company” or “Tandem” refer to Tandem Diabetes Care, Inc., together with its wholly-owned subsidiaries.

The Company manufactures, sells, and supports insulin pump products that are designed to address the evolving needs and preferences of differentiated segments of the insulin-dependent diabetes market. The Company recently expanded its insulin pump portfolio, which now includes both the t:slim X2 and the Tandem Mobi. Both pumps feature Control-IQ technology, which is the Company’s advanced algorithm for managing insulin delivery, using information received from integrated continuous glucose monitoring (CGM) sensors. New software for the insulin pumps may be updated remotely by the individual users as new advancements become available and are compatible with other complementary digital health offerings, such as the mobile application and cloud-based diabetes management applications. The Company’s insulin pump systems products are generally considered durable medical equipment and have an expected lifespan of at least four years. In addition to insulin pumps, the Company sells single-use components that are used together with the pumps and are replaced every few days, including cartridges for storing and delivering insulin, and infusion sets that connect the insulin pump to a user’s body.

Basis of Presentation and Principles of Consolidation

The Company has prepared the accompanying unaudited condensed consolidated financial statements in accordance with accounting principles generally accepted in the United States of America (U.S. GAAP) for interim financial information and pursuant to the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and disclosures required by U.S. GAAP for complete financial statements. In the opinion of management, all adjustments which are of a normal and recurring nature and considered necessary for a fair presentation of the financial information contained herein, have been included.

Interim financial results are not necessarily indicative of results anticipated for the full year or any other period(s). These unaudited condensed consolidated financial statements should be read in conjunction with the Company’s audited consolidated financial statements and accompanying notes included in the Company’s Annual Report on Form 10-K for the year ended December 31, 2023 (Annual Report), from which the consolidated balance sheet presented as of December 31, 2023 herein was derived. The condensed consolidated financial statements include the accounts of Tandem Diabetes Care, Inc. and its wholly-owned subsidiaries. All significant intercompany balances and transactions have been eliminated in consolidation.

The functional currency of the Company’s foreign subsidiaries is their respective local currency. The Company translates the financial statements of its foreign subsidiaries into U.S. dollars using period-end exchange rates for assets and liabilities and average exchange rates for each period for revenue, costs and expenses. Translation related adjustments are included in other comprehensive income (loss) in the condensed consolidated statements of operations, and in accumulated other comprehensive income (loss) in the stockholders’ equity section of the Company’s condensed consolidated balance sheets. Foreign exchange gains or losses resulting from balances denominated in a currency other than the functional currency are recognized in interest income and other, net in the Company’s condensed consolidated statements of operations.

2. Summary of Significant Accounting Policies

There have been no material changes to the Company’s significant accounting policies during the nine months ended September 30, 2024, as compared to those disclosed in the Annual Report.

Use of Estimates

The preparation of the condensed consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and the disclosure of contingent assets and liabilities in the Company's condensed consolidated financial statements and accompanying notes as of the date of the condensed consolidated financial statements. Some of those judgments can be subjective and complex, and therefore, actual results could differ materially from those estimates under different assumptions or conditions.

Accounts Receivable

The Company grants credit to various customers in the ordinary course of business and is paid directly by customers who use its products, distributors and third-party insurance payors. The Company maintains an allowance for its current estimate of expected credit losses. Provisions for expected credit losses are estimated based on historical experience, assessment of specific customer-related risks, review of outstanding invoices, forecasts about the future, and various other assumptions and estimates that are believed to be reasonable under the circumstances, including changes to credit risks as a result of recessionary concerns, changes in discretionary spending, increased interest rates, and other macroeconomic factors. Uncollectible accounts are written off against the allowance after appropriate collection efforts have been exhausted and when it is deemed that a balance is uncollectible.

Operating Lease Right-of-Use Assets and Liabilities

Operating lease right-of-use assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent its obligation to make lease payments arising from the lease. Operating lease right-of-use assets and liabilities are recognized when the Company takes possession of the leased property (Commencement Date) based on the present value of lease payments over the lease term. For lease agreements that contain lease and non-lease components, the Company accounts for both of those components as a single lease component. Rent expense on noncancelable leases containing known future scheduled rent increases is recorded on a straight-line basis over the term of the respective leases beginning on the Commencement Date. The difference between rent expense and rent paid is accounted for as a component of operating lease right-of-use assets on the Company's condensed consolidated balance sheets. Landlord improvement allowances and other similar lease incentives are recorded as a reduction of the right-of-use leased assets, and are amortized on a straight-line basis as a reduction to operating lease costs.

Intangible Assets Subject to Amortization

Finite-lived intangible assets are recorded at cost, net of accumulated amortization and, if applicable, impairment charges. Amortization of finite-lived intangible assets is recognized over their estimated useful lives on a straight-line basis. The Company did not recognize any intangible asset impairment losses during the three and nine months ended September 30, 2024 and 2023.

Strategic Investments

The Company held equity investments totaling \$30.4 million and \$10.1 million in private companies at September 30, 2024 and December 31, 2023, respectively. The investments were included as a component of other long-term assets on the condensed consolidated balance sheets at September 30, 2024 and December 31, 2023. The investments were carried at cost minus impairment, if any, adjusted for changes in observable prices. The Company monitors these investments to evaluate whether any increase or decline in its value has occurred, based on the implied value of recent company financings, public market prices of comparable companies and general market conditions.

In November 2024, the Company signed an investment agreement with one of its private company investees. Per the agreement, the Company will invest an additional \$46.4 million. The investment is expected to close in the fourth quarter of 2024, and represent a cumulative investment of more than 20% of the private company's outstanding equity. The investment will be recorded using the equity method and will be included in long-term assets on the Company's consolidated balance sheet.

The Company did not record any impairment charges related to its strategic investments in the three months ended September 30, 2024. During the nine months ended September 30, 2024, the Company recorded an impairment charge of \$2.0 million related to one of its investments in a private company. The Company did not record any impairment charges related to its strategic investments in the three and nine months ended September 30, 2023.

Approximately \$22.2 million of the total strategic investments balance was previously held in the form of subordinated convertible notes of one private investee company. The subordinated notes were converted into equity of the private company at final maturity, which occurred in June 2024. As a result of the note conversion, the Company received shares of the private investee company. As of September 30, 2024, and December 31, 2023, each of the Company's equity investments in private companies represented less than 15% of the outstanding equity of the respective private company.

Revenue Recognition

Revenue is generated primarily from sales of insulin pumps, single-use insulin cartridges and infusion sets to individual customers with third-party insurance coverage and through a network of distributors that resell the products to insulin-dependent diabetes customers. The Company recognizes revenue when it transfers control of the promised goods or services to customers in an amount that reflects the consideration to which the Company expects to be entitled in exchange for those goods or services, net of estimated rebates and returns.

Revenue Recognition for Arrangements with Multiple Performance Obligations

The Company considers the individual deliverables in its product offerings to be separate performance obligations. The transaction price is determined based on the consideration expected to be received, based either on the stated value in contractual arrangements or the estimated cash to be collected in non-contracted arrangements. The Company allocates the consideration to the individual performance obligations and recognizes the consideration based on when the performance obligation is satisfied, considering whether or not this occurs at a point in time or over time. Generally, insulin pumps, cartridges, infusion sets, and accessories are deemed performance obligations that are satisfied at a point in time when the customer obtains control of the promised good, which typically is upon shipment for our distributor arrangements and upon receipt for sales directly to individual customers. Complementary products, such as the Company's data management and software update platforms, are considered distinct performance obligations that are satisfied over time, as access and support for these products is provided throughout the typical four-year warranty period of the insulin pumps. Accordingly, revenue related to the complementary products is deferred and recognized over a four-year period. Where there is no standalone value for the complementary product, the Company determines its value by applying the expected cost plus a margin approach and then allocates the residual to the insulin pumps.

Revenue Recognition for Tandem Choice Program

In September 2022, the Company launched a new technology access program referred to as Tandem Choice, that provides eligible, in-warranty t:slim X2 customers in the United States with the flexibility to obtain the newest hardware platform, Tandem Mobi, when commercially available. Participating customers have the right to purchase the alternative Tandem pump for a fee, referred to as a choice right. The program was determined to create a material right for which a portion of each t:slim X2 pump transaction price was allocated and deferred.

The Company determined that the ability for a customer to upgrade to a new technology represents a material right because the pricing inherent in such option provides the customer with a discount that is incremental to the range of discounts that would otherwise be granted for the related goods and services to comparable customers. The standalone selling price for the choice right was estimated based on the adjusted market assessment approach and contemplated the likelihood that the respective option will be exercised.

The Company began selling Tandem Mobi insulin pumps in the first quarter of 2024 and eligibility for the Tandem Choice program ended in February 2024. Consequently, the Company ceased to allocate and defer a portion of the transaction price for the material right for pumps sold after that date. Eligible customers who purchased a t:slim X2 insulin pump during the program period will have until December 31, 2024 to exercise the option to switch to the Tandem Mobi for a stated fee.

The Company will recognize the deferred sales when the obligations under the Tandem Choice program are satisfied. If a customer elects to participate in the program, the Company will recognize upgrade fees received, and the associated cost of goods sold at the time of fulfilling the obligation. Any remaining deferrals will be recognized at program expiration on December 31, 2024, provided all obligations under the Tandem Choice program are satisfied. For the nine months ended September 30, 2024, the net effect of Tandem Choice deferrals and fulfillments was negligible.

At September 30, 2024 and December 31, 2023, current deferred revenue balance was \$30.1 million and \$30.6 million, respectively, related to the Tandem Choice program.

Sales Rebates

The Company is subject to certain rebates on pricing programs with managed care organizations, such as governmental and third-party commercial payors. The Company estimates provisions for rebates based on contractual arrangements, estimates of products sold subject to rebate, known events or trends and channel inventory data. Estimated sales rebates included in other long-term liabilities have an estimated payment due date beyond twelve months from the balance sheet date. Accordingly, actual rebates paid may differ from estimated amounts recorded in the accompanying condensed consolidated financial statements.

As of September 30, 2024 and December 31, 2023, total estimated sales rebates were included in the following condensed consolidated balance sheet accounts (in thousands):

	September 30, 2024	December 31, 2023
Other current liabilities	\$ 3,012	\$ 505
Other long-term liabilities	6,503	8,042
Total sales rebate	\$ 9,515	\$ 8,547

Warranty Reserve

The Company generally provides a four-year warranty on its insulin pumps to end-user customers and may replace any pumps that do not function as intended in accordance with the product specifications within the warranty period. Additionally, the Company offers a six-month warranty on single-use insulin cartridges and infusion sets. Estimated warranty costs are recorded at the time of shipment, and the Company reevaluates the estimate of the warranty reserve obligation at each reporting period. Warranty costs are estimated primarily based on the current expected product replacement cost and expected replacement rates using historical experience. Insulin pumps returned to the Company may be refurbished and redeployed. Experience has shown that initial data for any given pump version or pump platform may be insufficient. Therefore, the Company's process relies on long-term historical averages of existing platforms until sufficient data are available. As actual experience becomes available, the Company uses the data to update the historical averages. The Company may make further adjustments to the warranty reserve when deemed appropriate, giving additional consideration to revised future expectations of performance based on enhanced hardware components, or new features and capabilities that may become available through Tandem Device Updater. Warranty expense is recorded as a component of cost of sales in the condensed consolidated statements of operations.

The following table provides a reconciliation of the changes in product warranty liabilities for the three and nine months ended September 30, 2024 and 2023 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Balance at beginning of the period	\$ 37,356	\$ 38,917	\$ 37,173	\$ 36,537
Provision for warranties issued during the period	11,084	9,601	31,074	26,889
Settlements made during the period	(9,576)	(8,986)	(27,675)	(24,054)
Increases (decreases) in warranty estimates	1,882	(1,775)	174	(1,615)
Balance at end of the period	\$ 40,746	\$ 37,757	\$ 40,746	\$ 37,757

As of September 30, 2024 and December 31, 2023, total product warranty reserves were included in the following condensed consolidated balance sheet accounts (in thousands):

	September 30, 2024	December 31, 2023
Other current liabilities	\$ 19,832	\$ 18,135
Other long-term liabilities	20,914	19,038
Total warranty reserve	\$ 40,746	\$ 37,173

Stock-Based Compensation

Stock-based compensation cost is measured at the grant date based on the estimated fair value of the award, and the portion that is ultimately expected to vest is recognized as compensation expense over the requisite service period on a straight-line basis. The Company estimates the fair value of stock options issued under the Company's stock incentive plans, and the fair value of the employees' purchase rights under the Company's Employee Stock Purchase Plan (ESPP) using the Black-Scholes option pricing model on the date of grant. The Black-Scholes option pricing model requires the use of assumptions about a number of variables, including stock price volatility, expected term, dividend yield and risk-free interest rate (see Note 8, "Stockholders' Equity"). The fair value of restricted stock unit (RSU) awards issued under the Company's stock incentive plans that vest solely based on service, is estimated based on the fair market value of the underlying stock on the date of grant. The fair value of RSU awards that vest based upon the Company's actual performance relative to predefined performance metrics and the awardee's continuing service through the measurement date is generally estimated based on the fair market value of the underlying stock on the date of grant and the probability that the specified performance criteria will be met. At each reporting period, the Company reassesses the probability of the achievement of such performance metrics. Any expense change resulting from an adjustment in the estimated shares to be released is recorded in the period of adjustment.

Net Income (Loss) Per Share

Basic net income (loss) per share is calculated by dividing the net income or loss by the weighted average number of common shares outstanding for the period, without consideration for common stock equivalents. Diluted net income (loss) per share reflects the potential dilution that would occur if securities exercisable for or convertible into common stock were exercised for or converted into common stock. Dilutive common share equivalents are comprised of stock options and unvested RSUs outstanding under the Company's stock incentive plans, potential awards to be granted pursuant to the ESPP, and common stock warrants, each calculated using the treasury stock method, and shares issuable upon conversion of the convertible senior notes calculated using the if-converted method.

For the three and nine months ended September 30, 2024 and 2023, there was no difference in the weighted average number of shares used to calculate basic and diluted net loss per share due to the Company's net loss position for each of the periods presented.

Potentially dilutive securities outstanding and not included in the calculation of diluted net loss per share (because inclusion would be anti-dilutive) are as follows (in thousands, in common stock equivalent shares):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Options to purchase common stock	781	135	125	135
Unvested restricted stock units	3,964	2,930	2,995	2,011
Warrants to purchase common stock	194	194	194	194
Awards granted under the ESPP	292	173	147	80
Convertible senior notes (if-converted)	9,513	2,554	7,762	2,554
	<u>14,744</u>	<u>5,986</u>	<u>11,223</u>	<u>4,974</u>

Recently Issued Accounting Pronouncements Not Yet Adopted

In November 2023, the FASB issued ASU 2023-07 to improve the information that a public entity discloses about reportable segments and to address investor requests for more information about reportable segment expenses. The pronouncement requires a public entity to report a measure of segment profit or loss that the chief operating decision maker (CODM) uses to assess segment performance and make decisions about allocating resources. ASU 2023-07 also requires other specified segment items and amounts, such as depreciation, amortization, and depletion expense, to be disclosed under certain circumstances. The amendments in ASU 2023-07 are effective for fiscal years beginning after December 15, 2023 and interim periods within fiscal years beginning after December 15, 2024, adopted retrospectively. The Company is currently evaluating the effect of adoption of ASU 2023-07 on the Company's consolidated financial statements or disclosures.

3. Short-Term Investments

The Company invests in marketable securities primarily consisting of debt instruments of the United States Government, United States Government-sponsored enterprises, and financial institutions and corporations with strong credit ratings. The following represents a summary of the estimated fair value of short-term investments at September 30, 2024 and December 31, 2023 (in thousands):

At September 30, 2024	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Estimated Fair Value
Available-for-sale securities:				
United States Government-sponsored enterprises	\$ 166,401	\$ 1,718	\$ (9)	\$ 168,110
United States Treasury securities	112,169	448	(8)	112,609
Commercial paper	23,431	82	—	23,513
Corporate debt securities	116,314	653	(1)	116,966
Foreign government bonds	3,013	55	—	3,068
Total	\$ 421,328	\$ 2,956	\$ (18)	\$ 424,266

At December 31, 2023	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Estimated Fair Value
Available-for-sale securities:				
United States Government-sponsored enterprises	\$ 181,851	\$ 518	\$ (215)	\$ 182,154
United States Treasury securities	114,714	318	(28)	115,004
Commercial paper	72,505	33	(27)	72,511
Corporate debt securities	39,225	156	(6)	39,375
Total	\$ 408,295	\$ 1,025	\$ (276)	\$ 409,044

The contractual maturities of available-for-sale debt securities as of September 30, 2024, were as follows (in thousands):

At September 30, 2024	Years to Maturity			Estimated Fair Value
	Within One Year	One to Two Years	Two to Three Years	
United States Government-sponsored enterprises	\$ 60,575	\$ 24,215	\$ 83,320	\$ 168,110
United States Treasury securities	71,407	40,194	1,008	112,609
Commercial paper	23,513	—	—	23,513
Corporate debt securities	62,532	54,434	—	116,966
Foreign government bonds	—	—	3,068	3,068
Total	\$ 218,027	\$ 118,843	\$ 87,396	\$ 424,266

The Company has classified all marketable securities, regardless of maturity, as short-term investments based upon the Company's ability and intent to use any of those marketable securities to satisfy the Company's liquidity requirements.

The Company reviews the portfolio of available-for-sale debt securities quarterly to determine if any investment is impaired due to changes in credit risk or other potential valuation concerns. Unrealized losses on available-for-sale debt securities at September 30, 2024 were primarily due to an increase in market interest rates after certain debt securities were purchased, and the balance was not material to the Company's quarterly results.

4. Composition of Certain Financial Statement Items

Accounts Receivable

Accounts receivable, net consisted of the following at September 30, 2024 and December 31, 2023 (in thousands):

	September 30, 2024		December 31, 2023	
Accounts receivable	\$	113,249	\$	110,453
Less: allowance for credit losses		(6,061)		(4,898)
Accounts receivable, net	\$	107,188	\$	105,555

Allowance for Credit Losses

The following table provides a reconciliation of the changes in the allowance for estimated accounts receivable credit losses for the three and nine months ended September 30, 2024 and 2023 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,					
	2024	2023	2024	2023				
Balance at beginning of the period	\$	5,225	\$	4,842	\$	4,898	\$	4,327
Provision for expected credit losses		3,579		1,308		7,302		4,066
Write-offs and adjustments, net of recoveries		(2,743)		(795)		(6,139)		(3,038)
Balance at end of the period	\$	6,061	\$	5,355	\$	6,061	\$	5,355

Inventories

Inventories consisted of the following at September 30, 2024 and December 31, 2023 (in thousands):

	September 30, 2024		December 31, 2023	
Raw materials	\$	35,933	\$	42,783
Work-in-process		35,829		44,026
Finished goods		80,679		71,128
Total inventories	\$	152,441	\$	157,937

5. Fair Value Measurements

The following table presents information about the Company's financial assets and liabilities measured at fair value on a recurring basis as of September 30, 2024 and December 31, 2023, and indicates the fair value hierarchy of the valuation techniques used by the Company to determine such fair value (in thousands):

	Fair Value Measurements at September 30, 2024			
	Total	Level 1	Level 2	Level 3
Assets				
Cash equivalents ⁽¹⁾	\$ 38,830	\$ 38,830	\$ —	\$ —
United States Government-sponsored enterprises	168,110	—	168,110	—
United States Treasury securities	112,609	112,609	—	—
Commercial paper	23,513	—	23,513	—
Corporate debt securities	116,966	—	116,966	—
Foreign government bonds	3,068	—	3,068	—
Total assets	<u>\$ 463,096</u>	<u>\$ 151,439</u>	<u>\$ 311,657</u>	<u>\$ —</u>

	Fair Value Measurements at December 31, 2023			
	Total	Level 1	Level 2	Level 3
Assets				
Cash equivalents ⁽¹⁾	\$ 48,033	\$ 48,033	\$ —	\$ —
United States Government-sponsored enterprises	182,154	—	182,154	—
United States Treasury securities	115,004	115,004	—	—
Commercial paper	72,511	—	72,511	—
Corporate debt securities	39,375	—	39,375	—
Total assets	<u>\$ 457,077</u>	<u>\$ 163,037</u>	<u>\$ 294,040</u>	<u>\$ —</u>

(1) Generally, cash equivalents include money market funds and investments with a maturity of three months or less from the date of purchase.

The Company's Level 1 financial instruments, which are in active markets, are valued using unadjusted quoted market prices for identical instruments.

The Company's Level 2 financial instruments are valued using market prices on less active markets with observable valuation inputs such as interest rates and yield curves. The Company obtains the fair value of Level 2 financial instruments from quoted market prices, calculated prices or quotes from third-party pricing services. The Company validates these prices through independent valuation testing and review of portfolio valuations provided by the Company's investment managers.

There were no transfers into or out of Level 3 assets during the three months ended September 30, 2024 and 2023, respectively.

Fair Value of Financial Instruments

The carrying amounts of cash and cash equivalents, accounts receivable, accounts payable, accrued expenses, and employee-related liabilities are reasonable estimates of their fair values because of the short-term nature of these assets and liabilities. Short-term investments are carried at fair value.

The Company's convertible senior notes are carried at amortized cost on the condensed consolidated balance sheets (see Note 7, "Debt"). The Company estimated the fair value of its convertible senior notes based on Level 2 quoted market prices as follows (in thousands):

	Fair Value Measurements at	
	September 30, 2024	December 31, 2023
Convertible Senior Notes due 2025	\$ 39,130	\$ 271,688
Convertible Senior Notes due 2029	458,043	*
Total fair value of outstanding convertible senior notes	\$ 497,173	\$ 271,688

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

In March 2024, the Company issued \$316.3 million aggregate principal amount of the Company's Convertible Senior Notes Due 2029, and repurchased \$246.7 million of principal of the Company's Convertible Senior Notes due 2025 (see Note 7, "Debt").

6. Leases

The Company's leases consist of operating leases for general office space, research and development, manufacturing and warehouse facilities, and equipment. These noncancellable operating leases have initial lease terms from two years to thirteen years. Certain leases include an option to renew, with renewal terms that can extend the lease term for additional periods at the Company's sole discretion. The Company includes the renewal option period in the lease term for those leases reasonably expected to be extended at the time of lease commencement.

Operating Lease Impairment Charge

In 2023, the Company consolidated facilities by moving the administrative functions and other operations from the leased space on Vista Sorrento Parkway in San Diego, California (Vista Sorrento Lease) to the Company's new headquarters, located on High Bluff Drive in San Diego, California. In connection with permanently ceasing use of the Vista Sorrento Lease, the Company recorded a \$14.1 million impairment charge as the carrying amount of the assets related to the Vista Sorrento Lease exceeded its fair value based on the Company's estimate of future discounted cash flows related to the leased facility. The \$14.1 million charge was comprised of an \$11.2 million impairment of operating lease right-of-use assets and a \$2.9 million write-off of fixed assets, and was recorded as a component of selling, general and administrative expenses in the condensed consolidated statements of operations.

Supplemental Lease Disclosure Information

The Company's lease costs recorded in the condensed consolidated statements of operations were as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Operating lease cost	\$ 3,603	\$ 3,528	\$ 10,684	\$ 12,457
Short-term lease cost	22	22	65	87
Loss on lease termination and right-of-use asset impairment charges	—	—	—	11,224
Total lease cost	\$ 3,625	\$ 3,550	\$ 10,749	\$ 23,768

Maturities of operating lease liabilities at September 30, 2024 were as follows (in thousands):

Years Ending December 31,	
2024	\$ 4,433
2025	18,188
2026	18,146
2027	18,449
2028	14,934
Thereafter	90,326
Total undiscounted lease payments	164,476
Less: amount representing interest	(36,964)
Present value of operating lease liabilities	127,512
Less: current portion of operating lease liabilities	(18,033)
Operating lease liabilities - long-term	\$ 109,479

The weighted-average remaining lease term and weighted-average discount rate for operating leases were as follows:

	September 30, 2024	December 31, 2023
Weighted-average remaining lease term (in years)	9.4	10.2
Weighted-average discount rate used to determine operating lease liabilities	5.3 %	5.4 %

Cash amounts paid included in the measurement of lease liabilities, representing operating cash flows, were \$13.3 million and \$9.2 million for the nine months ended September 30, 2024 and 2023, respectively.

7. Debt

Convertible Senior Notes Due 2029

On March 8, 2024, the Company completed an offering of \$316.3 million aggregate principal amount of 1.50% Convertible Senior Notes due 2029 (the 2029 Notes). The proceeds from the issuance of the 2029 Notes were \$306.8 million, net of debt issuance costs. The Company used approximately \$246.1 million of the net proceeds to repurchase approximately \$246.7 million in aggregate principal amount of its Convertible Senior Notes Due 2025 (the 2025 Notes) concurrently with the pricing of the 2029 Notes in privately negotiated transactions.

The Company also paid \$1.3 million of accrued interest due at time of the note repurchase. As a result of the repurchase, the Company recognized a \$1.3 million loss on extinguishment of debt in the condensed consolidated statement of operations for the nine months ended September 30, 2024. The loss on extinguishment of debt included the unamortized debt issuance costs related to the portion of the 2025 Notes repurchased.

The Company used \$30.0 million of the net proceeds to repurchase shares of the Company's common stock from certain purchasers of the 2029 Notes at a purchase price equal to the last reported sale price per share of the Company's common stock on March 5, 2024, which was \$27.105 per share. In addition, the Company used \$15.8 million of the net proceeds to pay the cost of the capped call transactions (2029 Capped Call Transactions) discussed below.

The 2029 Notes are the Company's senior unsecured obligations. Interest is payable in cash semi-annually in arrears on March 15 and September 15 of each year beginning on September 15, 2024, at a rate of 1.50% per year. The 2029 Notes mature on March 15, 2029 unless repurchased, redeemed, or converted in accordance with their terms prior to the maturity date.

The initial conversion rate for the 2029 Notes is 28.9361 shares of common stock per \$1,000 principal amount of the 2029 Notes, which is equivalent to an initial conversion price of approximately \$34.56 per share of the Company's common stock (2029 Notes Conversion Price). The conversion rate is subject to customary adjustments for certain events as described in the indenture governing the 2029 Notes.

The Company may not redeem the 2029 Notes before March 22, 2027. The Company has the option to redeem for cash all or any portion of the 2029 Notes on or after March 22, 2027 if the last reported sale price of the Company's common stock has been at least 130% of the 2029 Notes Conversion Price then in effect for at least 20 trading days (whether or not consecutive), including the trading day immediately preceding the date on which the Company provides notice of redemption, during any 30 consecutive trading day period, at a redemption price equal to 100% of the principal amount of the 2029 Notes to be redeemed, plus accrued and unpaid interest. No sinking fund is provided for the 2029 Notes.

