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, 2024

OR

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

For the Transition Period from to

Commission File Number 001-36189

Tandem Diabetes Care, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**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 July 29, 2024, there were 65,464,900 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, 2024	December 31, 2023
Assets	(Unaudited)	(Note 1)
Current assets:		
Cash and cash equivalents	$ 47,697	$ 58,868
Short-term investments	404,718	409,044
Accounts receivable, net	98,117	105,555
Inventories	161,661	157,937
Prepaid and other current assets	21,195	16,585
Total current assets	733,388	747,989
Property and equipment, net	78,626	76,542
Operating lease right-of-use assets	88,243	87,791
Other long-term assets	37,246	40,336
Total assets	$ 937,503	$ 952,658
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 47,776	$ 49,586
Accrued expenses	13,225	12,726
Employee-related liabilities	42,871	43,430
Current portion of convertible senior notes, net	40,540	—
Operating lease liabilities	17,790	17,060
Deferred revenue	44,200	43,994
Other current liabilities	34,208	28,462
Total current liabilities	240,610	195,258
Convertible senior notes, net - long-term	307,392	285,035
Operating lease liabilities - long-term	111,392	113,572
Deferred revenue - long-term	11,736	13,331
Other long-term liabilities	32,498	31,830
Total liabilities	703,628	639,026
Commitments and contingencies (Note 13)	—	—
Stockholders' equity:		
Common stock, $0.001 par value; 200,000 shares authorized, 65,435 and 65,552 shares issued and outstanding at June 30, 2024 and December 31, 2023, respectively.	65	66
Additional paid-in capital	1,260,392	1,263,997
Accumulated other comprehensive income (loss)	(1,253)	1,369
Accumulated deficit	(1,025,329)	(951,800)
Total stockholders' equity	233,875	313,632
Total liabilities and stockholders' equity	$ 937,503	$ 952,658

See accompanying notes to unaudited condensed consolidated financial statements.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Sales	$ 221,910	$ 195,917	$ 413,584	$ 365,300
Cost of sales	109,116	94,182	206,118	180,658
Gross profit	112,794	101,735	207,466	184,642
Operating expenses:				
Selling, general and administrative	94,242	97,610	184,348	187,424
Research and development	49,326	42,933	95,570	85,093
Acquired in-process research and development expenses	—	—	—	78,750
Total operating expenses	143,568	140,543	279,918	351,267
Operating loss	(30,774)	(38,808)	(72,452)	(166,625)
Other income (expense), net:				
Interest income and other, net	2,824	5,784	8,138	11,649
Interest expense	(1,793)	(1,605)	(3,690)	(3,239)
Loss on extinguishment of debt	—	—	(1,268)	—
Total other income (expense), net	1,031	4,179	3,180	8,410
Loss before income taxes	(29,743)	(34,629)	(69,272)	(158,215)
Income tax expense	1,071	1,146	4,257	1,433
Net loss	$ (30,814)	$ (35,775)	$ (73,529)	$ (159,648)
Other comprehensive income (loss):				
Unrealized gain (loss) on short-term investments	$ (463)	$ (298)	$ (1,759)	$ 1,451
Foreign currency translation gains (losses)	145	(802)	(863)	(827)
Comprehensive loss	$ (31,132)	$ (36,875)	$ (76,151)	$ (159,024)
Net loss per share - basic and diluted	$ (0.47)	$ (0.55)	$ (1.13)	$ (2.47)
Weighted average shares used to compute basic and diluted net loss per share	64,994	64,830	65,160	64,690

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, 2024

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (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 Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2023	65,552	$ 66	$ 1,263,997	$ 1,369	$ (951,800)	$ 313,632
Stock repurchase and retirement of shares	(1,107)	(1)	(29,999)	—	—	(30,000)
Exercise of stock options	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
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 loss 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.

