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 June 30, 2025

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	**20-4327508**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
12400 High Bluff Drive San Diego, California	**92130**
(Address of principal executive offices)	**(Zip Code)**

(858) 366-6900
(Registrant's telephone number, including area code)

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

Title of Each Class	Trading Symbol(s)	Name of Exchange on Which Registered
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	☒	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
		Emerging growth company	☐

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 August 1, 2025, there were 67,569,471 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)

	June 30, 2025	December 31, 2024
Assets	(Unaudited)	(Note 1)
Current assets:		
Cash and cash equivalents	$ 64,112	$ 69,234
Short-term investments	251,249	369,095
Accounts receivable, net	128,443	114,585
Inventories	142,573	149,612
Prepaid and other current assets	28,440	21,965
Total current assets	614,817	724,491
Property and equipment, net	77,513	78,150
Operating lease right-of-use assets	98,436	85,306
Equity method investments	67,628	74,545
Other long-term assets	17,342	5,166
Total assets	$ 875,736	$ 967,658
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 55,838	$ 44,730
Accrued expenses	13,764	18,170
Employee-related liabilities	51,691	64,128
Current portion of convertible senior notes, net	—	40,670
Operating lease liabilities	19,888	18,208
Deferred revenue	10,516	11,831
Other current liabilities	99,993	49,312
Total current liabilities	251,690	247,049
Convertible senior notes, net - long-term	309,146	308,266
Operating lease liabilities - long-term	119,974	106,421
Deferred revenue - long-term	9,575	10,455
Other long-term liabilities	52,068	32,369
Total liabilities	742,453	704,560
Commitments and contingencies (Note 14)	—	—
Stockholders' equity:		
Common stock, $0.001 par value; 200,000 shares authorized, 67,531 and 66,264 shares issued and outstanding at June 30, 2025 and December 31, 2024, respectively.	68	66
Additional paid-in capital	1,360,251	1,312,804
Accumulated other comprehensive income (loss)	3,745	(1,947)
Accumulated deficit	(1,230,781)	(1,047,825)
Total stockholders' equity	133,283	263,098
Total liabilities and stockholders' equity	$ 875,736	$ 967,658

See accompanying notes to unaudited condensed consolidated financial statements.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Sales	$ 240,678	$ 221,910	$ 475,100	$ 413,584
Cost of sales	114,823	109,116	230,838	206,118
Gross profit	125,855	112,794	244,262	207,466
Operating expenses:				
Selling, general and administrative	109,596	94,242	223,449	184,348
Litigation and settlement expense	19,951	—	19,951	—
Research and development	48,118	49,326	98,333	95,570
Acquired in-process research and development expenses	—	—	75,217	—
Total operating expenses	177,665	143,568	416,950	279,918
Operating loss	(51,810)	(30,774)	(172,688)	(72,452)
Other income (expense), net:				
Interest income and other income (expense), net	(632)	2,824	3,561	8,138
Interest expense	(1,905)	(1,793)	(3,767)	(3,690)
Loss from equity method investments	(3,375)	—	(6,917)	—
Loss on extinguishment of debt	—	—	—	(1,268)
Total other income (expense), net	(5,912)	1,031	(7,123)	3,180
Loss before income taxes	(57,722)	(29,743)	(179,811)	(69,272)
Income tax expense (benefit)	(5,322)	1,071	3,145	4,257
Net loss	$ (52,400)	$ (30,814)	$ (182,956)	$ (73,529)
Other comprehensive income (loss):				
Unrealized gain (loss) on short-term investments	$ (98)	$ (463)	$ 325	$ (1,759)
Unrealized loss on cash flow hedges	(612)	—	(612)	—
Foreign currency translation gains (losses)	4,380	145	5,979	(863)
Comprehensive loss	$ (48,730)	$ (31,132)	$ (177,264)	$ (76,151)
Net loss per share - basic and diluted	$ (0.78)	$ (0.47)	$ (2.74)	$ (1.13)
Weighted average shares used to compute basic and diluted net loss per share	67,050	64,994	66,729	65,160

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 June 30, 2025

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at March 31, 2025	66,568	$ 67	$ 1,333,531	$ 75	$ (1,178,381)	$ 155,292
Exercise of stock options	10	—	171	—	—	171
Vesting of restricted stock units, net of shares withheld for taxes	502	1	(6,320)	—	—	(6,319)
Issuance of common stock for Employee Stock Purchase Plan	451	—	7,194	—	—	7,194
Stock-based compensation expense	—	—	25,675	—	—	25,675
Unrealized loss on short-term investments	—	—	—	(98)	—	(98)
Unrealized loss on cash flow hedges	—	—	—	(612)	—	(612)
Foreign currency translation gains	—	—	—	4,380	—	4,380
Net loss	—	—	—	—	(52,400)	(52,400)
Balance at June 30, 2025	67,531	$ 68	$ 1,360,251	$ 3,745	$ (1,230,781)	$ 133,283

Six Months Ended June 30, 2025

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2024	66,264	$ 66	$ 1,312,804	$ (1,947)	$ (1,047,825)	$ 263,098
Exercise of stock options	53	—	871	—	—	871
Vesting of restricted stock units, net of shares withheld for taxes	763	1	(11,708)	—	—	(11,707)
Issuance of common stock under Employee Stock Purchase Plan	451	1	7,194	—	—	7,195
Stock-based compensation expense	—	—	51,090	—	—	51,090
Unrealized gain on short-term investments	—	—	—	325	—	325
Unrealized loss on cash flow hedges	—	—	—	(612)	—	(612)
Foreign currency translation gains	—	—	—	5,979	—	5,979
Net loss	—	—	—	—	(182,956)	(182,956)
Balance at June 30, 2025	67,531	$ 68	$ 1,360,251	$ 3,745	$ (1,230,781)	$ 133,283

See accompanying notes to unaudited condensed consolidated financial statements.

Three Months Ended June 30, 2024

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at March 31, 2024	64,563	$ 65	$ 1,238,449	$ (935)	$ (994,515)	$ 243,064
Exercise of stock options	55	—	1,149	—	—	1,149
Vesting of restricted stock units, net of shares withheld for taxes	415	—	(10,438)	—	—	(10,438)
Issuance of common stock for Employee Stock Purchase Plan	402	—	6,286	—	—	6,286
Stock-based compensation expense	—	—	24,946	—	—	24,946
Unrealized loss on short-term investments	—	—	—	(463)	—	(463)
Foreign currency translation gains	—	—	—	145	—	145
Net loss	—	—	—	—	(30,814)	(30,814)
Balance at June 30, 2024	65,435	$ 65	$ 1,260,392	$ (1,253)	$ (1,025,329)	$ 233,875

Six Months Ended June 30, 2024

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive 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	70	—	1,397	—	—	1,397
Vesting of restricted stock units, net of shares withheld for taxes	518	—	(12,197)	—	—	(12,197)
Issuance of common stock under Employee Stock Purchase Plan	402	—	6,286	—	—	6,286
Exercise of common stock warrants	—	—	—	—	—	—
Stock-based compensation expense	—	—	46,537	—	—	46,537
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	—	—	—	(1,759)	—	(1,759)
Foreign currency translation losses	—	—	—	(863)	—	(863)
Net loss	—	—	—	—	(73,529)	(73,529)
Balance at June 30, 2024	65,435	$ 65	$ 1,260,392	$ (1,253)	$ (1,025,329)	$ 233,875

See accompanying notes to unaudited condensed consolidated financial statements.

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

	Six Months Ended June 30,	
	2025	**2024**
Operating Activities		
Net loss	$ (182,956)	$ (73,529)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation and amortization expense	8,678	8,151
Amortization of debt issuance costs	970	1,085
Provision for expected credit losses	3,577	3,723
Operating lease and other impairment charges	6,697	2,000
Accretion (amortization) of discount or premium on short-term investments	(1,780)	348
Loss from equity method investments	6,917	—
Stock-based compensation expense	51,130	46,936
Loss on extinguishment of debt	—	1,268
Acquired in-process research and development expenses	75,217	—
Other	424	335
Changes in operating assets and liabilities:		
Accounts receivable, net	(13,516)	2,862
Inventories	12,058	(5,157)
Prepaid and other current assets	(2,348)	(4,782)
Other long-term assets	3,524	93
Accounts payable and accrued expenses	5,739	241
Employee-related liabilities	(12,649)	(462)
Deferred revenue	(2,710)	(1,261)
Operating leases and other current liabilities	8,403	3,967
Other long-term liabilities	4,851	911
Net cash used in operating activities	(27,774)	(13,271)
Investing Activities		
Purchases of short-term investments	(26,496)	(177,724)
Proceeds from maturities and redemptions of short-term investments	146,447	180,051
Purchases of property and equipment	(9,171)	(10,923)
Acquisition of in-process research and development	(43,464)	—
Net cash provided by (used in) investing activities	67,316	(8,596)
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)
Principal payments on convertible senior notes due 2025	(40,760)	—
Payment for capped call transactions related to convertible senior notes due 2029	—	(15,813)
Repurchase and retirement of common stock	—	(30,000)
Cash used to settle withholding taxes on vested restricted stock, net of proceeds from issuance of common stock under Company stock plans	(3,641)	(4,513)
Other financing activities	—	183
Net cash provided by (used in) financing activities	(44,401)	10,584
Effect of foreign exchange rate changes on cash	(263)	112
Net increase (decrease) in cash and cash equivalents	(5,122)	(11,171)
Cash and cash equivalents at beginning of period	69,234	58,868
Cash and cash equivalents at end of period	$ 64,112	$ 47,697
Supplemental disclosures of cash flow information		
Income taxes paid	$ 4,892	$ 1,183
Supplemental schedule of non-cash investing and financing activities		
Operating lease right-of-use assets obtained in exchange for operating lease obligations	$ —	$ 3,783
Purchases of property and equipment included in accounts payable	$ 1,073	$ 1,505
Intangible costs in other long term-liabilities	$ 13,300	$ —

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, a global insulin delivery and diabetes technology company, manufactures and sells advanced automated insulin delivery systems that reduce the burden of diabetes management, while creating new possibilities for patients, their loved ones and healthcare providers. 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 offers an insulin pump portfolio, which 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 Company's mobile application and cloud-based diabetes management applications. The Company's durable insulin pump products generally 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, 2024 (Annual Report), from which the condensed consolidated balance sheet presented as of December 31, 2024 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 six months ended June 30, 2025, as compared to those disclosed in the Annual Report, except for the addition of the accounting policy related to derivatives and hedging activities, which is included herein.

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.

On May 21, 2025, the Company and various Roche entities (collectively "Roche") entered into a Settlement, Mutual Release and Cross-License Agreement (the "Settlement Agreement"). The Settlement Agreement resolved all actual or potential patent disputes as of the agreement date, including the actions pending before courts of the Unified Patent Court in France and Germany.

Under the terms of the Settlement Agreement, the Company agreed to pay Roche $36.0 million over a four-year period, with an initial cash payment of $8.0 million and four equal annual installments thereafter. The installment payments include approximately $4.4 million of imputed interest. As a result, the Company recorded a $31.6 million liability, representing the present value of the total settlement obligation. Upon payment of the initial installment, which occurred in the second quarter of 2025, both parties granted each other non-exclusive, non-royalty-bearing, non-transferrable, and irrevocable licenses to their respective insulin delivery system-related patents and applications for a period of 10 years.

The Company allocated the present value of the settlement consideration between the value of the licensed patents and the release of past and potential future claims. Based on a relative fair value approach, $13.3 million was capitalized as an intangible asset for the value of the license, which will be amortized over seven years, reflecting the estimated useful life of the acquired patents. The remaining consideration was expensed as settlement and litigation expense with related legal fees during the three and six months ended June 30, 2025.

The fair value of the licensed patents was estimated using a discounted cash flow model, which incorporated assumptions including projected revenues associated with the licensed technology, a technology migration rate, an estimated royalty rate, and a discount rate. The fair value of the past damages claimed was estimated based on applicable historical revenues and an estimated royalty rate.

Impairment of Long-Lived Assets

Long-lived assets, such as property and equipment, right-of-use lease assets, and acquired intangible assets subject to amortization, are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. If circumstances require a long-lived asset or asset group to be tested for possible impairment, the Company first compares undiscounted cash flows expected to be generated by that asset or asset group to its carrying amount. If the carrying amount of the long-lived asset or asset group is not recoverable on an undiscounted cash flow basis, an impairment is recognized to the extent that the carrying amount exceeds its fair value. Fair value is determined using unobservable (Level 3) inputs, including discounted cash flow models, future estimated sublease income, and third-party independent appraisals, as considered necessary. There is uncertainty in the projected undiscounted future cash flows used in the Company's impairment review analysis, which requires the use of estimates and assumptions. If actual performance does not meet or exceed projected performance, or if the assumptions used in the model change in the future, the Company may be required to recognize additional impairment charges in future periods. Other than the impairment of operating lease right-of-use assets recognized in the first half of 2025 (see Note 6, "Leases"), there were no other impairments of long-lived assets, including acquired intangible assets, during the three and six months ended June 30, 2025 and 2024.

Equity Method Investments

The Company held equity method investments of $67.6 million and $74.5 million at June 30, 2025 and December 31, 2024, respectively. The Company uses the equity method to account for investments in companies if it owns more than 20% of the investee company's outstanding equity or the investment provides the Company with the ability to exercise significant influence but not control over the operating and financial policies of the investee. The Company assesses whether it has significant influence by considering various factors, including the nature and magnitude of the investment, voting rights held and participation in the governance of the investee, if any. The Company may also consider additional relevant factors, such as the presence of other business relationships.

The Company's condensed consolidated net loss included its proportionate share of the net loss of its equity method investee, which was $3.4 million and $6.9 million for the three and six months ended June 30, 2025, respectively. For the three and six months ended June 30, 2024, the Company did not hold any equity method investments and therefore did not recognize a share of net income or loss from any equity method investments.

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, prompt payment discounts and a provision for product 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 net consideration to which the Company expects to be entitled, based either on the stated value in contractual arrangements or the estimated cash to be collected in non-contracted arrangements. The Company includes an estimate of variable consideration in the calculation of the transaction price at the time of sale. Variable consideration includes, but is not limited to: rebates, prompt payment discounts and a provision for product returns. The Company classifies these items as a reduction of accounts receivable when it is not required to make a payment and as a liability when it is required to make a payment.