Holders of the 2029 Notes may convert all or a portion of their 2029 Notes at their option before December 15, 2028, in multiples of \$1,000 principal amounts, only under the following circumstances:

- during any calendar quarter commencing after the quarter ending on June 30, 2024 (and only during such calendar quarter), if the last reported sale price of the Company's common stock, for at least 20 trading days (whether or not consecutive) during a period of 30 consecutive trading days ending on, and including, the last trading day of the immediately preceding calendar quarter is greater than or equal to 130% of the 2029 Notes Conversion Price on each applicable trading day;
- during the five business day period after any ten consecutive trading day period (the measurement period) in which the trading price per \$1,000 principal amount of the 2029 Notes for each trading day of the measurement period was less than 98% of the product of the last reported sale price of the Company's common stock and the applicable conversion rate of the 2029 Notes on such trading day;
- if the Company calls such 2029 Notes for redemption, at any time before the close of business on the scheduled trading day immediately preceding the redemption date, but only with respect to the 2029 Notes called (or deemed called) for redemption; or
- on the occurrence of specified corporate events.

On or after December 15, 2028, until the close of business on the second scheduled trading day immediately preceding the maturity date, holders may convert their 2029 Notes, in integral multiples of \$1,000 principal amount, at any time, regardless of the foregoing circumstances. Upon conversion, the Company will pay or deliver, as the case may be, cash, shares of common stock or a combination of cash and shares of common stock, at the Company's election, in the manner and subject to the terms and conditions provided in the indenture governing the 2029 Notes.

Convertible Senior Notes Due 2025

In May 2020, the Company completed an offering of \$287.5 million aggregate principal amount of 1.50% Convertible Senior Notes due 2025 (the 2025 Notes). The proceeds from the issuance of the Notes were \$244.6 million, net of debt issuance costs and cash used to pay the cost of the capped call transactions (Capped Call Transactions) discussed below.

In March 2024, the Company repurchased for cash \$246.7 million in aggregate principal amount of the 2025 Notes, concurrently with the pricing of the 2029 Notes in privately negotiated transactions.

The 2025 Notes are the Company's senior unsecured obligations. Interest is payable in cash semi-annually in arrears beginning on November 1, 2020 at a rate of 1.50% per year. The 2025 Notes mature on May 1, 2025 unless repurchased, redeemed, or converted in accordance with their terms before the maturity date. As of September 30, 2024 the outstanding balance of the 2025 Notes was classified in current liabilities on the Company's condensed consolidated balance sheets.

The 2025 Notes are convertible into cash, shares of the Company's common stock, or a combination of cash and shares of the Company's common stock, at the Company's election, at an initial conversion rate of 8.8836 shares of common stock per \$1,000 principal amount of the 2025 Notes, which is equivalent to an initial conversion price of \$112.57 (2025 Notes Conversion Price) per share of the Company's common stock. The conversion rate is subject to customary adjustments for certain events as described in the indenture governing the 2025 Notes.

The Company has the option to redeem for cash all or any portion of the 2025 Notes on or after May 6, 2023 if the last reported sale price of the Company's common stock has been at least 130% of the 2025 Notes Conversion Price then in effect for at least 20 trading days (whether or not consecutive), including the trading day immediately preceding the date on which the Company provides notice of redemption, during any 30 consecutive trading day period, at a redemption price equal to 100% of the principal amount of the 2025 Notes to be redeemed, plus accrued and unpaid interest. No sinking fund is provided for the 2025 Notes.

Holders of the 2025 Notes had the right to convert all or a portion of their 2025 Notes at their option before November 1, 2024, in multiples of \$1,000 principal amounts, under certain circumstances outlined in the offering agreement.

On or after November 1, 2024, until the close of business on the second scheduled trading day immediately preceding the maturity date, holders may convert their Notes at any time, regardless of the foregoing circumstances. Upon conversion, the Company will pay or deliver, as the case may be, cash, shares of common stock or a combination of cash and shares of common stock, at the Company's election, in the manner and subject to the terms and conditions provided in the indenture governing the 2025 Notes.

Holders of the 2025 Notes who convert in connection with a make-whole fundamental change or in connection with a redemption are entitled to an increase in the conversion rate. Additionally, in the event of a fundamental change, holders of the 2025 Notes may require us to repurchase all or a portion of the 2025 Notes at a price equal to 100% of the principal amount of the Notes, plus any accrued and unpaid interest.

The net carrying amount of the Company's convertible senior notes on the condensed consolidated balance sheets consisted of the following (in thousands):

	September 30, 2024	December 31, 2023
Principal amount:		
Convertible Senior Notes Due 2025	\$ 40,760	\$ 287,500
Convertible Senior Notes Due 2029	316,250	*
Total principal amount	357,010	287,500
Unamortized debt issuance costs	(8,576)	(2,465)
Total debt, net	\$ 348,434	\$ 285,035
Less: current portion	(40,605)	—
Long-term senior convertible notes	\$ 307,829	\$ 285,035

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

As of September 30, 2024 and December 31, 2023, the if-converted value of the 2025 Notes did not exceed the principal amount. As of September 30, 2024, the if-converted value of the 2029 Notes exceeded the principal amount by \$71.8 million.

In October 2023, the Company was notified that additional interest beyond the 1.50% per annum had been accruing on the 2025 Notes since May 2021, under the terms of the indenture. This additional interest accrued at a rate of 0.50% per annum on the outstanding principal amount of the Notes, and as of September 30, 2023 amounted to about \$3.1 million in the aggregate. The additional accrued interest was fully paid in November 2023.

The following table summarizes the effective interest rates for each of our convertible senior notes for the periods shown:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Effective interest rate:				
Convertible Senior Notes Due 2025	2.1 %	2.2 %	2.1 %	2.2 %
Convertible Senior Notes Due 2029	2.1 %	*	2.1 %	*

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

The following table details interest expense related to the Notes recognized for the three and nine months ended September 30, 2024, and 2023 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Contractual interest expense⁽¹⁾	\$ 1,339	\$ 4,138	\$ 3,823	\$ 6,368
Amortization of debt issuance costs	502	702	1,404	1,711
Total interest expense	\$ 1,841	\$ 4,840	\$ 5,227	\$ 8,079

(1) Contractual interest expense for the three and nine months ended September 30, 2023 includes \$3.1 million of additional interest as discussed above.

2029 Capped Call Transactions

In connection with the issuance of the 2029 Notes, the Company entered into Capped Call Transactions in March 2024 with certain counterparties at a net cost of \$15.8 million (2029 Capped Call Transactions). The 2029 Capped Call Transactions are expected generally to reduce potential dilution to the Common Stock upon any conversion of the 2029 Notes and/or offset any cash payments the Company is required to make in excess of the principal amount of converted 2029 Notes, as the case may be, with such reduction and/or offset subject to a cap based on a cap price initially equal to \$42.0128 per share, and is subject to certain adjustments under the terms of the 2029 Capped Call Transactions.

2025 Capped Call Transactions

In connection with the issuance of the 2025 Notes, the Company entered into Capped Call Transactions in May 2020 with certain counterparties at a net cost of \$34.1 million (2025 Capped Call Transactions). The 2025 Capped Call Transactions are expected generally to reduce potential dilution to the Common Stock upon any conversion of the 2025 Notes and/or offset any cash payments the Company is required to make in excess of the principal amount of converted 2025 Notes, as the case may be, with such reduction or offset subject to a cap. The cap price of the 2025 Capped Call Transactions is initially \$173.18 per share of the Company's common stock, and is subject to certain adjustments under the terms of the 2025 Capped Call Transactions.

In connection with the repurchase of certain 2025 Notes, the Company entered into unwind agreements with the existing option counterparties on March 5, 2024 to terminate a portion of the existing 2025 Capped Call Transactions in a notional amount corresponding to the amount of 2025 Notes repurchased (the Unwind Transactions). In connection with the Unwind Transactions, the Company received \$0.2 million in cash as a termination payment in respect of the portion of the existing 2025 Capped Call Transactions that were unwound. The amount received was based generally on the termination values of the unwound portions of the existing 2025 Capped Call Transactions.

For accounting purposes, each of the capped call transactions described above are separate transactions, and not part of the terms of the 2029 Notes or the 2025 Notes. As these transactions met certain criteria under the applicable accounting guidance, each of the capped call transactions were recorded in stockholders' equity and were not accounted for as derivatives. The cost of the transactions was recorded as a reduction of the Company's additional paid-in capital in the Company's condensed consolidated balance sheet and will not be remeasured.

8. Stockholders' Equity

Shares Reserved for Future Issuance

The following shares of the Company's common stock were reserved for future issuance at September 30, 2024 (in thousands):

Shares reserved for issuance upon conversion of Convertible Senior Notes	9,513
Shares underlying outstanding warrants	194
Shares underlying outstanding stock options	3,583
Shares underlying unvested restricted stock units	4,020
Shares authorized for issuance pursuant to awards granted under the ESPP	3,052
Shares authorized for future equity award grants	1,879
Total	22,241

Common Stock Warrants

Warrants outstanding to purchase shares of the Company's common stock as of September 30, 2024 were as follows:

Issue Date	Exercise Price Per Share	Warrants Outstanding	Expiration Date of Warrants Outstanding
March 2017	\$23.50	193,788	March 2027

Each warrant allows the holder to purchase one share of common stock at the per share exercise price of the warrant.

Stock Incentive Plans

In May 2023, the Company's stockholders approved the 2023 Long-Term Incentive Plan (2023 Plan), under which 2,602,184 shares of common stock were initially reserved for issuance. Under the 2023 Plan, the Company may grant stock options, stock appreciation rights, restricted stock and restricted stock units to individuals who are then employees, officers, directors or consultants of the Company. The 2023 Plan replaced the Company's Amended and Restated 2013 Stock Incentive Plan (2013 Plan), and no further equity awards will be granted under the 2013 Plan. In May 2024, the Company's stockholders approved the 2023 Long-Term Incentive Plan, as amended, to increase the number of shares authorized for issuance under the plan by 3,000,000 shares.

Stock-Based Compensation

The following table summarizes the allocation of stock-based compensation expense included in the condensed consolidated statements of operations for all stock-based compensation arrangements (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Cost of sales	\$ 1,675	\$ 1,812	\$ 5,506	\$ 5,154
Selling, general and administrative	16,395	12,466	45,200	41,448
Research and development	8,211	6,463	22,511	18,733
Total stock-based compensation expense	<u>\$ 26,281</u>	<u>\$ 20,741</u>	<u>\$ 73,217</u>	<u>\$ 65,335</u>

The total stock-based compensation expense capitalized as part of the cost of the Company's inventories was \$1.8 million at September 30, 2024, and \$2.0 million at December 31, 2023.

Restricted Stock Units

Restricted stock units (RSUs) have a grant value equal to the closing price of the Company's common stock on the award date.

The total number of RSUs granted and the respective weighted average grant date fair value were as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
RSUs granted	140,806	208,082	2,193,104	1,997,907
Weighted average grant date fair value (per share)	\$ 45.66	\$ 29.19	\$ 45.29	\$ 28.94

Employee Stock Purchase Plan

In May 2024, the Company's stockholders approved the 2013 Employee Stock Purchase Plan, as amended, to increase the number of shares authorized for issuance under the plan by 3,000,000 shares. The Company records stock-based compensation expense associated with the ESPP using the Black-Scholes option pricing model. Valuations are performed on the grant date at the beginning of the purchase period, which generally occurs in May and November of each year. The assumptions used in the Black-Scholes option pricing model for the ESPP were as follows:

	Nine Months Ended September 30,	
	2024	2023
Weighted average grant date fair value (per share)	\$ 21.45	\$ 12.52
Risk-free interest rate	5.1 %	4.7 %
Dividend yield	0.0 %	0.0 %
Expected volatility	70.2 %	60.9 %
Expected term (in years)	1.3	1.3

9. Employee Benefits

Employee 401(k) Plan

The Company has a defined contribution 401(k) plan for employees in the United States who are at least 18 years of age. Employees are eligible to participate in the plan beginning on the first day of the calendar month following their date of hire. Unless they affirmatively elect otherwise, employees are automatically enrolled in the plan following 30 days from date of hire or entry date. Under the terms of the plan, employees may make voluntary contributions as a percent of compensation and the Company may elect to match a discretionary percentage of employee contributions.

10. Income Taxes

For the three and nine months ended September 30, 2024, the Company recognized income tax expense of \$0.6 million and \$4.9 million, respectively, on a pre-tax loss of \$22.6 million and \$91.9 million, respectively. The Company calculated the provision for income taxes for the three and nine months ended September 30, 2024 by applying an estimate of the annual effective tax rate for the full year to ordinary income (loss) adjusted by the tax impact of discrete items. Income tax expense for the three and nine months ended September 30, 2024 was primarily attributable to federal, state and foreign income tax expense as a result of current taxable income in certain jurisdictions.

For the three and nine months ended September 30, 2023, the Company recognized income tax expense of \$2.2 million and \$3.7 million, respectively, on a pre-tax loss of \$30.7 million and \$188.9 million, respectively. Income tax expense for the three and nine months ended September 30, 2023 was primarily attributable to federal, state and foreign income tax expense as a result of current taxable income in certain jurisdictions. The Company calculated the provision for three and nine months ended September 30, 2023 by applying an estimate of the annual effective tax rate for the full year to ordinary income (loss) adjusted by the tax impact of discrete items.

The Company continues to maintain a full valuation allowance against its net deferred tax assets as of September 30, 2024, based on the current assessment that it is not more likely than not these future benefits will be realized before expiration.

11. Business Segment and Geographic Information

Segment Reporting

Operating segments are identified as components of an enterprise about which discrete financial information is available for evaluation by the chief operating decision-maker (CODM) in making decisions regarding resource allocation and assessing performance. The Company is organized based on its current product portfolio, which consists primarily of insulin pumps, single-use insulin cartridges and infusion sets for the storage and delivery of insulin. The Company views its operations and manages its business as one segment and a single reporting unit because key operating decisions and resource allocations are made by the CODM using consolidated financial data.

Disaggregation of Revenue

The Company primarily sells its products through national and regional distributors in the United States on a non-exclusive basis, and through distribution partners outside the United States. In the United States and Canada, the Company also uses a direct sales force. The Company disaggregates its revenue by geography, major sales channel and product as management believes these categories best depict how the nature, amount and timing of revenues and cash flows are affected by economic factors.

Revenues by Geographic Region and Customer Sales Channel

During the three and nine months ended September 30, 2024 and 2023, no individual country outside the United States generated revenue that represented more than 10% of total revenue. The table below sets forth revenues for the Company's two primary geographical markets, based on the geographic location to which its products are shipped (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
United States	\$ 171,650	\$ 130,222	\$ 458,122	\$ 403,964
Outside the United States	72,321	55,400	199,433	146,958
Total Sales	<u>\$ 243,971</u>	<u>\$ 185,622</u>	<u>\$ 657,555</u>	<u>\$ 550,922</u>

Sales to distributors accounted for 61% and 62% of the Company's United States sales for the three and nine months ended September 30, 2024, respectively, and 64% and 64% of the Company's United States sales for the three and nine months ended September 30, 2023, respectively. Sales to distributors accounted for the vast majority of the Company's sales outside the United States for the three and nine-month periods ended September 30, 2024 and 2023.

Revenues by Product

During the three and nine months ended September 30, 2024 and 2023, sales by product were as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Pump	\$ 114,799	\$ 88,037	\$ 309,961	\$ 274,415
Supplies and other	128,133	105,821	347,547	289,075
Net revenue recognized (deferred) for Tandem Choice program	1,039	(8,236)	47	(12,568)
Total Sales	<u>\$ 243,971</u>	<u>\$ 185,622</u>	<u>\$ 657,555</u>	<u>\$ 550,922</u>

12. Acquisitions

AMF Medical Acquisition

On December 10, 2022, the Company entered into a Share Purchase Agreement (Purchase Agreement) with AMF Medical SA, a corporation organized and existing under the laws of Switzerland (AMF Medical), and its shareholders to acquire all of the registered shares of AMF Medical (Transaction). AMF Medical is the developer of the Sigi Patch Pump, which is designed to be an ergonomic, rechargeable patch pump that reduces the burden of managing diabetes through its use of pre-filled insulin cartridges. The Sigi Patch Pump is under development and not commercially available.

On January 19, 2023, the Company completed the acquisition of AMF Medical under the terms of the Purchase Agreement. The total aggregate consideration for the Transaction included a previous strategic investment of Swiss Francs (CHF) 8.0 million made in the third quarter of 2022, a cash payment of CHF 62.4 million paid at the closing of the Transaction, and additional contingent earnout payments of up to CHF 129.6 million. The contingent earnout payments become payable upon the achievement of certain milestones, and are comprised of a payment of up to CHF 38.4 million upon the successful completion of key development milestones over the two years following the closing date of the Transaction, and a payment of up to CHF 91.2 million upon obtaining regulatory clearance from the FDA of an automated controller enabled (ACE) pump. The contingent consideration will be recognized as each contingency is resolved and the respective consideration is paid or becomes payable. As of September 30, 2024, the contingencies related to the earnout milestones were not yet resolved and, therefore, the related amounts were not included in the fair value of the asset acquired and were not recognized as a liability on the consolidated balance sheet at September 30, 2024. The Company funded the initial closing payment using existing cash balances.

The transaction was accounted for as an asset acquisition as substantially all the value of the gross assets was concentrated in a single asset. The Company recorded a \$78.8 million charge in 2023 representing the value of acquired in-process research and development assets with no alternative future use, and acquisition related expenses, on its condensed consolidated statements of operations in acquired in-process research and development expenses. The Company's results of operations included the operating results of AMF Medical since the date of acquisition.

13. Commitments and Contingencies

Legal and Regulatory Matters

On September 8, 2023, a purported stockholder of the Company filed a putative securities class action complaint (captioned *Lowe v. Tandem Diabetes Care, Inc., et al.*, Case No. 23-cv-1657 (“*Lowe*”)) in the United States District Court for the Southern District of California against the Company and certain of the Company's current executive officers (“defendants”). On December 6, 2023, the court appointed Mason Raines, Thomas O. Martel, and Linna Rae Martel to serve as co-lead plaintiffs (“plaintiffs”). On February 1, 2024, the plaintiffs filed their amended complaint. In the amended complaint, the plaintiffs alleged violations of the Securities Exchange Act of 1934, as amended, based on alleged materially false and misleading statements relating to our sales trends and financial forecasts. The plaintiffs sought to represent a class of persons who purchased or otherwise acquired Tandem common stock during the period between August 3, 2022, and November 2, 2022, inclusive. The plaintiffs also sought unspecified monetary damages, pre- and post-judgment interest, costs and fees, including attorneys' fees and expert fees, and other relief. The defendants filed their motion to dismiss the amended complaint on March 11, 2024. The plaintiffs filed a response in opposition to defendants' motion to dismiss on March 27, 2024, and on April 10, 2024, defendants filed their reply. On April 29, 2024, the court granted defendants' motion to dismiss with leave to file a second amended complaint within 30 days. The plaintiffs did not file a second amended complaint within 30 days. On June 4, 2024, the Court entered final judgment dismissing the action in its entirety with prejudice. On July 5, 2024, the plaintiffs' deadline to appeal the final judgment expired.

Two shareholder derivative cases were filed in the United States District Court for the Southern District of California on March 29, 2024 (captioned *Bushansky v. John F. Sheridan et al.*, Case No. 24-cv-608) and on April 23, 2024 (captioned *Amersi v. John F. Sheridan et al.*, Case No. 24-cv-726) against the individual members of Tandem's Board of Directors and the Company. These shareholder derivative lawsuits piggybacked on the *Lowe* case, and alleged that Tandem's Board breached its fiduciary duties by failing to properly oversee and monitor the risks affecting the Company's business, which resulted in reduced guidance, an associated stock drop, and the *Lowe* case. On May 16, 2024, the parties in the derivative actions filed a joint motion regarding consolidation and appointment of counsel. On June 13, 2024, the joint motion was granted and the derivative actions were consolidated. On July 12, 2024, the parties filed a joint request for voluntary dismissal of the consolidated derivative actions without prejudice. On the same day, July 12, 2024, the court granted the parties' joint request and dismissed the consolidated derivative actions without prejudice.

From time to time, the Company is involved in various other legal proceedings, regulatory matters, and other disputes or claims arising from or related to claims incident to the normal course of the Company's business activities, including actions with respect to intellectual property, data privacy, employment, regulatory, product liability and contractual matters. Although the results of such legal proceedings and claims cannot be predicted with certainty, as of September 30, 2024 the Company believes it is not currently a party to any legal proceedings, regulatory matters, or other disputes or claims for which a material loss was considered probable or for which the amount (or range) of loss was reasonably estimable. However, regardless of the merit of the claims raised or the outcome, legal proceedings may have an adverse impact on the Company as a result of defense and settlement costs, diversion of management time and resources, and other factors.

Letters of Credit

As of September 30, 2024, in connection with one of the Company's operating leases (see Note 6, "Leases"), the Company had a \$4.9 million unsecured irrevocable standby letter of credit arrangement with a bank, under which the landlord of the building is the beneficiary. The Company is required to maintain the standby letter of credit throughout the term of the lease, which expires in April 2035.

Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations.

You should read the following discussion and analysis together with our financial statements and related notes in Part I, Item 1 of this Quarterly Report on Form 10-Q for the quarter ended September 30, 2024 (Quarterly Report).

This Quarterly Report contains forward-looking statements within the meaning of the federal securities laws, which statements are subject to considerable risks and uncertainties. These forward-looking statements are intended to qualify for the safe harbor from liability established by the Private Securities Litigation Reform Act of 1995. All statements included or incorporated by reference in this Quarterly Report, other than statements of historical fact, are forward-looking statements. You can identify forward-looking statements by the use of words such as “may,” “will,” “could,” “anticipate,” “expect,” “intend,” “believe,” “continue” or the negative of such terms, or other comparable terminology. Forward-looking statements also include the assumptions underlying or relating to such statements. In particular, forward-looking statements contained in this Quarterly Report may relate to, among other things, our future or assumed financial condition, results of operations, liquidity, trends impacting our financial results, business forecasts and plans, research and product development plans, product pipelines, development timelines, manufacturing plans, strategic plans and objectives, capital needs and financing plans, product launches, geographic expansion, distribution plans, production capacity, clinical trials, regulatory approvals, competitive position and the impact of changes in the competitive environment, supply chain, and the businesses of our contract manufacturers and suppliers, integration of acquisitions and partner technologies, and the application of accounting guidance. We caution you that the foregoing list may not include all of the forward-looking statements made in this Quarterly Report.

Our forward-looking statements are based on our management’s current assumptions and expectations about future events and trends, which affect or may affect our business, strategy, operations or financial performance. Although we believe that these forward-looking statements are based upon reasonable assumptions, they are subject to numerous known and unknown risks and uncertainties and are made in light of information currently available to us. Our actual financial condition and results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth below in the section entitled “Risk Factors” in this Quarterly Report, as well as in the other public filings we make with the Securities and Exchange Commission. You should read this Quarterly Report with the understanding that our actual future financial condition and results may be materially different from and worse than what we expect.

Moreover, we operate in an evolving environment. New risk factors and uncertainties emerge from time to time and it is not possible for our management to predict all risk factors and uncertainties, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements.

Forward-looking statements speak only as of the date they were made and, except to the extent required by law or the rules of the Nasdaq Global Market, we undertake no obligation to update or review any forward-looking statement because of new information, future events or other factors.

We qualify all of our forward-looking statements by these cautionary statements.

Overview

We are a medical device company focused on the design, development and commercialization of technology solutions for people living with diabetes. We consider our primary addressable market to be people who live with type 1 diabetes. Through our product development efforts, we are seeking to expand our addressable market to include people living with type 2 diabetes who require intensive insulin therapy. Diabetes management can vary greatly from person-to-person, creating multiple market segments based on clinical needs and personal preferences. Our goal is to address the individual needs of people with insulin-dependent diabetes and their care team, by offering flexibility and choice in intelligent insulin delivery systems, through an accessible portfolio of market-leading pumps, applications, and insights.

From inception in 2012 through June 2018, we derived nearly all of our sales from the shipment of insulin pumps and associated supplies to customers in the United States. Starting in the third quarter of 2018, we began selling in select geographies outside the United States and our technology solutions are now available in approximately 25 countries worldwide.

Through our portfolio approach, we offer people living with diabetes a choice in their therapy management system based on their individual needs and preferences. In support of this strategy, we recently expanded our portfolio which now includes both the t:slim X2 and the Tandem Mobi insulin pumps. The Tandem Mobi insulin pump is the world's smallest durable automated insulin delivery (AID) system. At approximately half the size of our t:slim X2 pump, Tandem Mobi is designed for people who seek even greater discretion and flexibility, and includes features such as expanded pump-control from our iOS mobile application, inductive charging, and an on-pump button that can be used for bolusing and other actions. Since the beginning of 2024, we scaled the commercial release of Tandem Mobi in the United States, first offering integration with the Dexcom G6 sensor beginning in February followed by the Dexcom G7 beginning in June.

The vast majority of our customers use their insulin pump with CGM integration. This allows their insulin pump to receive CGM sensor readings, which can then be used in our AID algorithms, including our Control-IQ technology. Control-IQ is an advanced hybrid-closed loop feature designed to help increase a user's time in their targeted glycemic range. Multiple studies, including three publications in the *New England Journal of Medicine*, have demonstrated that use of Control-IQ technology provides people across all demographics with improved clinical outcomes that are both immediate and sustained.

The t:slim X2 was the first pump in the industry on which remote software updates were made commercially available in the United States and is now also available in the countries we serve worldwide. This has allowed our t:slim X2 and Tandem Mobi customers to update their own pump software. We believe this offering is a competitive advantage that allows us to bring our customers clinical and lifestyle enhancements within their warranty cycle without having to purchase a new pump. These enhancements include new developments in our AID technology, CGM integrations and mobile app features. For example, in 2024 we offered pump software updates to allow Tandem pump users access to integrate with new CGM sensors.

For more than a decade we have offered our customers, their caregivers and healthcare providers a data management application to provide a fast, easy and visual way to display diabetes therapy management data from our pumps and integrated CGMs. In the second quarter of 2023, we expanded our digital technology solutions with the launch of Tandem Source in the United States. In addition to displaying diabetes therapy management data, Tandem Source is also designed to serve as a portal for supplies reordering and pump software updates. In the second quarter of 2024, we began a scaled launch of Tandem Source outside the United States.

Our Strategy & Future Technology

Diabetes management can vary greatly from person-to-person, creating multiple market segments based on clinical needs and personal preferences. Our goal is to address the individual needs of people with insulin-dependent diabetes and their care team, by providing flexibility and choice in intelligent insulin delivery systems through an accessible portfolio of market-leading pumps, applications, and insights.

In support of this strategy, our portfolio of future technologies includes:

t:slim X3

Advancing our flagship t:slim platform, the t:slim X3 is planned to include enhanced technology, such as greater processing power and capacity to support our advanced algorithms, as well as increased battery life and improved durability.

Mobi: Tubeless

This offering is intended to provide an alternative tubeless infusion site option for Tandem Mobi pump users. It will allow a Tandem Mobi pump to be worn completely on the user's body with no tubing, while still providing the benefit of detachability. A goal of this design is to allow people living with diabetes to customize the way they wear their pump with each cartridge change, switching between tubed and tubeless wear configurations, to best suit their personal preferences and lifestyle.