Three Months Ended June 30, 2023

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at March 31, 2023	64,609	$ 65	$ 1,191,843	$ (93)	$ (853,062)	$ 338,753
Exercise of stock options	18	—	305	—	—	305
Vesting of restricted stock units, net of shares withheld for taxes	186	—	(3,163)	—	—	(3,163)
Issuance of common stock for Employee Stock Purchase Plan	249	—	6,804	—	—	6,804
Stock-based compensation expense	—	—	23,410	—	—	23,410
Unrealized loss on short-term investments	—	—	—	(298)	—	(298)
Foreign currency translation losses	—	—	—	(802)	—	(802)
Net loss	—	—	—	—	(35,775)	(35,775)
Balance at June 30, 2023	65,062	$ 65	$ 1,219,199	$ (1,193)	$ (888,837)	$ 329,234

See accompanying notes to unaudited condensed consolidated financial statements.

Six Months Ended June 30, 2023

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2022	64,513	$ 65	$ 1,170,888	$ (1,817)	$ (729,189)	$ 439,947
Exercise of stock options	63	—	1,162	—	—	1,162
Vesting of restricted stock units, net of shares withheld for taxes	237	—	(4,561)	—	—	(4,561)
Issuance of common stock under Employee Stock Purchase Plan	249	—	6,804	—	—	6,804
Exercise of common stock warrants	—	—	—	—	—	—
Stock-based compensation expense	—	—	44,906	—	—	44,906
Unrealized gain on short-term investments	—	—	—	1,451	—	1,451
Foreign currency translation losses	—	—	—	(827)	—	(827)
Net loss	—	—	—	—	(159,648)	(159,648)
Balance at June 30, 2023	65,062	$ 65	$ 1,219,199	$ (1,193)	$ (888,837)	$ 329,234

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,	
	2024	**2023**
Operating Activities		
Net loss	$ (73,529)	$ (159,648)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation and amortization expense	8,151	7,661
Amortization of debt issuance costs	1,085	1,009
Provision for expected credit losses	3,723	2,758
Operating lease termination and other impairment charges	2,000	14,099
Accretion of discount or premium on short-term investments	348	1,755
Stock-based compensation expense	46,936	44,594
Loss on extinguishment of debt	1,268	—
Acquired in-process research and development expenses	—	78,750
Other	335	(280)
Changes in operating assets and liabilities:		
Accounts receivable, net	2,862	13,553
Inventories	(5,157)	(35,945)
Prepaid and other current assets	(4,782)	(3,147)
Other long-term assets	93	(1,659)
Accounts payable and accrued expenses	241	5,557
Employee-related liabilities	(462)	(2,711)
Deferred revenue	(1,261)	2,946
Operating leases and other current liabilities	3,967	5,023
Other long-term liabilities	911	1,036
Net cash used in operating activities	(13,271)	(24,649)
Investing Activities		
Purchases of short-term investments	(177,724)	(235,525)
Proceeds from maturities and redemptions of short-term investments	180,051	303,110
Purchases of property and equipment	(10,923)	(16,205)
Acquisitions, including in-process research and development, net of cash acquired	—	(69,496)
Purchases of intangible assets and strategic investments	—	(2,515)
Net cash used in investing activities	(8,596)	(20,631)
Financing Activities		
Proceeds from issuance of convertible senior notes due 2029, net of $9,400 debt issuance costs	306,850	—
Repurchase of $246,740 principal amount of convertible senior notes due 2025	(246,123)	—
Payment for capped call transactions related to convertible senior notes due 2029	(15,813)	—
Repurchase and retirement of common stock	(30,000)	
Proceeds from issuance of common stock under Company stock plans, net of cash used to settle withholding taxes on vested restricted stock	(4,513)	3,407
Other financing activities	183	—
Net cash provided by (used in) financing activities	10,584	3,407
Effect of foreign exchange rate changes on cash	112	107
Net increase (decrease) in cash and cash equivalents	(11,171)	(41,766)
Cash and cash equivalents at beginning of period	58,868	172,517
Cash and cash equivalents at end of period	$ 47,697	$ 130,751
Supplemental disclosures of cash flow information		
Income taxes paid	$ 1,183	$ 1,771
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	$ 1,505	$ 3,027

See accompanying notes to unaudited condensed consolidated financial statements.

TANDEM DIABETES CARE, INC.