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.

Variable Consideration

The amount of variable consideration that is included in the transaction price is included in revenue only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. The Company is subject to certain rebates on pricing programs with managed care organizations, such as pharmacy benefit managers and governmental and third-party commercial payors, and may vary by customer. The Company estimates provisions for rebates based on contractual arrangements, estimates of products sold subject to rebate, known market 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 consolidated financial statements.

Revenue Recognition for Tandem Choice Program

From September 2022 to December 31, 2024, the Company offered a technology access program referred to as Tandem Choice that provided eligible in-warranty t:slim X2 customers in the United States with the flexibility to obtain the Tandem Mobi, once commercially available. The Company determined that the program created a material right for which a portion of each t:slim X2 pump sales transaction price was allocated and deferred. The Company began selling Tandem Mobi insulin pumps in February 2024 and eligibility for the Tandem Choice program ended at that time. Consequently, the Company ceased allocating and deferring 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 had until December 31, 2024 to exercise the option to switch to the Tandem Mobi for a stated fee.

The Company recognized the deferred sales when the obligations under the Tandem Choice program were satisfied. If a customer elected to participate in the program, the Company recognized upgrade fees received, and the associated cost of goods sold, at the time of fulfillment. The remaining deferrals were recognized at program expiration on December 31, 2024. For the six months ended June 30, 2024, the Company deferred $1.1 million of pump sales as the result of Tandem Choice, and recognized incremental sales of $0.2 million from individual Tandem Choice fulfillments. There was no comparative adjustment to pump sales in 2025.

Derivative Instruments and Hedging Activities

The Company records the fair value of derivative instruments as either current assets or current liabilities on the condensed consolidated balance sheets. Changes in the fair value of derivative instruments are recorded each period in current earnings or other comprehensive income (loss), depending on whether a derivative instrument is designated as part of a hedging transaction. For a derivative to qualify as a hedge at inception and throughout the hedged period, the Company formally documents the nature and relationships between the hedging instrument and hedged item.

For derivatives formally designated as hedges, the Company assesses both at inception and quarterly thereafter, whether the hedging derivatives are highly effective in offsetting changes in either the fair value or cash flows of the hedged item.

Gains or losses on cash flow hedges are reclassified from other comprehensive income (loss) to earnings when the hedged transaction occurs and affects consolidated results. If the Company determines that a forecasted transaction is no longer probable of occurring, the Company discontinues hedge accounting and any related unrealized gain or loss on the derivative instrument is recognized in current earnings.

Derivatives that are not designated and do not qualify as hedges are adjusted to fair value through current earnings.

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. In addition, 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 primarily estimated based on the current expected product replacement cost and expected replacement rates using historical experience. Returned insulin pumps may be refurbished and redeployed.

Experience has shown that initial data for any new pump version or pump platform may be insufficient. Therefore, the Company relies on long-term historical replacement data from existing platforms until sufficient data is available. As actual experience accumulates, the Company adjusts its warranty reserve estimate accordingly. In addition, the availability of replacement data may differ by country due to local compliance and privacy regulations, which may require the Company to estimate its warranty liability using available information or data from similar markets. The Company may make further adjustments to the warranty reserve when appropriate, considering revised expectations of product performance based on enhanced hardware, 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 consolidated statements of operations.

The following table provides a reconciliation of the changes in product warranty liabilities for the three and six months ended June 30, 2025 and 2024 (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Balance at beginning of the period	$ 52,210	$ 37,638	$ 51,408	$ 37,173
Provision for warranties issued during the period	9,656	9,581	18,473	19,990
Settlements made during the period	(9,308)	(9,062)	(17,699)	(18,099)
Increases (decreases) in warranty estimates	1,645	(801)	2,021	(1,708)
Balance at end of the period	$ 54,203	$ 37,356	$ 54,203	$ 37,356

As of June 30, 2025 and December 31, 2024, total product warranty reserves were included in the following consolidated balance sheet accounts (in thousands):

	June 30, 2025	December 31, 2024
Other current liabilities	$ 32,648	$ 31,048
Other long-term liabilities	21,555	20,360
Total warranty reserve	$ 54,203	$ 51,408

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 employee 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 Loss Per Share

Basic net loss per share is calculated by dividing the net loss by the weighted average number of common shares outstanding for the period, without consideration for common stock equivalents. Diluted net 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 six months ended June 30, 2025 and 2024, 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 in each period.

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 June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Options to purchase common stock	113	804	114	129
Unvested restricted stock units	3,117	3,322	2,734	2,865
Warrants to purchase common stock	194	194	194	194
Awards granted under the ESPP	54	59	53	29
Convertible senior notes (if-converted)	9,159	9,513	9,335	6,877
	12,637	13,892	12,430	10,094

Recently Issued Accounting Pronouncements

In December 2023, the FASB issued ASU 2023-09 Income Taxes (Topic 740): Improvements to Income Tax Disclosures, which requires the Company to disclose disaggregated jurisdictional and categorical information for the tax rate reconciliation, income taxes paid and other income tax related amounts. The guidance is effective for annual periods beginning after December 15, 2024, with early adoption permitted. The Company is currently evaluating ASU 2023-09 to determine the impact it may have on its consolidated financial statements.

Accounting Pronouncements Issued and Not Yet Adopted

In November 2024, the FASB issued ASU 2024-03 Income Statement–Reporting Comprehensive Income–Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses (ASU 2024-03), which requires entities to disclose information about purchases of inventory, employee compensation, and intangible asset amortization in each income statement line item that contains those expenses. ASU 2024-03 is effective for annual reporting periods beginning after December 15, 2026 and interim reporting periods beginning after December 15, 2027. Early adoption is permitted. The Company is currently evaluating ASU 2024-03 to determine the impact it may have on its consolidated financial statements.

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 June 30, 2025 and December 31, 2024 (in thousands):

At June 30, 2025	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Estimated Fair Value
Available-for-sale securities:				
United States Government-sponsored enterprises	$ 105,369	$ 640	$ —	$ 106,009
United States Treasury securities	72,791	63	(51)	72,803
Commercial paper	1,726	—	(1)	1,725
Corporate debt securities	70,600	122	(10)	70,712
Total	$ 250,486	$ 825	$ (62)	$ 251,249

At December 31, 2024	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Estimated Fair Value
Available-for-sale securities:				
United States Government-sponsored enterprises	$ 133,139	$ 275	$ (134)	$ 133,280
United States Treasury securities	103,645	197	(140)	103,702
Commercial paper	23,225	39	—	23,264
Corporate debt securities	105,635	248	(47)	105,836
Foreign government bonds	3,013	—	—	3,013
Total	$ 368,657	$ 759	$ (321)	$ 369,095

The contractual maturities of available-for-sale debt securities as of June 30, 2025, were as follows (in thousands):

	Years to Maturity			
At June 30, 2025	Within One Year	One to Two Years	Two to Three Years	Estimated Fair Value
United States Government-sponsored enterprises	$ 13,244	$ 82,700	$ 10,065	$ 106,009
United States Treasury securities	61,902	10,901	—	72,803
Commercial paper	1,725	—	—	1,725
Corporate debt securities	35,147	35,565	—	70,712
Total	$ 112,018	$ 129,166	$ 10,065	$ 251,249

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 June 30, 2025 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 June 30, 2025 and December 31, 2024 (in thousands):

	June 30, 2025	December 31, 2024
Accounts receivable	$ 134,538	$ 121,836
Less: allowance for credit losses	(6,095)	(7,251)
Accounts receivable, net	$ 128,443	$ 114,585

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 six months ended June 30, 2025 and 2024 (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Balance at beginning of the period	$ 7,125	$ 4,923	$ 7,251	$ 4,898
Provision for expected credit losses	2,146	1,525	3,577	3,723
Write-offs and adjustments, net of recoveries	(3,176)	(1,223)	(4,733)	(3,396)
Balance at end of the period	$ 6,095	$ 5,225	$ 6,095	$ 5,225

Inventories

Inventories consisted of the following at June 30, 2025 and December 31, 2024 (in thousands):

	June 30, 2025	December 31, 2024
Raw materials	$ 31,077	$ 32,602
Work-in-process	28,957	33,517
Finished goods	82,539	83,493
Total inventories	$ 142,573	$ 149,612

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 June 30, 2025 and December 31, 2024, 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 June 30, 2025			
	Total	Level 1	Level 2	Level 3
Assets				
Cash equivalents[1]	$ 53,993	$ 53,993	$ —	$ —
Available-for-sale securities:				
United States Government-sponsored enterprises	106,009	—	106,009	—
United States Treasury securities	72,803	72,803	—	—
Commercial paper	1,725	—	1,725	—
Corporate debt securities	70,712	—	70,712	—
Total assets	$ 305,242	$ 126,796	$ 178,446	$ —
Liabilities				
Foreign exchange forward contracts	$ 612	$ —	$ 612	$ —
Total liabilities	$ 612	$ —	$ 612	$ —

	Fair Value Measurements at December 31, 2024			
	Total	Level 1	Level 2	Level 3
Assets				
Cash equivalents[1]	$ 56,234	$ 56,234	$ —	$ —
United States Government-sponsored enterprises	133,280	—	133,280	—
United States Treasury securities	103,702	103,702	—	—
Commercial paper	23,264	—	23,264	—
Corporate debt securities	105,836	—	105,836	—
Foreign government bonds	3,013	—	3,013	—
Total assets	$ 425,329	$ 159,936	$ 265,393	$ —

(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 June 30, 2025 and 2024, 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 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	
	June 30, 2025	December 31, 2024
Convertible Senior Notes due 2025	$ —	$ 39,130
Convertible Senior Notes due 2029	304,514	407,752
Total fair value of outstanding convertible senior notes	$ 304,514	$ 446,882

6. Leases

The Company's leases consist of operating leases for facility space to support general office, 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.

Headquarters Lease

In September 2021, the Company entered into a lease agreement for 181,949 square feet of general administrative, laboratory, and research and development office space (the Premises) located on High Bluff Drive in San Diego, California (Headquarters Lease). Possession of the Premises was to be tendered to the Company in two phases, with Phase I consisting of 143,850 rentable square feet, which commenced in 2022, and Phase II consisting of 38,099 rentable square feet, which commenced in the first quarter of 2025. The Headquarters Lease term expires in April 2035. The Company has two options to extend the term of the lease, with each option providing for an additional period of five years. The Headquarters Lease term was determined assuming the renewal options would not be exercised.

In December 2023, the Company entered into an agreement to sublease the Phase II portion of the leased premises under the Headquarters Lease, from January 2025 through March 2029, for which accounting commenced in January 2025. Future minimum payments for base rent due under Phase II of the Headquarters Lease, net of sublease rent, are estimated to be $3.0 million in total for 2025 through 2028, and $22.2 million in total for 2029 through 2035.

The Company recognizes the sublease income on a straight-line basis over the term of the sublease which is classified in the Company's condensed consolidated statements of operations and comprehensive loss as a reduction of rent expense in selling, general and administrative expense (SG&A). The difference between sublease income recognized and cash received from the subtenant accrues as a deferred rent receivable.

Operating Lease Impairment Charges

As part of our evaluation of the sublease agreement related to the Headquarters Lease, the Company compared the estimated undiscounted sublease income to the net book value of the underlying right of use asset. Because the expected sublease income was less than the net book value of the sublease assets, the Company recorded a $3.6 million impairment charge in operating expenses in the first quarter of 2025 by reducing the net book value of the subleased assets to their estimated fair value, which is determined by discounting the estimated sublease income using the estimated incremental borrowing rate of the subtenant.

Additionally, during the first quarter of 2025, the Company relocated certain development activities from Lausanne, Switzerland to the United States. The Company reviewed the relocation activities and impact of losses on certain fixed assets associated with the lease. The Company also reviewed its assumptions for estimated future sublease income for its Vista Sorrento lease. As a result, the Company recorded a $3.1 million impairment charge in operating expenses in the first quarter of 2025, comprised of operating lease impairment charges and write off of fixed assets consisting primarily of leasehold improvements.

Supplemental Lease Disclosure Information

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Operating lease cost (excluding sublease income)	$ 4,304	$ 3,564	$ 8,523	$ 7,081
Short-term lease cost	111	21	118	43
Loss on lease termination and right-of-use asset impairment charges	—	—	6,697	—
Sublease income, gross	(566)	—	(1,132)	—
Total lease cost	$ 3,849	$ 3,585	$ 14,206	$ 7,124

Maturities of operating lease liabilities at June 30, 2025 were as follows (in thousands):

Years Ending December 31,	
2025	$ 9,445
2026	20,764
2027	21,048
2028	17,630
2029	16,553
Thereafter	97,125
Total undiscounted lease payments	182,565
Less: amount representing interest	(42,703)
Present value of operating lease liabilities	139,862
Less: current portion of operating lease liabilities	(19,888)
Operating lease liabilities - long-term	$ 119,974

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

	June 30, 2025	December 31, 2024
Weighted-average remaining lease term (in years)	9.1	9.2
Weighted-average discount rate used to determine operating lease liabilities	5.7 %	5.3 %

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 six months ended June 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 certain related capped call transactions. In March 2024, the Company repurchased for cash $246.7 million aggregate principal amount of the 2025 Notes, concurrently with the pricing of the 2029 Notes in privately negotiated transactions. The 2025 Notes matured in the second quarter of 2025, and the Company settled the balance of $40.8 million using existing cash balances.

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

	June 30, 2025	December 31, 2024
Principal amount:		
Convertible Senior Notes Due 2025	$ —	$ 40,760
Convertible Senior Notes Due 2029	316,250	316,250
Total principal amount	316,250	357,010
Unamortized debt issuance costs	(7,104)	(8,074)
Total debt, net	$ 309,146	$ 348,936
Less: current portion	—	(40,670)
Long-term senior convertible notes	$ 309,146	$ 308,266

As of June 30, 2025, the if-converted value of the 2029 Notes did not exceed the principal amount. As of December 31, 2024, the if-converted value of the 2029 Notes exceeded the principal amount by $13.4 million.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Effective interest rate:				
Convertible Senior Notes Due 2025[(1)]	2.2 %	2.2 %	2.2 %	2.2 %
Convertible Senior Notes Due 2029	2.1 %	2.1 %	2.1 %	2.1 %

(1) The effective interest rate presented represents the rate applicable for the period outstanding. The 2025 Notes matured in May 2025, and the outstanding principal balance was settled using cash balances.