Sigi

The ergonomic, rechargeable and detachable Sigi Patch Pump is intended to reduce the burden of managing diabetes through its use of pre-filled insulin cartridges and compatibility with AID technology.

Extended Wear Infusion Sets

Infusion sets provide additional choice and flexibility to people living with diabetes. We are currently developing extended wear infusion set technology. Our goals for future infusion set innovations include solutions that enhance user experience, while reducing occlusions, body burden and waste.

Control-IQ Advancements

We are continuing to drive innovation in our algorithms, emphasizing automation, personalization and simplification to continue to improve therapeutic outcomes and provide a positive patient experience. In late 2023, an enhanced version of our Control-IQ technology was cleared with additional features for people with type 1 diabetes age 2 and older. In the third quarter of 2024, we completed a pivotal study to support expanding indications to include people living with type 2 diabetes. We are also pursuing the use of different insulins with our Control-IQ technology. For example, in the first half of 2024 we received approval for both the addition of Trurapi U-100 in Canada and Lyumjev in the European Union as compatible insulins that can be used with our t:slim X2 pump with Control-IQ technology.

Pump Reimbursement Cycle

Insulin pumps in the markets we serve worldwide are generally subject to a four-year reimbursement cycle, imposed by the third-party insurance carrier, government plan or healthcare system that serves as the primary payor. At the end of the typical four-year reimbursement cycle, customers may be eligible to purchase a new insulin pump, subject to the rules and requirements of their primary insurance payor. While warranties generally expire four years from the original pump shipment date, those customers that renew take on average up to one year from date of warranty expiration to purchase a subsequent pump. While the majority of our insulin pump sales from initial commercialization through the current period have been generated by sales to new customers, the opportunity to make subsequent sales of renewal insulin pumps to existing customers increases each period as an escalating number of customer warranties expire. With programs dedicated to customer retention efforts, we expect such renewal purchases to represent an increasing portion of our pump shipments over time.

At the end of 2023, we had approximately 450,000 users in our in-warranty installed base, approximately one-third of whom live outside the United States.

The ordering patterns of, and levels of inventory carried by, our distributors outside the United States for pumps and supplies have historically been highly variable from period to period due to a number of factors, including summer vacations, the timing of product launches into new geographies and variability due to supply chain logistics, particularly during the global pandemic. This also influences the timing in which renewal eligibility begins for existing customers, which may not initially be consistent with trends in the United States market. We recently began completing full four-year reimbursement cycles in an increasing number of our markets outside of the United States.

Trends and Uncertainties Impacting Financial Results

Our financial condition and operating results have historically fluctuated on a quarterly or annual basis. We expect these periodic fluctuations will continue to be impacted by a number of trends and uncertainties, including the following:

Regulatory Approvals and Actions

- Sales of new products are subject to local government regulations. The requirements and timelines to receive regulatory clearance can vary substantially from country to country and delays may impact our ability to expand our worldwide customer base and bring products to market in a competitive timeframe. These delays, or failure to receive regulatory approval could adversely impact our revenue and results of operations.
- Any adverse event involving products that we distribute could result in future corrective actions, such as recalls or customer notifications, or regulatory agency action, which could include inspection, mandatory recall or other enforcement action. Any action by regulatory bodies against us, and any regulatory challenges we encounter could have a negative impact on our product sales and harm our reputation.

Markets, Seasonality, Competition, and Product Launches

- We expect our business to be impacted by the introduction of new diabetes devices and treatments by us or our competitors. The success of our products is variable and we believe it correlates to market acceptance, anticipated product launches and commercial availability. We anticipate that our Tandem Choice program, and its related financial and accounting impact, may continue to materially impact our business until the conclusion of the program.
- Seasonality in the United States is associated with annual insurance deductibles and coinsurance requirements of the medical insurance plans used by our customers and the customers of our distributors. In the United States, we typically experience a higher volume of pump shipments in the second half of the year due to the nature of the reimbursement environment. Other factors that may impact sales across the year include the timing of winter, summer and other seasonal holidays, particularly in our markets outside the United States.
- We believe our July 2023 announcement of U.S. Food and Drug Administration (FDA) clearance of Tandem Mobi and its anticipated launch impacted the timing of purchasing decisions by our current and prospective customers in the second half of 2023 up through the United States commercial availability of Tandem Mobi in February 2024, resulting in delays that were unlike historical seasonal patterns or purchasing behaviors. Regulatory approval and/or upcoming launches of other new Tandem or competitor products could also adversely impact timing of purchasing decisions.
- In periods following new product launches, particularly with new hardware platforms, our cost of sales may increase on a per unit basis until the new products achieve manufacturing scale and operating expenses may be elevated by increased sales and marketing spend to support the product launches.
- We have expanded our business and launched new products in select geographies outside the United States. The ordering patterns of our distributors outside the United States has historically been highly variable from period to period. For example, we began operations of a European distribution center which led to a reduction of inventory levels at our distributors, significantly impacting sales patterns in the second half of 2022 and first half of 2023.

Reimbursement

- Our insulin pump products are generally considered durable medical equipment (DME) and have an expected lifespan of at least four years. In addition to insulin pumps, we sell single-use products that are used together with our pumps and are replaced every few days, including cartridges for storing and delivering insulin, and infusion sets that connect the insulin pump to a user's body. Because of the DME classification, our pumps and supplies are typically reimbursed through a medical benefit. As our portfolio expands, we are pursuing a multi-channel managed care strategy and are in discussions to begin serving Mobi customers through the pharmacy channel.
- We generally have had broad insurance coverage for our current products from third-party payors. Our revenue and results of operations may be impacted by the failure to secure or retain adequate coverage, changes in reimbursement structures or availability of affordable options for our customers.

Macroeconomic Factors

- Global economic and market uncertainty, such as recessionary concerns, changes in discretionary spending and increased interest rates have impacted our customers' purchasing decisions and the buying patterns of our distributors.
- High inflation, fluctuations in foreign currency valuations and the effects of other macroeconomic factors and concerns has disrupted and may continue to disrupt our relationships with suppliers, third-party manufacturers, healthcare providers, distributors and our existing or potential customers.

Components of Results of Operations

Sales

We offer products for people with insulin-dependent diabetes, including a portfolio of hardware platforms, single-use insulin cartridges and infusion sets, data management platforms and mobile applications. Our primary customers are the end users of our products, non-exclusive distribution partners whose level of service varies based on geography, the healthcare professionals who prescribe our products and the healthcare systems or payors who provide insurance coverage and access to our products. Our sales may fluctuate from period to period, particularly due to seasonality in the United States associated with the timing of insurance deductible resets, which generally reflect in a significant decline in pump shipments from any fourth quarter to the following first quarter. Therefore, the lowest percentage of sales is typically reported in the first quarter of each calendar year and the highest percentage is typically reported in the fourth quarter. See also “Trends and Uncertainties Impacting Financial Results—Seasonality” above.

From September 2022 through February 2024, we offered the Tandem Choice program to eligible t:slim X2 customers to provide a pathway to ownership of our newest hardware platform, Tandem Mobi, for a fee when available. Eligible customers who purchased a t:slim X2 insulin pump during the program period have until December 31, 2024 to exercise the option to switch to the Tandem Mobi for a stated fee. The accounting treatment for Tandem Choice is complex (see Note 2, “Summary of Significant Accounting Policies”). The program required the deferral of some portion of sales for shipments of eligible pumps between the third quarter of 2022 and the first quarter of 2024. No election was made by the customer at the time of the initial sale, nor did the right offered to the customer impact the economics associated with how or when the initial pump sale was reimbursed. If a customer elects to participate in Tandem Choice, we will recognize the existing sales deferral, incremental fees received and the associated costs of goods sold for the new insulin pump, Tandem Mobi, at the time of fulfillment. Qualifying customers were able to elect participation in Tandem Choice starting near the end of the second quarter of 2024. Any remaining deferrals will be recognized when the program ends on December 31, 2024, provided all obligation under the Tandem Choice program are satisfied. The balance of the Tandem Choice deferral was \$30.1 million as of September 30, 2024.

Cost of Sales

Cost of sales includes raw materials, labor costs, manufacturing overhead expenses, product training costs, royalties, freight, reserves for expected warranty costs, costs of supporting our digital health platforms, scrap and charges for excess and obsolete inventories. Manufacturing overhead expenses include expenses relating to quality assurance, manufacturing engineering, material procurement, inventory control, facilities, equipment, information technology and operations supervision and management. When taking into consideration the differences in reimbursement levels and cost structure, pumps have, and are expected to continue to have, a higher gross profit and gross margin percentage than our pump-related supplies on a per unit basis. Therefore, the percentage of pump sales relative to total sales could have a significant impact on our overall gross margin percentage.

Selling, General and Administrative

Our selling, general and administrative (SG&A) expenses primarily consist of salary, cash-based incentive compensation, fringe benefits and non-cash stock-based compensation for our sales, marketing and administrative functions, which also includes our clinical, customer support, technical services, insurance verification and regulatory affairs personnel. Our sales territories in the United States are generally maintained by sales representatives and field clinical specialists, and supported by managed care liaisons, additional sales management and other customer support personnel. Other significant SG&A expenses typically include those incurred for commercialization activities associated with new product launches, travel, trade shows, outside legal fees, independent auditor fees, outside consultant fees, insurance premiums, facilities costs and information technology costs.

Research and Development

Our research and development (R&D) activities primarily consist of engineering and research programs associated with our hardware, software and digital health products under development, as well as activities associated with our core technologies and processes. R&D expenses are primarily related to employee compensation, including salary, cash-based incentive compensation, fringe benefits and non-cash stock-based compensation. We also incur R&D expenses for supplies, development prototypes, outside design and testing services, depreciation, allocated facilities and information services, clinical trials, payments under our licensing, development and commercialization agreements and other indirect costs.

Acquired In-process Research and Development (IPR&D)

Acquired IPR&D reflects costs of external research and development projects acquired directly in a transaction other than a business combination, that do not have an alternative future use.

Other Income and Expense

Other income and expense primarily consists of interest earned on our cash equivalents and short-term investments, foreign currency transaction gains and losses and interest expense which includes the amortization of debt issuance costs related to our convertible senior notes.

In October 2023, we were notified that \$3.1 million of additional interest beyond the 1.50% per annum had been accruing on the 2025 Notes since May 2021, pursuant to the terms of the indenture (see Note 7, "Debt").

Income Tax Expense (Benefit)

Because the Company maintains a full valuation allowance against its net deferred tax assets, income tax expense is expected to primarily consist of current federal, state and foreign cash tax expense as a result of taxable income anticipated or incurred in those jurisdictions.

Results of Operations

(in thousands, except percentages)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Sales:				
United States	\$ 171,650	\$ 130,222	\$ 458,122	\$ 403,964
Outside the United States	72,321	55,400	199,433	146,958
Total sales	243,971	185,622	657,555	550,922
Cost of sales	119,318	95,869	325,436	276,527
Gross profit	124,653	89,753	332,119	274,395
Gross margin	51 %	48 %	51 %	50 %
Operating expenses:				
Selling, general and administrative	99,639	79,328	283,987	266,752
Research and development	51,107	41,970	146,677	127,063
Acquired in-process research and development	—	—	—	78,750
Total operating expenses	150,746	121,298	430,664	472,565
Operating loss	(26,093)	(31,545)	(98,545)	(198,170)
Other income (expense), net:				
Interest income and other, net	5,344	5,656	13,482	17,305
Interest expense	(1,865)	(4,840)	(5,555)	(8,079)
Loss on extinguishment of debt	—	—	(1,268)	—
Total other income (expense), net	3,479	816	6,659	9,226
Loss before income taxes	(22,614)	(30,729)	(91,886)	(188,944)
Income tax expense	637	2,232	4,894	3,665
Net loss	<u>\$ (23,251)</u>	<u>\$ (32,961)</u>	<u>\$ (96,780)</u>	<u>\$ (192,609)</u>

Comparison of the Three Months Ended September 30, 2024 and 2023

Sales

For the three months ended September 30, 2024, we shipped more than 31,000 pumps worldwide. Sales were \$244.0 million, which included \$72.3 million of sales outside the United States. Sales were \$185.6 million for the three months ended September 30, 2023, which included \$55.4 million of sales outside the United States. For the three months ended September 30, 2024, we recognized incremental pump sales of \$1.0 million as a result of Tandem Choice fulfillments. For the three months ended September 30, 2023, our revenues were reduced by \$8.2 million for pump sales as a result of deferrals related to Tandem Choice. The Tandem Choice program launched in the United States in September of 2022 and eligibility to participate in the program (and our associated sales deferrals) ended in February 2024 in conjunction with the launch of Tandem Mobi.

Sales by product in the United States were as follows (in thousands):

	Three Months Ended September 30,	
	2024	2023
Pump	\$ 86,722	\$ 66,365
Supplies and other	83,889	72,093
Net revenue recognized (deferred) for Tandem Choice program	1,039	(8,236)
Total Sales in the United States	<u>\$ 171,650</u>	<u>\$ 130,222</u>

Pump sales in the United States were \$86.7 million for the third quarter of 2024, compared to \$66.4 million in the third quarter of 2023. Our pump shipments in the United States increased more than 20% to nearly 21,000 pumps in the third quarter of 2024 compared to the third quarter of 2023. We also benefited from an increase in average selling prices across all product lines due to price increases, customer mix and a continued shift to a higher percent of direct sales versus in our distribution channel. Sales to distributors accounted for 61% and 64% of the Company's United States sales for the three months ended September 30, 2024 and 2023, respectively. Sales of pump-related supplies increased primarily due to a year-over-year increase in our installed base of customers in the United States, as well as an increase in average selling prices. Tandem Choice fulfillments in the third quarter of 2024 resulted in incremental sales of \$1.0 million. Sales in the United States for the three months ended September 30, 2023 were reduced by \$8.2 million in sales deferrals related to Tandem Choice.

Sales by product outside the United States were as follows (in thousands):

	Three Months Ended September 30,	
	2024	2023
Pump	\$ 28,077	\$ 21,672
Supplies and other	44,244	33,728
Total Sales Outside the United States	<u>\$ 72,321</u>	<u>\$ 55,400</u>

Pump sales outside the United States were \$28.1 million for the third quarter of 2024, compared to \$21.7 million in the third quarter of 2023. Our pump shipments outside the United States increased by over 30% to nearly 11,000 pumps for the third quarter of 2024 compared to the third quarter of 2023. We also benefited from an increase in average selling prices due primarily to geographical mix. Sales of pump-related supplies increased due to a year-over-year increase in our installed base of customers outside the United States.

Cost of Sales and Gross Profit

Our cost of sales for the three months ended September 30, 2024 was \$119.3 million, resulting in gross profit of \$124.7 million, compared to cost of sales of \$95.9 million and gross profit of \$89.8 million for the same period in 2023. Cost of sales for the three months ended September 30, 2024 included a charge of \$0.7 million for Tandem Choice fulfillments. There was no comparable charge during the same period in 2023. The gross margin for the three-month periods ended September 30, 2024 and 2023 was 51% and 48%, respectively.

The effect of our Tandem Choice program on gross profit and gross margin was negligible for the three months ended September 30, 2024. Gross profit for the three months ended September 30, 2023 was reduced by \$8.2 million, or approximately two percentage points of gross margin due to Tandem Choice. The impact on gross margin from Tandem Choice will continue to fluctuate through the end of the program based on the number of eligible customers who ultimately elect to participate.

Excluding the impact of Tandem Choice, gross margin was flat compared to the prior year period. Gross margin benefited from pricing improvement across all product lines and lower pump materials cost, offset by higher labor and overhead on a per-unit basis as we continued to scale the launch of Tandem Mobi. Gross margin was positively impacted by product mix. Pump sales, which have the highest gross margin, were 47% of total worldwide sales in the third quarter of 2024, compared to 43% in the third quarter of 2023. Excluding the impact of Tandem Choice, pump sales for the third quarter of 2024 were 47% of worldwide sales and 45% of worldwide sales for the third quarter of 2023.

Operating Expenses

Our operating expenses for the three months ended September 30, 2024 were \$150.7 million, compared to \$121.3 million for the three months ended September 30, 2023. The \$29.4 million increase was primarily driven by increased development efforts for pipeline products as well as the ramp up of sales and marketing for Mobi.

Selling, General and Administrative Expenses. SG&A expenses were \$99.6 million for the three months ended September 30, 2024, compared to \$79.3 million for the same period in 2023. The \$20.3 million increase was largely driven by higher employee-related expenses of \$12.7 million due to increased headcount and overall higher cost of salaries and benefits. We also experienced a \$7.6 million increase in outside consulting and services largely to support business growth.

Research and Development Expenses. R&D expenses increased to \$51.1 million for the three months ended September 30, 2024, from \$42.0 million for the same period in 2023. The increase in R&D expenses was primarily the result of an increase of \$6.0 million in employee benefits and salaries due to an increase in personnel to support our product development efforts. We also experienced an increase in other non-employee discretionary spending, including clinical trial expenses, supplies and equipment costs.

Other Income (Expense), Net

Total other income (expense), net for the three months ended September 30, 2024 was \$3.5 million income, compared to \$0.8 million income in the same period in 2023. Other income, net for the three months ended September 30, 2024 primarily consisted of \$5.6 million of interest income earned on our cash equivalents and short-term investments, and \$1.9 million of interest expense which included the amortization of debt issuance costs related to our convertible senior notes due 2025 and 2029 (the 2025 Notes and the 2029 Notes, respectively). Other income, net for the three months ended September 30, 2023 primarily consisted of \$5.9 million of interest income earned on our cash equivalents and short-term investments partially offset by \$4.8 million of interest expense which included \$3.1 million of additional accrued interest as discussed above, as well as the amortization of debt issuance costs related to the 2025 Notes.

Income Tax Expense

We recognized income tax expense of \$0.6 million on a pre-tax loss of \$22.6 million for the three months ended September 30, 2024, compared to income tax expense of \$2.2 million on a pre-tax loss of \$30.7 million for the three months ended September 30, 2023. Income tax expense for the three months ended September 30, 2024 and 2023 was primarily attributable to state and foreign income tax expense as a result of current taxable income in certain jurisdictions.

Comparison of the Nine Months Ended September 30, 2024 and 2023

Sales

For the nine months ended September 30, 2024, we shipped nearly 87,000 pumps worldwide. Sales were \$657.6 million, which included \$199.4 million of sales outside the United States. For the nine months ended September 30, 2024, there was negligible net impact to our revenues as a result of sales deferrals and fulfillments related to our Tandem Choice program. Pump sales that occurred after February 2024 were not eligible for Tandem Choice. Sales were \$550.9 million for the same period in 2023, which included \$147.0 million of sales outside the United States. For the nine months ended September 30, 2023, we deferred \$12.6 million of pump sales as the result of Tandem Choice.

Sales by product in the United States were as follows (in thousands):

	Nine Months Ended September 30,	
	2024	2023
Pump	\$ 230,187	\$ 207,180
Supplies and other	227,888	209,352
Net revenue recognized (deferred) for Tandem Choice program	47	(12,568)
Total Sales in the United States	<u>\$ 458,122</u>	<u>\$ 403,964</u>

Pump sales in the United States were \$230.2 million for the nine months ended September 30, 2024 compared to \$207.2 million for the same period in 2023. Our pump shipments in the United States increased by nearly 10% to more than 56,000 pumps for the nine months ended September 30, 2024, compared to the nine months ended September 30, 2023. The scaled launch of Tandem Mobi has impacted, and may continue to impact, the timing of customer purchases across the quarters. For example, Tandem Mobi became commercially available in the United States in February 2024 initially with Dexcom G6 sensor integration, followed by Dexcom G7 sensor integration in June 2024. We also benefited from an increase in average selling prices across all product lines due to price increases, customer mix and a continued shift to a higher percent of direct sales versus in our distribution channel. Sales of pump-related supplies increased primarily due to a year-over-year increase in our ending estimated installed base of customers in the United States, as well as increase in average selling prices. The net sales impact from revenue deferrals and fulfillments of our Tandem Choice program in the United States for the nine months ended September 30, 2024 was negligible. For the nine months ended September 30, 2023, revenues were reduced by \$12.6 million as the result of sales deferrals related to Tandem Choice. The decrease in the net revenue deferral for Tandem Choice in 2024 as compared to 2023 was primarily due to the cessation of the sales deferral period in February 2024, which coincided with the launch of Tandem Mobi. Pump sales that occurred after February 2024 were not eligible for Tandem Choice, nor subject to a sales deferral.

Sales by product outside the United States were as follows (in thousands):

	Nine Months Ended September 30,	
	2024	2023
Pump	\$ 79,774	\$ 67,235
Supplies and other	119,659	79,723
Total Sales Outside the United States	<u>\$ 199,433</u>	<u>\$ 146,958</u>

Our pump shipments outside the United States increased by over 20% to more than 30,000 pumps for the nine months ended September 30, 2024 compared to the nine months ended September 30, 2023. Pump sales outside the United States were \$79.8 million for the nine months ended September 30, 2024, compared to \$67.2 million for the same period in 2023. Throughout 2024, we have seen increased customer demand for our products. In the first half of 2023, pump and supply shipments were impacted by an operational transition to a centralized European distribution center which resulted in significant disruption in distributor ordering patterns. The transition was completed by the second half of 2023. The increase in pump sales was offset by a slight decrease in pump average selling prices due primarily to geographical mix. In addition to the distribution center transition, sales of pump-related supplies outside the United States increased due to growth in our installed base of customers. Sales to distributors accounted for the overwhelming majority of our total sales outside the United States for the nine-month periods ended September 30, 2024, and 2023.

Cost of Sales and Gross Profit

Our cost of sales for the nine months ended September 30, 2024 was \$325.4 million resulting in gross profit of \$332.1 million, compared to cost of sales of \$276.5 million and gross profit of \$274.4 million for the same period in 2023. The gross margin for the nine months ended September 30, 2024 was 51% compared to 50% in the same period in 2023.

The effect of Tandem Choice was negligible for the nine months ended September 30, 2024 compared to a gross margin reduction of approximately 1 percentage point for the nine months ended September 30, 2023. The impact on gross margin from our Tandem Choice program will fluctuate through the expiration of the program based on the number and timing of eligible customers who ultimately elect to participate.

Gross margin benefited from pricing improvement and lower materials cost, offset by higher labor and overhead costs on a per-unit basis as we continue to scale the launch of Tandem Mobi. Gross margin was negatively impacted by product mix. Pump sales, which have the highest gross margin, were 47% of total worldwide sales for the nine months ended September 30, 2024, compared to 48% of worldwide sales for the first nine months of 2023. Excluding the impact of Tandem Choice, pump sales for the nine months ended September 30, 2024 were 47% of total worldwide sales compared to 49% in the first nine months of 2023.

Operating Expenses

Our operating expenses for the nine months ended September 30, 2024 were \$430.7 million, compared to \$472.6 million for the nine months ended September 30, 2023. The \$41.9 million decrease was primarily driven by \$78.8 million of acquired in-process research and development expenses incurred in 2023 in connection with our acquisition of AMF Medical, for which there was no comparable expense in 2024. In 2023, we also incurred a non-recurring operating lease impairment charge in SG&A of \$14.1 million as a result of a facilities consolidation (see Note 6, "Leases"), and employee severance costs of \$2.7 million. These non-recurring expenses from 2023 were partially offset by higher operating expenses in 2024 related to development efforts for pipeline products as well as the ramp up of sales and marketing for Tandem Mobi.

Selling, General and Administrative Expenses. SG&A expenses increased 6% to \$284.0 million for the nine months ended September 30, 2024, from \$266.8 million for the same period in 2023. Expenses for the nine months ended September 30, 2023 included non-recurring expenses of \$14.1 million related to lease impairment charges and \$2.1 million in severance costs in 2023. Expenses for the nine months ended September 30, 2024 increased mainly due to higher employee-related, marketing and consulting expenses which related to new product launches.

Research and Development Expenses. R&D expenses increased 15% to \$146.7 million for the nine months ended September 30, 2024, from \$127.1 million for the same period in 2023. The increase in R&D expenses was primarily the result of an increase in salaries and related benefits from our acquisitions and an increase in personnel to support our product development efforts. We also experienced an increase in other non-employee discretionary spending, including clinical trials costs and equipment expenses.

Acquired In-Process Research and Development Expenses. Acquired IPR&D expenses of \$78.8 million for the nine months ended September 30, 2023 represented the value of assets acquired, and acquisition related expenses, in connection with our acquisition of AMF Medical (see Note 12, "Acquisitions").

Other Income (Expense), Net

Total other income (expense), net for the nine months ended September 30, 2024 was \$6.7 million income, compared to \$9.2 million income in the same period in 2023. Other income, net for the nine months ended September 30, 2024 primarily consisted of \$16.7 million of interest income earned on our cash equivalents and short-term investments, partially offset by \$5.6 million of interest expense which included the amortization of debt issuance costs related to our 2025 Notes and 2029 Notes. Other income, net for the nine months ended September 30, 2023 primarily consisted of \$15.2 million of interest income earned on our cash equivalents and short-term investments, and \$2.0 million in foreign currency transaction gains, partially offset by \$8.1 million of interest expense which included \$3.1 million of additional interest as discussed above and the amortization of debt issuance costs related to our 2025 Notes.

Income Tax Expense

We recognized income tax expense of \$4.9 million on a pre-tax loss of \$91.9 million for the nine months ended September 30, 2024, compared to income tax expense of \$3.7 million on a pre-tax loss of \$188.9 million for the nine months ended September 30, 2023. Income tax expense for the nine months ended September 30, 2024 and 2023 was primarily attributable to federal, state and foreign income tax expense as a result of current taxable income in certain jurisdictions.

Liquidity and Capital Resources

At September 30, 2024, we had \$473.3 million in cash and cash equivalents and short-term investments. We believe that our cash and cash equivalents, short-term investments, and future cash flows from operations will be sufficient to fund our ongoing core business activities for at least the next 12 months.

Our historical cash outflows have primarily been associated with cash used for operating activities such as research and development activities, sales, marketing and commercialization of our products worldwide, expansion of clinical and customer support organizations, the acquisition of intellectual property, equity investments and acquired assets, capital expenditures and debt service costs.

Historically, our principal sources of cash have included cash collected from product sales, private and public offerings of equity securities, exercises of employee stock awards, and debt financing. We expect to rely on these sources of cash, primarily from product sales, to fund our material cash requirements in both the short and long term.

The following table shows a summary of our cash flows for the nine months ended September 30, 2024, and 2023 (in thousands):

	Nine Months Ended September 30,	
	2024	2023
Net cash provided by (used in):		
Operating activities	\$ 13,508	\$ (24,594)
Investing activities	(28,492)	(69,156)
Financing activities	6,065	1,496
Effect of foreign exchange rate changes on cash	(910)	(652)
Net decrease in cash and cash equivalents	\$ (9,829)	\$ (92,906)

Operating Activities. Net cash provided by operating activities was \$13.5 million for the nine months ended September 30, 2024, compared to \$24.6 million cash used in the same period in 2023. For the nine months ended September 30, 2024, net loss was \$96.8 million, net non-cash adjustments were \$98.8 million, and change in working capital balances was an increase of \$11.5 million. For the nine months ended September 30, 2023, net loss was \$192.6 million, net non-cash adjustments were \$177.4 million and change in working capital balances was a decrease of \$9.4 million. For the nine months ended September 30, 2023, net non-cash adjustments included \$78.8 million of acquired in-process research and development expenses related to our acquisition of AMF Medical, and a \$14.1 million operating lease impairment charge.