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

1. Organization and Basis of Presentation

The Company

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

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

Basis of Presentation and Principles of Consolidation

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

Interim financial results are not necessarily indicative of results anticipated for the full year or any other period(s). These unaudited condensed consolidated financial statements should be read in conjunction with the Company's audited consolidated financial statements and accompanying notes included in the Company's Annual Report on Form 10-K for the year ended December 31, 2023 (Annual Report), from which the balance sheet information 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, 2024, as compared to those disclosed in the Company's 2023 Annual Report.

Use of Estimates

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

Accounts Receivable

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

Operating Lease Right-of-Use Assets and Liabilities

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

Intangible Assets Subject to Amortization

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

Strategic Investments

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

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

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

Revenue Recognition

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

Revenue Recognition for Arrangements with Multiple Performance Obligations

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

Revenue Recognition for Tandem Choice Program

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

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

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

The Company will recognize the deferred amount of sales at the earlier of when the obligations under the Tandem Choice program are satisfied or when the program expires. If a customer elects to participate in the program, the Company will recognize upgrade fees received, and the associated cost of goods sold at the time of fulfilling the obligation. For the six months ended June 30, 2024, the Company deferred $1.1 million of pump sales that qualified for Tandem Choice, and recognized incremental sales of $0.2 million from individual Tandem Choice fulfillments.

At June 30, 2024 and December 31, 2023, current deferred revenue balance was $31.0 million and $30.6 million, respectively, related to the Tandem Choice program.

Sales Rebates

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

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

	June 30, 2024	December 31, 2023
Other current liabilities	$ 490	$ 505
Other long-term liabilities	8,494	8,042
Total sales rebate	$ 8,984	$ 8,547

Warranty Reserve

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Balance at beginning of the period	$ 37,638	$ 37,152	$ 37,173	$ 36,537
Provision for warranties issued during the period	9,581	8,915	19,990	17,288
Settlements made during the period	(9,062)	(7,385)	(18,099)	(15,068)
Increases (decreases) in warranty estimates	(801)	235	(1,708)	160
Balance at end of the period	$ 37,356	$ 38,917	$ 37,356	$ 38,917

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

	June 30, 2024	December 31, 2023
Other current liabilities	$ 18,155	$ 18,135
Other long-term liabilities	19,201	19,038
Total warranty reserve	$ 37,356	$ 37,173

Stock-Based Compensation

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

Net Income (Loss) Per Share

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

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Options to purchase common stock	804	138	129	138
Unvested restricted stock units	3,322	2,032	2,865	1,677
Warrants to purchase common stock	194	194	194	194
Awards granted under the ESPP	59	32	29	16
Convertible senior notes (if-converted)	9,513	2,554	6,877	2,554
	13,892	4,950	10,094	4,579

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, 2024 and December 31, 2023 (in thousands):

At June 30, 2024	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Estimated Fair Value
Available-for-sale securities:				
United States Government-sponsored enterprises	$ 176,311	$ 37	$ (754)	$ 175,594
United States Treasury securities	90,505	14	(189)	90,330
Commercial paper	45,520	1	(52)	45,469
Corporate debt securities	93,392	70	(137)	93,325
Total	$ 405,728	$ 122	$ (1,132)	$ 404,718

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

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

	Years to Maturity			
At June 30, 2024	Within One Year	One to Two Years	Two to Three Years	Estimated Fair Value
United States Government-sponsored enterprises	$ 66,707	$ 30,914	$ 77,973	$ 175,594
United States Treasury securities	54,404	34,941	985	90,330
Commercial paper	45,469	—	—	45,469
Corporate debt securities	53,092	40,233	—	93,325
Total	$ 219,672	$ 106,088	$ 78,958	$ 404,718

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, 2024 were primarily due to an increase in market interest rates after certain debt securities were purchased. The Company does not intend to sell the available-for-sale debt securities that are in an unrealized loss position, and it is not more likely than not that the Company will be required to sell these debt securities before recovery of their amortized cost bases, which may be at maturity. Based on the credit quality of the available-for-sale debt securities in an unrealized loss position, and the Company's estimates of future cash flows to be collected from those securities, the Company believes the unrealized losses are not credit losses. Accordingly, the Company did not record an allowance for credit losses related to its available-for-sale debt securities at June 30, 2024 and December 31, 2023.