The following table details interest expense related to the Notes recognized for the three and six months ended June 30, 2025 and 2024 (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Contractual interest expense	$ 1,237	$ 1,339	$ 2,576	$ 2,484
Amortization of debt issuance costs	465	435	970	902
Total interest expense	$ 1,702	$ 1,774	$ 3,546	$ 3,386

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 were 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 was 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 was initially $173.18 per share of the Company's common stock and was 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 in March 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 with respect to 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. The remaining 2025 Capped Call Transactions expired when the 2025 Notes matured in May 2025.

Promissory Note Payable

In connection with the acquisition of Capillary Biomedical, Inc. in 2022, the Company assumed a $4.7 million promissory note payable. The promissory note accrues interest at the rate of 5.0% per year, and becomes due and payable upon the first sale or license of the commercialized product. At June 30, 2025 and December 31, 2024, the loan balance, including accrued interest, was $4.9 million and $4.8 million, respectively, and was included as a component of other long-term liabilities on the condensed consolidated balance sheets.

8. Stockholders' Equity

Shares Reserved for Future Issuance

The following shares of the Company's common stock were reserved for future issuance at June 30, 2025 (in thousands):

Shares reserved for issuance upon conversion of Convertible Senior Notes	9,335
Shares underlying outstanding warrants	194
Shares underlying outstanding stock options	3,054
Shares underlying unvested restricted stock units	4,351
Shares authorized for issuance pursuant to awards granted under the ESPP	2,233
Shares authorized for future equity award grants	328
Total	19,495

Common Stock Warrants

Warrants outstanding to purchase shares of the Company's common stock as of June 30, 2025 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-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 June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Cost of sales	$ 1,751	$ 1,760	$ 3,476	$ 3,830
Selling, general and administrative	16,544	15,518	32,919	28,807
Research and development	7,347	7,619	14,735	14,299
Total stock-based compensation expense	$ 25,642	$ 24,897	$ 51,130	$ 46,936

The total stock-based compensation expense capitalized as part of the cost of the Company’s inventories was $1.7 million at June 30, 2025, and $1.8 million at December 31, 2024.

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 June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
RSUs granted	1,953,827	1,694,239	2,044,370	2,052,298
Weighted average grant date fair value (per share)	$ 20.77	$ 48.30	$ 21.06	$ 44.30

Employee Stock Purchase Plan

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:

	Six Months Ended June 30,	
	2025	2024
Weighted average grant date fair value (per share)	$ 10.86	$ 21.45
Risk-free interest rate	4.1 %	5.1 %
Dividend yield	0.0 %	0.0 %
Expected volatility	74.9 %	70.2 %
Expected term (in years)	1.3	1.3

9. Derivatives

Due to the global nature of the Company's operations, a portion of revenue and operating expense are denominated in currencies other than the U.S. dollar, exposing the Company to foreign currency exchange rate fluctuations. To mitigate the impact of these fluctuations, the Company uses foreign currency forward contracts to hedge a portion of its forecasted international revenue and operating expense. The Company's foreign currency forward contracts are denominated primarily in Euros, Swiss Francs and Canadian dollars.

As of June 30, 2025, foreign currency forward contracts outstanding had durations ranging from one to three months. These contracts are designated as cash flow hedges. Unrealized gains or losses on these contracts are recorded in accumulated other comprehensive income (loss) (AOCI). Realized gains and losses of such contracts are recognized in revenue and operating expenses in the same period during which the hedged transactions affect the consolidated results of operations. The Company recognizes all cash flow hedge reclassifications from AOCI and fair value changes of excluded portions in the same line item in the condensed consolidated statements of income that has been impacted by the hedged item. The cash flow effects of our derivative contracts in the condensed consolidated statements of cash flows are included in net cash provided by operating activities. All derivative instruments are used solely for risk management purposes and are not for speculative trading purposes for up to a 90-day duration. For the periods presented, the Company did not have any non-designated hedges.

The notional value of foreign currency forward contracts outstanding related to forecasted transactions was $37.7 million as of June 30, 2025. The unrealized loss of foreign currency forward contracts was $0.6 million for the three and six months ended June 30, 2025.

The following table summarizes the effect of foreign currency forward contracts designated as hedging instruments in our condensed consolidated statements of income (in thousands):

	Three and Six Months Ended June 30, 2025
	Net Gains (Losses) Reclassified from AOCI into Operating Income
Designated cash flow hedges:	
Revenue	$ (478)
Operating expense	(27)

The Company did not enter into any foreign currency forward contracts that qualified for hedge accounting in 2024, and therefore there were no derivative assets or liabilities, nor adjustments to revenue or operating expense as a result of cash flow hedges during the three and six months ended June 30, 2024.

10. Employee Benefits

Defined Contribution Plans

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

11. Income Taxes

For the three and six months ended June 30, 2025, the Company recognized income tax benefit of $5.3 million and tax expense of $3.1 million, respectively, on a pre-tax loss of $57.7 million and $179.8 million, respectively. The Company calculated the benefit and provision for income taxes for the three and six months ended June 30, 2025, respectively, by applying an estimate of the annual effective tax rate for the full year to ordinary loss adjusted by the tax impact of discrete items. Income tax benefit and expense for the three and six months ended June 30, 2025 was primarily attributable to federal, state and foreign income tax benefit and expense as a result of current taxable losses and income in certain jurisdictions.

For the three and six months ended June 30, 2024, the Company recognized income tax expense of $1.1 million and $4.3 million, respectively, on a pre-tax loss of $29.7 million and $69.3 million, respectively. The Company calculated the provision for three and six months ended June 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 six months ended June 30, 2024 was primarily attributable to federal, state and foreign income tax expense as a result of current taxable income in certain jurisdictions.

The Company continues to maintain a full valuation allowance against its net deferred tax assets as of June 30, 2025, based on the current assessment that it is not more likely than not these future benefits will be realized before expiration.

12. 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 reporting segment because key operating decisions and resource allocations are made by the CODM using consolidated financial data. Accordingly, the Company is organized as a single operating segment and therefore a single reportable segment: Insulin Pumps and Supplies.

The Company's CODM is the Chief Executive Officer (CEO), who evaluates segment performance based on segment net income (loss) on a consolidated basis. Segment net income (loss) was consistent with the net loss amounts reported in the Company's condensed consolidated statement of operations and comprehensive loss for the three and six months ended June 30, 2025 and 2024. There were no significant segment expenses that are regularly provided to the CODM other than those reported in the Company's condensed consolidated statement of operations and comprehensive loss for the three and six months ended June 30, 2025 and 2024.

The Company's CODM is provided segment assets information on a consolidated basis for the evaluation of Company performance. Total segment assets were consistent with total assets reported in the Company's condensed consolidated balance sheets for June 30, 2025 and December 31, 2024.

Disaggregation of Revenue

Segment revenues were consistent with revenue reported in the Company's condensed consolidated statement of operations and comprehensive loss for the three and six months ended June 30, 2025 and 2024. 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 six months ended June 30, 2025 and 2024, 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 June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
United States	$ 170,209	$ 156,711	$ 320,841	$ 286,472
Outside the United States	70,469	65,199	154,259	127,112
Total Sales	$ 240,678	$ 221,910	$ 475,100	$ 413,584

Revenues by Product

During the three and six months ended June 30, 2025 and 2024, sales by product were as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Pump	$ 111,871	$ 107,875	$ 213,962	$ 195,162
Supplies and other	128,807	113,881	261,138	219,414
Net revenue recognized (deferred) for Tandem Choice program	—	154	—	(992)
Total Sales	$ 240,678	$ 221,910	475,100	413,584

Sales to distributors accounted for 61% of the Company's United States sales for both the three and six months ended June 30, 2025 and 63% and 62% for the three and six months ended June 30, 2024, respectively. Sales to distributors accounted for the vast majority of the Company's sales outside the United States for the three and six-month periods ended June 30, 2025 and 2024.

13. Acquisitions

In December 2022, the Company entered into a share purchase agreement to acquire all of the registered shares of AMF Medical (Original Transaction). AMF Medical is the original developer of the Sigi Patch Pump, which continued to be under development and was not yet commercially available as of June 30, 2025.

In the first quarter of 2023, the Company completed the acquisition of AMF Medical. The total aggregate consideration for the Original 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 consideration was to be recognized as certain defined contingencies were resolved and the respective consideration was paid or became payable.

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, including acquisition-related expenses, on its condensed consolidated statements of operations in acquired in-process research and development expenses (IPR&D).

In January 2025, the Company entered into a revised agreement that removed contingent liabilities previously included in the Original Transaction. Under the revised term, the Company agreed to pay CHF 68 million, consisting of a CHF 40 million payment made in January 2025 and a final payment of CHF 28 million due in October 2025. All other payment obligations in the Original Transaction were removed. The total amount of CHF 68 million was recognized as acquired IPR&D in the Company's condensed consolidated statement of operations and comprehensive loss. As of June 30, 2025, the remaining CHF 28 million was recorded as a short-term accrued liability for $35.2 million on the Company's condensed consolidated balance sheet.

14. Commitments and Contingencies

Legal and Regulatory Matters

In November 2023, at the Unified Patent Court (UPC), Paris Central Division (UPC Paris), the Company 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. 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 certain claims of the '231 patent. The Company contended that the t:slim X2 pump did not infringe the '231 patent and that the claims of the '231 patent were invalid over the prior art and should be revoked

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 alleged the Company's t:slim X2 insulin pump, and the offering, marketing, using, importing, possessing, and supplying of such devices infringed EP Patent No. 1 970 677 B1 (the '677 patent) and the Company alleged that the t:slim X2 pump did not infringe the '677 patent and that the claims of the '677 patent were invalid over the prior art and should be revoked.

On May 21, 2025 the Company entered into a Settlement, Mutual Release and Cross-License Agreement to resolve all actual or potential patent disputes with Roche, including related to the matters above (see Intangible Assets Subject to Amortization, Note 2, "Summary of Significant Accounting Policies").

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 June 30, 2025 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 June 30, 2025, 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 June 30, 2025 (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, the impact of our foreign currency forward hedging contracts, 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.

In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Quarterly Report, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements.

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 global insulin delivery and diabetes technology company focused on the design, development and commercialization of technology solutions that reduce the burden of diabetes management. We consider our primary addressable market to be people who live with type 1 diabetes, and recently expanded our U.S. addressable market to include people living with type 2 diabetes who require intensive insulin therapy. We sell to customers in approximately 25 countries worldwide, with the majority of our sales derived from customers in the United States. 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.

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, our portfolio includes both the t:slim X2 and 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. In the first half of 2024, we scaled the commercial release of Tandem Mobi in the United States. In May 2025, we received CE Mark approval for the Tandem Mobi insulin delivery system with Control-IQ+ technology. We are pursuing additional regulatory and pre-commercial activities, such as securing in-country registrations and reimbursement, before launching Tandem Mobi outside the United States.

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 four publications in the *New England Journal of Medicine* with the most recent in March 2025, have demonstrated that use of Control-IQ+ technology, and its predecessor Control-IQ technology, provide 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 feature allows our customers to update their pump software independently. 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 generally include new developments in our AID technology, CGM integrations and mobile app features.

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 the second quarter of 2024, we began the launch of Tandem Source outside 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.

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 redefine global leadership in insulin delivery with an accessible portfolio of transformational devices, applications and services that reduce the daily burden of living with diabetes.

In support of this strategy, our portfolio of future technologies includes enhancing the features and capabilities of our t:slim X2 and Tandem Mobi insulin pump platforms, including adding a tubeless infusion site option for Tandem Mobi users. Our development efforts also include Sigi, our ergonomic and rechargeable patch pump, in addition to extended wear infusion technology and algorithm advancement in pursuit of offering fully closed loop 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. With programs dedicated to customer retention efforts, renewal sales have become a meaningful opportunity and key growth driver for our business.

At December 31, 2024, we had more than 480,000 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, expansion 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 periodic fluctuations will continue based on 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.

- 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.

- Regulatory approval and/or upcoming launches of other new Tandem or competing 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 spending to support the product launches.

Reimbursement

- In 2025, we began implementing a multi-channel managed care strategy. Historically, our insulin pump products have generally been considered durable medical equipment (DME) with 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. In the first quarter of 2025, we began serving Tandem Mobi customers through the pharmacy channel on a scaled basis, and are preparing to serve t:slim X2 customers for their cartridges and infusion sets beginning in the fourth quarter of 2025.

- 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 consistent with current reimbursement levels, 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, uncertainty regarding tariffs and trade relations, and the effects of other macroeconomic factors and concerns have disrupted and may continue to disrupt our relationships with suppliers, third-party manufacturers, healthcare providers, distributors and our existing or potential customers, as well as impact our cost structure as more of our business is exposed to foreign currency fluctuations.

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 — Markets, Seasonality, Competition, and Product Launches" 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 Tandem Mobi for a fee once available. Eligible customers who purchased a t:slim X2 insulin pump during the program period had until December 31, 2024 to exercise the option to switch to the Tandem Mobi for a stated fee. The accounting treatment for Tandem Choice was 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. When a customer elected to participate in Tandem Choice, we recognized 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 beginning in the second quarter of 2024. The remaining deferral balance was recognized as revenue when the program ended on December 31, 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.

Litigation and Settlement Expense

Litigation and settlement expense reflects costs of litigation and settlement in conjunction with a cross-license agreement with F. Hoffmann-La Roche AG and its subsidiaries, entered into during the second quarter of 2025.

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, which do not have an alternative future use.