Investing Activities. Net cash used in investing activities was \$28.5 million for the nine months ended September 30, 2024, which primarily consisted of \$251.4 million of purchases of short-term investments, and \$16.2 million in purchases of property and equipment, offset by \$239.0 million in proceeds from maturities and redemptions of short-term investments. Net cash used in investing activities was 69.2 million for the nine months ended September 30, 2023, which was primarily related to \$391.0 million of purchases of short-term investments, \$69.5 million for the acquisition of AMF Medical, including transaction costs (see Note 12, "Acquisitions"), and \$21.6 million in purchases of property and equipment, of which \$8.7 million was associated with improvements to the new headquarters lease facility, completed in 2023, offset by \$415.5 million in proceeds from maturities and redemptions of short-term investments.

Financing Activities. Net cash provided by financing activities was \$6.1 million for the nine months ended September 30, 2024, which primarily consisted of net proceeds of \$306.9 million from the issuance of the 2029 Notes which was partially offset by \$246.1 million used in the repurchase of 2025 Notes, \$30.0 million used in the repurchase and retirement of common stock and \$15.8 million used to purchase Capped Call Options related to the 2029 Notes. In addition, \$9.0 million was used in payments for tax withholdings related to the issuance of common stock under our stock plans, net of proceeds received from common stock issuances for the period. Net cash provided by financing activities was \$1.5 million for the nine months ended September 30, 2023, which primarily consisted of proceeds from the issuance of common stock under our stock plans, net of payments for related tax withholdings.

Our liquidity position and capital requirements are subject to fluctuation based on a number of factors. In particular, our cash inflows and outflows are principally impacted by the following:

- our ability to generate sales, the timing of those sales, the mix of products sold and the collection of receivables from period to period;
- contractual debt obligations, including periodic interest payments;
- the timing of any additional financings, and the net proceeds raised from such financings;
- the timing and amount of proceeds from the issuance of equity awards pursuant to employee stock plans;

- fluctuations in gross and operating margins; and
- fluctuations in working capital, including changes in accounts receivable, inventories, accounts payable, employee-related liabilities, and operating lease liabilities.

Both our primary short-term and long-term capital needs are expected to include expenditures related to:

- support of our commercialization efforts related to our current and future products;
- expansion of our customer support resources for our growing installed customer base;
- research and product development efforts, including clinical trial costs;
- acquisitions, including contingent earnout payments that become payable upon the achievement of certain milestones;
- leasing or licensing of equipment, technology, intellectual property and other assets;
- additional facilities leases and related tenant improvements;
- investments for the development, improvement and acquisition of manufacturing, testing and packaging equipment to support business growth and increase capacity;
- payments under licensing, development and commercialization agreements; and
- integration costs related to acquisitions of businesses, products and technologies.

Critical Accounting Policies

Our discussion and analysis of our financial condition and results of operations are based on our condensed consolidated financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of these condensed consolidated financial statements requires management to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and the disclosure of contingent assets and liabilities in our condensed consolidated financial statements and accompanying notes as of the date of the financial statements. We evaluate our estimates and judgments on an ongoing basis. 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 our financial condition and results of operations that are not readily apparent from other sources. Some of those judgments can be subjective and complex, and therefore, actual results could differ materially from those estimates under different assumptions or conditions.

There have been no material changes to our critical accounting policies and estimates from the information provided in Part II, Item 7, “Management’s Discussion and Analysis of Financial Condition and Results of Operations – Critical Accounting Policies Involving Management Estimates and Assumptions,” included in our Annual Report on Form 10-K for the year ended December 31, 2023.

Item 3. Quantitative and Qualitative Disclosures about Market Risk.

There were no material changes to our quantitative and qualitative disclosures about market risk during the nine months ended September 30, 2024. See Part II, Item 7A of our Annual Report on Form 10-K for the fiscal year ended December 31, 2023 for a detailed discussion of our market risks.

As of September 30, 2024, we had \$357.0 million aggregate principal amount outstanding under our 2025 Notes and our 2029 Notes, which convertible senior notes both bear interest at a fixed rate of 1.50% per year. Accordingly, we are not subject to interest rate fluctuation risk related to our convertible senior notes (see Note 7, “Debt”).

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, that are designed to ensure that information required to be disclosed in the reports we file with the SEC under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure.

As of September 30, 2024, we carried out an evaluation, under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures. Based on this evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective at a reasonable assurance level as of September 30, 2024.

Our disclosure controls and procedures are designed to provide reasonable assurance of achieving their objectives as specified above. Management does not expect, however, that our disclosure controls and procedures will prevent or detect all error and fraud. Any control system, no matter how well designed and operated, is based upon certain assumptions and can provide only reasonable, not absolute, assurance that its objectives will be met. Further, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, within the Company have been detected.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act) during the quarter ended September 30, 2024 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings.

Except as set forth above under the caption “Commitments and Contingencies - Legal and Regulatory Matters” in Part I, Notes to Unaudited Condensed Consolidated Financial Statements, Note 13 of this Quarterly Report, as of September 30, 2024, we do not believe there are any material pending legal proceedings to which we or any of our subsidiaries are a party or of which any of our property is subject. See also “Patent litigation in the medical device industry is common, and we may be subject to litigation that could cause us to incur substantial costs and divert the attention of management from our business” in Part II, Item 1A of this Quarterly Report.

Item 1A. Risk Factors.

Below is a summary of material factors that make an investment in our securities speculative or risky. Importantly, this summary does not address all of the risks that we face. Additional discussion of the risks summarized in this risk factor summary, as well as other risks that we face, can be found below, under the heading “Risk Factors” in Part II, Item 1A of this Quarterly Report, and should be carefully considered, together with other information in this Quarterly Report and the Annual Report, before making investment decisions regarding our securities.

Risks Related to Our Business and Industry

- We have incurred significant operating losses since inception and cannot assure you that we will achieve sustained profitability.
- We currently rely on sales of insulin pump products to generate a significant portion of our revenue, and any factors that negatively impact sales of these products may adversely affect our business, financial condition and operating results.
- Our ability to maintain and grow our revenue depends in part on retaining a high percentage of our customer base.
- Competing products, therapeutic techniques or other technological developments and breakthroughs for the monitoring, treatment or prevention of diabetes may render our products obsolete or less desirable.
- Failure of our insulin pumps and related products to achieve and maintain market acceptance could result in us achieving sales below our expectations, which would cause our business, financial condition and operating results to be materially and adversely affected.
- Failure to secure or retain adequate coverage or reimbursement for our current products and our potential future products by third-party payors could adversely affect our business, financial condition and operating results.
- Any concerns regarding the safety or efficacy of our products could limit sales and cause unforeseen negative effects to our business prospects and financial results.
- Our sales and marketing efforts are dependent on independent distributors who are free to market products that compete with our products. If we are unable to maintain or expand our network of independent distributors, our sales may be negatively affected.
- We are dependent on clinical investigators and clinical sites to enroll participants in our current and anticipated clinical trials and human factors studies, and the failure to successfully complete clinical trials and studies could prevent us from obtaining regulatory clearances, certifications, or approvals for or commercializing our products.
- We depend on a limited number of third-party suppliers for certain components and products, and the loss of any of these suppliers, their inability to provide us with an adequate supply of components or products, or our inability to adequately forecast customer demand, could harm our business.
- We depend on the knowledge and skills of our senior management and other key employees, and if we are unable to retain and motivate them or recruit additional qualified personnel, our business may suffer.

Risks Related to Our International Operations

- Commercializing our products outside of the United States may result in a variety of risks associated with international operations that could materially adversely affect our business.
- Failure to obtain any required regulatory authorization, clearance or certification in foreign jurisdictions will prevent us from marketing our products in international markets.
- Because our business is global, our sales and profits may fluctuate or decline in response to changes in foreign currency exchange rates or other international risks.

Risks Related to Macroeconomic Conditions and External Factors

- Uncertainty in current global economic and political conditions could adversely affect our ability to predict product demand and impact our financial results and makes it more likely that our actual results could differ materially from expectations.
- Public health threats, epidemics, or pandemics could have a material adverse effect on our operations, the operations of our business partners, and the global economy as a whole.
- Climate change or other extreme weather conditions and related regulations may have a long-term impact on our business.

Risks Related to Our Future Financings and Financial Results

- We may need to raise additional funds in the future and if we are unable to raise additional funds when necessary or desirable, we may not be able to achieve our strategic objectives.
- Our operating results may fluctuate significantly from quarter to quarter.

Risks Related to Privacy and Security

- If our information technology systems or those third parties upon which we rely, our data, or our software are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; harm to our reputation; loss of revenue or profits; loss of customers or sales; and other adverse consequences.
- If we are found to have violated laws concerning the privacy and security of patient health information or other personal information, we could be subject to civil or criminal penalties, which could increase our liabilities and harm our reputation or our business.

Risks Related to Legal and Intellectual Property

- Our ability to comprehensively protect our intellectual property and proprietary technology is uncertain.
- Patent litigation in the medical device industry is common, and we may be subject to litigation that could cause us to incur substantial costs and divert the attention of management from our business.
- We may be subject to damages resulting from claims that we, or our employees, have wrongfully used or disclosed trade secrets or other proprietary information of our competitors.

Risks Related to Our Regulatory Environment

- Our products and operations are subject to extensive governmental regulation, and failure to comply with applicable requirements could cause our business to suffer.

- New products or modifications to our existing products may require new 510(k) clearances, PMAs or certifications, or may require us to cease marketing or recall the modified products until clearances, certifications or approvals are obtained.
- A recall or suspension of our products, or the discovery of serious safety issues with our products, could have a significant negative impact on us.

General Risks

- The price of our common stock may continue to fluctuate significantly.
- Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.
- If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud, which could harm our business and result in a decline in the trading price of our common stock.

Risks Related to Our Indebtedness

- We have incurred a significant amount of indebtedness and the agreements governing such indebtedness subject us to required debt service payments, as well as financial and operational covenants, any of which may restrict our financial flexibility and affect our ability to operate our business.
- Servicing the Notes will require a significant amount of cash, and we may not have sufficient cash flow from our business to repay the Notes.
- We may take actions which could limit our ability to make payments on the Notes.

An investment in our common stock, or in securities convertible into or exchangeable for our common stock, involves a high degree of risk. You should carefully consider the risks described below, together with all of the other information included in this Quarterly Report, as well as in our other filings with the SEC, in evaluating our business. If any of the following risks actually occur, our business, financial condition, operating results and future prospects could be materially and adversely affected. In that case, the trading price of our common stock may decline and you might lose all or part of your investment. The risks described below are not the only ones we face. Additional risks that we currently do not know about or that we currently believe to be immaterial may also impair our business, financial condition, operating results, liquidity, and future prospects. Certain statements below are forward-looking statements. For additional information, see “Cautionary Note Regarding Forward-Looking Statements” at the beginning of this Quarterly Report and Part I, Item 2, Management’s Discussion and Analysis of Financial Condition and Results of Operations of this Quarterly Report.

The risk factors set forth below marked with an asterisk () next to the title did not appear as separate risk factors in, or contain changes to the similarly titled risk factor included in, Part I, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2023.*

Risks Related to Our Business and Our Industry

We have incurred significant operating losses since inception and cannot assure you that we will achieve sustained profitability.*

Since our inception in January 2006, we have incurred a significant net loss. As of September 30, 2024, we had an accumulated deficit of \$1.0 billion. To date, we have funded our operations primarily through cash collected from product sales, private and public offerings of our equity securities, and debt financing. We have devoted substantially all of our resources to the design, development and commercialization of our products, the scaling of our manufacturing and business operations, and the research and development of our current products and products under development.

Since the first quarter of 2013, we have been able to manufacture and sell our insulin pump products at a cost and in volumes sufficient to allow us to achieve a positive overall gross margin. Although we have achieved a positive overall gross margin during the years ended December 31, 2023 and 2022, we had net losses from operations in those years, and we may continue to incur net losses from operations in the future.

To implement our business strategy and achieve consistent profitability, we need to, among other things, increase sales of our products and the gross profit associated with those sales, maintain an appropriate customer service, training and support infrastructure, fund ongoing research and development (R&D) activities, create additional efficiencies in our manufacturing processes while adding to our capacity, and obtain regulatory clearance, certification or approval to commercialize our products currently under development both in the United States and the more than 25 countries outside the United States in which our insulin pumps are available. We expect our expenses will continue to increase as we pursue these objectives and make investments in our business. Additional increases in our expenses without commensurate increases in sales could significantly increase our operating losses.

The extent of our future operating losses and the timing of our profitability are highly uncertain in light of a number of factors, including the timing of the launch of new products and product features by us and our competitors, market acceptance of our products and competing products by people with insulin-dependent diabetes, their caregivers and healthcare providers, the timing of regulatory clearance, certification, or approval of our products and the products of our competitors, the actual efficiencies gained in our manufacturing processes, and general economic conditions. Any additional operating losses will have an adverse effect on our stockholders' equity, and we cannot assure you that we will be able to sustain profitability.

We currently rely on sales of insulin pump products to generate a significant portion of our revenue, and any factors that negatively impact sales of these products may adversely affect our business, financial condition and operating results.*

We generate nearly all of our revenue from the sale of our insulin pumps and the related insulin cartridges and infusion sets, including our recently launched Tandem Mobi insulin pump. Sales of these products may be negatively impacted by many factors, including:

- market acceptance of the insulin pumps and related products manufactured and sold by our key competitors, including Insulet, Medtronic, Ypsomed and Beta Bionics;
- the potential that breakthroughs for the monitoring, treatment or prevention of diabetes may render our insulin pumps obsolete or less desirable;
- adverse regulatory or legal actions relating to our products, or similar products or technologies of our competitors;
- failure of our Tandem Device Updater to accurately and timely provide customers with remote access to new product features and functionality as anticipated, or our failure to obtain regulatory clearance, certification, or approval for any such updates;
- changes in reimbursement rates or policies relating to insulin pumps or similar products or technologies by third-party payors;
- competitive pricing and attrition rates of consumers who cease using our products;
- our inability to enter into contracts with third-party payors on a timely basis and on acceptable terms;
- problems arising from the expansion of our manufacturing capabilities and commercial operations, or destruction, loss, or temporary shutdown of our manufacturing facilities;
- concerns regarding the perceived safety, reliability or cybersecurity of any of our products, or any component thereof, particularly in connection with the launch of additional mobile app features and functionality and other software products; and
- claims that any of our products, or any component thereof, infringes on patent rights or other intellectual property rights of third parties.

In addition, sales of any of our current or future insulin pump products with CGM integration are subject to the continuation of our applicable agreements with Dexcom, Abbott, or other third parties which, under some circumstances, may be subject to termination, with or without cause, on relatively short notice. Sales of our current or future products may also be negatively impacted in the event of any regulatory or legal actions relating to CGM products that are compatible with our pumps, or in the event of any disruption to the availability of the applicable CGM-related supplies, such as sensors or transmitters, in a given market in which our products are sold. Sales of our products may also be adversely impacted if the CGM products that are compatible with our pumps are not viewed as superior to competing CGM products in markets where our products are sold, or if the price of these products is not competitive with similar products available in the market.

Because we currently rely on sales of our insulin pumps, and related products to generate a significant majority of our revenue, any factors that negatively impact sales of these products (or negatively impact the products or components integrated with these products) could adversely affect our business, financial condition and operating results. Furthermore, any disruption in our supply chain could negatively impact our ability to manufacture or otherwise supply sufficient product quantities to meet current customer demand, or any unexpected increase in demand, which could also have the effect of magnifying the negative impact of any of the factors described above.

Uncertainty in current global economic and political conditions could adversely affect our ability to predict product demand and impact our financial results.

Our operations and performance depend in part on worldwide economic and political conditions. Many of the jurisdictions in which our products are sold have experienced and could continue to experience unfavorable general economic conditions, such as a recession or economic slowdown, which could negatively affect the affordability of, and consumer demand for, our products. Under difficult economic conditions, consumers may seek to modify spending priorities and reduce discretionary spending by delaying purchases of our products, which could reduce our profitability and could negatively affect our overall financial performance. Other financial uncertainties in our major markets and unstable political conditions in certain markets, including civil unrest and governmental changes, could undermine global consumer confidence and reduce consumers' purchasing power, thereby reducing demand for our products. 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.

Our ability to maintain and grow our revenue depends in part on retaining a high percentage of our customer base.

A key to maintaining and growing our revenue is the retention of a high percentage of our customers due to the potentially significant revenue generated from ongoing purchases of single-use infusion sets, insulin cartridges and other supplies. In addition, our pumps are designed and tested to remain effective for at least four years and a customer may consider purchasing another product from us when the time comes to replace the pump. We have developed retention programs, including our Tandem Choice Program, aimed at our customers, their caregivers and healthcare providers, which include discounts, training specific to our products, ongoing support by our sales and clinical employees, and technical support and customer service. Demand for our products from our existing customers could decline or could fail to increase as anticipated or projected as a result of a number of factors, including the introduction of competing products, breakthroughs for the monitoring, treatment or prevention of diabetes, changes in reimbursement rates or policies, manufacturing problems, perceived safety or reliability issues with our products or components or the products of our competitors, the failure to secure regulatory clearance, certification, or approvals for products or product features in a timely manner or at all, product development or commercialization delays, the impacts and disruption from health epidemics or pandemics, international conflicts, or for other reasons.

The failure to retain a high percentage of our customers and increase sales to these customers consistent with our forecasts would have a material adverse effect on our business, financial condition and operating results.

We operate in a very competitive industry and if we fail to compete successfully against our existing or potential competitors, or if the competitive environment harms our business partners, our financial condition and operating results may be negatively affected.*

The medical device industry is intensely competitive, subject to rapid change and highly sensitive to the introduction of new products, treatment techniques or technologies, as well as other activities of industry participants. To continue to compete effectively, we must continue to create, invest in or acquire advanced technology, incorporate this technology into our proprietary products, obtain regulatory clearance, certification, or approvals in a timely manner, and manufacture and successfully market our products. Given these factors, we cannot guarantee that we will be able to compete effectively or continue our level of success.

Our primary competitors are major medical device companies, primarily Insulet, Medtronic, Ypsomed and Beta Bionics. There are also a number of other companies developing and marketing their own insulin delivery systems and/or related software applications, including insulin pumps and Bluetooth-enabled insulin pens to support MDI therapy. Our primary competitors may enjoy several competitive advantages over us, including:

- greater financial and human resources for sales and marketing, product development, customer service and clinical resources;
- greater ability to respond to competitive pressures, regulatory uncertainty, or challenges within the financial markets;
- established relationships with healthcare providers, third-party payors and regulatory agencies;
- established reputation and name recognition among healthcare providers and other key opinion leaders in the medical industry generally and the diabetes industry in particular;
- larger and more established distribution networks;
- greater ability to cross-sell products or provide incentives to healthcare providers to use their products; and
- more experience in conducting R&D, manufacturing, clinical trials, and obtaining regulatory approval or clearance.

In addition, the competitive environment in which we operate has resulted and may continue to result in competitive pressures on our manufacturers, suppliers, distributors, collaboration partners and other business constituents. For example, we have entered into development agreements with Dexcom, which provide us non-exclusive licenses to integrate various generations of Dexcom CGM technology with our insulin pump products. Abbott also offers glucose sensors which compete with Dexcom CGMs. We have also entered into agreements with Abbott to develop and commercialize integrated diabetes solutions using Abbott's glucose sensors. There can be no assurance that our collaborations with Dexcom and Abbott will be successful or that we will not experience delays, business disputes, or other unanticipated challenges. Competitive pressures within our industry could negatively impact the financial condition of our business partners and impact their ability to fulfill contractual obligations to us, which could negatively impact our product sales, result in delays in obtaining regulatory clearances, certifications, or approvals for new products, harm our reputation, and result in harm to our financial condition and operating results.

For these and other reasons, we may not be able to compete successfully against our current or potential future competitors, which could have a material adverse impact on our financial condition and operating results.

Competing products, therapeutic techniques or other technological developments and breakthroughs for the monitoring, treatment or prevention of diabetes may render our products obsolete or less desirable.*

Our ability to grow our business and achieve our strategic objectives will depend, among other things, on our ability to develop and commercialize products for the treatment of diabetes that offer distinct features and functionality, are easy-to-use, provide superior treatment outcomes, receive adequate coverage and reimbursement from third-party payors, and are otherwise more appealing than available alternatives. Our primary competitors, as well as a number of other companies and medical researchers are pursuing new delivery devices, delivery technologies, therapeutic techniques, sensing technologies, treatment techniques, procedures, drugs and other therapies for the monitoring, treatment and prevention of diabetes. Any breakthroughs in diabetes monitoring, treatment or prevention could reduce the potential market for our products or render our products obsolete altogether, which would significantly reduce our sales or cause our sales to grow at a slower rate than we currently expect. In addition, even the perception that new products may be introduced, or that technological or treatment advancements could occur, could cause consumers to delay the purchase of our products.

Because the insulin-dependent diabetes market is large and growing, we anticipate companies will continue to dedicate significant resources to developing competing products and technologies. The introduction by competitors of products that are or claim to be superior to our products may create market confusion that may make it difficult to differentiate the benefits of our products over competing products. In addition, some of our competitors employ aggressive pricing strategies, including the use of discounts, rebates, low-cost product upgrades or other financial incentives that could adversely affect sales of our products. If a competitor develops a product that competes with or is perceived to be superior to our products, or if competitors continue to utilize strategies that place downward pressure on pricing within our industry, our sales may decline, our operating margins could be reduced and we may fail to meet our financial projections, which would materially and adversely affect our business, financial condition and operating results.

Moreover, we have designed our hardware products to resemble modern consumer electronic devices to address certain wearability and functionality concerns consumers have raised with respect to traditional pumps. Similarly, our newer mobile software applications are being designed to incorporate features and functions that are common to other consumer-oriented applications. These consumer industries are themselves highly competitive, and characterized by continuous new product introductions, rapid developments in technology, and subjective and changing consumer preferences. If, in the future, consumers cease to view our products as contemporary or convenient as compared to then-existing consumer technology, our products may become less desirable.

The failure of our insulin pumps and related products to achieve and maintain market acceptance could result in us achieving sales below our expectations, which would cause our business, financial condition and operating results to be materially and adversely affected.*

Our current business and growth strategy is highly dependent on our insulin pumps and related products achieving and maintaining market acceptance. For us to sell our products to people with insulin-dependent diabetes, we must demonstrate to them, their caregivers and healthcare providers that our products are an attractive alternative to competitive products for the treatment of diabetes, including traditional insulin pump products and MDI therapies, as well as alternative diabetes monitoring, treatment or prevention methodologies. Market acceptance and adoption of our products depends on educating people with diabetes, as well as their caregivers and healthcare providers, about the distinct features, ease-of-use, beneficial treatment outcomes, and other perceived benefits of our products as compared to competing products. If we are not successful in educating existing and potential customers of the benefits of our products, or if we are not able to achieve the support of caregivers and healthcare providers for our products, our sales may decline or we may achieve sales below our expectations.

Market acceptance of our products could be negatively impacted by many factors, including:

- the failure of our products to achieve and maintain wide acceptance among people with insulin-dependent diabetes, their caregivers, healthcare providers, third-party payors and key opinion leaders in the diabetes treatment community;
- lack of evidence supporting the safety, effectiveness, ease-of-use or other perceived benefits of our products over competing products or other currently available insulin treatment methodologies;
- perceived risks or uncertainties associated with the use of our products, or components thereof (including due to any product recalls), or of similar products or technologies of our competitors;
- adverse regulatory or legal actions relating to our insulin pump products or similar products or technologies; and
- results of clinical studies relating to our existing products or products under development or similar competitive products.

In addition, the rapid evolution of technology and treatment options within our industry may cause consumers to delay the purchase of our products in anticipation of advancements or breakthroughs, or the perception that advancements or breakthroughs could occur, in our products or the products offered by our competitors. It is also possible that consumers interested in purchasing any of our future products currently under development may delay the purchase of one of our current products.

If our insulin pump products do not achieve and maintain widespread market acceptance, we may fail to achieve sales consistent with our projections, in which case our business, financial condition and operating results could be materially and adversely affected.

Failure to secure or retain adequate coverage or reimbursement for our current products and our potential future products by third-party payors could adversely affect our business, financial condition and operating results.*

A substantial portion of the purchase price of an insulin pump is typically paid for by third-party payors, including private insurance companies, preferred provider organizations and other managed care providers. Future sales of our current and future products will be limited unless our customers can rely on third-party payors to pay for all or part of the associated purchase cost. Access to adequate coverage and reimbursement for our current and future products by third-party payors is essential to the acceptance of our products by customers.

As guidelines in setting their coverage and reimbursement policies, many third-party payors in the United States use coverage decisions and payment amounts determined by the Centers for Medicare and Medicaid Services (CMS), which administers the U.S. Medicare program. Medicare periodically reviews its reimbursement practices for diabetes-related products, and there is uncertainty as to the future Medicare coverage structure and reimbursement rate for our products. It is also possible that CMS may continue to review and modify the current coverage and reimbursement of diabetes-related products in connection with anticipated changes to the regulatory approval process for insulin pumps and related products, software applications and services. In addition, third-party payors that do not follow the CMS guidelines may adopt different coverage and reimbursement policies for our current and future products. Further, it is possible that some third-party payors will not offer any coverage for our current or future products. For instance, it is possible that third-party payors may adopt policies in the future that designate one or more of our competitors as their preferred, in-network durable medical equipment provider of insulin pumps and that such policies would discourage or prohibit the payors' members from purchasing our products, which would adversely impact our ability to sell our products.

We are pursuing a multi-channel managed care strategy and are in discussions to offer Mobi through the pharmacy channel. However, the commercial opportunity in the pharmacy channel will be limited unless a substantial portion of the sales price for Mobi is covered by third-party payors, including private insurance companies, health maintenance organizations, preferred provider organizations, federal and state government healthcare agencies, intermediaries, Medicare, Medicaid and other managed care providers. Medicare Part D plan sponsors may provide coverage for Mobi under the Medicare Part D prescription drug program, which requires negotiating with third-party payors to provide Mobi through the pharmacy channel in the United States. If our efforts to enter into additional contracts with intermediaries and third-party payors are not successful, our ability to offer Mobi through the pharmacy channel will be limited.

We currently have contracts establishing reimbursement for our insulin pump products with a number of national and regional third-party payors in the United States. While we may enter into additional contracts both in the United States and the more than 25 countries outside the United States in which our insulin pumps are available through third-party payors, and add coverage for future products under our current agreements, we cannot guarantee that we will succeed in doing so or that the reimbursement contracts that we are able to negotiate will enable us to sell our products on a profitable basis or in certain channels, including the pharmacy channel. In particular, we have limited experience securing reimbursement in international markets other than Canada, as that process is managed by local distributors. Government involvement in funding healthcare may limit access to or reimbursement for the Company's products. In addition, existing contracts with third-party payors generally include numerous quality and compliance related requirements, including audit rights, and can be modified or terminated by the third-party payor without cause and with little or no notice to us. Our compliance with the administrative procedures or requirements may result in increased costs for us and delays in processing approvals by those third-party payors for customers to obtain coverage for our products, and any payor audits of our compliance obligations may result in requests for refunds or other costs. Failure to secure or retain adequate coverage or reimbursement for our current and future products by third-party payors, or delays in processing approvals by those payors, could result in the loss of sales, which could have a material adverse effect on our business, financial condition and operating results.