4. Composition of Certain Financial Statement Items

Accounts Receivable

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

	June 30, 2024	December 31, 2023
Accounts receivable	$ 103,342	$ 110,453
Less: allowance for credit losses	(5,225)	(4,898)
Accounts receivable, net	$ 98,117	$ 105,555

Allowance for Credit Losses

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Balance at beginning of the period	$ 4,923	$ 4,467	$ 4,898	$ 4,327
Provision for expected credit losses	1,525	1,372	3,723	2,758
Write-offs and adjustments, net of recoveries	(1,223)	(997)	(3,396)	(2,243)
Balance at end of the period	$ 5,225	$ 4,842	$ 5,225	$ 4,842

Inventories

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

	June 30, 2024	December 31, 2023
Raw materials	$ 45,457	$ 42,783
Work-in-process	28,455	44,026
Finished goods	87,749	71,128
Total inventories	$ 161,661	$ 157,937

5. Fair Value Measurements

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

	Fair Value Measurements at June 30, 2024			
	Total	Level 1	Level 2	Level 3
Assets				
Cash equivalents[(1)]	$ 34,513	$ 34,513	$ —	$ —
United States Government-sponsored enterprises	175,594	—	175,594	—
United States Treasury securities	90,330	90,330	—	—
Commercial paper	45,469	—	45,469	—
Corporate debt securities	93,325	—	93,325	—
Total assets	$ 439,231	$ 124,843	$ 314,388	$ —

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

(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, 2024 and 2023, respectively.

Fair Value of Financial Instruments

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

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

	Fair Value Measurements at	
	June 30, 2024	December 31, 2023
Convertible Senior Notes due 2025	$ 39,130	$ 271,688
Convertible Senior Notes due 2029	438,701	*
Total fair value of outstanding convertible senior notes	$ 477,831	$ 271,688

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

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

6. Leases

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

Supplemental Lease Disclosure Information

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Operating lease cost	$ 3,564	$ 4,299	$ 7,081	$ 8,774
Short-term lease cost	21	124	43	220
Loss on lease termination and right-of-use asset impairment charges	—	11,224	—	11,224
Total lease cost	$ 3,585	$ 15,647	$ 7,124	$ 20,218

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

Years Ending December 31,	
2024	$ 8,874
2025	18,046
2026	17,946
2027	18,229
2028	14,714
Thereafter	90,004
Total undiscounted lease payments	167,813
Less: amount representing interest	(38,631)
Present value of operating lease liabilities	129,182
Less: current portion of operating lease liabilities	(17,790)
Operating lease liabilities - long-term	$ 111,392

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

	June 30, 2024	December 31, 2023
Weighted-average remaining lease term (in years)	9.9	10.2
Weighted-average discount rate used to determine operating lease liabilities	5.3 %	5.4 %

Cash amounts paid included in the measurement of lease liabilities, representing operating cash flows, were $4.7 million and $4.4 million for the six months ended June 30, 2024 and 2023, respectively.

7. Debt

Convertible Senior Notes Due 2029

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

Concurrently, 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 prior to 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 prior to 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.

During the three months ended June 30, 2024, the conversion feature of the 2029 Notes was triggered and therefore the 2029 Notes are currently convertible, in whole or in part, at the option of the holders from July 1, 2024 through September 30, 2024. Whether the 2029 Notes will be convertible following the stated period will depend on the continued satisfaction of this condition or another conversion condition. The Company has not received any conversion notices through the issuance date of its condensed consolidated financial statements. The Company may elect to settle conversions of the 2029 Notes in shares of common stock. Since the Company has the ability and intent to settle conversions in shares of common stock, it continued to classify the 2029 Notes as long-term debt on its condensed consolidated balance sheet as of June 30, 2024.

Convertible Senior Notes Due 2025

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

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

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

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

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

Holders of the 2025 Notes may convert all or a portion of their 2025 Notes at their option before November 1, 2024, in multiples of $1,000 principal amounts, only under the following circumstances:

- if the last reported sale price of the Company's common stock for at least 20 trading days (whether or not consecutive) during the period of 30 consecutive trading days ending on the last trading day of the immediately preceding calendar quarter is greater than or equal to 130% of the applicable conversion price of the 2025 Notes on each such trading day;

- during the five business day period after any five consecutive trading day period in which the trading price per $1,000 principal amount of the 2025 Notes for each day of that five consecutive trading day 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 2025 Notes on such trading day;

- if the Company calls any or all of the 2025 Notes for redemption, at any time prior to the close of business on the scheduled trading day immediately preceding the redemption date; or

- on the occurrence of specified corporate events.