Other Income and Expense

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

Income Tax Expense (Benefit)

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

Results of Operations

(in thousands, except percentages)	Three Months Ended June 30, 2025	Three Months Ended June 30, 2024	Six Months Ended June 30, 2025	Six Months Ended June 30, 2024
Sales:				
United States	$ 170,209	$ 156,711	$ 320,841	$ 286,472
Outside the United States	70,469	65,199	154,259	127,112
Total sales	240,678	221,910	475,100	413,584
Cost of sales	114,823	109,116	230,838	206,118
Gross profit	125,855	112,794	244,262	207,466
Gross margin	52 %	51 %	51 %	50 %
Operating expenses:				
Selling, general and administrative	109,596	94,242	223,449	184,348
Litigation and settlement expense	19,951	—	19,951	—
Research and development	48,118	49,326	98,333	95,570
Acquired in-process research and development expenses	—	—	75,217	—
Total operating expenses	177,665	143,568	416,950	279,918
Operating loss	(51,810)	(30,774)	(172,688)	(72,452)
Other income (expense), net:				
Interest income and other income (expense), net	(632)	2,824	3,561	8,138
Interest expense	(1,905)	(1,793)	(3,767)	(3,690)
Loss from equity method investments	(3,375)	—	(6,917)	—
Loss on extinguishment of debt	—	—	—	(1,268)
Total other income (expense), net	(5,912)	1,031	(7,123)	3,180
Loss before income taxes	(57,722)	(29,743)	(179,811)	(69,272)
Income tax expense (benefit)	(5,322)	1,071	3,145	4,257
Net loss	$ (52,400)	$ (30,814)	$ (182,956)	$ (73,529)

Comparison of the Three Months Ended June 30, 2025 and 2024

Sales

For the three months ended June 30, 2025, we shipped more than 30,000 pumps worldwide. Sales were $240.7 million, which included $70.5 million of sales outside the United States. Sales were $221.9 million for the three months ended June 30, 2024, which included $65.2 million of sales outside the United States. For the three months ended June 30, 2024, we recognized incremental pump sales of $0.2 million as a result of Tandem Choice fulfillment.

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

	Three Months Ended June 30, 2025	Three Months Ended June 30, 2024
Pump	$ 85,467	$ 81,745
Supplies and other	84,742	74,812
Net revenue recognized for Tandem Choice program	—	154
Total Sales in the United States	$ 170,209	$ 156,711

Pump and supply sales in the United States increased due to growth in volumes and average selling prices. Pump shipments increased to approximately 21,000 in the second quarter of 2025, compared to approximately 20,000 in the second quarter of 2024. Sales in the second quarter of 2024 included $0.2 million in sales from Tandem Choice fulfillment, for which there was no comparable adjustment in 2025.

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

	Three Months Ended June 30,	
	2025	2024
Pump	$ 26,404	$ 26,130
Supplies and other	44,065	39,069
Total Sales Outside the United States	$ 70,469	$ 65,199

For the second quarter of 2025, total sales outside the United States increased primarily due to growth in supply volumes, improved average selling prices, geographical mix, and favorable changes in foreign exchange rates. Pump shipments decreased slightly to approximately 9,000 pumps for the second quarter of 2025 compared to nearly 10,000 pumps in the second quarter of 2024.

Cost of Sales and Gross Profit

Our cost of sales for the three months ended June 30, 2025 was $114.8 million, resulting in gross profit of $125.9 million, compared to cost of sales of $109.1 million and gross profit of $112.8 million for the same period in 2024. The gross margins for the three-month periods ended June 30, 2025 and 2024 were 52% and 51%, respectively. This increase in gross margin was primarily driven by improvement in average selling prices, partially offset by the impact of less favorable product mix and non-manufacturing costs.

Operating Expenses

Our operating expenses for the three months ended June 30, 2025 were $177.7 million, compared to $143.6 million for the three months ended June 30, 2024. The $34.1 million increase was primarily driven by $20.0 million in litigation and settlement expenses. Additionally, operating expenses increased due primarily to higher employee-related expenses.

Selling, General and Administrative Expenses. SG&A expenses were $109.6 million for the three months ended June 30, 2025, compared to $94.2 million for the same period in 2024. The increase was driven by commercial investments in the sales infrastructure, including sales force expansion in the United States, costs to support direct operations in Europe and initiatives to create future efficiencies in operations.

Litigation and Settlement Expense. Litigation and settlement expenses of $20.0 million for the three months ended June 30, 2025 related to a Settlement, Mutual Release and Cross-License Agreement with F. Hoffmann-La Roche AG and its subsidiaries (the “Cross-License Agreement”) (see *Intangible Assets Subject to Amortization,* Note 2, “Summary of Significant Accounting Policies”). We did not incur any legal settlement expenses for the three months ended June 30, 2024.

Research and Development Expenses. R&D expenses decreased to $48.1 million for the three months ended June 30, 2025, from $49.3 million for the same period in 2024. The decrease in R&D expenses was primarily due to lower employee-related expenses as a result of restructuring activities that occurred in the first quarter of 2025.

Other Income (Expense), Net

Total other income (expense), net for the three months ended June 30, 2025 was a $5.9 million loss, compared to $1.0 million of income for the same period in 2024. Other expense, net for the three months ended June 30, 2025 primarily consisted of $4.3 million of unrealized losses on foreign currency remeasurements, $3.4 million loss on equity investment and $1.9 million of interest expense which included the amortization of debt issuance costs related to our convertible senior notes, partially offset by $3.4 million of interest income earned on our cash equivalents and short-term investments. Other income, net for the three months ended June 30, 2024 was $1.0 million of income, primarily consisting of $5.3 million of interest income earned on our cash equivalents and short-term investments, partially offset by $2.0 million impairment on a strategic investment in a private company, and $1.8 million of interest expense which included the amortization of debt issuance costs.

Income Tax Expense

We recognized income tax benefit of $5.3 million on a pre-tax loss of $57.7 million for the three months ended June 30, 2025, compared to income tax expense of $1.1 million on a pre-tax loss of $29.7 million for the three months ended June 30, 2024. Income tax benefit and expense for the three months ended June 30, 2025 and 2024, respectively, was primarily attributable to federal, state and foreign income tax benefit and expense as a result of current taxable income in certain jurisdictions.

Comparison of the Six Months Ended June 30, 2025 and 2024

Sales

For the six months ended June 30, 2025, we shipped approximately 59,000 pumps worldwide. Sales were $475.1 million, which included $154.3 million of sales outside the United States. Sales were $413.6 million for the six months ended June 30, 2024, which included $127.1 million of sales outside the United States. For the six months ended June 30, 2024, we deferred $1.0 million of pump sales as the result of Tandem Choice.

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

	Six Months Ended June 30,	
	2025	2024
Pump	$ 157,608	$ 143,465
Supplies and other	163,233	143,999
Net revenue deferred for Tandem Choice program	—	(992)
Total Sales in the United States	$ 320,841	$ 286,472

Pump and supply sales in the United States increased primarily due to growth in shipment volumes and increased average selling prices. Pumps shipments increased to over 38,000 for the six months ended June 30, 2025, compared to nearly 36,000 for the six months ended June 30, 2024. Sales in the first half of 2024 were reduced by $1.0 million from net sales deferrals related to Tandem Choice, for which there were no comparable adjustments for the same period in 2025.

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

	Six Months Ended June 30,	
	2025	2024
Pump	$ 56,354	$ 51,697
Supplies and other	97,905	75,415
Total Sales Outside the United States	$ 154,259	$ 127,112

For the six months ended June 30, 2025, both pumps and pump-related supply sales increased due to a year-over-year increase in shipment volumes and average selling prices, with pump shipments growing to over 20,000 pumps in the six months ended June 30, 2025, compared to approximately 19,000 in the six months ended June 30, 2024.

Cost of Sales and Gross Profit

Our cost of sales for the six months ended June 30, 2025 was $230.8 million, resulting in gross profit of $244.3 million, compared to cost of sales of $206.1 million and gross profit of $207.5 million for the same period in 2024. The gross margins for the six-month periods ended June 30, 2025 and 2024 were 51% and 50%, respectively. This increase in gross margin was primarily driven by improved average selling prices, partially offset by the impact of less favorable product mix.

Operating Expenses

Our operating expenses for the six months ended June 30, 2025 were $417.0 million, compared to $279.9 million for the six months ended June 30, 2024. The $137.1 million increase was primarily driven by a $75.2 million charge to IPR&D in connection with the revised AMF purchase agreement (see Note 13, "Acquisitions") and a $20.0 million litigation and settlement expense, as well as costs related to operating lease impairment and restructuring charges related to relocation of certain research and development activities and sales force expansion.

Selling, General and Administrative Expenses. SG&A expenses, including one-time charges for non-recurring facility impairment costs of $6.7 million and restructuring costs of $2.2 million, were $223.4 million for the six months ended June 30, 2025, compared to $184.3 million for the same period in 2024. After one-time costs, the remaining increase was largely driven by commercial investments in sales infrastructure, including sales force expansion in the United States, costs to support direct operations in Europe and initiatives to create future efficiencies in operations.

	Six Months Ended June 30,	
	2025	2024
Selling, general and administrative	$ 214,562	$ 184,348
Non-recurring facility impairment costs	6,697	—
Restructuring costs	2,190	—
Total SG&A expenses	$ 223,449	$ 184,348

Litigation and Settlement Expense. Litigation and settlement expenses of $20.0 million for the six months ended June 30, 2025 related to the Cross-License Agreement. We did not incur any legal settlement expenses for the six months ended June 30, 2024.

Research and Development Expenses. R&D expenses, including one-time charges for non-recurring restructuring costs of $2.3 million, increased to $98.3 million for the six months ended June 30, 2025, from $95.6 million for the same period in 2024. After one-time costs, R&D expenses were relatively flat compared to the prior year.

	Six Months Ended June 30,	
	2025	2024
Research and development	$ 96,053	$ 95,570
Restructuring costs	2,280	—
Total R&D expenses	$ 98,333	$ 95,570

Acquired In-Process Research and Development (IPR&D) Expenses. Acquired IPR&D expenses were $75.2 million for the six months ended June 30, 2025, which represented costs associated with the revised AMF purchase agreement (see Note 13, "Acquisitions"). We did not incur any IPR&D expenses for the six months ended June 30, 2024.

Other Income (Expense), Net

Total other income (expense), net for the six months ended June 30, 2025 was a $7.1 million loss, compared to $3.2 million for the same period in 2024. Other expense, net for the six months ended June 30, 2025 primarily consisted of $6.9 million loss on equity investment and $3.8 million of interest expense which included the amortization of debt issuance costs related to our convertible senior notes, and $4.3 million unrealized loss from foreign currency remeasurement, offset by $7.9 million of interest income earned on our cash equivalents and short-term investments. Other income, net for the six months ended June 30, 2024 primarily consisted of $10.8 million of interest income earned on our cash equivalents and short-term investments, partially offset by $3.7 million of interest expense which included the amortization of debt issuance costs, and $1.3 million loss on debt extinguishment.

Income Tax Expense

We recognized income tax expense of $3.1 million on a pre-tax loss of $179.8 million for the six months ended June 30, 2025, compared to income tax expense of $4.3 million on a pre-tax loss of $69.3 million for the six months ended June 30, 2024. Income tax expense for the six months ended June 30, 2025 and 2024 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 June 30, 2025, we had $315.4 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 asset acquisitions, 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 six months ended June 30, 2025 and 2024 (in thousands):

	Six Months Ended June 30,	
	2025	2024
Net cash provided by (used in):		
Operating activities	$ (27,774)	$ (13,271)
Investing activities	67,316	(8,596)
Financing activities	(44,401)	10,584
Effect of foreign exchange rate changes on cash	(263)	112
Net increase (decrease) in cash and cash equivalents	$ (5,122)	$ (11,171)

Operating Activities. Net cash used in operating activities was $27.8 million for the six months ended June 30, 2025, compared to $13.3 million used in the same period in 2024. For the six months ended June 30, 2025, net loss was $183.0 million, net non-cash adjustments were $151.8 million, and the change in working capital balances was an increase of $3.4 million. For the six months ended June 30, 2024, net loss was $73.5 million, net non-cash adjustments were $63.8 million and the change in working capital balances was a decrease of $3.6 million.

Investing Activities. Net cash provided by investing activities was $67.3 million for the six months ended June 30, 2025, which primarily consisted of $146.4 million in proceeds from maturities and redemptions of short-term investments, offset by $43.5 million paid for IPR&D, $26.5 million in purchases of short-term investments, and $9.2 million in purchases of property and equipment. Net cash used in investing activities was $8.6 million for the six months ended June 30, 2024, which primarily consisted of $177.7 million in purchases of short-term investments, and $10.9 million in purchases of property and equipment, offset by $180.1 million in proceeds from maturities and redemptions of short-term investments.

Financing Activities. Net cash used in financing activities was $44.4 million for the six months ended June 30, 2025, which consisted of $40.6 million used to pay the principal of the 2025 Notes and 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 $10.6 million for the six months ended June 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, $4.5 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.

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 costs, 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 commercial resources for our growing installed customer base;
- research and product development efforts, including clinical trial costs;
- acquisitions, including strategic investments, equity method investments and future contingent payments associated with acquisitions;
- 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, 2024.

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 six months ended June 30, 2025 contained in Part II, Item 7A of our Annual Report on Form 10-K for the fiscal year ended December 31, 2024, other than our entry into foreign currency forward contracts to mitigate the impact of foreign currency exchange rate fluctuations on the portions of our revenue and operating expenses that are denominated in currencies other than the U.S. dollar. See Note 9 in Part I, Item 1 of this Quarterly Report on Form 10-Q for more information.

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 June 30, 2025, 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 June 30, 2025.

Our disclosure controls and procedures are designed to provide reasonable assurance of achieving their objectives as specified above. However, management does not expect that our disclosure controls and procedures will prevent or detect all errors 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 June 30, 2025 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings.

See "Commitments and Contingencies - Legal and Regulatory Matters" in Part I, Notes to Unaudited Condensed Consolidated Financial Statements, Note 14 of this Quarterly Report, as of June 30, 2025.

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 immediately after this summary, 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.
- Failure to secure or retain adequate coverage or reimbursement for our current and future products by third-party payors could adversely affect 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 future competitors, or if the competitive environment harms our business partners, our financial condition and operating results may be negatively affected.
- 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 or reduce the size of our potential market.
- 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.
- Our sales and marketing efforts in the United States are largely 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.
- 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.
- 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.