Further, the healthcare industry in the United States is increasingly focused on cost containment as government and private insurers seek to control healthcare costs by imposing lower payment rates and negotiating reduced contract rates with third-party payors. If third-party payors deny coverage or reduce their current levels of payment, or if our production costs increase faster than increases in reimbursement levels, we may be unable to sell our products on a profitable basis.

We may face unexpected challenges in marketing and selling our products, and training new customers on the use of our products, which could harm our ability to achieve our sales forecasts.

We have limited experience marketing and selling our newer products as well as training new customers on their use, particularly in markets outside of United States. In addition, the vast majority of our existing customers are individuals with type 1 diabetes, and we have limited experience marketing and selling our products to customers with type 2 diabetes.

Our financial condition and operating results are and will continue to be highly dependent on our ability to adequately promote, market and sell our insulin pump and related products, and the ability of our diabetes educators to train new customers on the use of our products. If our sales and marketing representatives or diabetes educators are restricted in their ability to interact with healthcare professionals and customers, our sales could decrease or may not increase at levels that are in line with our forecasts.

If we are unable to maintain our existing sales, marketing, clinical and customer service infrastructure, we may fail to increase our sales to meet our forecasts.

A key element of our business strategy involves our sales, marketing, clinical and customer service personnel driving adoption of our products. We have significantly increased the number of sales, marketing, clinical and customer service personnel employed by us since we began commercial sales. However, we have faced considerable challenges in growing and managing these resources, including with respect to recruiting, training and assimilation of sales territories and new clinical training staff. We expect to continue to face significant challenges as we seek to further increase the number of our sales, clinical and customer service personnel to optimize the coverage of our existing sales territories, as well as expand the number and scope of our existing sales territories. These challenges may be even greater in connection with our commercial expansion outside of the United States, where we have limited experience. Unexpected turnover among our sales, marketing, clinical and customer service personnel, or unanticipated challenges in recruiting additional personnel, would have a negative impact on our ability to achieve our sales projections. Further, if a sales, marketing or clinical representative was to depart and be retained by one of our competitors, we may fail to prevent him or her from helping competitors solicit business from our existing customers, which could adversely affect our sales. Similarly, if we are not able to recruit and retain a network of diabetes educators and customer service personnel, we may not be able to successfully train and service new customers, which could delay new sales and harm our reputation. These risks may be greater in the event of general labor shortages in the United States.

If we are unable to retain our personnel in line with our strategic plans, we may not be able to effectively commercialize our existing products or products under development, or enhance the strength of our brand, either of which could result in the failure of our sales to increase in line with our projections or cause sales to decline.

Our sales and marketing efforts are dependent on independent distributors who are free to market products that compete with our products. If we are unable to maintain or expand our network of independent distributors, our sales may be negatively affected.

We believe a majority of our sales will continue to be to independent distributors for the foreseeable future, and it is possible that the percentage of our sales to independent distributors could increase, particularly in light of our reliance on independent distributors outside of the United States. For example, our dependence upon independent distributors in the United States could increase if third-party payors decide to contract with independent distributors directly in lieu of contracting with us to supply our products to their members directly. Our dependence upon independent distributors could also increase if customers prefer to purchase all of their diabetes supplies through a single source, instead of purchasing pump-related products through us and other diabetes supplies through other suppliers. If we are unable to maintain or expand our network of independent distributors, our sales may be negatively affected.

None of our independent distributors in the United States have been required to sell our products exclusively and each of them may freely sell the products of our competitors. As a result, our independent distributors may not devote a sufficient level of resources and the support required to generate awareness of our products and grow or maintain product sales at the levels we expect, which may negatively affect our sales.

For the year ended December 31, 2023, two independent distributors each accounted for more than 10% of our worldwide sales. If any of our key independent distributors were to cease to distribute our products or reduce their promotion of our products as compared to the products of our competitors, our sales could be adversely affected. In that case, we may need to seek alternative independent distributors or increase our reliance on our other independent distributors or our direct sales representatives, which may not prevent our sales from being adversely affected. Additionally, to the extent we enter into additional arrangements with independent distributors to perform sales, marketing or distribution services, the terms of the arrangements could result in our product margins being lower than if we directly marketed and sold our products.

If the third parties on which we increasingly rely to assist us with our current and anticipated pre-clinical development or clinical trials do not perform as expected, we may not be able to obtain regulatory clearance, certification, or approval or commercialize our products.

As our clinical infrastructure expands, we expect to increasingly rely on third parties, such as contract research organizations, medical institutions, clinical investigators and contract laboratories to conduct some of our current and anticipated pre-clinical investigations and clinical trials. If we are not able to reach mutually acceptable agreements with these third parties on a timely basis, these third parties do not successfully carry out their commitments or regulatory obligations or meet expected deadlines, or the quality or accuracy of the data they obtain is compromised due to the failure to adhere to agreed-upon clinical protocols or regulatory requirements or for other reasons, our pre-clinical development activities or clinical trials may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory clearance, certification, or approval for, or successfully commercialize, our products on a timely basis, if at all, and our business, operating results and prospects may be adversely affected.

We are dependent on clinical investigators and clinical sites to enroll participants in our current and anticipated clinical trials and human factors studies, and the failure to successfully complete those trials and studies could prevent us from obtaining regulatory clearances, certifications, or approvals for or commercializing our products.

As part of our product development efforts, we expect to increasingly rely on clinical investigators and clinical sites to enroll participants in our clinical trials or users in our human factors testing and other third parties to manage such trials and testing 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 or other studies. If these clinical investigators and clinical sites fail to enroll a sufficient number of patients, fail to ensure compliance by patients with clinical protocols, or fail to comply with regulatory requirements, we may be unable to successfully complete our clinical trials or other studies, which could prevent us from obtaining regulatory clearances, certifications, or approvals for our products and commercializing our products, which would have an adverse impact on our business.

If important assumptions about the potential market for our products are inaccurate, or if we have failed to understand what people with insulin-dependent diabetes are seeking in an insulin pump, our business and operating results may be adversely affected.*

Our business strategy was developed based on a number of important assumptions about the diabetes industry in general, and the insulin-dependent diabetes market in particular, any one or more of which may prove to be inaccurate or may change over time. For example, we believe that the benefits of insulin pump therapy as compared to other common insulin treatment alternatives will continue to drive growth in the market for insulin pump therapy. In addition, World Health Organization data indicates that the incidence of diabetes in the United States and worldwide is increasing. Further, diabetes management can vary greatly from person to person, creating multiple market segments based on clinical needs and personal preferences. However, each of these assumptions may prove to be inaccurate and limited sources exist to compare treatment alternatives and obtain reliable market data. The actual incidence of diabetes, and the actual demand for our products or competing products, could differ materially from our projections. In addition, our strategy of focusing exclusively on the insulin-dependent diabetes market may limit our ability to increase sales or achieve profitability.

Another key element of our business strategy is using market research to understand what people with diabetes are seeking to improve in their diabetes therapy management. This strategy underlies our entire product design, marketing and customer support approach and is the basis on which we developed our current products and are pursuing the development of new products. However, our market research is based on interviews, focus groups and online surveys involving people with insulin-dependent diabetes, their caregivers and healthcare providers, which represent only a small percentage of the overall insulin-dependent diabetes market. As a result, the responses we receive may not be reflective of the broader market and may not provide us accurate insight into the desires of people with insulin-dependent diabetes. In addition, understanding the meaning and significance of such market research responses necessarily requires that analysis be conducted and conclusions be drawn. We may not be able to perform an analysis that yields meaningful results, or the conclusions we draw from the analysis could be misleading or incorrect. Moreover, even if our market research has allowed us to better understand the features and functionality consumers are seeking in an insulin pump to improve management of their diabetes therapy, there can be no assurance that consumers will actually purchase our products or that our competitors will not develop products with similar features.

We expect to face complexities frequently encountered by companies in competitive and rapidly evolving markets, which may make it difficult to evaluate our business and forecast our future sales and operating results.*

We operate in a competitive and rapidly evolving market. Important industry changes, such as FDA approval, authorization by comparable foreign authorities or CE Certification by Notified Bodies and the launch of new products by our competitors, as well as changes specific to our business, such as the timing of our launch of new products currently in development, increasing reliance on digital health products and connected devices, and our potential expansion of commercial sales in international markets, combine to make it more difficult for us to predict our future sales and operating results, as well as our expected timeframe to achieve profitability. In assessing our business prospects, you should consider these factors as well as the various risks and difficulties frequently encountered by companies in competitive and rapidly evolving markets, particularly those companies that manufacture and sell medical devices.

These risks include our ability to:

- implement and execute our business strategy;
- manage and improve the productivity of our sales, marketing, clinical and customer service infrastructure to grow sales of our existing and proposed products, and enhance our ability to provide service and support to our customers;
- achieve and maintain market acceptance of our products and increase awareness of our brand among people with insulin-dependent diabetes, their caregivers and healthcare providers;
- comply with a broad range of regulatory requirements within a highly regulated industry;
- enhance our manufacturing capabilities, increase production of products efficiently while maintaining quality standards, and adapt our manufacturing facilities to the production of new products;
- respond effectively to competitive pressures and developments;
- enhance our existing products and develop proposed products;
- manage cybersecurity and other technological risks associated with our expanding portfolio of digital health products, and align these products to a dynamic threat landscape;
- obtain and maintain regulatory clearance, certification, or approval to enhance our existing products and commercialize proposed products;
- perform clinical trials and other studies with respect to our existing products and proposed products; and
- attract, retain and motivate qualified personnel in various areas of our business.

As a result of these or other risks, we may not be able to execute key components of our business strategy, and our business, financial condition and operating results may suffer.

Our ability to achieve profitability will depend, in part, on our ability to reduce the per-unit cost of our products while also increasing production volume.

We believe our ability to reduce the per-unit cost of our insulin pumps and related products will have a significant impact on our ability to achieve profitability. Our cost of sales includes raw materials and component parts, labor costs, product training expenses, freight, reserves for expected warranty costs, royalties, scrap and charges for excess and obsolete inventories. It also includes manufacturing overhead costs, including expenses relating to quality assurance, manufacturing engineering, material procurement and inventory control, facilities, equipment, information technology and operations supervision and management. Our warranty reserve requires a significant amount of judgment and is primarily estimated based on historical experience. Recently released versions of our pump may not incur warranty costs in a manner similar to previously released pumps and the launch of our mobile app also may result in unanticipated changes in historical trends.

If we are unable to increase our production volumes while sustaining or reducing our overall cost of sales, including through arrangements such as volume purchase discounts, negotiation of pricing and cost reductions with our suppliers, more efficient training programs for customers, improved warranty performance or fluctuations in warranty estimates, it will be difficult to reduce our per-unit costs and our ability to achieve profitability will be constrained.

In addition, the per-unit cost of our products is significantly impacted by our overall production volumes, and any factors that prevent our products from achieving market acceptance, cause our production volumes to decline, alter our product mix, result in our sales growing at a slower rate than we expect, or result in the closure of our manufacturing facilities, would significantly impact our expected per-unit costs, which would adversely impact our gross margins. Further, we may not achieve anticipated improvements in manufacturing efficiency as we undertake actions to expand our manufacturing capacity. We are also subject to other general market and economic conditions that may increase our expenses, including unpredictable variability in commodity prices, wage increases and inflation. If we are unable to effectively manage our overall costs while increasing our production volumes and lowering our per-unit costs, we may not be able to achieve or sustain profitability, which would have an adverse impact on our business, financial condition and operating results.

Manufacturing risks may adversely affect our ability to manufacture products, which could negatively impact our sales and operating margins.

Our business strategy depends on our ability to manufacture our current and proposed products in sufficient quantities and on a timely basis to meet consumer demand, while adhering to product quality standards, complying with regulatory requirements and managing manufacturing costs. We are subject to numerous risks related to our manufacturing capabilities, including:

- quality or reliability defects in product components that we source from third-party suppliers;
- our inability to secure product components in a timely manner due to shipping delays at ports of entry or exit, the impact of natural disasters, global conflicts, health pandemics or other issues, in sufficient quantities and on commercially reasonable terms;
- difficulty identifying and qualifying alternative suppliers for components in a timely manner;
- implementing and maintaining acceptable quality systems while experiencing rapid growth;
- our failure to increase production of products to meet demand;
- our inability to modify production lines and expand manufacturing facilities to enable us to efficiently produce future products or implement changes in current products in response to consumer demand or regulatory requirements;
- our inability to manufacture multiple products simultaneously while utilizing common manufacturing equipment;
- government-mandated or voluntary closures of, or operational limitations impacting, our manufacturing facilities; and
- potential damage to or destruction of our manufacturing equipment or manufacturing facilities.

As demand for our products increases, and as the number of our commercial products expands, we will have to invest additional resources to purchase components, hire and train employees, and enhance our manufacturing processes and quality systems. We may also increase our utilization of third parties to perform contracted manufacturing services for us, and we may need to acquire additional custom designed equipment to support the expansion of our manufacturing capacity. In addition, although we expect some of our products under development to share product features and components with our current products, manufacturing of these products may require modification of our production lines, hiring of specialized employees, identification of new suppliers for specific components, qualifying and implementing additional equipment and procedures, obtaining new regulatory clearances, certifications, or approvals, or developing new manufacturing technologies. Ultimately, it may not be possible for us to manufacture these products at a cost or in quantities sufficient to make these products commercially viable.

We continue to monitor factors that could negatively impact our supply chain, such as shortages of semiconductors and copper that are needed to manufacture our insulin pumps and accessories and custom components for our insulin pumps and cartridges where we rely on a limited number of qualified suppliers. If we continue to experience these or similar manufacturing challenges, or if these challenges worsen in the future, it could have a negative impact on product sales and harm our reputation.

If we and our suppliers fail to increase our production capacity to meet consumer demand while also maintaining product quality standards, obtaining and maintaining regulatory clearances, certifications, or approvals, and efficiently managing costs, our sales and operating margins could be negatively impacted, which would have an adverse impact on our financial condition and operating results.

We depend on a limited number of third-party suppliers for certain components and products, and the loss of any of these suppliers, their inability to provide us with an adequate supply of components or products, or our inability to adequately forecast customer demand, could harm our business.*

We currently rely, and expect to continue to rely, on third-party suppliers to supply components of our current products and our potential future products, including our single-use insulin cartridges. For example, we rely on plastic injection molding companies to provide plastic molded components, electronic manufacturing suppliers to provide electronic assemblies, and machining companies to provide machined mechanical components. We also purchase all of our infusion sets and pump accessories from third-party suppliers. For our business strategy to be successful, our suppliers must be able to provide us with components and products in sufficient quantities, in compliance with regulatory requirements and quality control standards, in accordance with agreed-upon specifications, at acceptable costs and on a timely basis.

Although we have long-term supply agreements with many of our suppliers, these agreements do not include long-term capacity commitments. Under most of our supply agreements, we make purchases on a purchase order basis and have no obligation to buy any given quantity of components or products until we place written orders, and our suppliers have no obligation to manufacture for us or sell to us any given quantity of components or products until they accept an order. In addition, our suppliers may encounter problems that limit their ability to manufacture components or products for us, including financial difficulties, damage to their manufacturing equipment or facilities, inability to obtain raw materials or other components, or problems with their own suppliers. If we fail to obtain sufficient quantities of high-quality components to meet demand on a timely basis, we could lose customer orders, our reputation may be harmed, and our business could suffer.

We generally use a small number of suppliers for our components and products, some of which are located outside the United States, including in China, Mexico and Costa Rica. Depending on a limited number of suppliers exposes us to risks, including limited control over costs, including tariffs, availability, quality and delivery schedules. Moreover, in some cases we do not have long-standing relationships with our manufacturers and may not be able to convince suppliers to continue to make components available to us unless there is demand for such components from their other customers. As a result, there is a risk that certain components could be discontinued and no longer available to us at acceptable prices, or at all. We have in the past been, and we may in the future be, required to make significant “last time” purchases of component inventories that are being discontinued by the manufacturer to ensure supply continuity. If any one or more of our suppliers cease to provide us with sufficient quantities of components in a timely manner or on terms acceptable to us, we would have to seek alternative sources of supply. We are actively pursuing alternative suppliers of several existing components and qualifying new alternatives to existing select components, but there is no assurance that we will be able to identify alternative sources that meet our requirements and at comparable prices, or at all. Because of factors such as the proprietary nature of our products, our quality control standards and applicable regulatory requirements, we cannot quickly engage additional or replacement suppliers for some of our critical components. Failure of any of our suppliers to deliver products at the level our business requires could harm our reputation and limit our ability to meet our sales projections, which could have a material adverse effect on our business, financial condition and operating results.

We place orders with our suppliers using our forecasts of customer demand, which are based on a number of assumptions and estimates, in advance of purchase commitments from our customers. As a result, we incur inventory and manufacturing costs in advance of anticipated sales, which sales ultimately may not materialize or may be lower than expected. If we overestimate customer demand, we may experience higher inventory carrying costs and increased excess or obsolete inventory, which would negatively impact our results of operations. By the same token, if we underestimate future demand, we may be unable to meet future production requirements or our inventory of critical materials may be below our targeted stocking levels. We expect it will be particularly difficult to accurately forecast demand during the global pandemic and even for some time while travel and social-distancing restrictions are lifted.

We may also have difficulty obtaining components from other suppliers that are acceptable to the FDA or other comparable foreign regulatory authorities, or Notified Bodies, and the failure of our suppliers to comply with regulatory requirements could expose us to regulatory action including warning letters, product recalls, termination or interruption of distribution, operating restrictions, product seizures, delays in obtaining approval or clearance of future products, suspension or withdrawal of approvals, clearances, or certification, fines, civil penalties, or criminal prosecution. Such a failure by our suppliers could also require us to cease using the components, seek alternative components or technologies, and modify our products to incorporate alternative components or technologies, which could necessitate additional regulatory clearances, certifications, or approvals. Any disruption of this nature, or any increased expenses associated with any such disruption, could negatively impact our ability to manufacture our products on a timely basis, in sufficient quantities, or at all, which could harm our commercialization efforts and have a material adverse impact on our operating results.

Any disruption at one of our facilities could adversely affect our business and operating results.

Although we operate in multiple locations, most of our current operations are still conducted in San Diego, California, including our final pump assembly, some manufacturing processes, and the majority of our research and development, management and administrative functions. In addition, the majority of our inventories of component supplies and finished goods is stored at two facilities in San Diego. We take precautions to safeguard our facilities and data infrastructure, including by acquiring insurance, employing back-up generators, adopting health and safety protocols, implementing cybersecurity protections, and utilizing off-site storage of computer data. However, vandalism, terrorism, unplanned power outages, cyberattacks or a natural disaster, such as an earthquake, fire or flood, or other catastrophic event, could damage or destroy our manufacturing equipment or our inventories of component supplies and finished goods, cause substantial delays in our operations, result in the loss of key information, result in reduced sales, and cause us to incur additional expenses. Our insurance coverage may not be sufficient to provide coverage with respect to the damages incurred in any particular case, and our insurance carrier may deny coverage with respect to all or a portion of our claims. Regardless of the level of insurance coverage or other precautions taken, damage to our facilities may have a material adverse effect on our business, financial condition and operating results.

We may not experience the anticipated operating efficiencies of our manufacturing and warehousing operations.

We continue to scale our business operations and add manufacturing requirements for products currently under development. We have outsourced the majority of our slim cartridge manufacturing demand to an experienced third-party contract manufacturer. We may consider outsourcing other aspects of our operations in the future. If we fail to achieve the operating efficiencies that we anticipate, our manufacturing and operating costs may be greater than expected, which would have a material adverse impact on our operating results. In addition, we or our third-party contract manufacturers may encounter problems during manufacturing for a variety of reasons, including failure to follow specific protocols and procedures, failure to comply with applicable regulations, equipment malfunction, component part supply constraints and environmental factors, any of which could delay or impede our ability to meet customer demand and have a material adverse impact on our business, financial condition and operating results. Further, because of the custom nature of our cartridge manufacturing process and product components, and the highly regulated nature of our products overall, in the event of any problems with a contract manufacturer, we may not be able to quickly establish additional or alternative arrangements.

We expect that the management and support of our facilities, increasing reliance on third-party contract manufacturers and the increase of our manufacturing volumes will place significant burdens on our management team, particularly in areas relating to operations, quality, regulatory, facilities and information technology. We may not be able to effectively manage our ongoing manufacturing operations and we may not achieve the operating efficiencies that we anticipate, either from our own facilities or from our use of contract manufacturing. Further, additional increases in demand for our products may require that we further expand our business operations, which may require that we obtain additional facilities, make additional investments in capital equipment or increase our utilization of third-party contract manufacturing.

Any concerns regarding the safety and efficacy of our products could limit sales and cause unforeseen negative effects to our business prospects and financial results.

Studies to evaluate the safety or effectiveness of our latest products in a controlled setting are only available over the past few years. As a result, people with insulin-dependent diabetes and healthcare providers may not be familiar with our studies and may be slower to adopt or recommend our products. Further, even with data from controlled studies third-party payors may not be willing to provide coverage or reimbursement for our products. We remain subject to regulatory and product liability risks, and these and other factors could slow the adoption of our products and result in our sales being lower than anticipated. In addition, future studies or clinical experience may indicate that treatment with our products is not superior to treatment with competing products. Such results could slow the adoption of our products and significantly reduce our sales, which could prevent us from achieving our forecasted sales targets or achieving or sustaining profitability.

If the results of clinical studies or other experience, such as our monitoring or investigation of customer complaints, indicate that our products may cause or create an unacceptable risk of unexpected or serious complications or other unforeseen negative effects, we could be required to inform our customers of these risks or complications or, in more serious circumstances, we could be subject to mandatory product recalls, suspension or withdrawal of clearance, certification, or approval from regulatory authorities or Notified Bodies, product recalls or seizure, operating restrictions, interruption of production, fines, civil penalties and criminal prosecution which could result in significant legal liability, harm to our reputation, and a decline in our product sales.

Any alleged illness or injury associated with any of our products or product recalls may negatively impact our financial results and business prospects depending on a number of factors, including the scope and seriousness of the problem, degree of publicity, reaction of our customers and healthcare professionals, competitive response, and consumer perceptions generally. Even if such an allegation or product liability claim lacks merit, cannot be substantiated, is unsuccessful or is not fully pursued, the negative publicity surrounding any assertion that our products have caused or carry a risk of causing illness, injury or death could adversely affect our reputation with customers, healthcare professionals, third-party payors, and existing and potential collaborators, and could adversely affect our operating results and cause a decline in our stock price. Furthermore, general concerns regarding the perceived safety or reliability of any of our products, or any component thereof, may have a similar adverse effect on us.

We may enter into collaborations, licensing arrangements, joint ventures, strategic alliances or partnerships with third parties that may not result in the development of commercially viable products or the generation of significant future revenues.

In the ordinary course of our business, we may enter into collaborations, licensing arrangements, joint ventures, strategic alliances or partnerships to develop proposed products or technologies, pursue new markets, or protect our intellectual property assets. We may also elect to amend or modify similar agreements that we already have in place. Proposing, negotiating and implementing collaborations, licensing arrangements, joint ventures, strategic alliances or partnerships may be a lengthy and complex process, and may subject us to business risks. For example, other companies, including those with substantially greater financial, marketing, sales, technology or other business resources, may compete with us for these opportunities, or may be the counterparty in any such arrangements. We may not be able to identify or complete any such collaboration in a timely manner, on a cost-effective basis, on acceptable terms or at all. In addition, we may not realize the anticipated benefits of any such collaborations that we do identify and complete. In particular, these collaborations may not result in the development of products or technologies that achieve commercial success or result in positive financial results, or may otherwise fail to have the intended impact on our business.

Additionally, we may not be in a position to exercise sole decision-making authority regarding a collaboration, licensing or other similar arrangement, which could create the potential risk of creating impasses on decisions. Further, our collaborators and business partners may have economic or business interests or goals that are, or that may become, inconsistent with our business interests or goals. It is possible that conflicts may arise with our collaborators and other business partners, such as conflicts concerning the achievement of performance milestones, or the interpretation of significant terms under any agreement, such as those related to financial obligations, termination rights or the ownership or control or other licenses of intellectual property rights. If any conflicts arise with our current or future collaborators, they may act in their self-interest, which may be adverse to our best interest, and they may breach their obligations to us. In addition, we have limited control over the amount and timing of resources that our current collaborators, such as Dexcom and Abbott, or any future collaborators devote to our arrangement with them or our future products. Disputes between us and our current, future or potential collaborators may result in litigation or arbitration which would increase our expenses and divert the attention of our management. Further, these transactions and arrangements are contractual in nature and may be terminated or dissolved under the terms of the applicable agreements and, in such event, we may not continue to have rights to the products relating to such transaction or arrangement or may need to purchase such rights at a premium. For example, we have entered into multiple development and commercialization agreements with Dexcom, which provide us non-exclusive licenses to integrate various currently available and future generations of Dexcom's CGM technology with our insulin pump products. Under certain circumstances, these agreements may be terminated by either party without cause or on short notice. Our current agreements with Dexcom do not grant us rights to integrate future generations of Dexcom CGM technology, beyond G7 CGM devices, with any of our current or future products. Termination of any of our agreements with Dexcom would require us to redesign certain current products and products under development, and attempt to integrate an alternative CGM system into our insulin pump systems, which would require significant development and regulatory activities that could result in an interruption or substantial delay in the availability of the product to our customers. The termination of our existing commercial agreements with Dexcom would disrupt our ability to commercialize our existing products and our development of future products, which could have a material adverse impact on our financial condition and results of operations, negatively impact our ability to compete and cause our stock price to decline.

We depend on the knowledge and skills of our senior management and other key employees, and if we are unable to retain and motivate them or recruit additional qualified personnel, our business may suffer.

We have benefited substantially from the leadership and performance of our senior management, as well as certain key employees. For example, key members of our management have experience successfully scaling an early-stage medical device company to achieve profitability. Our success will depend on our ability to retain our current management and key employees, and to attract and retain qualified personnel in the future. In our industry, it is common to attract and retain executive talent and other employees with compensation packages that include a significant equity component. We have issued, and may continue to issue, additional equity incentives that we believe will enhance our ability to retain our current key employees and attract the necessary additional executive talent.