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

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

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

	June 30, 2024	December 31, 2023
Principal amount:		
Convertible Senior Notes Due 2025	$ 40,760	$ 287,500
Convertible Senior Notes Due 2029	316,250	*
Total principal amount	357,010	287,500
Unamortized debt issuance costs	(9,078)	(2,465)
Total debt, net	$ 347,932	$ 285,035
Less: current portion	$ (40,540)	$ —
Long-term senior convertible notes	$ 307,392	$ 285,035

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

As of June 30, 2024 and December 31, 2023, the if-converted value of the 2025 Notes did not exceed the principal amount. As of June 30, 2024, the if-converted value of the 2029 Notes exceeded the principal amount by $52.4 million.

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

	June 30, 2024	June 30, 2023
Effective interest rate:		
Convertible Senior Notes Due 2025	2.2 %	2.2 %
Convertible Senior Notes Due 2029	2.1 %	*

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Contractual interest expense	$ 1,339	$ 1,078	$ 2,484	$ 2,156
Amortization of debt issuance costs	435	450	902	897
Total interest expense	$ 1,774	$ 1,528	$ 3,386	$ 3,053

2029 Capped Call Transactions

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

2025 Capped Call Transactions

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

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

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

8. Stockholders' Equity

Shares Reserved for Future Issuance

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

Shares reserved for issuance upon conversion of Convertible Senior Notes	9,513
Shares underlying outstanding warrants	194
Shares underlying outstanding stock options	3,711
Shares underlying unvested restricted stock units	4,260
Shares authorized for issuance pursuant to awards granted under the ESPP	3,052
Shares authorized for future equity award grants	1,895
Total	22,625

Common Stock Warrants

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

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

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

Stock Incentive Plans

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

Stock-Based Compensation

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Cost of sales	$ 1,760	$ 1,749	$ 3,830	$ 3,343
Selling, general and administrative	15,518	14,871	28,807	28,982
Research and development	7,619	6,781	14,299	12,269
Total stock-based compensation expense	$ 24,897	$ 23,401	$ 46,936	$ 44,594

The total stock-based compensation expense capitalized as part of the cost of the Company's inventories was $1.6 million at June 30, 2024, and $2.0 million at December 31, 2023.

Restricted Stock Units

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
RSUs granted	1,694,239	1,635,679	2,052,298	1,789,825
Weighted average grant date fair value (per share)	$ 48.30	$ 27.61	$ 44.30	$ 28.92

Employee Stock Purchase Plan

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

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

9. Employee Benefits

Employee 401(k) Plan

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

10. Income Taxes

For the three and 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 income taxes for the 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.

For the three and six months ended June 30, 2023, the Company recognized income tax expense of $1.1 million and $1.4 million, respectively, on a pre-tax loss of $34.6 million and $158.2 million, respectively. Income tax expense for the three and six months ended June 30, 2023 was primarily attributable to federal, state and foreign income tax expense as a result of current taxable income in certain jurisdictions. The Company calculated the provision for three and six months ended June 30, 2023 using a discrete effective tax rate method as the annual effective tax rate method would not provide a reliable estimate.

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

11. Business Segment and Geographic Information

Segment Reporting

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

Disaggregation of Revenue

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

Revenues by Geographic Region and Customer Sales Channel

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
United States	$ 156,711	$ 142,501	$ 286,472	$ 273,743
Outside the United States	65,199	53,416	127,112	91,557
Total Sales	$ 221,910	$ 195,917	$ 413,584	$ 365,300

Sales to distributors accounted for 63% and 62% of the Company's United States sales for the three and six months ended June 30, 2024, respectively, and 64% and 65% of the Company's United States sales for the three and six months ended June 30, 2023, 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, 2024 and 2023.