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.

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, any of which may restrict our financial flexibility and affect our ability to operate 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 Macroeconomic Conditions and External Factors

- International trade policies, including tariffs, sanctions and trade barriers may adversely affect our business, financial condition, and operating results.
- Uncertainty in current global economic and political conditions could adversely affect our ability to predict product demand and impact our financial results and make it more likely that our actual results could differ materially from expectations.
- 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 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.
- 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.

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.

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.
- 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.

Other Risks

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

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 the cautionary note regarding forward-looking statements at the beginning of 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, 2024.

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 June 30, 2025, we had an accumulated deficit of $1.2 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 financings. 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, 2024, 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 through various sales channels 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 24 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 achieve and 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. 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 Beta Bionics, Insulet, Medtronic, Sequel and Ypsomed;
- the potential that breakthroughs for the monitoring, treatment or prevention of diabetes may render our insulin pumps obsolete or less desirable or reduce the size of our potential market;
- 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;
- our inability to expand our sales channels, including the pharmacy channel in the United States;
- 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 continuous glucose monitoring (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.

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 pump from us when the time comes to replace it. We have developed retention programs aimed at our customers, their caregivers and healthcare providers, which include 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.

Failure to secure or retain adequate coverage or reimbursement for our current and 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. In July 2025, the Centers for Medicare and Medicaid Services (CMS), which administers the U.S. Medicare program, outlined a proposed competitive bidding process for some medical equipment, including continuous glucose monitors and insulin pumps that could affect reimbursement rates for our products. In addition, CMS outlined a proposed change in payment for these devices to a monthly rental basis which could impact when our pumps are shipped and corresponding revenue is recognized.

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 CMS. 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 have begun offering Tandem Mobi through the pharmacy channel and are preparing to offer cartridge and infusion sets for the t:slim X2 customers through the pharmacy channel beginning in the fourth quarter of 2025. However, the commercial opportunity in the pharmacy channel will be limited unless a substantial portion of the sales price for any products offered through the pharmacy channel 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 certain products under the Medicare Part D prescription drug program, which requires negotiating with third-party payors to provide these products through the pharmacy channel in the United States. If our efforts to enter into and maintain additional contracts with intermediaries and third-party payors for products we offer or seek to offer through the pharmacy channel take longer than anticipated or are not successful, our ability to successfully offer these products or any future products through the pharmacy channel will be limited.

We believe that there will continue to be proposals by legislators at both the federal and state levels, regulators and third-party payors to reduce costs while expanding individual healthcare benefits, particularly in light of the change of administration. The current administration is pursuing policies to reduce regulations and expenditures across government including at the U.S. Department of Health and Human Services (HHS), the FDA, CMS and related agencies. It is possible that certain of these changes could impose additional limitations on the rates we will be able to charge for our current and future products or the amounts of reimbursement available for our current and future products from governmental agencies or third-party payors. Current and future healthcare reform legislation and policies could have a material adverse effect on our business and financial condition.

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 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. Government involvement in funding healthcare may limit access to or reimbursement for our 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 continues to be 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 operate in a very competitive industry and if we fail to compete successfully against our existing or future 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 Beta Bionics, Insulet, Medtronic, Sequel and Ypsomed. 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 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 with non-exclusive licenses to integrate various generations of Dexcom CGM technology with our insulin pump products. 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 or reduce the size of our potential market.*

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 and could result in delayed purchases or a decline in market share. For example, since 2023, ongoing adoption of the GLP-1 class of drugs in diabetes and news surrounding the expansion of use of GLP-1 drugs in obesity likely had a negative impact on the insulin therapy market.

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.

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.

Our sales and marketing efforts in the United States are largely 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 within the United States 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. 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.

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 with 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 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.

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.

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 the 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 have also increased our use of third parties to perform contracted manufacturing services for us and failure in our oversight of these third parties or any disruption to their network business could negatively impact our business operations. We may also 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 modifying our production lines, hiring specialized employees, identifying 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.

If we, our contract manufacturers or 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 consistently evaluate 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 t:slim cartridge manufacturing demand to an experienced third-party contract manufacturer and consistently evaluating the outsourcing of other aspects of our operations. 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.

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.

Modifications to our business strategy or restructuring of our operations could lead to higher costs or otherwise impact the profitability of our business or the value of our assets.*

As changes occur in our business environment, we have adjusted, and may continue to adjust, our business strategies, including our pursuit of a multi-channel managed care strategy to include offering certain products through the pharmacy channel. We may also decide to further restructure our operations, specific business functions, or assets. However, any new structure and strategies may not deliver the expected benefits, such as supporting our growth objectives or enhancing shareholder value and could prove less effective than our previous approach. Additionally, external factors, including evolving technology, shifting consumer behaviors, acceptance of our products, and macroeconomic changes, could negatively impact the value of our assets. These changes or events may lead to costs associated with adjusting our business strategy and potentially necessitate writing down asset values.

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 24 countries in which our products are offered outside the United States, which accounted for approximately 28% of our total sales during 2024, 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 compared to the protection that exists in the United States;
- 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, effectively transition to direct sales in certain European countries, 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 certain 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.

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, 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). In March 2024, we completed the offering of $316.3 million aggregate principal amount of 1.50% Convertible Senior Notes due 2029 (the 2029 Notes), which are governed by the terms of an indenture (the indenture). 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 in the second quarter of 2025, all remaining 2025 Notes were paid in full. The 2029 Notes are our senior unsecured obligations, and interest on the 2029 Notes is payable in cash semi-annually at a rate of 1.50% per year.

Our failure to comply with certain obligations under the 2029 Notes, or inability to make required debt service payments, could result in an event of default under the 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 2029 Notes will require a significant amount of cash, and we may not have sufficient cash flow from our business to repay the 2029 Notes.*

Our ability to make scheduled payments of the principal and interest on the 2029 Notes, or to refinance the 2029 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 2029 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 2029 Notes, or our future indebtedness.

In addition, we may from time to time seek to retire or purchase our outstanding debt, including the 2029 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 2029 Notes upon a fundamental change, or to settle conversions of the 2029 Notes.*

Holders of the 2029 Notes have the right to require us to repurchase their 2029 Notes upon the occurrence of a fundamental change (as defined in the indenture) at a repurchase price equal to 100% of the principal amount of the 2029 Notes to be repurchased, plus accrued and unpaid interest, if any. In addition, upon conversion of the 2029 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 2029 Notes or settle conversions of the 2029 Notes. In addition, our ability to repurchase the 2029 Notes or to pay cash upon conversions of the 2029 Notes may be limited by agreements governing our future indebtedness. Our failure to repurchase 2029 Notes at a time when the repurchase is required by the indenture, or to pay any cash payable on future conversions of the 2029 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 2029 Notes will, to the extent we deliver shares upon conversion of such 2029 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 2029 Notes will dilute the ownership interests of existing stockholders to the extent we deliver shares upon conversion of any of the 2029 Notes. Any sales in the public market of the common stock issued upon the conversion of the 2029 Notes could adversely affect prevailing market prices of our common stock. In addition, the perception that some or all of the 2029 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 2029 Notes may delay or prevent an otherwise beneficial takeover attempt.*

Certain provisions in the indenture governing the 2029 Notes may make it more difficult or expensive for a third party to acquire us. For example, the terms of the 2029 Notes require us to offer to repurchase the 2029 Notes in the event of a fundamental change and, in certain circumstances, to increase the conversion rate for a holder that converts its 2029 Notes in connection with a make-whole fundamental change (as defined in the indenture governing the 2029 Notes). A takeover of the Company may trigger the requirement that we offer to repurchase the 2029 Notes and/or increase the conversion rate of the 2029 Notes for a holder that elects to convert its 2029 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 2029 Notes and our common stock.*

In connection with the issuance of the 2029 Notes, we entered into capped call transactions (the 2029 Capped Call Transactions) with certain financial institutions (the 2029 option counterparties). The 2029 Capped Call Transaction is expected generally to reduce the potential dilution to our common stock upon any conversion of the 2029 Notes and/or offset any cash payments we are 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.

The 2029 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 maturity of the 2029 Notes. This activity could also cause or avoid an increase or a decrease in the market price of our common stock or the 2029 Notes, which could affect a note holder's ability to convert the 2029 Notes.

The potential effect, if any, of any of these transactions and activities on the market price of our common stock or the 2029 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 2029 Notes and, under certain circumstances, the ability of the note holders to convert the 2029 Notes.

We are subject to counterparty risk with respect to the 2029 Capped Call Transactions.*

The 2029 option counterparties are financial institutions, and we will be subject to the risk that any or all of them may default under the 2029 Capped Call Transactions. If a 2029 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 2029 Capped Call Transaction with such 2029 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 a 2029 option counterparty, we may suffer more dilution than we currently anticipate with respect to our common stock.

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 June 30, 2025, we had $315.4 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, including any changes by CMS to reimbursement rates and payment schedule through a proposed competitive bidding process insulin pumps;
- 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, including as a result of our anticipated initiation of direct sales in select European countries beginning in 2026;
- 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 Macroeconomic Conditions and External Factors

International trade policies, including tariffs, sanctions and trade barriers may adversely affect our business, financial condition and operating results.*

We operate in a global economy, and our business depends on a global supply chain for the development, manufacturing, and distribution of our products, and for the advancement of our preclinical and clinical development programs. Based on the complex relationships between the United States and certain foreign countries, there is inherent risk that political, diplomatic and national security influences might lead to trade disputes, trade restrictions, tariffs and impacts and/or disruptions to our operations. There is currently significant uncertainty about the future relationship between the United States and China, Mexico, Canada, the European Union and other foreign countries, including uncertainty with respect to trade policies, treaties, tariffs, taxes, and other limitations on cross-border operations. We import various components, subcomponents and finished products from both Mexico and China and tariffs, trade barriers, and other regulatory requirements could have an adverse effect on our business, financial condition and operating results, the extent of which cannot be predicted with certainty at this time. While we currently rely on existing tariff exemptions, our pumps require FDA clearance, CE marking, and other regulatory approvals that specify our manufacturing processes and component suppliers, making changes to processes and/or suppliers that are less affected by tariffs, trade barriers or other regulatory requirements, difficult and costly. Changes to suppliers or manufacturing locations may require regulatory resubmissions and new approvals, a process that takes significant time and costs. These regulatory constraints significantly limit our ability to quickly adapt our supply chain in response to tariff changes. Moreover, the dynamic and unpredictable tariff and trade landscape creates substantial uncertainty and significant planning challenges for our operations. Changes in tariff classifications, exemptions, country-of-origin requirements, or customs procedures can occur with limited notice. This uncertainty complicates our long-term investment decisions regarding manufacturing facilities, supply chain optimization, and research and development locations.

Current or future tariffs could also result in increased research and development expenses, including with respect to increased costs associated with raw materials, laboratory equipment and research materials and components. Trade restrictions affecting the import of materials necessary for clinical trials could result in delays to our development timelines. Increased development costs and extended development timelines could place us at a competitive disadvantage compared to companies operating in regions with more favorable trade relationships and could reduce investor confidence and negatively impact our business, financial condition and operating results.

Foreign governments may also adopt non-tariff measures, such as procurement preferences or informal disincentives to engage with, purchase from or invest in U.S. entities, which may limit our ability to compete internationally and attract non-U.S. investment, employees, customers and suppliers. Foreign governments may also take other retaliatory actions against U.S. entities, such as decreased intellectual property protection, increased enforcement actions, or delays in regulatory approvals, which may result in heightened international legal and operational risks. In addition, the United States and other governments have imposed and may continue to impose additional sanctions, such as trade restrictions or trade barriers, which could restrict us from doing business directly or indirectly in or with certain countries or parties and may impose additional costs and complexity to our business.

Trade disputes, tariffs, restrictions and other political tensions between the United States and other countries may also exacerbate unfavorable macroeconomic conditions including inflationary pressures, foreign exchange volatility, financial market instability, and economic recessions or downturns. The ultimate impact of current or future tariffs and trade restrictions remains uncertain and could materially and adversely affect our business, financial condition, and growth prospects. While we actively monitor these risks, any prolonged economic downturn, escalation in trade tensions, or deterioration in international perception of U.S.-based companies could materially and adversely affect our business, ability to access the capital markets or other financing sources, results of operations, financial condition and growth prospects. In addition, tariff and trade developments have and may continue to heighten the risks related to the other risk factors described elsewhere in this report.

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

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.

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 28% of our total sales during 2024. Foreign currency fluctuations could result in volatility of our revenue and expenses. 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. 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. In 2025, we began actively hedging our exposure to currency rate fluctuations; however, future foreign currency fluctuations are difficult to predict and there is no guaranty that our foreign currency hedging transactions will have the desired effect. As a result of these hedging transactions and future foreign currency fluctuations, the volatility of our revenue, profitability, and stock price could increase and be favorably or unfavorably impacted. These and other risks may have a material adverse effect on our business, financial condition and results of operations as a whole.

The effects of inflation could adversely affect our business.

Inflation has the potential to negatively impact our liquidity, business, financial condition, and results of operations by increasing our overall cost structure. The presence of inflation in the economy has led to, and may continue to lead to, higher interest rates, increased capital costs, supply shortages, and rising labor, component, manufacturing, and shipping costs, along with weaker exchange rates and other similar effects. As a result, we have experienced, and may continue to experience, higher costs. While we may implement measures to mitigate inflation's impact, if these measures prove ineffective, our business, financial condition, results of operations, and liquidity could be significantly harmed. Even if these measures are successful, there may be a delay between the implementation of these actions and their effect on our operations, compared to when the inflationary costs are incurred.

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.

A number of U.S. laws govern 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 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.

Numerous U.S. states 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. 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, under 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 per intentional violation; the CCPA also allows private litigants affected by certain data breaches to recover significant statutory damages. 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.

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, the CCPA, and the GDPR govern the processing of 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.

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.

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 or have already adopted similarly stringent data localization and cross-border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal data, 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, or if the requirements for a legally compliant transfer are too onerous, we could face significant adverse consequences. 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.

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. 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). 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 and security. Regulators in the United States are increasingly scrutinizing these statements, and if these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, misleading, 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 third parties with whom we work. We and the third parties with whom we work process 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.