Competition for senior management and key employees in our industry is intense and over the past year we have also experienced general labor shortages in various areas of our business. We cannot guarantee that we will be able to retain our personnel or attract new, qualified personnel. In addition, adoption of new work models and requirements about when or how often employees work on site or remotely may present new challenges. As certain jobs and employers increasingly operate remotely, competition for talent may change in ways that cannot be fully predicted at this time. Moreover, we may need to increase employee wages, equity incentives, and benefits to attract and retain our personnel, which would increase our expenses. It may be difficult to continue to incentivize employees with meaningful equity incentives while limiting the use of the share reserve under our current long-term incentive plans. The loss of the services of certain members of our senior management or key employees could prevent or delay the implementation and completion of our strategic objectives, or divert management's attention to seeking qualified replacements, and any general labor shortages could also negatively impact our ability to expand and scale functions that are needed to support the ongoing development of our products and the future growth of our business. Each member of senior management, as well as the vast majority of our employees may terminate employment without notice and without cause or good reason. The members of our senior management are not subject to non-competition agreements. Accordingly, the adverse effect resulting from the loss of certain members of senior management could be compounded by our inability to prevent them from competing with us.

We may seek to grow our business through acquisitions of products or technologies, or investments in businesses, and the failure to successfully manage these acquisitions or investments, or the failure to integrate them with our existing business, could have a material adverse effect on our business, financial condition and operating results.

From time to time, we may consider opportunities to acquire or invest in other companies, products or technologies that may enhance our product platform or technology, expand the breadth of our markets or customer base, or otherwise advance our business strategies. Potential and completed acquisitions and investments involve numerous risks, including:

- problems assimilating, maintaining or operating the acquired products or technologies;
- issues maintaining uniform standards, procedures, controls and policies;
- unanticipated costs, liabilities, impairment charges or write-offs associated with acquisitions or investments;
- diversion of management's attention from our existing business;
- risks associated with entering new markets in which we have limited or no experience; and
- increased legal and accounting costs relating to the acquisitions or to comply with regulatory requirements or other compliance matters.

We do not know if we will be able to identify future acquisitions or investments we deem suitable, whether we will be able to successfully complete any such acquisitions or investments on favorable terms or at all, or whether we will be able to successfully integrate any acquired products or technologies into our business. Our potential inability to integrate any acquired products or technologies effectively may adversely affect our business, operating results and financial condition.

Risks Related to Our International Operations

*Commercializing our products outside of the United States may result in a variety of risks associated with international operations that could materially adversely affect our business.**

Our sales in the approximately 25 countries in which our products are offered outside the United States, which accounted for approximately 26% of our total sales during 2023, are accompanied by certain financial and other risks related to international business markets, including:

- local product preferences and differing regulatory requirements for product clearances, certifications, or approvals;
- differing U.S. and foreign medical device import and export rules;
- more restrictive privacy and security laws relating to personal information of end-users and employees, including GDPR and other E.U. Member State national legislation;
- reduced protection for our intellectual property rights in certain countries outside the United States than exists in the United States;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation and workforce instability, and political instability in foreign economies and markets;
- compliance with tax, employment, immigration and labor laws, such as the Foreign Corrupt Practices Act and comparable foreign legislation;
- difficulties associated with foreign legal systems, including increased costs associated with enforcing contractual obligations in foreign jurisdictions;
- political instability and actual or anticipated military or political conflicts;
- difficulties in managing international relationships, including any relationships that we establish with foreign partners, distributors, or sales or marketing agents;
- foreign taxes, including withholding and payroll taxes;
- different reimbursement systems; and
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country.

In addition, entry into international markets may require significant financial resources, impose additional demands on our manufacturing, quality, regulatory, customer support and other general and administrative personnel, and could divert management's attention from managing our core business. We have limited experience with regulatory environments and market practices internationally, and we may not be able to penetrate or successfully operate in new markets. If we are unable to expand internationally, manage the complexity of our global operations successfully or if we incur unanticipated expenses, we may not achieve the expected benefits of this expansion and our financial condition and results of operations could be materially and adversely impacted.

Failure to obtain any required regulatory authorization, clearance or certification in foreign jurisdictions will prevent us from marketing our products in international markets.

We sell our products in approximately 25 countries outside the United States and may seek to begin commercial sales of our products in additional geographies in the future. As we continue to expand our operations outside of the United States and launch new products, we are increasingly subject to additional regulatory and legal requirements in the international markets. These additional legal and regulatory requirements may result in our incurring significant costs and expenditures. We have limited experience complying with applicable laws and regulations in international markets generally, and in particular when we enter new markets, and if we are not able to comply with any such requirements, our international expansion and business could be significantly harmed.

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

The FCPA, the U.K. Bribery Act, and similar anti-bribery laws enacted in other jurisdictions generally prohibit companies and their intermediaries from making improper payments to foreign officials 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 subject to such anti-bribery laws. Because we do business in the U.K., the U.K. Bribery Act also extends to our interaction with public and private sector entities and persons outside the U.K., including in the United States. Our policies mandate compliance with these anti-bribery laws. We operate in parts of the world that have experienced governmental corruption to some degree, and in certain circumstances strict compliance with anti-bribery laws may conflict with local customs and practices. Despite our training and compliance programs, our internal control policies and procedures may not always protect us from reckless or criminal acts committed by our employees or agents. Violations of anti-bribery laws, or allegations of such violations, could disrupt our business and have a material adverse effect on our results of operations, financial condition, and cash flows.

Because our business is global our sales and profits may fluctuate or decline in response to changes in foreign currency exchange rates or other international risks.

Activities outside the United States accounted for approximately 26% of our total sales during 2023. Foreign currency fluctuations could result in volatility of our revenue. In addition, we are exposed to transaction risk because we incur some of our sales and expenses in currencies other than the U.S. dollar. Our most significant currency exposures are to the Canadian dollar, the Euro and Swiss franc, and the exchange rates between these currencies and the U.S. dollar may fluctuate substantially. We do not actively hedge our exposure to currency rate fluctuations. The strengthening of the U.S. dollar would likely negatively impact our results. We price some of our products in U.S. dollars, and thus changes in exchange rates can make our products more expensive in some offshore markets and reduce our sales. Inflation could also make our products more expensive and increase the credit risks to which we are exposed. Future foreign currency fluctuations could favorably or unfavorably impact and increase the volatility of our revenue, profitability, and stock price. These and other risks may have a material adverse effect on our business, financial condition and results of operations as a whole.

Risks Related to Macroeconomic Conditions and External Factors

Uncertainty in current global economic and political conditions could adversely affect our ability to predict product demand and impact our financial results and makes it more likely that our actual results could differ materially from expectations.*

Our operations and performance depend in part on worldwide economic and political conditions. Many of the jurisdictions in which our products are sold have experienced and could continue to experience unfavorable general economic conditions, such as a recession or economic slowdown, including as a result of political instability and military hostilities in certain geographies, concerns over the potential downgrade of United States sovereign debt and continued sovereign debt, monetary and financial uncertainties in Europe and other geographies, and domestic and global inflationary trends, any of which could negatively affect the affordability of, and consumer demand for, our products. Under difficult economic conditions, consumers may seek to modify spending priorities and reduce discretionary spending by delaying purchases of our products, which could reduce our profitability and could negatively affect our overall financial performance. Other financial uncertainties in our major markets and unstable political conditions in certain markets, including civil unrest and governmental changes, could undermine global consumer confidence and reduce consumers' purchasing power, thereby reducing demand for our products. 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.

In October 2023, Hamas initiated an attack against Israel, provoking a state of war and subsequently a larger regional conflict. While we cannot predict the broader consequences, these conflicts and retaliatory and counter-retaliatory actions could materially adversely affect global trade, currency exchange rates, inflation, regional economies, and the global economy, which in turn may disrupt sales through our local distributor in Israel.

Public health threats, epidemics, or pandemics could have a material adverse effect on our operations, the operations of our business partners, and the global economy as a whole.

Public health threats and other highly communicable diseases and outbreaks could adversely impact our operations, the operations of our customers, suppliers, distributors and other business partners, as well as the healthcare system in general. For example, certain development activities, such as human factors studies associated with our product development efforts and activities supporting the manufacturing scale-up for new products and the recruitment of participants in ongoing clinical studies, may be modified or delayed due to impacts of public health threats, which could our development timelines and regulatory strategies. These delays could have a negative impact on our product commercialization efforts and the future demand for our products.

In addition to the foregoing impacts, disruptions from outbreaks or epidemics, could result in delays in or the suspension of our manufacturing operations, research and product development activities, regulatory work streams, clinical development programs and other important commercial functions. In particular, if we or our third-party manufacturers are required to delay or suspend our manufacturing operations, we may encounter severe product shortages, which would adversely affect our results of operations and harm our reputation. We are also dependent upon our third-party suppliers for many of our product components and for our manufacturing-related equipment, and the incidence of disease could have a material adverse impact on the operations of our suppliers, which could prevent them from timely delivering products to us or supporting our requirements for manufacturing-related equipment. The full extent of the impact of potential future public health threats on our business and operations is subject to change and will continue to depend on a number of factors, including the scope and duration of the pandemic and any resulting changes to general economic conditions in the countries in which we operate and sell our products.

Climate change or other extreme weather conditions and related regulations may have a long-term impact on our business.

Climate-related events, including the increasing frequency of extreme weather events and their impact on the United States, Mexico, Canada, and other major regions' critical infrastructure along with potential related regulations, have the potential to disrupt our business, our third-party suppliers, and/or the business of our customers. For example, our third-party contract manufacturers are located in regions subject to natural disasters, including earthquakes, hurricanes, floods, fires and other catastrophic events. We strive to partner with organizations that mitigate their business risks associated with climate change. However, we recognize that inherent risks related to climate change, other extreme weather conditions and related regulations exist wherever global business is conducted. While these dangers currently have a low-assessed risk of disrupting our normal business operations, they pose a potential long-term impact on our business.

Although it is difficult to predict and adequately prepare to meet the challenges to our business posed by climate change, if new laws or regulations are more stringent than current legal or regulatory requirements, we may experience increased compliance burdens and costs to meet the regulatory obligations as well as adverse impacts on raw material sourcing, manufacturing operations and the distribution of our products.

Risks Related to Our Future Financings and Financial Results

We may need or otherwise determine to raise additional funds in the future and if we are unable to raise additional funds when necessary or desirable, we may not be able to achieve our strategic objectives.*

As of September 30, 2024, we had \$473.3 million in cash, cash equivalents and short-term investments. Our management expects the continued growth of our business, including the expansion of our customer service infrastructure to support our growing base of customers, our plans to continue expanding commercial sales of our products outside of the United States, the growth of our manufacturing and warehousing operations, and the increase of our facility footprint to accommodate additional headcount and R&D activities, will continue to increase our expenses. In addition, the amount of our future product sales is difficult to predict and actual sales may not be in line with our forecasts. Accordingly, our future capital requirements will depend on many factors, including:

- revenue generated by sales of our products, as well as the gross profits and gross margin we realize from such sales;

- the costs associated with maintaining and expanding an appropriate sales, marketing, clinical and customer service infrastructure;
- expenses associated with developing and commercializing our proposed products or technologies, including capital expenditures we make to maintain or enhance our manufacturing operations and distribution capabilities;
- the cost of obtaining and maintaining regulatory clearance, certification, or approval for our products and our manufacturing facilities, and of ongoing compliance with other legal and regulatory requirements;
- expenses we incur in connection with current or future litigation or governmental investigations;
- expenses we may incur or other financial commitments we may make in connection with current and potential new acquisitions, investments, business or commercial collaborations, development agreements or licensing arrangements; and
- general and administrative expenses.

As a result of these and other factors we may in the future seek capital from public or private offerings of our equity or debt securities, or from other sources. If we issue equity or debt securities to raise additional funds, our existing stockholders may experience dilution, we may incur significant financing or debt service costs, and the new equity or debt securities may have rights, preferences and privileges senior to those of our existing stockholders. In addition, if we raise additional funds through collaborations, licensing, joint ventures, strategic alliances, partnership arrangements or other similar arrangements, it may be necessary to relinquish valuable rights to our potential future products or proprietary technologies, or grant licenses on terms that are not favorable to us.

If we are unable to raise additional capital when necessary, we may not be able to maintain our existing sales, marketing, clinical and customer service infrastructure, enhance our current products or develop new products, take advantage of future opportunities, respond to competitive pressures, changes in supplier relationships, or unanticipated changes in customer demand. Any of these events could adversely affect our ability to achieve our strategic objectives, which could have a material adverse effect on our business, financial condition and operating results.

Our operating results may fluctuate significantly from quarter to quarter.

There has been and may continue to be meaningful variability in our operating results from quarter to quarter, as well as within each quarter, especially around the time of anticipated new product launches or regulatory clearances, certifications, or approvals by us or our competitors, and as a result of the commercial launch of our products in geographies outside of the United States. Our operating results, and the variability of these operating results, will be affected by numerous factors, including:

- our ability to commercialize and sell our current and future products and our ability to increase sales and gross profit from our products, including insulin pumps and the related insulin cartridges and infusion sets;
- the number and mix of our products sold in each quarter;
- acceptance of our products by people with insulin-dependent diabetes, their caregivers, healthcare providers and third-party payors;
- the pricing of our products and competing products, including the use of discounts, rebates or other financial incentives by us or our competitors;
- the effect of third-party coverage and reimbursement policies;
- our ability to maintain our existing infrastructure;
- the amount of, and the timing of the payment for, insurance deductibles required to be paid by our customers and potential customers under their existing insurance plans;
- interruption in the manufacturing or distribution of our products;
- our ability to simultaneously manufacture multiple products that meet quality, reliability and regulatory requirements;

- seasonality and other factors affecting the timing of purchases of our products;
- timing of new product offerings, acquisitions, licenses or other significant events by us or our competitors;
- results of clinical research and trials on our existing and future products;
- the ability of our suppliers to timely provide us with an adequate supply of components that meet our requirements for product quality and reliability;
- regulatory clearances, certifications, or approvals, or adverse regulatory or legal actions, affecting our products or those of our competitors; and
- the timing of revenue and expense recognition associated with our product sales pursuant to applicable accounting standards.

In addition, we expect our operating expenses will continue to increase as we expand our business, which may exacerbate the quarterly fluctuations in our operating results. If our quarterly or annual operating results fall below the expectation of investors or securities analysts, the price of our common stock could decline substantially. Further, any quarterly or annual fluctuations in our operating results may, in turn, cause the price of our common stock to fluctuate substantially, and these price fluctuations could result in further pressure on our stock price. We believe quarterly comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

Risks Related to Privacy and Security

*We may be subject to stringent and evolving United States and foreign laws, regulations, and rules, contractual obligations, policies and other obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation (including class claims) and mass arbitration demands; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; loss of customers or sales; and other adverse business consequences.**

In the ordinary course of business, we process personal data. Our data processing activities may subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal data privacy and security policies, and contractual requirements.

There are a number of laws in the United States governing the privacy and security of personal data, including data breach notification laws, data privacy laws, consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), and other similar laws at the federal and state levels (e.g., wiretapping laws). For example, the United States Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) as amended by the Health Information Technology for Economic and Clinical Health Act (“HITECH”), imposes specific requirements relating to the privacy of protected health information.

As another example, the Controlling the Assault of Non-Solicited Pornography and Marketing Act of 2003 (“CAN-SPAM”) and the Telephone Consumer Protection Act of 1991 (“TCPA”) impose specific requirements on communications with customers. For example, the TCPA imposes various consumer consent requirements and other restrictions on certain telemarketing activity and other communications with consumers by phone, fax or text message. TCPA violations can result in significant financial penalties, including penalties or criminal fines imposed by the Federal Communications Commission or fines of up to 1,500 U.S. dollars per violation imposed through private litigation or by state authorities.

In recent years, numerous United States states—including California, Virginia, Colorado, Connecticut, and Utah—have enacted comprehensive data privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents with certain rights concerning their personal data. As applicable, such rights may include the right to access, correct, or delete certain personal data, and to opt-out of certain data processing activities, such as targeted advertising, profiling, and automated decision-making. The exercise of these rights may impact our business and ability to provide our products and services. These state laws also allow for statutory fines for noncompliance. For example, as per the California Consumer Privacy Act of 2018 (CCPA), as amended by the California Privacy Rights Act of 2020 (CPRA) (collectively, “CCPA”), noncompliance may carry fines of up to 7,500 U.S. dollars per intentional violation; the CCPA also allows private litigants affected by certain data breaches to recover significant statutory damages. While these laws generally exempt some data processed in the context of clinical trials and data governed by HIPAA, these developments further complicate compliance efforts, and increase legal risk and compliance costs for us, the third parties with whom we work, and our customers. Similar laws are being considered in several other states, as well as at the federal and local levels, and we expect more states to pass similar laws in the future.

Outside the United States, an increasing number of laws, regulations, and industry standards govern data privacy and security. For example, the European Union’s General Data Protection Regulation (“EU GDPR”), the United Kingdom’s General Data Protection Regulation (“UK GDPR”) (collectively, “GDPR”), and Canada’s Personal Information Protection and Electronic Documents Act (“PIPEDA”) or the applicable provincial alternatives, impose strict requirements for processing personal data.

For example, under the GDPR, companies may face temporary or definitive bans on personal data processing and other corrective actions; fines of up to 20 million Euros under the EU GDPR / 17.5 million Pounds Sterling under the UK GDPR or, in each case, 4% of annual global revenue, whichever is greater; or private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests. In Canada, PIPEDA and various related provincial laws, as well as Canada’s Anti-Spam Legislation (“CASL”), may apply to our operations.

Additionally, regulators are increasingly scrutinizing companies that process children’s data. Numerous laws, regulations, and legally-binding codes, such as the Children’s Online Privacy Protection Act (“COPPA”), California’s Age Appropriate Design Code (effective in July 2024), the CCPA, other United States state comprehensive data privacy laws, the GDPR, and the UK Age Appropriate Design Code, impose various obligations on companies that process children data, including requiring certain consents to process such data and extending certain rights to children and their parents with respect to that personal data. Some of these obligations have wide ranging applications, including for services that do not intentionally target child users (defined in some circumstances as a user under the age of 18 years old). These laws may be, or in some cases have already been, subject to legal challenges and changing interpretations, which may further complicate our efforts to comply with these laws.

Our employees and personnel may use Artificial Intelligence (“AI”) technologies (including generative AI) to perform their work. The use and disclosure of personal data in AI technologies is subject to various data privacy laws and other data privacy obligations. Governments have passed and are likely to pass additional laws regulating generative AI. Our use of this technology could result in additional compliance costs, regulatory investigations and actions, and lawsuits. If we are unable to use AI, it could make our business less efficient and result in competitive disadvantages.

The development and use of AI/Machine Learning (“ML”) technologies present various data privacy risks that may impact our business. AI/ML are subject to data privacy laws, as well as increasing regulation and scrutiny. Several jurisdictions around the globe, including the European Union and certain U.S. states, have proposed or enacted, or are considering, laws governing the development and use of AI/ML. For example, European regulators have proposed a stringent AI regulation, and we expect other jurisdictions will adopt similar laws. Additionally, certain data privacy laws extend rights to consumers (such as the right to delete certain personal data) and regulate automated decision-making, which may prove to be incompatible with our desired uses of AI/ML. These obligations may make it harder for us to conduct our business using AI/ML, require us to change our business practices and/or retrain our AI/ML, prevent or limit our use of AI/ML, or lead to regulatory fines or penalties. For example, the FTC has required other companies to turn over (or disgorge) valuable insights or trainings generated through the use of AI/ML where they allege the company has violated data privacy and consumer protection laws. If we cannot use AI/ML or that use is restricted, our business may be less efficient, or we may be at a competitive disadvantage.

We may be subject to certain new laws governing the privacy of consumer health data. For example, Washington’s My Health My Data Act (“MHMD”) broadly defines consumer health data, places restrictions on processing such data (including imposing stringent requirements for consent), provides consumers certain rights with respect to their health data, and creates a private right of action to allow individuals to sue for violations of the law. Other states are considering and may adopt similar laws.

In the ordinary course of business, we may transfer personal data from Europe and other jurisdictions to the United States or other countries. Europe and other jurisdictions have enacted laws requiring certain data to be localized or limiting the transfer of personal data to other countries. In particular, the European Economic Area (EEA) and the UK have significantly restricted the transfer of personal data to the United States and other countries whose data privacy laws it deems inadequate. Other jurisdictions may adopt similarly stringent interpretations of their data localization and cross-border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law, such as the EEA standard contractual clauses, the UK's International Data Transfer Agreement / Addendum, and the EU-U.S. Data Privacy Framework and the UK extension thereto (which allows for transfers to relevant organizations based in the United States who self-certify and participate in the Framework), these mechanisms are subject to legal challenges. If these legal challenges change or invalidate these transfer mechanisms, there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States. If there is no lawful mechanism for us to transfer personal data from the EEA, the UK or other jurisdictions to the United States, or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Additionally, companies that transfer personal data out of the EEA and UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants, and activist groups. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers out of Europe for allegedly violating the GDPR's cross-border data transfer obligations. Additionally, in May 2023, the Irish Data Protection Commission determined that a major social media company's use of the standard contractual clauses to transfer personal data from Europe to the United States was insufficient and levied a 1.2 billion Euro fine against the company and prohibited the company from transferring EU personal data to the United States.

Additionally, under various privacy laws and other obligations, we may be required to obtain certain consents to process personal data. For example, some of our data processing practices may be challenged under wiretapping laws, if we obtain consumer information from third parties through various methods, including chatbot and session replay providers, or by third-party marketing pixels. These practices may be subject to increased challenges by class action plaintiffs. Our inability or failure to obtain consent for these practices could result in adverse consequences, including class action litigation and mass arbitration demands.

In addition to data privacy laws, we are contractually subject to industry standards adopted by industry groups. For example, we are subject to the Payment Card Industry Data Security Standard ("PCI DSS"). The PCI DSS requires companies to adopt certain measures to ensure the security of cardholder information, including using and maintaining firewalls, adopting proper password protections for certain devices and software, and restricting data access. Noncompliance with PCI-DSS can result in penalties ranging from 5,000 to 100,000 U.S. dollars per month by credit card companies, litigation, damage to our reputation, and revenue losses. We are also bound by other contractual obligations related to data privacy, including those imposed by our payors and business partners, including obligations to comply with applicable data privacy laws. Our failure to comply with our contractual obligations may result in a loss of revenue, loss of existing and future business opportunities, and payment of financial damages to the other parties involved. We publish privacy policies, marketing materials and other statements, such as compliance with certain certifications or self-regulatory principles, regarding data privacy. If these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators or other adverse consequences.

Obligations related to data privacy are quickly changing, becoming increasingly stringent, and creating uncertainty. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions. Preparing for and complying with these obligations requires us to devote significant resources, which may necessitate changes to our services, information technologies, systems, and practices and to those of any third parties with whom we work. In addition, these obligations may require us to change our business model. We may at times fail (or be perceived to have failed) in our efforts to comply with our data privacy obligations. Moreover, despite our efforts, our employees and personnel or third parties with whom we work, may fail to comply with such obligations, which could negatively impact our business operations. In addition, a shift in consumers' data privacy expectations or other social, economic or political developments could impact the regulatory enforcement of these obligations, which could increase the cost of and complicate our compliance with applicable obligations.

If we or the third parties with whom we work fail, or are perceived to have failed to address or comply with applicable data privacy obligations, we could face significant consequences, including but not limited to: government enforcement actions (e.g., investigations, fines, penalties, audits, inspections, and similar); litigation (including class-action claims) and mass arbitration demands; additional reporting requirements and/or oversight; bans on processing of personal data; orders to destroy or not use personal data; and imprisonment of company officials. In particular, plaintiffs have become increasingly more active in bringing data privacy-related claims against companies, including class claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis; if viable, these claims carry the potential for monumental statutory damages, depending on the volume of personal data and the number of violations.

Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: loss of customers; interruptions or stoppages in our business operations (including, as relevant, clinical trials); inability to process personal data or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or substantial changes to our business model or operations.

If our information technology systems or those of third parties with whom we work, our data, or our software are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; harm to our reputation; loss of revenue or profits; loss of customers or sales; and other adverse consequences.*

In the ordinary course of business, the efficient operation of our business depends on our information technology and communication systems, as well as those of our suppliers, contract manufacturers, distributors and other third parties with whom we work. We and the third parties with whom we work collect, receive, store, process, use, generate, disclose, make accessible, protect, secure, dispose of, share, and transmit confidential, personal, or other sensitive data, including health information, proprietary sales and marketing data, accounting and financial information, manufacturing and quality records, inventory management data, product development tasks, research and development data, customer service and technical support information. These systems and the underlying data are vulnerable to damage or interruption from a number of causes, including earthquakes, fires, floods and other natural disasters, terrorist attacks, attacks by computer viruses or hackers, malware, ransomware or other destructive software, cyber-attacks, social-engineering attacks (including phishing and deep fakes, which may be increasingly more difficult to identify as fake), malicious code, denial-of-service attacks, credential harvesting, supply chain attacks, power losses, and computer system, data network failures, and other similar threats.

Cyber-attacks, malicious internet-based activity, online and offline fraud, and other similar activities threaten the confidentiality, integrity, and availability of our sensitive information and information technology systems, and those of the third parties with whom we work. Such threats are prevalent and continue to rise, are increasingly difficult to detect, and come from a variety of sources, including traditional computer “hackers,” threat actors, “hacktivists,” organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation states, and nation-state-supported actors.

Some actors now engage and are expected to continue to engage in cyber-attacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we, and the third parties with whom we work may be vulnerable to a heightened risk of these attacks, including retaliatory cyber-attacks, that could significantly disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our goods and services.

Our systems, those of the third parties with whom we work, and the underlying data are vulnerable to damage or interruption from a number of causes, including earthquakes, fires, floods and other natural disasters, terrorist attacks. We and the third parties with whom we work are also subject to a variety of evolving threats, including but not limited to, social-engineering attacks (including phishing and deep fakes, which may be increasingly more difficult to identify as fake), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks, credential stuffing, credential harvesting, supply chain attacks, personnel misconduct or error, ransomware attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, attacks enhanced or facilitated by AI, and other similar threats. Notably, severe ransomware attacks are becoming increasingly prevalent and can lead to significant interruptions in our operations, impact our ability to provide our products or services, loss of sensitive data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments.

In addition, our insulin pumps and other products rely on software and hardware, some of which is developed by third-party service providers or other third parties with whom we work, that could contain vulnerabilities. We take steps designed to detect, mitigate and remediate vulnerabilities in our information systems (such as our hardware and/or software, including that of third parties with whom we work), but we may not be able to detect, mitigate, and remediate such vulnerabilities, including on a timely basis. Further, we may experience delays in developing and deploying remedial measures and patches designed to address identified vulnerabilities. Our risks may increase significantly due to the use of mobile and cloud-based applications in our medical devices. For example, while use of our Tandem Device Updater is designed to give us the ability to quickly recover from certain risks and/or vulnerabilities, the use of mobile applications enables third parties to store their information on mobile devices that we do not control. Vulnerabilities could be exploited and result in a security incident. In addition to vulnerabilities, the reliance of our insulin pumps and other products on software and hardware exposes us and our customers to risks that may impact the performance of our products. For example, in March 2024, we issued a recall of our Apple iOS t:connect mobile app in the United States relating to an issue that could cause rapid depletion of a user's t:slim X2 insulin pump battery (the "March 2024 Recall"). On August 20, 2024, we released an updated version of the impacted app to correct the issue described in the March 2024 recall.