Revenues by Product

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	**2023**	**2024**	**2023**
Pump	$ 107,875	$ 101,677	$ 195,162	$ 186,379
Supplies and other	113,881	96,549	219,414	183,253
Net revenue recognized (deferred) for Tandem Choice program	154	(2,309)	(992)	(4,332)
Total Sales	$ 221,910	$ 195,917	413,584	365,300

12. Acquisitions

AMF Medical Acquisition

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

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

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

13. Commitments and Contingencies

Legal and Regulatory Matters

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

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

Although the Company intends to vigorously defend against these claims, there is no guarantee that the Company will prevail. Accordingly, the Company is unable to determine the ultimate outcome of these lawsuits or determine the amount or range of potential losses associated with these lawsuits.

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, 2024 the Company believes it is not currently a party to any legal proceedings, regulatory matters, or other disputes or claims for which a material loss was considered probable or for which the amount (or range) of loss was reasonably estimable. However, regardless of the merit of the claims raised or the outcome, legal proceedings may have an adverse impact on the Company as a result of defense and settlement costs, diversion of management time and resources, and other factors.

Letters of Credit

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

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

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

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

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

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

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

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

Overview

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

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

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

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

The t:slim X2 was the first pump on which remote software updates were made commercially available in the United States and is now also available in the countries we serve worldwide. This has allowed our t:slim X2 and Tandem Mobi customers to update their own pump software. We believe this offering is a competitive advantage that allows us to bring our customers clinical and lifestyle enhancements, such as new developments in our AID technology, CGM integrations and mobile app features. As an example, we recently launched pump software updates to allow Tandem pump users access to integrate with new CGM sensors.

Our insulin pump products are generally considered durable medical equipment (DME) and have an expected lifespan of at least four years. In addition to insulin pumps, we sell single-use products that are used together with our pumps and are replaced every few days, including cartridges for storing and delivering insulin, and infusion sets that connect the insulin pump to a user's body. Because of the DME classification, our pumps and supplies are typically reimbursed through a medical benefit. As our portfolio expands, we are pursuing a multi-channel managed care strategy and are in discussions to begin serving Mobi customers through the pharmacy channel.

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

Our Strategy & Future Technology

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

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

t:slim X3

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

Mobi: Tubeless

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

Sigi

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

Extended Wear Infusion Sets

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

Control-IQ Advancements

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

Pump Reimbursement Cycle

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

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

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

Trends and Uncertainties Impacting Financial Results

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

Regulatory Approvals and Actions

- Sales of new products are subject to local government regulations. The requirements and timelines to receive regulatory clearance can vary substantially from country to country and delays may impact our ability to expand our worldwide customer base and bring products to market in a competitive timeframe. These delays, or failure to receive regulatory approval could adversely impact our revenue and results of operations.
- Any adverse event involving any 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.

Product - Launches and Reimbursement

- We expect our business to be impacted by the introduction of new diabetes devices and treatments by us or our competitors. The success of our products is variable and we believe it correlates to market acceptance, anticipated product launches and commercial availability. We anticipate that our Tandem Choice program, and its related financial and accounting impact, may continue to materially impact our business until the conclusion of the program.

- We have historically experienced higher net sales in our third and fourth quarters compared to the first half of the year. We believe our July 2023 announcement of U.S. Food and Drug Administration (FDA) clearance of Tandem Mobi and its anticipated launch impacted the timing of purchasing decisions by our current and prospective customers in the second half of 2023 up through the United States commercial availability of Tandem Mobi in February 2024, resulting in delays that were unlike historical seasonal patterns or purchasing behaviors. Regulatory approval and/or upcoming launches of other new Tandem or competitor products could also adversely impact timing of purchasing decisions.

- In periods following new product launches, particularly with new hardware platforms, our cost of sales may increase on a per unit basis until the new products achieve manufacturing scale and operating expenses may be elevated by increased sales and marketing spend to support the product launches.

- Our revenue and results of operations may be impacted by the failure to secure or retain adequate coverage or reimbursement for our current and future products from third-party payors, as well as changes in reimbursement structures.

Foreign Markets

- We have expanded our business and launched new products in select geographies outside the United States. The ordering patterns of our distributors outside the United States has historically been highly variable from period to period. For example, we began operations of a European distribution center which led to a reduction of inventory levels at our distributors, significantly impacting sales patterns in the second half of 2022 and first half of 2023.