Cyberattacks, 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 cyberattacks, 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 cyberattacks.

Our systems, those of the third parties with whom we work, and the underlying data are vulnerable to damage or interruption from a variety of threats, including without limitation earthquakes, fires, floods, other natural disasters, terrorist attacks, 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. 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 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) and products, 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 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. The Tandem Device Updater may also not operate as intended if the software being transmitted contains errors, vulnerabilities or viruses. Vulnerabilities in our products and information systems 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 in the future, as they have in the past, 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 products and 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 increased risks to our information technology systems and data. 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. 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 of security incidents, or to take other actions. Such disclosures and related actions can be costly, and the disclosure or the failure to comply with applicable requirements could lead to adverse consequences.

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 (e.g., 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.

Our sensitive information could be leaked, disclosed, or revealed as a result of or in connection with our employees', personnel's, or third parties with whom we work using 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.

Cyberattacks aimed at our devices, products, services, or related systems, with the intent to alter or misuse them in ways that are inconsistent with our FDA clearances and approvals, could pose risks to users.

Medical devices are increasingly connected to the internet, personal technology devices, hospital networks, and other medical devices to enhance healthcare features, improve treatment capabilities for healthcare providers, and help patients manage their conditions. However, these same advancements can also heighten cybersecurity risks, including the potential for unauthorized access and misuse by third parties. As a result, cyberattacks that infiltrate, disrupt, or compromise our devices, products, services, or related systems could affect the quality-of-care patients receive or compromise the confidentiality of patient information. Additionally, any alteration or misuse of these devices, products, or services in ways that are inconsistent with our FDA clearances and approvals could create risks for users and expose the company to potential liabilities.

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, we were involved in a multi-year patent dispute with F. Hoffman-La Roche AG and Roche Diabetes Care GmbH until our entry into a settlement agreement in May 2025. See Note 14, "Commitments and Contingencies."

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.

Adhering to regulations concerning public company corporate governance and reporting requirements may place a strain on our resources and distract management from other priorities.

Numerous laws and regulations, particularly those enacted under the Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, new SEC rules, and Nasdaq Stock Market listing requirements, impose obligations on public companies like ours. These have expanded the scope, complexity, and cost of corporate governance, reporting, and disclosure practices. Complying with these laws, including new disclosure requirements, has required and will continue to require substantial management time and oversight, as well as significant accounting and legal expenses. Additionally, changes to accounting rules or standards, such as a potential mandate for U.S. companies to prepare financial statements using International Financial Reporting Standards, could negatively impact our financial results and business, potentially leading to higher accounting fees. These laws and regulations, often vague in their details, are subject to interpretation, and their application may evolve as new guidance emerges from regulatory bodies. This uncertainty could lead to higher costs due to ongoing updates in governance and disclosure practices. We plan to continue investing resources to comply with these evolving laws and regulations, which may increase general and administrative expenses and divert management's attention from revenue-generating activities to compliance efforts. If our compliance efforts differ from regulatory expectations due to ambiguities in the laws, authorities may initiate legal action, which could negatively impact our business.

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, CE Marks or other 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 the Notified Body that carried out the conformity assessment of the medical devices we market or sell in the EEA of any planned significant changes to the products or if there are substantial changes to our quality assurance systems affecting those products. The Notified Body will then assess the changes and determine whether additional audits or actions are required prior to their implementation. 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. Moreover, any substantial changes that take place in the coming years may impact the continuing validity of our CE Certificates of Conformity that were issued on the basis of the Medical Device Directive.

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.

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. In addition, we have in the past relied on our distributors for assistance with market surveillance in Europe and we may face additional challenges in responding to a voluntary or mandatory recall, requirement to repair or similar corrective action during and after our planned transition to direct sales in select European countries beginning in 2026.

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.

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, former 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. In addition, on July 4, 2025, the annual reconciliation bill, the "One Big Beautiful Bill Act" ("OBBBA"), was signed into law which is expected to reduce Medicaid spending and enrollment by implementing work requirements for some beneficiaries, capping state-directed payments, reducing federal funding, and limiting provider taxes used to fund the program. OBBBA also narrows access to the Affordable Care Act marketplace exchange enrollment and declines to extend the Affordable Care Act enhanced advanced premium tax credits, set to expire in 2025, which, among other provisions in the law, are anticipated to reduce the number of Americans with health insurance.

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 (and in Northern Ireland), 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 and has applied as of January 2025, 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 Great Britain (i.e., England, Wales and Scotland), but does apply in Northern Ireland. In Great Britain, 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 UK's regulator, the Medicines & Healthcare products Regulatory Agency, or MHRA, has published a roadmap to new regulations for medical devices. The first of the regulations, which strengthen post-market surveillance requirements, is scheduled to come into force on June 17, 2025. Further updated regulations are scheduled to follow in 2025 and 2026. 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.

Our advertising and promotion may include claims about our product in comparison to competing products, which could expose us to heightened regulatory scrutiny, enforcement risks, and the potential for litigation.

The FDA applies a heightened level of scrutiny to comparative claims in advertising and promotion, ensuring that promotional labeling is truthful and not misleading. There may be differing interpretations of whether certain communications align with a product's FDA-required labeling, and the FDA assesses these communications on a case-by-case basis. Additionally, making comparative claims may raise concerns among our competitors. If a company claims in its advertising that its product is superior to a competitor's or that the competitor's product is inferior, it could face the risk of a lawsuit from the competitor under federal and state false advertising, unfair trade practices, or potentially state libel laws. Such lawsuits could seek injunctive relief to stop further advertising, a court order for corrective advertising, and compensatory or punitive damages, where allowed by law.

Direct-to-consumer marketing and social media initiatives may subject us to increased regulatory scrutiny.

Our efforts to promote our products through direct-to-consumer marketing and social media initiatives may lead to increased scrutiny of how we communicate risk information, benefits, or claims, under the oversight of the FDA, FTC, HHS-OCR, or other regulatory bodies.

Risks Related to Environmental, Social and Governance Matters

Environmental, social, and governance (ESG) regulations, initiatives, directives, policies, and requirements could expose us to various risks.

Some regulators, customers, investors, employees, and other stakeholders are focused on ESG issues and related disclosures. These evolving regulations and shifting stakeholder expectations have led, and may continue to lead, to higher general and administrative costs, as well as increased management time and attention spent on compliance. For instance, collecting, measuring, and reporting ESG-related data is becoming more complex due to changing reporting standards, including from international regulatory bodies. In 2023, California passed three separate climate bills addressing greenhouse gas emissions data, climate-related financial risks, and emissions-related claims and carbon offsets. These ESG requirements and initiatives are subject to change, can be unpredictable, and may be challenging and costly for us to meet due to the complexity of our supply chain and the outsourced manufacturing of certain components. If we fail to comply or are unable to ensure our suppliers' compliance with these policies, customers may stop purchasing from us or pursue legal action, potentially damaging our reputation, revenue, and financial performance.

Our business could be adversely affected by changing expectations and challenges associated with implementing ESG initiatives, establishing ESG-related goals, gathering ESG data, and disclosing ESG-related information.

We may disclose certain ESG-related initiatives and goals in our SEC filings or other public communications. However, implementing these initiatives and goals could be challenging and costly, with the technologies required potentially being inefficient or slow to develop. Additionally, we may face criticism regarding the accuracy, adequacy, or completeness of our disclosures. Statements about our ESG initiatives, goals, and progress may rely on evolving measurement standards, developing internal controls and processes, and assumptions that could change over time. Furthermore, we may be criticized for the scope or nature of these initiatives or goals, or for any revisions made to them. If our ESG data, processes, or reporting are incomplete or inaccurate, or if we fail to make timely progress toward our ESG goals, our reputation, business, financial performance, and growth may suffer.

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, wildfires 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.

Other 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.

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 motivate and retain our current management and key employees, and to attract, motivate and retain qualified personnel in the future. In our industry, it is common to attract, motivate 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.

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 certain amendments to the certificate of incorporation and 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.

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.

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

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, 2024, we had accumulated federal and state NOL carryforwards of approximately $96.5 million, and $248.0 million, respectively. Of the total federal NOL carryforwards, approximately $13.2 million were generated after January 1, 2018, and therefore do not expire but can only be utilized to offset 80% of future taxable income. The remaining federal NOL carryforwards of $83.2 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, or by bodies such as the European Commission or the Organization for Economic Co-operation and Development (OECD),could materially affect our tax obligations (including the costs of compliance) 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.

The U.S. government recently enacted the OBBBA that (along with other recent U.S. federal tax reform) has resulted in significant changes to the taxation of business entities including, among other changes, changes to the taxation of income derived from international operations, changes in the deduction and amortization of research and development expenditures, and limitations on the deductibility of business interest. Future guidance from the Internal Revenue Service and other tax authorities with respect to any legislation may affect us, and certain aspects of such legislation could be repealed or modified or sunset in future years.

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 led by the OECD and other initiatives led by the OECD or the European Commission. In particular, the OECD is leading work on an iteration of the project based on two "pillars," involving the reallocation of taxing rights with respect to 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) (Pillar One) and imposing a minimum effective corporate tax rate on certain multinational enterprises (Pillar Two). A number of countries in which we conduct business, including through our subsidiaries, such as the Netherlands and Switzerland, have enacted, or are in the process of enacting, core elements of the Pillar Two rules. Based on the minimum revenue thresholds contained in the Pillar Two rules, we expect that we are likely to fall within their scope in the short-to-medium term, subject to the application of any relevant transition or safe harbor rules. We are monitoring developments and evaluating the potential impacts of these new rules, including on our effective tax rates and associated compliance costs, and considering our eligibility to qualify for any relevant transition or 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.

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				Provided Herewith
		Form	File No.	Date of First Filing	Exhibit Number	
3.1	Amended and Restated Certificate of Incorporation of the Registrant (as amended and currently in effect).	10-Q	001-36189	August 3, 2023	3.1	
3.2	Amended and Restated Bylaws of the Registrant (as amended and currently in effect).	10-Q	001-36189	August 3, 2023	3.2	
10.1	Settlement, Mutual Release and Cross-License Agreement, dated May 21, 2025, by and between Tandem Diabetes Care, Inc. and F. Hoffmann-La Roche AG					X
10.2	First Amendment to Settlement, Mutual Release and Cross-License Agreement, dated May 28, 2025, by and between Tandem Diabetes Care, Inc. and F. Hoffmann-La Roche AG					X
31.1	Certification of John F. Sheridan, Chief Executive Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
31.2	Certification of Leigh A. Vosseller, Chief Financial Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
32.1*	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.					X
32.2*	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.					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: August 6, 2025

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: August 6, 2025

By: /s/ Leigh A. Vosseller

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

Settlement, Mutual Release and Cross-License Agreement

This Settlement, Mutual Release and Cross-License Agreement ("**Agreement**") is made and entered into as of the 21 May 2025 (hereinafter referred to as "**Effective Date**"), by and among

F. Hoffmann-La Roche AG, Grenzacherstr. 124, 4058 Basel, Switzerland,

Roche Diabetes Care GmbH, Sandhofer Straße 116, 68305 Mannheim, Germany,

Roche Diabetes Care, Inc., 9115 Hague Road, Indianapolis IN 46250, United States,

Roche Diagnostics Operations Inc., 9115 Hague Road, Indianapolis IN 46250, United States,

Roche Diagnostics GmbH, Sandhofer Straße 116, 68305 Mannheim, Germany and

Roche Diagnostics International AG, Forrenstrasse 2. 6343 Rotkreuz, Switzerland,

- collectively, the "Roche Parties" -

and

Tandem Diabetes Care, Inc., 12400 High Bluff Drive, CA 92130, San Diego, USA, and

- "Tandem" –

Tandem Diabetes Care Europe B.V., Schiphol Boulevard 359, WTC Schiphol Airport, D-Tower 11th floor, 1118 BJ, Schiphol, Niederlande,

- collectively, the "Tandem Parties" -

PREAMBLE

WHEREAS, the Roche Parties are part of a group of affiliated companies ("the Roche Group") with F. Hoffmann-La Roche AG being the parent company. The Roche Group is one of the biggest healthcare companies worldwide and develops, manufactures and commercializes a variety of healthcare related technologies, including technologies related to the treatment of diabetes. The Roche Parties own various patent applications and registered patent rights.

WHEREAS, the Tandem Parties are part of a group of affiliated companies ("the Tandem Diabetes Group") with Tandem Diabetes Care, Inc. being the parent company. The Tandem Group develops, manufactures and commercializes medical technologies for the treatment of diabetes, including insulin infusion therapy. The Tandem Parties own various patent applications and registered patent rights.

WHEREAS, the Parties (defined below) have been involved in various patent disputes since December 2023, including infringement and nullity actions concerning EP 2 196 231 ("**EP 231**") and EP 1 970 677 ("**EP 677**") before the Unified Patent Court ("**UPC**").

On 30 November 2023 the Tandem Parties filed an action for a declaration of non- infringement of EP 231 ("**DNI**"; docket no.: ACT_589999/2023 UPC_CFI_455/2023) and a revocation action with the Central Division Paris (docket no.: ACT_589997/2023 UPC_CFI_454/2023) against Roche Diabetes Care GmbH. With order of 25 March 2024 the Central Division Paris stayed the DNI proceedings. With the decision of 18 December 2024 the Central Division Paris dismissed the revocation action and maintained EP 231 as granted. Tandem Parties filed an appeal against this decision with the Court of Appeal on 17 February 2025 (docket no.: APL_7604/2025 UPC_CoA_120/2025).

Roche Diabetes Care GmbH filed an infringement action for the infringement of EP 231 against the Tandem Parties and their German distributor VitalAire GmbH with the Local Division Hamburg (docket no.: ACT_10800/2024 UPC_CFI_88/2024) on 29 February 2024. On 17 June 2024 VitalAire GmbH filed a counterclaim for revocation (docket no.: CC_36199/2024 UPC_CFI_325/2024) against F. Hoffmann-La Roche AG and Roche Diabetes Care GmbH.