Any of the previously identified or similar threats and risks could cause a security incident or other interruption that could result in the unauthorized, unlawful or accidental disclosure, access, acquisition, modification, destruction, loss, alteration, or encryption of our sensitive information or our information technology systems or those of the third parties with whom we work. A security incident or other interruption could disrupt our ability (and that of third parties with whom we work) to provide our platform/products/services.

Furthermore, many of the third parties with whom we work are subject to similar risks. We rely on third parties and technologies to operate critical business systems to process sensitive information in a variety of contexts, including, without limitation, cloud-based infrastructure, data center facilities, encryption and authentication technology, employee email, and other functions and systems. Our ability to monitor information security practices of these third parties is limited, and these third parties may not have adequate information security measures in place. If the third parties with whom we work experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if these third parties fail to satisfy their privacy- or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such an award. In addition, supply chain attacks have increased in frequency and severity, and we cannot guarantee that infrastructure belonging to these third parties in our supply chain, or the supply chains of third parties with whom we work have not been compromised.

Moreover, remote work has become more common and has increased risks to our information technology systems and data, as more of our employees use network connections, computers and devices outside our premises or network, including working at home, while in transit, and in public locations. Additionally, future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program.

We may expend significant resources or modify our business activities to try to protect against security incidents. Whether or not our security measures and those of the third parties with whom we work are ultimately successful, our expenditures on those measures could have an adverse impact on our financial condition and results of operations, and divert management's attention from pursuing our strategic objectives. Certain data privacy and security obligations may require us to implement and maintain reasonable or specific security measures or industry standards to protect our information technology systems and sensitive information.

Applicable data privacy and security obligations may require us, or we may voluntarily choose, to notify relevant stakeholders, including affected individuals, customers, regulators, and investors, of security incidents, or to take other actions, such as providing credit monitoring and identify theft protection services. Such disclosures and related actions can be costly, and the disclosure or the failure to comply with applicable requirements could lead to adverse consequences. It may be difficult and/or costly to detect, investigate, mitigate, contain, and remediate a security incident. Whether a security incident is reportable to our investors may not be straightforward, may take considerable time to determine, and may be subject to change as the investigation of the incident progresses, including changes that may significantly alter any initial disclosure that we provide. Our efforts to investigate, mitigate, contain, and remediate a security incident may not be successful. Actions taken by us or the third parties with whom we work to detect, investigate, mitigate, contain, and remediate a security incident could result in outages, data losses, and disruptions of our business. Threat actors may also gain access to other networks and systems after a compromise of our networks and systems.

If we (or a third party with whom we work) experience a security incident (such as the phishing attack we experienced in 2020) or are perceived to have experienced a security incident, we may experience adverse consequences, such as government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing sensitive information (including personal data); litigation (including class claims) and mass arbitration demands; indemnification obligations; negative publicity; reputational harm; loss of investor, partner or customer confidence in the effectiveness of our cybersecurity measures; monetary fund diversions; diversion of management attention; interruptions in our operations (including availability of data); financial loss; and other similar harms. Security incidents and attendant consequences may cause customers to stop using our products, prevent customers from using our products, deter new customers from using our products, and negatively impact our ability to grow and operate our business.

Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. We cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims.

In addition to experiencing a security incident, third parties may gather, collect, or infer sensitive information about us from public sources, data brokers, or other means that reveals competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position.

The failure of our information technology systems or those of the third parties with whom we work, or of our pumps' software or other mobile or cloud applications to perform as we anticipate, or our failure to effectively identify, investigate and mitigate potential threats through ongoing maintenance and enhancement of software applications, information technology systems and privacy policies and controls, could disrupt our entire operation or adversely affect our software products or ability to provide our products and services. For example, we market our Tandem Device Updater as having the unique capability to deploy software updates to our pumps, which allows customers remote access to new and enhanced features. The failure of our Tandem Device Updater to provide software updates as we anticipate, including as a result of our inability to secure and maintain necessary regulatory approvals, the inability of our pumps to properly receive software updates, or errors, vulnerabilities or viruses embedded within the software being transmitted, or the failure of our customers to properly use the system to complete the update, could result in decreased sales, increased warranty costs, and harm to our reputation, any of which could have a material adverse effect on our business, financial condition and operating results.

Our sensitive information could be leaked, disclosed, or revealed as a result of or in connection with our employees', personnel's, or vendors' (or other third parties upon whom we rely) use of generative artificial intelligence ("AI") or machine learning ("ML") technologies (collectively, "AI/ML" technologies). Any sensitive information (including confidential, competitive, proprietary, or personal data) that we input into a third-party generative AI platform could be leaked or disclosed to others, including if sensitive information is used to train the third parties' AI model. Additionally, where AI/ML technologies ingest personal data and makes connections using such data, those technologies may reveal other personal or sensitive information generated by the model. Moreover, AI models may create flawed, incomplete, or inaccurate outputs, some of which may appear correct. This may happen if the inputs that the model relied on were inaccurate, incomplete or flawed (including if a bad actor "poisons" the AI with bad inputs or logic), or if the logic of the AI is flawed (a so-called "hallucination"). We may use AI/ML outputs to make certain decisions. Due to these potential inaccuracies or flaws, the model could be biased and could lead us to make decisions that could bias certain individuals (or classes of individuals), and adversely impact their rights, employment, and ability to obtain certain pricing, products, services, or benefits. If such AI-based outputs are deemed to be biased, we could face adverse consequences, including exposure to reputational and competitive harm, customer loss, and legal liability.

We experienced a breach of our information technology systems in January 2020.*

On January 17, 2020, we learned that an unauthorized person gained access to a few employees' email accounts through a cyber-attack commonly known as "phishing." As a result, we defended a lawsuit entitled *Joseph Deluna et al. v. Tandem Diabetes Care, Inc.*, which was filed in the Superior Court of the State of California in the County of San Bernardino. On November 28, 2022, the court granted our motion for summary adjudication on the plaintiffs' allegations that we violated the Confidentiality of Medical Information Act. On February 8, 2023, the plaintiffs asked the court to dismiss their remaining two claims with prejudice, which terminated the case at the Superior Court. On March 7, 2023, the plaintiffs filed a notice of appeal of the Court's order granting the Company's motion for summary adjudication. On August 15, 2023, the parties reached a settlement and on August 21, 2023, the Court issued an order dismissing the appeal. The risks posed by any future similar matters include civil monetary damages, attorney fees and costs, other legal penalties, reputational damage, loss of goodwill, and competitive harm.

Risks Related to Legal and Intellectual Property

Our ability to comprehensively protect our intellectual property and proprietary technology is uncertain.

We rely primarily on patent, trademark and trade secret laws, as well as confidentiality and non-disclosure agreements, to protect our proprietary technologies. However, such methods may not be adequate to protect us or permit us to gain or maintain a competitive advantage. We have applied for patent protection relating to certain existing and proposed products and processes. If we fail to file a patent application timely in any jurisdiction, it could result in us forfeiting certain patent rights in that jurisdiction. Further, we cannot assure you that any of our patent applications will be granted in a timely manner or at all. The rights granted to us under our patents, and the rights we are seeking to have granted in our pending patent applications, may not provide us with any commercial advantage. In addition, those rights could be opposed, contested or circumvented by our competitors, or be declared invalid or unenforceable in judicial or administrative proceedings. The failure of our patents to adequately protect our technology might make it easier for our competitors to offer the same or similar products or technologies. Due to differences between foreign and U.S. patent laws, our patented intellectual property rights may not receive the same degree of protection in foreign countries as they would in the United States. Even if patents are granted outside of the United States, effective enforcement in those countries may not be available.

We rely on our trademarks and trade names to distinguish our products from the products of our competitors, and have registered or applied to register many of these trademarks. We cannot assure you that our current or future trademark applications will be approved in a timely manner or at all. From time to time, third parties oppose our trademark applications, or otherwise challenge our use of trademarks. In the event that our trademarks are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition, and could require us to devote additional resources to marketing new brands. Further, we cannot assure you that competitors will not infringe upon our trademarks, or that we will have adequate resources to enforce our trademarks.

We have entered into confidentiality agreements and intellectual property assignment agreements with our officers, employees, temporary employees and consultants regarding our intellectual property and proprietary technology. We also enter into confidentiality agreements with potential collaborators and other counterparties, and the terms of our collaboration agreements typically contain provisions governing the ownership and control of intellectual property. In the event of unauthorized use or disclosure or other breaches of those agreements, we may not be provided with meaningful protection for our trade secrets or other proprietary information.

To protect our proprietary rights, we may in the future need to assert claims of infringement against third parties, which may be difficult, expensive and time consuming. The outcome of litigation to enforce our intellectual property rights in patents, copyrights, trade secrets or trademarks is subject to rapid change and constant evolution and, consequently, intellectual property protection in our industry can be uncertain. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially valuable. 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 attorneys' fees. The occurrence of any of these events may have a material adverse effect on our business, financial condition and operating results.

Patent litigation in the medical device industry is common, and we may be subject to litigation that could cause us to incur substantial costs and divert the attention of management from our business.*

Our success will depend in part on not infringing the patents or violating the other proprietary rights of third parties. While we review third party patents in advance of product launches to try to identify and avoid any infringement concerns, the large number of patents, the rapid rate of new patent issuances, and the complexity of the technology involved mean that there can be no assurance that all potentially relevant patents are identified or that our products do not infringe existing patents or patents that may be granted in the future. As such, there is a risk that third parties may assert patent infringement claims against us. Despite our efforts to avoid infringement and to resolve any claims that may arise, litigation may be necessary to defend against these claims, which could result in substantial costs and diversion of resources and may have a material adverse effect on our business, financial condition, and results of operations. Our competitors in both the United States and markets outside of United States may have applied for or obtained or may in the future apply for and obtain, patents that will prevent, limit or otherwise interfere with our ability to make and sell our current products or products under development.

From time to time, we may receive communications from third parties alleging our infringement of their intellectual property rights or offering a license to their intellectual property relating to products that we are currently developing could require us to do one or more of the following:

- stop selling current products, developing new products or using technology that allegedly infringes on third-party intellectual property;
- try to obtain a license to intellectual property from the third parties, which may not be available on reasonable terms or at all;
- try to re-design our products around third-party intellectual property;
- incur significant royalty payments and legal expenses; or
- pay substantial damages to the party whose intellectual property rights we are allegedly infringing.

For example, in November 2023, at the Unified Patent Court (“UPC”), Paris Central Division (the “UPC Paris”), we filed a revocation action and an action for a declaration of non-infringement of EP Patent No. 2 196 231 B1 (the “‘231 patent”) against Roche Diabetes Care GmbH. While Roche contends that Tandem’s t:slim X2 pump infringes the ‘231 patent, we contend that our t:slim X2 pump does not infringe the ‘231 patent. Furthermore, we contend that the claims of the ‘231 patent are invalid over the prior art and should be revoked. In February 2024, Roche filed an infringement action against Tandem and its distributor in Germany at the UPC, Hamburg Local Division (“UPC Hamburg”) contending that Tandem’s t:slim X2 pump, and the offering, marketing, using, importing, possessing, and supplying of such devices, infringes the ‘231 patent. Roche seeks, among other things, damages and other monetary relief, costs and expenses of the legal proceedings, and an order to cease and desist the allegedly infringing activities. At the UPC Hamburg, Tandem has asserted that the t:slim X2 pump does not infringe the claims of the ‘231 patent and Tandem’s distributor has asserted that the t:slim X2 pump does not infringe the claims of the ‘231 patent and that the claims of the ‘231 patent are invalid and should be revoked. On November 6, 2024, the UPC Paris will hold a hearing on Tandem’s action to revoke the claims of the ‘231 patent.

In December 2023, F. Hoffman-La Roche AG and Roche Diabetes Care GmbH (collectively, “Roche”), filed an infringement action at the UPC, Dusseldorf Division (“UPC Dusseldorf”) against Tandem Diabetes Care, Inc. and Tandem Diabetes Care Europe B.V. and Tandem’s distributors in Germany, France, the Netherlands and Denmark. Roche alleges our t:slim X2 insulin pump, and the offering, marketing, using, importing, possessing, and supplying of such devices, infringe EP Patent No. 1 970 677 B1 (the “‘677 patent”). While Roche contends that Tandem’s t:slim X2 pump infringes the ‘677 patent, we contend that our t:slim X2 pump does not infringe the ‘677 patent. Furthermore, we contend that the claims of the ‘677 patent are invalid over the prior art and should be revoked. Roche seeks, among other things, damages and other monetary relief, costs and expenses of the legal proceedings, and an order to cease and desist the allegedly infringing activities. On April 9, 2025, the UPC Dusseldorf will hold a hearing on Roche’s action asserting infringement of the ‘677 patent, Tandem and its distributors’ counterclaims that the t:slim X2 pump does not infringe the ‘677 patent, and Tandem and its distributors’ actions to revoke the claims of the ‘677 patent.

As the UPC is a new court system that came into effect in 2023, enforcement and litigation under the UPC is new and we cannot accurately predict the outcome of such proceedings.

If any of our products are found to infringe Roche’s patents and Roche’s patents are also found to be valid, we could be required to redesign our technology or obtain a license from Roche to continue importing, marketing and selling our dosing devices in certain countries in Europe. However, we may not be successful in the redesign of our technology or able to obtain any such license on commercially reasonable terms or at all. We also could be forced, including by court order, to cease importing, marketing and selling certain of our products in certain countries in Europe that are found to be infringing until the patents expire. Even if we were ultimately to prevail, litigation with Roche could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business. We cannot reasonably estimate the final outcome, including any potential liability or any range of potential future charges associated with litigation.

We do not maintain insurance to cover the expense or any liability that may arise from an intellectual property dispute. Any litigation or claim against us may cause us to incur substantial costs, divert the attention of management from our business and harm our reputation. Further, as we launch new products, increase our sales and expand the geographic regions in which we commercialize our products we believe the likelihood of our involvement in intellectual property disputes will increase.

We may be subject to damages resulting from claims that we, or our employees, have wrongfully used or disclosed trade secrets or other proprietary information of our competitors.

Many of our employees were previously employed at other medical device companies, including those that are our competitors or could become our competitors. We may be subject to claims that we, or our employees, have used or disclosed trade secrets or other proprietary information. In addition, we may be subject to allegations that we caused an employee to breach the terms of his or her non-competition or non-solicitation agreement. Even if we successfully defend against these claims, any resulting litigation could cause us to incur substantial costs, divert the attention of management from our business and harm our reputation. If our defense of those allegations fails, in addition to paying monetary damages, we may lose valuable intellectual property rights or key personnel. A loss of key personnel or intellectual property rights could limit our ability to commercialize products, which could have an adverse effect on our business.

We may incur product liability losses, and insurance coverage may be inadequate or unavailable to cover these losses.

Our business exposes us to potential product liability claims that are inherent in the medical device industry. We are subject to product liability lawsuits alleging that component failures, manufacturing defects, design defects, or inadequate disclosure of product-related risks or information resulted in an unsafe condition, injury or death to customers. The risk of product liability claims may be even greater after we launch new products with new features or enter new markets where we have no prior experience selling our products. In addition, the misuse of our products or the failure of customers to adhere to operating guidelines could cause significant harm to customers, which could result in product liability claims. Product liability lawsuits and claims, safety alerts or product recalls could cause us to incur substantial costs, divert the attention of management from our business, harm our reputation and adversely affect our ability to attract and retain customers.

Although we maintain third-party product liability insurance coverage, it is possible that claims against us may exceed the coverage limits of our insurance policies. Even if any product liability loss is covered by an insurance policy, these policies have substantial deductibles. In addition, we expect the cost of our product liability insurance will increase as our sales increase. Product liability claims in excess of applicable insurance coverage could have a material adverse effect on our business, financial condition and operating results. In addition, any product liability claim brought against us, with or without merit, could result in further increases of our product liability insurance premiums and make it more difficult to obtain insurance coverage in the future.

Risks Related to Our Regulatory Environment

Our products and operations are subject to extensive governmental regulation, and failure to comply with applicable requirements could cause our business to suffer.*

The medical device industry is regulated extensively by governmental authorities, principally the FDA and corresponding state regulatory agencies in the United States, foreign regulatory authorities, and Notified Bodies in the EU. The regulations are very complex and are subject to rapid change and varying interpretations. Regulatory restrictions or changes could limit our ability to carry on or expand our operations or result in higher than anticipated costs or lower than anticipated sales. The FDA and other United States governmental agencies and comparable foreign regulatory authorities and Notified Bodies regulate numerous elements of our business, including:

- product design and development;
- pre-clinical and clinical testing and trials;
- product safety;
- establishment registration and product listing;
- labeling, packaging and storage;
- marketing, manufacturing, sales and distribution;
- import and export;
- pre-market clearance, certification, or approval;
- servicing and post-market surveillance;

- advertising and promotion; and
- recalls and field safety corrective actions.

Before we can market or sell a new regulated product or a significant modification to an existing product in the United States, we must obtain either clearance under Section 510(k) of the Food, Drug and Cosmetic Act (510(k) or approval of a pre-market approval (PMA) application from the FDA, unless an exemption from pre-market review applies. The process of obtaining regulatory clearances, certification, or approvals to market a medical device can be costly and time-consuming, which may be exacerbated if the FDA or other comparable regulatory authorities or Notified Bodies in the EU changes their clearance, certification, and approval policies, and we may not be able to obtain these clearances, certification for our proposed products or approvals on a timely basis or at all, including as a result of:

- our inability to demonstrate that our products are safe and effective for their intended users;
- the data from our pre-clinical studies or clinical trials may be insufficient to support clearance, certification, or approval; or
- the failure of the manufacturing process or facilities we use to meet applicable requirements.

Any delay in, or failure to receive or maintain, clearance, certification, or approval for our products under development could prevent us from generating revenue from these products or achieving profitability. Further, regulatory enforcement or inquiries, or other increased scrutiny on us, could dissuade some customers from using our products and adversely affect our reputation and the perceived safety and efficacy of our products.

Since our inception we have been audited or inspected by various regulatory authorities and Notified Bodies on numerous occasions. We also regularly respond to routine inquiries from regulatory authorities and Notified Bodies. In some instances, these audits, inspections and inquiries result in findings that require us to take corrective actions, which could include changes to our internal policies, procedures or operations, revisions to our product labeling, issuances of customer notifications or the initiation of product recalls, any of which could result in product liability claims and lawsuits. Our failure to appropriately respond to these findings and take corrective action, or to comply with applicable regulations for any other reason, could jeopardize our ability to sell our products and result in enforcement actions such as fines, civil or criminal penalties, injunctions, warning letters, product recalls, operating restrictions, interruption of production, delays in the introduction of products into the market, refusal of the FDA or other comparable foreign regulatory authorities or Notified Bodies to grant future clearances, certification, or approvals, and the suspension or withdrawal of existing clearances, certifications, or approvals by the FDA, other comparable foreign regulatory authorities or Notified Bodies. Any of these sanctions could result in higher than anticipated costs, lower than anticipated sales, and diversion of management time and resources, any of which could have a material adverse effect on our reputation, business, financial condition and operating results.

New products or modifications to our existing products may require new 510(k) clearances, PMAs or certifications, or may require us to cease marketing or recall the modified products until clearances, certifications or approvals are obtained.

Any modification to a 510(k)-cleared device that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, design, or manufacture, requires a new 510(k) clearance or, possibly, a PMA. The FDA requires every manufacturer to make this determination in the first instance, but the FDA may review any manufacturer's decision. The FDA may not agree with our decisions regarding whether new clearances or approvals are necessary for changes that we have made to our products. If the FDA disagrees with our determination and requires us to submit new 510(k) notifications or PMAs for modifications to our previously cleared or approved products, for which we concluded that new clearances or approvals were not necessary, we may be required to cease marketing or to recall the modified product until we obtain clearance or approval, and we may be subject to significant regulatory fines or penalties.

Further, the FDA's ongoing review of and potential changes to the 510(k) program may make it more difficult for us to modify our previously cleared products, either by imposing stricter requirements on when a new 510(k) for a modification to a previously cleared product must be submitted, or by applying more onerous review criteria to such submissions.

For those medical devices sold in the EU and for which we have obtained a CE Certificate of Conformity by a Notified Body, we must notify our Notified Body if significant changes are made to the products or if there are substantial changes to our quality assurance systems affecting those products. Obtaining variation of existing CE Certificates of Conformity or a new CE Certificate of Conformity can be a time-consuming process, and delays in obtaining required future clearances, certifications or approvals would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our future growth.

A recall or suspension of our products, or the discovery of serious safety issues with our products, could have a significant negative impact on us.

The FDA and equivalent foreign regulatory authorities have the authority to require the recall or suspension, either temporarily or permanently, of commercialized products in the event of material deficiencies or defects in quality systems, product design or manufacture or in the event that a product poses an unacceptable risk to health. Regulatory authorities have broad discretion to require the recall or suspension of a product or to require that manufacturers alert customers of safety risks, and may do so even in circumstances where we do not believe our product poses an unacceptable risk to health. In addition, manufacturers may, under their own initiative, recall a product or suspend sales if any material deficiency in a product is found or alert customers of unanticipated safety risks. A government-mandated or voluntary recall or suspension by us, one of our distributors or any of our other third-party suppliers could occur as a result of an unacceptable risk to health, component failures, manufacturing errors, design or labeling defects or other deficiencies and issues. Recalls, suspensions or other notices relating to any products that we distribute would divert managerial and financial resources, and have an adverse effect on our reputation, financial condition and operating results.

Further, under the FDA's Medical Device Reporting regulations and equivalent regulations and requirements in other geographies, we are required to maintain appropriate quality systems and report incidents in which our product may have caused or contributed to serious injury or death in which our product malfunctioned and, if the malfunction were to recur, would likely cause or contribute to serious injury or death. Repeated product malfunctions may result in a voluntary or involuntary product recall or suspension of product sales, which could divert managerial and financial resources, impair our ability to manufacture our products in a cost-effective and timely manner and have an adverse effect on our reputation, financial condition and operating results. We have initiated product recalls in the past, and our risk of future product recalls may increase as we launch new products or offer new software updates for existing products.

Any adverse event involving any products that we distribute could result in future voluntary corrective actions, such as recalls or customer notifications, or regulatory authority action, which could include inspection, mandatory recall or other enforcement action. For example, the Australian Therapeutic Goods Administration (TGA) temporarily suspended our pump product sales in Australia starting November 24, 2020, however sales of pump-related supplies were allowed to continue. Effective April 1, 2021, following discussions with the TGA, the temporary suspension was lifted for our t:slim X2 with Basal-IQ technology, subject to certain post-market surveillance obligations and other conditions. We discontinued sales of earlier generation products in Australia and we started offering our Control-IQ technology in Australia. There can be no assurance that the TGA will not reimpose the suspension of our pump product sales or impose other regulatory restrictions in the future. In addition, other regulatory authorities may take similar actions against us, and any regulatory challenges we encounter could have a negative impact on our product sales and harm our reputation. Any corrective actions we take in response to this action or future matters with the TGA or other regulatory authorities, whether voluntary or involuntary, will require the dedication of our time and capital, may distract management from operating our business, may harm our reputation and financial results or could result in additional regulatory scrutiny in other geographies.

In addition, we may be required to conduct costly post-market testing and surveillance to monitor the safety or effectiveness of our products in the EU. We must comply with medical device reporting requirements, including the reporting of adverse events and malfunctions related to our products. Later discovery of previously unknown problems with our products, including unanticipated adverse events or adverse events of unanticipated severity or frequency, manufacturing problems, or failure to comply with regulatory requirements may result in changes to labeling, restrictions on such products or manufacturing processes, withdrawal of the products from the market, voluntary or mandatory recalls, a requirement to repair, replace or refund the cost of any medical device we manufacture or distribute, fines, suspension, variation or withdrawal of CE Certificates of Conformity, product seizures, injunctions or the imposition of civil or criminal penalties that would adversely affect our business, operating results and prospects.

Our failure to comply with United States federal and state fraud and abuse laws, including anti-kickback laws and other United States federal and state anti-referral laws, or comparable foreign legislation, could have a material, adverse impact on our business.*

The United States has numerous federal and state laws pertaining to healthcare fraud and abuse. Violations of these laws are punishable by criminal and civil sanctions, including, imprisonment, significant monetary penalties and exclusion from participation in federal funded programs such as Medicare and Medicaid.

Healthcare fraud and abuse regulations are complex and evolving. Minor irregularities can potentially give rise to claims. The laws that may affect our ability to operate include:

- the federal and state Anti-Kickback Statutes, which prohibit, among other things, persons from knowingly and willfully soliciting, receiving, offering, paying or providing remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind in exchange for or to induce either the referral of an individual for, or the purchase, lease, order or recommendation of, any good or service for which payment may be made under federal healthcare programs such as the Medicare and state Medicaid programs;
- federal and state false claims laws which prohibit, among other things, persons from knowingly presenting, or causing to be presented, false or fraudulent claims for payment to Medicare, state Medicaid programs, or other third-party payors;
- federal and state physician self-referral laws, such as the Stark Law, which prohibit a physician from referring Medicare or Medicaid patients to an entity providing “designated health services,” including a company that furnishes durable medical equipment, with which the physician or their immediate family member has a financial relationship unless that financial relationship meets an exception under the applicable law;
- federal and state laws, such as the Civil Monetary Penalties Law, that prohibit an individual or entity from offering or transferring remuneration to any person eligible for benefits under a federal or state health care program which such individual or entity knows or should know are likely to influence such eligible individual’s choice of provider, practitioner or supplier of any item or service for which payment may be made under federal health care programs such as Medicare and state Medicaid programs;
- federal criminal laws enacted as part of HIPAA that prohibit, among other things, executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- federal and state disclosure laws, such as the Physician Payments Sunshine Act, which require certain manufacturers, including medical device manufacturers, to submit annual data pertaining to payments or other transfers of value to covered recipients, including physicians and certain other healthcare providers, and teaching hospitals, as well as information regarding ownership and investment interests held by physicians and their immediate family members;
- federal and state laws governing the use, disclosure and security of personal information, including protected health information, such as HIPAA and the HITECH; and
- foreign and United States state law equivalents of each of the above federal laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers.

Outside the United States, interactions between medical device companies and healthcare professionals are also governed by strict laws, such as national anti-bribery laws of European countries, national sunshine rules, regulations, industry self-regulation codes of conduct and physicians’ codes of professional conduct. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

Our relationships with healthcare providers and other third parties are subject to scrutiny under these laws. Violations of any of these laws and other applicable healthcare fraud and abuse laws may be punishable by criminal and civil sanctions, including significant fines and civil monetary penalties, the possibility of exclusion from federal healthcare programs (including Medicare and Medicaid), disgorgement and corporate integrity agreements, which impose, among other things, rigorous operational and monitoring requirements on companies. Any action against us for violation of these laws, even if we successfully defend against it, could result in a material adverse effect on our reputation, business, financial condition and operating results. Federal government agencies continue to issue proposed and final rules implementing additional process, controls and guidelines for compliance under these laws with which we will be required to comply. We cannot predict the impact of any changes in these laws and whether they might be retroactive. Further, the United States Department of Justice (DOJ) in conjunction with other federal agencies, has increased its scrutiny of interactions between healthcare companies and healthcare providers. Adjusting to new regulatory guidelines and responding to investigations can be time and resource-consuming and can divert management's attention from our core business. Additionally, if we settle an investigation, we may be forced to agree to additional onerous compliance and reporting requirements as part of a consent decree or corporate integrity agreement. All of the foregoing could increase our costs or otherwise have an adverse effect on our business.

The scope and enforcement of these laws is uncertain and subject to rapid change in the current environment of healthcare reform. Our current or future activities could be subject to challenge under these laws. Any of these challenges could have a material adverse effect on our reputation, business, financial condition and operating results.

We may be liable if we engage in the promotion of the off-label use of our products.*

Our promotional materials and training methods must comply with FDA and other applicable laws and regulations, including the prohibition against the promotion of the off-label use of our products or the pre-promotion of unapproved products. Healthcare providers may use our products off-label, as the FDA does not restrict or regulate a physician's choice of treatment within the practice of medicine. However, if the FDA or other foreign regulatory authorities determine that our promotional materials or training constitutes promotion of an off-label use or the pre-promotion of an unapproved product, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fines and criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our promotional or training materials to constitute promotion of an unapproved use, which could result in significant fines or penalties. Although our policy is to refrain from statements that could be considered off-label promotion of our products or pre-promotion of an unapproved product, the FDA or another regulatory authority could disagree and conclude that we have engaged in improper promotional activities. In addition, the off-label use of our products may increase the risk of product liability claims, which are expensive to defend and could result in substantial damage awards against us and harm our reputation.

The advertising and promotion of medical devices in the EU is subject to Regulation 2017/745 on medical devices, Regulation 2017/746 on in vitro diagnostic medical devices, the related national law of individual EU Member States, or MDR, Directive 2006/114/EC concerning misleading and comparative advertising, and Directive 2005/29/EC on unfair commercial practices, as well as other national legislation of individual EU Member States governing the advertising and promotion of medical devices. EU Member States' national legislation may also restrict or impose limitations on our ability to advertise our products directly to the general public. In addition, voluntary EU and national industry Codes of Conduct provide guidelines on the advertising and promotion of our products to the general public and may impose limitations on our promotional activities with healthcare professionals.

Legislative or regulatory healthcare reforms, or other regulatory reforms, may result in downward pressure on the price of and decrease reimbursement for our products, and uncertainty regarding the healthcare regulatory environment could have a material adverse effect on our business.*

The sales of our products depend in part on the availability of coverage and reimbursement from third-party payors such as government health administration authorities, private health insurers, health maintenance organizations and other healthcare-related organizations. Both the federal and state governments in the United States continue to propose and pass new legislation and regulations designed to, among other things, expand healthcare coverage to more individuals, contain or reduce the cost of healthcare, and improve the quality of healthcare outcomes. For example, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the “Affordable Care Act”) has substantially changed the way healthcare is financed by both governmental and private insurers and encourages improvements in the quality of healthcare items and services. In the future, additional changes could be made to governmental healthcare programs that could significantly impact the success of our products. This legislation and regulation may result in decreased reimbursement for medical devices, which may create additional pressure to reduce the prices charged for medical devices. Reduced reimbursement rates could significantly decrease our revenue, which in turn would place significant downward pressure on our gross margins and impede our ability to become profitable. Further, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 (the “IRA 2022”) into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in the Affordable Care Act marketplaces through plan year 2025. The IRA 2022 also eliminates the “donut hole” under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and through a newly established manufacturer discount program.

We cannot predict which, if any, additional healthcare reform proposals will be adopted, when they may be adopted or what impact they may have on the existing regulatory environment, or our ability to operate our business. Any of these factors could have a material adverse effect on our operating results and financial condition.

In the EU, the MDR became applicable on May 26, 2021, repealing and replacing both the MDD and Directive 90/385/EEC on active implantable medical devices. The MDR establishes transitional provisions. However, the changes to the regulatory system implemented in the EU by the MDR include stricter requirements for clinical evidence and pre-market assessment of safety and performance, new classifications to indicate risk levels, requirements for third party testing by Notified Bodies, tightened and streamlined quality management system assessment procedures and additional requirements for the quality management system, additional requirements for traceability of products and transparency as well a refined responsibility of economic operators. We are also required to provide clinical data in the form of a clinical evaluation report. Fulfillment of the obligations imposed by the MDR may cause us to incur substantial costs. We may be unable to fulfil these obligations, or our Notified Body may consider that we have not adequately demonstrated compliance with our related obligations to merit a CE Certificate of Conformity on the basis of the MDR.

Moreover, in the EU, some EU Member States may, after a medical device is CE marked, require the completion of additional studies that compare the cost-effectiveness of a particular medical device candidate to currently available therapies. This Health Technology Assessment, or HTA process, which is currently governed by the national laws of the individual EU Member States, is the procedure according to which the assessment of the public health impact, therapeutic impact and the economic and societal impact of use of a given medical device in the national healthcare systems of the individual country is conducted. The outcome of HTA regarding specific medical device will often influence the pricing and reimbursement status granted to these products by the competent authorities of individual EU Member States. In December 2021, Regulation No 2021/2282 on HTA, amending Directive 2011/24/EU, was adopted in the EU. This Regulation, which entered into force in January 2022 will apply as of January 2025. It is intended to boost cooperation among EU Member States in assessing health technologies, including new medical devices, and providing the basis for cooperation at EU level for joint clinical assessments in these areas. The Regulation will permit EU Member States to use common HTA tools, methodologies, and procedures across the EU to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual EU Member States will continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technologies, and making decisions on pricing and reimbursement. If the conclusions of these assessments are negative, or compare our products unfavorably with competing products, this may impact our pricing and reimbursement status. If we are unable to obtain or maintain favorable pricing and reimbursement status in EU Member States for our medical devices or medical devices that we may successfully develop and for which we may obtain certification, any anticipated revenue from and growth prospects for those products in the EU could be negatively affected.

In addition, the exit of the UK from the EU, commonly referred to as “Brexit” could lead to further regulatory divergence between the EU and the UK. On May 26, 2021, the MDR became applicable in the EU. However, the MDR is not applicable in the UK. In the UK, medical devices are governed by the Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002) which, for the time being, retains a regulatory framework similar to the framework set out by the MDD. The government plans to introduce new legislation governing medical devices with an aim for core aspects of the future regime for medical devices to apply from July 1, 2025. New legislation has been proposed and is also anticipated for adoption during 2024 to bring into force strengthened post-market surveillance requirements ahead of the wider future regulatory regime. Should the UK or Great Britain further diverge from the EU from a regulatory perspective, tariffs could be put into place in the future. We could therefore, both now and in the future, face significant additional expenses to operate our business, which could significantly and materially harm or delay our ability to generate revenue or achieve profitability of our business. Any further changes in international trade, tariff and import/export regulations as a result of Brexit or otherwise may impose unexpected duty costs or other non-tariff barriers on us. These developments, or the perception that any of them could occur, may significantly reduce global trade and, in particular, trade between the EU and the UK.

Governments outside the United States tend to impose strict price controls, reimbursement approval and rebate policies, which may adversely affect our ability to generate revenue.

In some countries, particularly EU countries and EFTA member states, the pricing, reimbursement and rebates of health products is subject to governmental control, and in such countries, there can be considerable pressure by governments and other stakeholders on prices, as well as reimbursement and rebates. If reimbursement of our products is unavailable or limited in scope or amount or if pricing or rebates are set at unsatisfactory levels in any such country, our prospects for generating revenue outside of the United States, if any, could be adversely affected and our business could be harmed. For example, in August 2023, a rebate agreement with the French Comité économique des produits de santé (CEPS) for sales of our t:slim X2 with Control-IQ pump in France went into effect. The rebate agreement with CEPS provides for specified reimbursements and requires specified rebates be paid, and we are currently in the process of determining the impact and allocation of such reimbursements and rebates under the agreement. While we currently cannot estimate the amount of such reimbursements and rebates that will be allocable to us, we may ultimately determine that we need to pay all or a portion of the rebates. Any such rebates that we are required to pay could adversely affect our ability to generate revenue from sales of t:slim X2 with Control-IQ in France.

General Risks

The price of our common stock may continue to fluctuate significantly.

The trading price of our common stock has been and will continue to be volatile in response to a variety of factors, including the following:

- actual or anticipated fluctuations in our financial and operating results from period to period;
- market acceptance of our current products and products under development, and the recognition of our brand;
- introduction of proposed products, technologies or treatment techniques by us or our competitors;
- announcements of significant contracts, acquisitions, divestitures or partnerships by us, our competitors or our collaboration partners;
- regulatory clearance, certification, or approval of our products or the products of our competitors or collaboration partners, or the failure to obtain such clearances, certifications, or approvals on the projected timeline or at all;
- the announcement of a product recall, suspension or other safety notice associated with our products or the products of our competitors, or other similar regulatory enforcement actions;
- financial and operating results relative to the expectations of securities analysts and other market participants and the issuance of securities analysts’ reports or recommendations;
- threatened or actual litigation, regulatory proceedings, or government investigations; and

- general political or economic conditions.

In addition, the trading price of our common stock may fluctuate substantially due to other factors, including the numerous risks and uncertainties described in this section. Fluctuations in our stock price may negatively affect the liquidity of our common stock, which could further impact our stock price. Further, our common stock may be susceptible to significant price and volume fluctuations as a result of stock market dynamics, which may impact our common stock without regard to our financial condition or operating performance. Given the competitiveness of the life sciences and medical device industry, the prices at which our common stock trades may fluctuate more significantly than might otherwise be typical, even with other market conditions, including general volatility, held constant. This volatility could negatively impact our ability to raise additional capital or utilize equity as consideration in any acquisition transactions we may pursue, and could make it more difficult for existing stockholders to sell their shares of the common stock at a price they consider acceptable or at all.

Anti-takeover provisions in our organizational documents and Delaware law may delay or prevent a change of control, which could reduce our stock price and prevent our stockholders from removing our current board of directors.*

Our amended and restated certificate of incorporation and bylaws contain provisions that could delay or prevent a change of control of our company or changes in our board of directors that our stockholders might consider favorable. Some of these provisions:

- authorize the issuance of preferred stock with powers, preferences and rights that may be senior to our common stock, which can be created and issued by the board of directors without prior stockholder approval;
- provide for the removal of a director only with cause and then by the affirmative vote of the holders of a majority of the outstanding shares;
- prohibit stockholders from calling special stockholder meetings;
- prohibit stockholders from acting by written consent without holding a meeting of stockholders;
- require the vote of at least two-thirds of the outstanding shares to approve amendments to the certificate of incorporation or bylaws; and
- require advance written notice of stockholder proposals and director nominations.

We are also subject to the provisions of Section 203 of the Delaware General Corporation Law, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These and other provisions in our amended and restated certificate of incorporation, bylaws and Delaware law could make it more difficult for stockholders or potential acquirers to obtain control of our board of directors or initiate actions that are opposed by our then-current board of directors, including a merger, tender offer or proxy contest involving our company. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.*

Under current law, federal net operating losses (NOLs) incurred in tax years beginning after December 31, 2017, may be carried forward indefinitely, but the deductibility of such federal NOL carryforwards in a taxable year is limited to 80% of taxable income in such year. As of December 31, 2023, we had accumulated federal and state NOL carryforwards of approximately \$168.0 million, and \$262.4 million, respectively. Of the total federal NOL carryforwards, approximately \$78.4 million were generated after January 1, 2018, and therefore do not expire under current law but can only be utilized to offset 80% of future taxable income. The remaining federal NOL carryforwards of \$89.6 million will begin to expire in 2033, and state tax loss carryforwards continue to expire.

In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, and corresponding provisions of state law, if a corporation undergoes an “ownership change,” which is generally defined as a greater than 50% change in its equity ownership value over a three-year period, the corporation’s ability to use its pre-change NOL and research credit carryforwards may be subject to substantial limitations, which could cause U.S. federal income taxes to be paid earlier than would be paid if such limitations were not in effect and could cause NOL carryforwards to expire unused. Similar rules may apply under state tax laws. In addition, there may be other limitations under state law on our ability to utilize NOL carryforwards, including temporary suspensions or other limitations on the use of NOL carryforwards to offset taxable income. We believe we experienced at least one ownership change that significantly reduced our ability to utilize our pre-2018 NOL and research credit carryforwards before they expire. Additionally, future ownership changes under Section 382 may also limit our ability to fully utilize any remaining tax benefits.

Uncertainties in the interpretation and application of existing, new and proposed tax laws and regulations could materially affect our tax obligations and effective tax rate.

The tax regimes to which we are subject or under which we operate are unsettled and may be subject to significant change. The issuance of additional guidance related to existing or future tax laws, or changes to tax laws or regulations proposed or implemented by the current or a future United States presidential administration, Congress, or taxing authorities in other jurisdictions, including jurisdictions outside of the United States, could materially affect our tax obligations and effective tax rate. To the extent that such changes have a negative impact on us, including as a result of related uncertainty, these changes may adversely impact our business, financial condition, results of operations, and cash flows.

The amount of taxes we pay in different jurisdictions depends on the application of the tax laws of various jurisdictions, including the United States, to our international business activities, tax rates, new or revised tax laws, or interpretations of tax laws and policies, and our ability to operate our business in a manner consistent with our corporate structure and intercompany arrangements. The taxing authorities of the jurisdictions in which we operate may challenge our methodologies for pricing intercompany transactions pursuant to our intercompany arrangements or disagree with our determinations as to the income and expenses attributable to specific jurisdictions. If such a challenge or disagreement were to occur, and our position was not sustained, we could be required to pay additional taxes, interest, and penalties, which could result in one-time tax charges, higher effective tax rates, reduced cash flows, and lower overall profitability of our operations. Our financial statements could fail to reflect adequate reserves to cover such a contingency. Similarly, a taxing authority could assert that we are subject to tax in a jurisdiction where we believe we have not established a taxable connection, often referred to as a “permanent establishment” under international tax treaties, and such an assertion, if successful, could increase our expected tax liability in one or more jurisdictions.

Effective January 1, 2022, the Tax Cuts and Jobs Act of 2017 eliminated the option to deduct research and development expenses for tax purposes in the year incurred and requires taxpayers to capitalize and subsequently amortize such expenses over five years for research activities conducted in the United States and over 15 years for research activities conducted outside the United States. Although there have been legislative proposals to repeal or defer the capitalization requirement to later years, there can be no assurance that the provision will be repealed or otherwise modified. Future guidance from the Internal Revenue Service and other tax authorities with respect to such legislation may affect us, and certain aspects of such legislation could be repealed or modified in future legislation.

Our tax obligations and effective tax rate in the jurisdictions in which we conduct business could increase, including as a result of the base erosion and profit shifting (BEPS) project that is being led by the Organization for Economic Co-operation and Development (OECD), and other initiatives led by the OECD or the European Commission. For example, the OECD is leading work on proposals, commonly referred to as “BEPS 2.0,” which, if and to the extent implemented, would make important changes to the international tax system. These proposals are based on two “pillars,” involving the reallocation of taxing rights in respect of certain multinational enterprises above a fixed profit margin to the jurisdictions in which they carry on business (subject to certain revenue threshold rules which we do not currently meet but may meet in the future) (referred to as “Pillar One”) and imposing a minimum effective corporate tax rate on certain multinational enterprises (referred to as “Pillar Two”). A number of countries in which we conduct business, including through our subsidiaries, such as the Netherlands and Switzerland, have enacted with effect from January 1, 2024, or are in the process of enacting, core elements of the Pillar Two rules. Based on our current understanding of the minimum revenue thresholds contained in the Pillar Two proposal, we expect that we are likely to fall within the scope of its rules in the short-to-medium term. The OECD has issued administrative guidance providing transition and safe harbor rules in relation to the implementation of the Pillar Two proposal. We are monitoring developments and evaluating the potential impacts of these new rules, including on our effective tax rates, and considering our eligibility to qualify for these safe harbor rules.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud, which could harm our business and result in a decline in the trading price of our common stock.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement adequate controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations, or to prevent the circumvention of our controls or fraud. For example, Mr. Sheridan, our principal executive officer, and Ms. Vosseller, our principal financial and accounting officer, are involved in a personal relationship and share a primary residence. While our board of directors is informed of the relationship and appropriate actions have been taken to ensure compliance with SEC rules and Company policies and procedures, the existence of this relationship could create additional risk, or the perception of additional risk, that our controls and procedures may not be effective. In addition, any testing by us conducted in connection with Section 404(a) of the Sarbanes-Oxley Act, or any testing conducted by our independent registered public accounting firm in connection with Section 404(b) of the Sarbanes-Oxley Act may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses, may require prospective or retroactive changes to our consolidated financial statements, or may identify other areas for further attention or improvement. Any failure to implement appropriate internal controls could also cause investors to lose confidence in our reported financial information, which could harm our business and result in a decline in the trading price of our common stock.

Risks Related to Our Indebtedness

We have incurred a significant amount of indebtedness, and the agreements governing such indebtedness subject us to required debt service payments, as well as financial and operational covenants, any of which may restrict our financial flexibility and affect our ability to operate our business.*

From time to time, we have financed our liquidity needs under various credit arrangements and we may borrow additional funds in the future. For example, in May 2020, we completed the offering of \$287.5 million aggregate principal amount of 1.50% Convertible Senior Notes due 2025 (the 2025 Notes), which are governed by the terms of an indenture (the 2025 indenture). In March 2024, we completed the offering of \$316.25 million aggregate principal amount of 1.50% Convertible Senior Notes due 2029 (the 2029 Notes and, together with the 2025 Notes, the Notes), which are governed by the terms of an indenture (the 2029 indenture and, together with the 2025 Notes, the indentures). In March 2024, we used the proceeds from the offering of the 2029 Notes to repurchase approximately \$246.7 million aggregate principal amount of the 2025 Notes in privately negotiated transactions with holders of the 2025 Notes and as of September 30, 2024, we had approximately \$40.8 million aggregate principal amount of the 2025 Notes outstanding. The Notes are our senior unsecured obligations, and interest on the Notes is payable in cash semi-annually at a rate of 1.50% per year.

Our failure to comply with certain obligations under the Notes, or inability to make required debt service payments, could result in an event of default under the relevant indenture. A default, if not cured or waived, could result in acceleration of the indebtedness, which could have a material adverse effect on our business, financial condition and liquidity. Further, if our indebtedness is accelerated, we cannot be certain that cash will be available to pay the indebtedness and we may not have the ability to refinance the indebtedness on terms satisfactory to us or at all.

In addition, our current or future level of indebtedness could affect our business, operations and strategy in several important ways, including the following:

- we may be required to dedicate a portion of our current liquidity or cash flow from operations to interest payments, limiting the availability of cash for other purposes;
- covenants contained in future agreements governing indebtedness may limit our ability to borrow additional funds, refinance indebtedness or make certain investments;
- debt covenants may affect our flexibility in planning for, and reacting to, changes in the economy and our industry;
- a high level of indebtedness may increase our vulnerability to adverse economic and competitive conditions; and
- a high level of indebtedness may limit our ability to obtain additional financing in the future or negatively impact the terms on which additional financing may be obtained.

Servicing the Notes will require a significant amount of cash, and we may not have sufficient cash flow from our business to repay the Notes.

Our ability to make scheduled payments of the principal and interest on the Notes, or to refinance the Notes depends on our future business operations and liquidity, which are subject, to numerous risks and uncertainties, including, market acceptance of our products, regulatory clearance, certification, or approval for our products, and the competitive environment in which we operate. Our business may not generate or sustain a level of cash flow from operations sufficient to service the Notes and any future indebtedness we may incur. If we are unable to generate sufficient cash flow, we may be required to adopt one or more alternatives, such as reducing or delaying capital expenditures, selling or licensing assets, refinancing indebtedness, or obtaining additional equity capital. Our ability to successfully engage in these activities will depend on a number of factors, including the value of our assets, our operating results and financial condition, the value of our common stock, and the status of the capital markets 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 under the Notes, or our future indebtedness.

In addition, we may from time to time seek to retire or purchase our outstanding debt, including the Notes, through cash purchases and/or exchanges for equity securities, in open market purchases, privately negotiated transactions or otherwise. Such repurchases or exchanges, if any, will depend on prevailing market conditions, our liquidity requirements, contractual restrictions, and other factors. The amounts involved in any such transactions, individually or in the aggregate, may be material. Further, any such purchases or exchanges may result in us acquiring and retiring a substantial amount of such indebtedness, which could impact the trading liquidity of such indebtedness.

We may not have sufficient cash or be able to obtain financing to repurchase the Notes upon a fundamental change, or to settle conversions of the Notes.*

Holders of the Notes have the right to require us to repurchase their Notes upon the occurrence of a fundamental change (as defined in the applicable indenture governing the Notes) at a repurchase price equal to 100% of the principal amount of the Notes to be repurchased, plus accrued and unpaid interest, if any. In addition, upon conversion of the Notes, unless we elect to deliver solely shares of our common stock to settle such conversion, we will be required to settle all or a portion of our conversion obligation through the payment of cash, which could adversely affect our liquidity. However, we may not have enough available cash or be able to obtain financing at the time we are required to make repurchases of the Notes or settle conversions of the Notes. In addition, our ability to repurchase the Notes or to pay cash upon conversions of the Notes may be limited by agreements governing our future indebtedness. Our failure to repurchase Notes at a time when the repurchase is required by the indenture, or to pay any cash payable on future conversions of the Notes as required by the indenture, would constitute an event of default under the indenture. A default under an indenture, or the fundamental change itself, could also lead to a default under agreements governing our existing or future indebtedness, including the other indenture. 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 and repurchase the notes or make cash payments upon conversions thereof.

Conversion of the Notes will, to the extent we deliver shares upon conversion of such Notes, dilute the ownership interest of existing stockholders and may otherwise have a negative impact on the trading price of our common stock.

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 issued upon the conversion of the Notes could adversely affect prevailing market prices of our common stock. In addition, the perception that some or all of the Notes may be converted into shares of our common stock in the future could have a negative impact on the trading price of our common stock.

Certain provisions in the indentures governing the Notes may delay or prevent an otherwise beneficial takeover attempt.*

Certain provisions in the indenture governing the Notes may make it more difficult or expensive for a third party to acquire us. For example, the terms of the Notes require us to offer to repurchase the Notes in the event of a fundamental change and, in certain circumstances, to increase the conversion rate for a holder that converts its Notes in connection with a make-whole fundamental change (as defined in the indenture governing the Notes). A takeover of the Company may trigger the requirement that we offer to repurchase the Notes and/or increase the conversion rate of the Notes for a holder that elects to convert its Notes, which could make it more costly for a potential acquirer to engage in such takeover. These and other provisions set forth in the indenture may have the effect of delaying or preventing a takeover of the Company that would otherwise be beneficial to investors.

The Capped Call Transactions may affect the value of the Notes and our common stock.*

In connection with the issuance of the 2025 Notes, we entered into capped call transactions (the 2025 Capped Call Transactions) with certain financial institutions (the option counterparties) and in connection with the issuance of the 2029 Notes, we entered into capped call transactions (the 2029 Capped Call Transactions and, together with the 2025 Capped Call Transactions, the Capped Call Transactions) with certain financial institutions (the 2029 option counterparties and, together with the 2025 option counterparties, the option counterparties). The Capped Call Transactions are expected generally to reduce the potential dilution to our common stock upon any conversion of the Notes and/or offset any cash payments we are required to make in excess of the principal amount of converted Notes, as the case may be, with such reduction and/or offset subject to a cap.

The option counterparties 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 or other securities of ours in secondary market transactions before the applicable maturity of the Notes. This activity could also cause or avoid an increase or a decrease in the market price of our common stock or the Notes, which could affect a Note holder's ability to convert the Notes.

The potential effect, if any, of any of these transactions and activities on the market price of our common stock or the Notes will depend in part on market conditions and cannot be ascertained at this time, but any of these activities could adversely affect the value of our common stock and the value of the Notes and, under certain circumstances, the ability of the Note holders to convert the Notes.

We are subject to counterparty risk with respect to the Capped Call 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 Capped Call Transactions. 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 the Capped Call Transaction with such option counterparty. Our exposure will depend on many factors but, in general, an increase in our exposure will be correlated to an increase in the market price and volatility of our common stock. In addition, upon a default by an option counterparty, we may suffer more dilution than we currently anticipate with respect to our common stock.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

None.

Item 5. Other Information.

None.

Item 6. Exhibits.

Exhibit Number	Exhibit Description	Incorporated by Reference			Exhibit Number	Provided Herewith
		Form	File No.	Date of First Filing		
3.1	<u>Amended and Restated Certificate of Incorporation of the Registrant (as amended and currently in effect).</u>	10-Q	001-36189	August 3, 2023	3.1	
3.2	<u>Amended and Restated Bylaws of the Registrant (as amended and currently in effect).</u>	10-Q	001-36189	August 3, 2023	3.2	
31.1	<u>Certification of John F. Sheridan, Chief Executive Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u>					X
31.2	<u>Certification of Leigh A. Vosseller, Chief Financial Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u>					X
32.1*	<u>Certification of John F. Sheridan, Chief Executive Officer, pursuant to U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</u>					X
32.2*	<u>Certification of Leigh A. Vosseller, Chief Financial Officer, pursuant to U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</u>					X
101.INS	Inline XBRL Instance 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 (embedded within the Inline XBRL Document contained in Exhibit 101).					X

* This certification is not deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, 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 the registrant 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.

Tandem Diabetes Care, Inc.

Dated: November 6, 2024

By: /s/ John F. Sheridan

John F. Sheridan
President and Chief Executive Officer
(on behalf of the registrant and as the registrant's
Principal Executive Officer)

Dated: November 6, 2024

By: /s/ Leigh A. Vosseller

Leigh A. Vosseller
Executive Vice President, Chief Financial Officer and Treasurer
(Principal Financial and Accounting Officer)

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, John F. Sheridan, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Tandem Diabetes Care, Inc.
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Tandem Diabetes Care, Inc.

By: /s/ John F. Sheridan

John F. Sheridan
President, Chief Executive Officer and Director

Dated: November 6, 2024

**CERTIFICATION OF CHIEF FINANCIAL OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Leigh A. Vosseller, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Tandem Diabetes Care, Inc.
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Tandem Diabetes Care, Inc.

By: /s/ Leigh A. Vosseller

Leigh A. Vosseller
Executive Vice President, Chief Financial Officer and
Treasurer

Dated: November 6, 2024

CERTIFICATION**Pursuant to U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002**

In connection with the Quarterly Report on Form 10-Q of Tandem Diabetes Care, Inc. (the "Company") for the period ended September 30, 2024, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, John F. Sheridan, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company as of the dates and for the periods presented.

Date: November 6, 2024

/s/ John F. Sheridan

John F. Sheridan
President, Chief Executive Officer and Director

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. Section 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing. A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

CERTIFICATION**Pursuant to U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002**

In connection with the Quarterly Report on Form 10-Q of Tandem Diabetes Care, Inc. (the "Company") for the period ended September 30, 2024, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Leigh A. Vosseller, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company as of the dates and for the periods presented.

Date: November 6, 2024

/s/ Leigh A. Vosseller

Leigh A. Vosseller
Executive Vice President, Chief Financial Officer and
Treasurer

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. Section 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing. A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.