Furthermore, F. Hoffmann-La Roche AG and Roche Diabetes Care GmbH filed an infringement action for the infringement of EP 677 with the Local Division Düsseldorf (docket no.: ACT_597323/2023 UPC_CFI_504/2023) on 27 December 2023 against the Tandem Parties as well as their distributors VitalAire GmbH (Germany), Dinno Santé s.a.i. (France), Air Liquide Healthcare Nederland B.V. (Netherlands) and Rubin Medical ApS (Denmark). The Tandem Parties and Rubin Medical ApS filed a counterclaim for revocation (docket no.: CC_20972/2024 UPC_CFI_504/2023) on 19 April 2024, the other distributors filed a separate counterclaim for revocation on the same day (docket no.: CC_21542/2024 UPC_CFI_504/2023).

WHEREAS, the Parties now wish to settle their mutual Dispute (defined below) and bring it to a comprehensive end on the terms and subject to the conditions set forth in this Agreement.

WHEREAS, The Roche Parties wish to settle the Distributor Actions (defined below) with the Accused Distributors (defined below), and the Tandem Parties wish to facilitate such settlement.

NOW, THEREFORE, in consideration of the mutual covenants and agreements contained herein, the Parties agree to enter into this Agreement:

Section 1 – DEFINITIONS

When used in this Agreement, the following terms shall have the meaning which is indicated below:

(1) "Agreement" has the meaning set forth in the introductory paragraph of this Agreement.

(2) “Affiliate” shall mean an organization which, during the term of the Agreement: a) directly or indirectly controls a Party; b) is directly or indirectly controlled by a Party; c) is controlled, directly or indirectly, by the ultimate parent company of a Party.
“Controls” or “controlled” as per a) to c) is defined as owning fifty percent or more of the voting stock of a company or having otherwise the power to govern the financial and the operating policies or to appoint the management of an organization. An organization shall be deemed to constitute an Affiliate of a Party only for so long as such control exists. With respect to the Roche Parties, the terms “Affiliate” shall not include [***], and its subsidiaries, unless the Roche Parties opt for such inclusion of [***] and its subsidiaries by giving written notice at a time when [***] otherwise meets the definition of Affiliate.

(3) “Change of Control” means, with respect to an entity, one or more of the following (whether effected as a single transaction or series of transactions) has occurred with respect to such entity: (i) a sale, transfer or other disposition of all or substantially all of the assets of such entity on an aggregate basis; (ii) such entity enters into a merger, business combination, consolidation, reorganization, corporate restructuring or other similar transaction or series of transactions with a Third Party or group of Third Parties (an “Acquiring Person”) in which less than fifty percent (50%) of the voting power of the outstanding capital stock of the surviving entity (with rights to election of directors) is held directly or indirectly by persons who were shareholders of such entity immediately prior to such transaction (or series of transactions); or (iii) the acquisition by an Acquiring Person resulting in more than 50% of the voting power of the then-outstanding capital stock of an entity with respect to the election of directors.

(4) “Controlled” means, with respect to any Party (other than in the context of the definition of Affiliate) and a patent or patent application, that such Party (a) owns such patent or patent application or (b) has the ability to grant a license or sublicense or otherwise provide access or other right in, to or under such patent or patent application on the terms of this Agreement.

(5) “Dispute” means all past and present (as of the Effective Date) disputes, potential disputes, actions, causes of action, suits, arbitrations, charges, complaints, legal responsibilities, damages, judgments, claims, injuries, liabilities, penalties, fines, losses, expenses, and demands between the Parties based on EP 231 and EP 677 in any jurisdiction throughout the world, whether at law or in equity, whether known or unknown, suspected or unsuspected, contingent or matured, and whether accrued or unaccrued, including claims for compensatory, equitable or injunctive relief, general, specific, direct, indirect, special, consequential or punitive damages, costs, losses, expenses and compensation; in each case, including (a) the Proceedings; and (b) any allegations, claims, counterclaims or defences that (i) were asserted in any way in the Proceedings prior to the Effective Date or (ii) could have been asserted based on the facts and circumstances alleged or described in documents or other communications exchanged between the Parties in the Proceedings or the conduct of settlement negotiations.

(6) "Accused Distributors” means VitalAire GmbH, Dinno Santé s.a.i., Air Liquide Healthcare Nederland B.V. and Rubin Medical ApS.

(7) "Distributor Actions" means all patent infringement actions and counterclaims for revocation of patents brought before the UPC listed in the preamble that are between the Roche Parties and the Accused Distributors.

(8) "Effective Date” has the meaning set forth in the introductory paragraph of this Agreement.

(9) “Initial Payment Deadline” means [***].

(10) “Licensed Field” means insulin delivery systems, [***].

(11) "Licensed Patents" mean all patents and patent applications which have or will have issued claims within the Licensed Field [***].

(12) "Party" means each of the Roche Parties and the Tandem Parties.

(13) "Parties" means the Roche Parties and the Tandem Parties collectively.

(14) "Proceedings" means all patent infringement actions, revocation actions, counterclaims for revocation and actions for declaration of non-infringement of patents brought before the UPC listed in the preamble that are between the Parties.

(15) "Roche Parties" means the Roche entities which are a party of this Agreement collectively.

(16) "Roche Products" means all products and services of the Roche Parties or their Affiliates made by or on behalf of the Roche Parties or their Affiliates [***].

(17) "Roche Releasees" means the Roche Parties, their Affiliates, and their respective employees, officers, directors, agents, insurers, underwriters, and legal representatives.

(18) "Tandem Parties" means the Tandem entities which are a party of this Agreement collectively.

(19) "Tandem Products" means all products and services of the Tandem Parties or their Affiliates made by or on behalf of the Tandem Parties or their Affiliates [***].

(20) "Tandem Releasees" means the Tandem Parties, their Affiliates, and their respective employees, officers, directors, agents, insurers, underwriters, and legal representatives.

(21) "Third Party" means any person or entity other than the Parties and their Affiliates.

Section 2 – REPRESENTATION AND WARRANTIES

(1) Each Party represents and warrants that it has the right to grant the license under Section 6.

(2) Each Party represents and warrants that such Party: (a) is duly organized, validly existing and in good standing under the laws of the jurisdiction of its incorporation; (b) has full corporate power and authority to execute and deliver this Agreement to carry out the provisions hereof, and has taken all necessary action to authorize the execution and delivery of this Agreement and performance hereunder; (c) its signatory has the necessary authority to act on behalf of the respective Party and to validly sign this Agreement; and (d) the execution, delivery and performance of this Agreement by such Party does not conflict with any agreement or any provision thereof, or any instrument or understanding, oral or written, to which it is a party or by which it is bound.

(3) EXCEPT FOR THE EXPRESS WARRANTIES SET FORTH IN THIS SECTION 2, EACH PARTY HEREBY DISCLAIMS ALL REPRESENTATIONS OR WARRANTIES OF ANY KIND RELATING TO THE LICENSED PATENTS OR OTHER SUBJECT MATTER OF THIS AGREEMENT, WHETHER ORAL OR WRITTEN, EXPRESS, IMPLIED, STATUTORY OR OTHERWISE, INCLUDING WITHOUT LIMITATION ANY WARRANTY OF MERCHANTABILITY, FITNESS FOR ANY PARTICULAR PURPOSE OR NON- INFRINGEMENT OF THIRD PARTY PATENTS.

Section 3 – RESOLUTION OF LITIGATION

(1) With this Agreement the Parties conclude their Dispute by way of settlement and bring it to a comprehensive end. Each Party shall take all actions necessary to procure dismissal of the Proceedings as contemplated in this Section 3, including the execution and delivery of any and all documents and performance of any other acts reasonably requested by any other Party to effect such dismissal.

(2) For this, the Parties jointly ask each applicable Court (the "Court") to confirm the settlement by decision of the Court and request each Court to order that details of the settlement are confidential. This includes the appeal proceedings before the Court of Appeal (docket no. UPC_CoA_120/2025, APL_7604/2025), the DNI proceedings before the Central Division Paris (docket no. UPC_CFI_455/2023, ACT_589999/2023), the infringement and counterclaim for revocation proceedings before the Local Division Düsseldorf (docket no. UPC_CFI_504/2023, ACT_597323/2023; CC_20972/2024) and the infringement proceedings before the Local Division Hamburg (docket no. UPC_CFI_88/2024, ACT_10800/2024). The Parties will jointly ask the Court to confirm the settlement by decision after coordination between the legal counsels of the Parties immediately after the Parties have signed this Agreement, but not later than 3 business days after the Effective Date of the Agreement.

(3) The Parties understand that joint requests to confirm the settlement by decision of the Court finally terminate the Proceedings between the Parties. In the case that the UPC requires further declarations from the Parties to finally terminate the Proceedings between the Parties, the Parties undertake to file those declarations with the Court. This includes but is not limited to the withdrawal of an action and the declaration of consent with a withdrawal of an action.

(4) Each Party bears and is responsible for their respective attorneys' fees, court fees and other costs and expenses. The Parties will jointly ask the Court with their request to confirm the settlement by decision to give a decision as to the costs that each Party shall bear their own costs and that no fees shall be reimbursed.

(5) F. Hoffmann-La Roche AG and Roche Diabetes Care GmbH shall use commercially reasonable efforts to enter into a separate agreement with the Accused Distributors on a joint request to confirm the settlement of the Proceedings by decision of the Court and a cost settlement (collectively, "Distributor Actions Settlement").

(6) Tandem Parties shall use commercially reasonable efforts to encourage and facilitate the settlement of Distributor Actions.

Section 4 – NO ADMISSION OF LIABILITY

(1) Neither the Agreement nor any payments made or actions taken thereunder shall constitute an admission of liability by any Party. The Agreement constitutes a compromise and resolves the Dispute for the purpose of avoiding the expense and risk of further legal proceedings.

(2) The Parties agree that this Agreement [***].

Section 5 – SETTLEMENT PAYMENT

(1) The Tandem Parties shall pay F. Hoffmann-La Roche AG the total sum of USD 36,000,000.00 over a period of five years as settlement payment, which payment will be due on the following schedule:

a. The Tandem Parties shall make an initial payment of USD 8,000,000.00 within the Initial Payment Deadline.

b. The remaining sum of USD 28,000,000.00 shall be paid in four equal installments of USD 7,000,000.00, due on the first, second, third, and fourth anniversaries of the Initial Payment Deadline.

(2) All amounts payable hereunder shall be paid by wire transfer to F. Hoffmann-La Roche AG to the following account:
[***]

(3) Any costs for making a payment under Section 5 of this Agreement shall be borne solely by the Tandem Parties and may not be credited against or withheld from the amount due to F. Hoffmann-La Roche AG.

(4) If the Tandem Parties do not make the payments described in this Section 5 to F. Hoffmann-La Roche AG in full and in accordance with the provisions above, F. Hoffmann- La Roche AG shall provide written Notice to the Tandem Parties of such failure to make payments. From the date of receipt of such Notice, any outstanding balance shall bear interest at the applicable statutory rate until the date of effective receipt of such balance by F. Hoffmann-La Roche AG. The foregoing obligation in no way limits any other rights or remedies available to F. Hoffmann-La Roche AG with respect to any nonpayment.

(5) All amounts payable hereunder shall be payable in United States Dollars.

(6) If the Roche Parties materially breach the Agreement, Tandem shall provide written notice of the material breach to the Roche Parties describing the breach in reasonable detail ("Breach Notice"). [***].

(7) So long as the Roche Parties [***].

Section 6 – CROSS-LICENSES

(1) Effective upon receipt of the initial payment according to Sections 5 (1) and (2), Roche Parties hereby grant to Tandem Parties and their Affiliates a world-wide, non-exclusive, non-sublicensable, non-royalty-bearing, non-transferrable (other than subject to Section 9), and irrevocable license, under any one or more claims of the Licensed Patents in the Licensed Field to make, have made, use, sell, offer for sale, distribute, have distributed, import and have imported any product which is made by or has been made, by or on behalf of the Tandem Parties or their Affiliates that, but for the license, would infringe such claim. This license is revokable solely if the Tandem Parties materially breach their obligation under the payment obligations under Section 5(1), the covenant not to sue in Section 8 or any release in Section 7 ("Tandem Material Breach"). In the event of a Tandem Material Breach, the Roche Parties may revoke the license only (i) after providing the Tandem Parties with written notice describing in reasonable detail the Tandem Material Breach and (ii) [***]. Any revocation of the license shall not affect products sold or otherwise in commerce before revocation, and such products shall remain licensed.

(2) Effective upon the grant of the license in Section 6(1), the Tandem Parties hereby grant to Roche Parties and their Affiliates a world-wide, non-exclusive, non-sublicensable, non- royalty-bearing, non-transferrable (other than subject to Section 9), and irrevocable license under any one or more claims of the Licensed Patents in the Licensed Field to make, have made, use, sell, offer for sale, distribute, have distributed, import and have imported any product which is made by or has been made by or on behalf of the Roche Parties or their Affiliates that, but for the license, would infringe such claim. This license is revokable solely if the Roche Parties materially breach their obligation under the covenant not to sue in Section 8 or any release in Section 7 ("Roche Material Breach"). In the event of a Roche Material Breach, the Tandem Parties may revoke the license only (i) after providing the Roche Parties with written notice describing in reasonable detail the Roche Material Breach and (ii) [***]. Any revocation of the license shall not affect products sold or otherwise in commerce before revocation, and such products shall remain licensed.

(3) The licenses in Section 6 (1) and (2) shall be granted for a term of 10 years from the Effective Date. For clarity, the granting of these licenses under this Agreement does not and shall not be construed as restricting the Parties' ability to grant non-exclusives licenses outside of this Agreement to any third-party in any way nor requiring any noticing of the other Parties.

Section 7 – MUTUAL RELEASES

(1) Effective upon receipt of the initial payment according to Sections 5 (1) and (2), the Roche Parties hereby irrevocably release, relinquish, acquit, forever discharge, and waive any and all claims, counterclaims, demands, damages, liabilities, obligations, causes of action, or assertions against, the Tandem Releasees existing prior to or as of the Effective Date based upon, arising out of, or in any way relating to the Roche Parties' Licensed Patents, including both known and unknown claims, in each case, to the fullest extent permitted by law. This explicitly includes any awards of fees or costs.

(2) Effective upon receipt of the initial payment according to Sections 5 (1) and (2), the Roche Parties hereby irrevocably release, relinquish, acquit, forever discharge, and waive any and all claims, counterclaims, demands, damages, liabilities, obligations, causes of action, or assertions against, the Tandem Releasees, Tandem's suppliers, manufacturers, distributors, end-users, and other customers relating to the making, selling, supplying, distributing, importation, or use of Tandem's Products before the Effective Date or the use, resale, resupply, or further distribution after the Effective Date of Tandem's Products first sold, supplied, or distributed before the Effective Date, including both known and unknown claims, in each case, to the fullest extent permitted by law.

(3) Effective upon the grant of the releases in Sections 7(1) and 7(2), the Tandem Parties hereby irrevocably release, relinquish, acquit, forever discharge, and waive any and all claims, counterclaims, demands, damages, liabilities, obligations, causes of action, or assertions against, the Roche Releasees existing prior to or as of the Effective Date based upon, arising out of, or in any way relating to Tandem Parties' Licensed Patents, including both known and unknown claims, in each case, to the fullest extent permitted by law. This explicitly includes any awards of fees or costs.

(4) Effective upon the grant of the releases in Sections 7(1) and 7(2), the Tandem Parties hereby irrevocably release, relinquish, acquit, forever discharge, and waive any and all claims, counterclaims, demands, damages, liabilities, obligations, causes of action, or assertions against, the Roche Releasees, Roche's suppliers, manufacturers, distributors, end-users, and other customers relating to the making, selling, supplying, distributing, importation, or use of Roche's Products before the Effective Date or the use, resale, resupply, or further distribution after the Effective Date of Roche's Products first sold, supplied, or distributed before the Effective Date, including both known and unknown claims, in each case, to the fullest extent permitted by law.

(5) Notwithstanding anything to the contrary in this Agreement, nothing in this Agreement is intended to prevent or preclude any Party from initiating or in any way participating in future proceedings that bear upon or relate to the Parties' respective obligations or rights under this Agreement, including (a) post-Effective Date treatment or resolution of issues related to this Agreement, or any representation, warranty, or covenant herein or (b) the enforcement of this Agreement.

(6) EACH PARTY ACKNOWLEDGES THAT IT MAY HEREAFTER DISCOVER CLAIMS OR FACTS IN ADDITION TO OR DIFFERENT FROM THOSE WHICH IT NOW KNOWS OR BELIEVES TO EXIST WITH RESPECT TO THE APPLICABLE RELEASED CLAIMS AND THE FACTS AND CIRCUMSTANCES EXISTING AT THE TIME OF ENTRY INTO THIS AGREEMENT, WHICH, IF KNOWN OR SUSPECTED AT THE TIME OF EXECUTING THIS AGREEMENT, MAY HAVE MATERIALLY AFFECTED THIS AGREEMENT. NEVERTHELESS, EACH PARTY HEREBY ACKNOWLEDGES THAT THE RELEASED CLAIMS INCLUDE WAIVERS OF ANY RIGHTS, CLAIMS OR CAUSES OF ACTION THAT MIGHT ARISE AS A RESULT OF SUCH DIFFERENT OR ADDITIONAL CLAIMS OR FACTS. EACH PARTY ACKNOWLEDGES THAT IT UNDERSTANDS THE SIGNIFICANCE AND POTENTIAL CONSEQUENCES OF SUCH A RELEASE OF UNKNOWN CLAIMS AND OF SUCH A SPECIFIC WAIVER OF RIGHTS. WITHOUT LIMITING THE FOREGOING, EACH PARTY IS AWARE OF CALIFORNIA CIVIL CODE SECTION 1542, WHICH PROVIDES AS FOLLOWS:

"A general release does not extend to claims that the creditor or releasing party does not know or suspect to exist in his or her favor at the time of executing the release and that, if known by him or her, would have materially affected his or her settlement with the debtor or released party."

EACH PARTY AGREES TO EXPRESSLY WAIVE ANY RIGHTS IT MAY HAVE UNDER THIS CODE SECTION OR UNDER NATIONAL, MULTINATIONAL, FEDERAL, STATE OR COMMON LAW STATUTES, JUDICIAL DECISIONS OR OTHER LAWS OF A SIMILAR NATURE, AND KNOWINGLY AND VOLUNTARILY WAIVES SUCH UNKNOWN CLAIMS.

Section 8 - COVENANT NOT TO SUE

(1) The Tandem Parties covenant not to sue [***].

(2) The Tandem Parties further covenant not to sue [***].

(3) The Roche Parties covenant not to sue [***].

(4) The Roche Parties further covenant not to sue [***].
[***].

Section 9 – ASSIGNMENT/ACQUISITION

(1) No Roche Party may assign the agreement without [***].

(2) A Roche Party shall promptly provide [***].

(3) In the event [***].

(4) If any Roche Party or Tandem Party [***].

(5) The Parties are free to abandon any or all of the Licensed Patents. In such event, the Parties shall have no damage claims against the other Party. The obligations under Section 5 of this Agreement remain unaffected by any abandonment of any or all of the Licensed Patents.

Section 10 – CONFIDENTIALITY

(1) The Parties agree to keep all of the terms of the Agreement and the discussions between the Parties in relation to the negotiation of this Agreement confidential and not disclose them to any Third Party except (i) to the extent necessary to obtain a court order confirming the settlement as agreed in Section 3 and as necessary for any possible enforcement of such court order (ii) as necessary to obtain a court order confirming the settlement of the Distributor Actions and as necessary for any possible enforcement of such court order; (iii) and as necessary for any possible enforcement of the Agreement;; (iv) as required by law, regulation, or stock exchange rules or in response to a court order or subpoena; (v) to the extent necessary, to accountants, advisors, bankers, insurers, investors, and lawyers, and prospective insurers, lenders or investors, on the condition that such persons agree to be bound by the confidentiality and non-use obligations contained in this Agreement or (vi) to the extent necessary to comply with the Party's obligations when transferring a Licensed Patent. Notwithstanding the foregoing, (x) the terms of the Agreement may be disclosed by the Tandem Parties to the Accused Distributors and (y) confidential information does not include information that is or comes into the public domain through no breach of this Agreement.

(2) In case of any production of this Agreement in accordance with Section 10 (1) above, the producing Party is obliged to request all available and reasonable measures to ensure confidentiality and to disclose only that portion of the Agreement which its legal counsel determines the producing Party is legally required to disclose.

(3) In case one Party receives a request for disclosure of all or a portion of this Agreement from a court or other governmental authorities, such Party shall provide the other Parties with a written prompt notice of each such request, and each Party shall reasonably cooperate with the other Parties to obtain strict protection orders with the highest standard available in the applicable jurisdiction, thereby taking all possible protective measures available to preserve the confidentiality of the content of this Agreement.

Section 11 – EFFECTIVE DATE/TERM/TERMINATION

(1) This Agreement is effective as of the Effective Date.

(2) The Roche Parties may collectively terminate the Agreement if any Tandem Party materially breaches the Agreement [***]. The Tandem Parties may collectively terminate the Agreement if any Roche Party materially breaches the Agreement [***]. Upon the expiration of [***] period, the Party providing the breach notice may immediately terminate the agreement by giving written notice of termination to the other Parties.

Section 12 - FINAL PROVISIONS

(1) This Agreement shall be governed by the laws of the State of Delaware, United States of America, without regard to its conflicts of laws provisions.

(2) The Parties irrevocably agree that the federal district court in the State of Delaware shall have exclusive jurisdiction regarding any disputes arising out of or in connection with this Agreement and that, accordingly, any proceedings arising out of or in connection with this Agreement shall be brought in the United States District Court for the District of Delaware. Notwithstanding the foregoing, if there is any dispute for which the federal district court in the State of Delaware does not have subject matter jurisdiction, the state courts in Delaware shall have jurisdiction. In connection with any dispute arising out of or in connection with this Agreement, each Party hereby expressly consents and submits to the personal jurisdiction of the federal and state courts in the State of Delaware.

(3) Any changes to this Agreement must be in a writing executed by both Parties. This applies also to changing of this requirement of a writing.

(4) Any waiver of a right provided for in this Agreement by any Party shall be made in writing. The waiver by a Party to require from any other Party strict compliance with the provisions contained in this Agreement may not be interpreted as a waiver of any other right provided for in this Agreement, nor as a waiver to require compliance with the same right in the future occasions.

Any notice required or permitted to be given hereunder shall be sent in writing by express courier, registered or certified airmail, postage prepaid, return receipt requested or hand delivery addressed to the Party whom it is to be given. Additionally, courtesy copies of any such notices shall, concurrent with the mailing, be sent via email to following addresses:

To the Roche Parties:
[***]

To the Tandem Parties:
[***]

(5) This Agreement contains all provisions relating to the subject matter of this Agreement and replaces all previous provisions agreed between the Parties in respect of the subject matter of this Agreement. No ancillary agreements have been made.

(6) Should any of the provisions in this Agreement be or become invalid or unenforceable, in whole or in part, this shall not affect the validity of the remaining provisions. The Parties shall replace any invalid provision by a valid and enforceable provision which comes as close as possible to the economic purpose of the Parties.

(7) The Parties agree that the electronic signatures appearing on this Agreement in electronic form are the same as handwritten signatures on paper agreement for the purposes of legal validity, enforceability and admissibility.

(8) Headings in this Agreement are for convenience of reference only and shall not affect their interpretation or construction. The words "herein," "hereof" and "hereunder" and other words of similar import refer to this Agreement as a whole, as the same may from time to time be amended or supplemented, and not to any particular subdivision contained in this Agreement. The word "including" when used herein is not intended to be exclusive, or to limit the generality of the preceding words, and means "including, without limitation". Except where the context otherwise requires, the term "or" will be interpreted in the inclusive sense commonly associated with the term "and/or" and no inferences or conclusions of any sort shall be drawn from the fact that in some instances in this Agreement, the word "or" is preceded by "and/" while in other instances it is not. The word "will" has the same meaning as the word "shall".

[Signature page follows.]

IN WITNESS WHEREOF, the Parties have executed this Agreement as of the Effective Date.

Roche Parties

F. Hoffmann-La Roche AG

By: _____
Name: [***]
Title: [***]

By: _____
Name: [***]
Title: [***]

Roche Diabetes Care GmbH

By: _____
Name: [***]
Title: [***]

By: _____
Name: [***]
Title: [***]

Roche Diabetes Care, Inc.

By: _____
Name: [***]
Title: [***]

Roche Diagnostics Operations, Inc.

By: _____
Name: [***]
Title: [***]

Roche Diagnostics GmbH

By: _____
Name: [***]
Title: [***]

By: _____
Name: [***]
Title: [***]

Roche Diagnostics International AG

By: _____
Name: [***]
Title: [***]

By: _____
Name: [***]
Title: [***]

Tandem Parties

Tandem Diabetes Care, Inc.

By: _____
Name: [***]
Title: [***]

Tandem Diabetes Care Europe B.V.

By: _____
Name: [***]
Title: [***]

First Amendment to Settlement, Mutual Release and Cross-License Agreement

This first amendment (the "**First Amendment**") to that certain Settlement, Mutual Release and Cross-License Agreement with an Effective Date of 21 May 2025 (the "**Agreement**") is made and entered into as of the 28 May 2025 (hereinafter referred to as the "**Amendment Effective Date**"), by and among

F. Hoffmann-La Roche AG, Grenzacherstr. 124, 4058 Basel, Switzerland,

Roche Diabetes Care GmbH, Sandhofer Straße 116, 68305 Mannheim, Germany,

Roche Diabetes Care, Inc., 9115 Hague Road, Indianapolis IN 46250, United States,

Roche Diagnostics Operations Inc., 9115 Hague Road, Indianapolis IN 46250, United States,

Roche Diagnostics GmbH, Sandhofer Straße 116, 68305 Mannheim, Germany and

Roche Diagnostics International AG, Forrenstrasse 2. 6343 Rotkreuz, Switzerland,

- collectively, the "Roche Parties" -

and

Tandem Diabetes Care, Inc., 12400 High Bluff Drive, CA 92130, San Diego, USA, and

- "Tandem" –

Tandem Diabetes Care Europe B.V., Schiphol Boulevard 359, WTC Schiphol Airport, D-Tower 11th floor, 1118 BJ, Schiphol, Niederlande,

- collectively, the "Tandem Parties" -

Capitalized terms not defined in this First Amendment shall have the meaning ascribed to them in the Agreement.

WHEREAS, the Agreement contained inaccurate bank account information that the Parties now desire to correct by way of this First Amendment.

NOW, THEREFORE, in consideration of the mutual covenants and agreements contained herein, the Parties agree to the following:

1) The text appearing within Section 5(2) of the Agreement is hereby deleted in its entirety and amended to read as follows:

   (2) All amounts payable hereunder shall be paid by wire transfer to F. Hoffmann- La Roche AG to the following account:

   [***]

2) All other terms and conditions set forth in the Agreement shall remain in full force and effect.

[Signature page follows.]

IN WITNESS WHEREOF, the Parties have executed this First Amendment as of the Amendment Effective Date.

Roche Parties

F. Hoffmann-La Roche AG

By: _____
Name: [***]
Title: [***]

By: _____
Name: [***]
Title: [***]

Roche Diabetes Care GmbH

By: _____
Name: [***]
Title: [***]

By: _____
Name: [***]
Title: [***]

Roche Diabetes Care, Inc.

By: _____
Name: [***]
Title: [***]

Roche Diagnostics Operations, Inc.

By: _____
Name: [***]
Title: [***]

Roche Diagnostics GmbH

By: _____
Name: [***]
Title: [***]

By: _____
Name: [***]
Title: [***]

Roche Diagnostics International AG

By: _____
Name: [***]
Title: [***]

By: _____
Name: [***]
Title: [***]

Tandem Parties

Tandem Diabetes Care, Inc.

By: _____
Name: [***]
Title: [***]

Tandem Diabetes Care Europe B.V.

By: _____
Name: [***]
Title: [***]

Exhibit 31.1

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: August 6, 2025

Exhibit 31.2

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: August 6, 2025

Exhibit 32.1

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 June 30, 2025, 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: August 6, 2025

/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.

Exhibit 32.2

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 June 30, 2025, 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: August 6, 2025

/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.