Seasonality

- 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 third and fourth quarters 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.

Macroeconomic Factors

- Global economic and market uncertainty, such as recessionary concerns, inflation, changes in discretionary spending and increased interest rates have impacted our customers' purchasing decisions and the buying patterns of our distributors.

- High inflation and the effects of other macroeconomic factors and concerns has disrupted and may continue to disrupt our relationships with suppliers, third-party manufacturers, healthcare providers, distributors and our existing or potential customers.

Components of Results of Operations

Sales

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

From September 2022 through February 2024, we offered the Tandem Choice program to eligible t:slim X2 customers to provide a pathway to ownership of our newest hardware platform, Tandem Mobi, for a fee when available. Eligible customers who purchased a t:slim X2 insulin pump during the program period have until December 31, 2024 to exercise the option to switch to the Tandem Mobi for a stated fee. The accounting treatment for Tandem Choice is complex (see Note 2, "Summary of Significant Accounting Policies"). The program required the deferral of some portion of sales for shipments of eligible pumps between the third quarter of 2022 and the first quarter of 2024. No election was made by the customer at the time of the initial sale, nor did the right offered to the customer impact the economics associated with how or when the initial pump sale was reimbursed. If a customer elects to participate in Tandem Choice, we will recognize the existing sales deferral, incremental fees received and the associated costs of goods sold of providing the new insulin pump, Tandem Mobi, at the time of fulfillment. Qualifying customers were able to elect participation in Tandem Choice starting near the end of the second quarter of 2024. Any remaining deferrals will be recognized when the program ends on December 31, 2024. The balance of the Tandem Choice deferral was $31.0 million as of June 30, 2024.

Cost of Sales

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

Selling, General and Administrative

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

Research and Development

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

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

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

Other Income and Expense

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

Income Tax Expense (Benefit)

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

Results of Operations

(in thousands, except percentages)	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Sales:				
United States	$ 156,711	$ 142,501	$ 286,472	$ 273,743
Outside the United States	65,199	53,416	127,112	91,557
Total sales	221,910	195,917	413,584	365,300
Cost of sales	109,116	94,182	206,118	180,658
Gross profit	112,794	101,735	207,466	184,642
Gross margin	51 %	52 %	50 %	51 %
Operating expenses:				
Selling, general and administrative	94,242	97,610	184,348	187,424
Research and development	49,326	42,933	95,570	85,093
Acquired in-process research and development	—	—	—	78,750
Total operating expenses	143,568	140,543	279,918	351,267
Operating loss	(30,774)	(38,808)	(72,452)	(166,625)
Other income (expense), net:				
Interest income and other, net	2,824	5,784	8,138	11,649
Interest expense	(1,793)	(1,605)	(3,690)	(3,239)
Loss on extinguishment of debt	—	—	(1,268)	—
Total other income (expense), net	1,031	4,179	3,180	8,410
Loss before income taxes	(29,743)	(34,629)	(69,272)	(158,215)
Income tax expense	1,071	1,146	4,257	1,433
Net loss	$ (30,814)	$ (35,775)	$ (73,529)	$ (159,648)

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

Sales

For the three months ended June 30, 2024, we shipped more than 30,000 pumps worldwide. Sales were $221.9 million, which included $65.2 million of sales outside the United States. Sales were $195.9 million for the three months ended June 30, 2023, which included $53.4 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. For the three months ended June 30, 2023, our revenues were reduced by $2.3 million for pump sales as a result of sales deferrals related to Tandem Choice. The Tandem Choice program launched in the United States in September of 2022 and eligibility to participate in the program ended in February 2024 in conjunction with the launch of Tandem Mobi.

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

	Three Months Ended June 30,	
	2024	2023
Pump	$ 81,745	$ 74,360
Supplies and other	74,812	70,450
Net revenue recognized (deferred) for Tandem Choice program	154	(2,309)
Total Sales in the United States	$ 156,711	$ 142,501

Our pump shipments in the United States increased by 8% to more than 20,000 pumps in the second quarter of 2024 compared to the second quarter of 2023. Pump sales in the United States were $81.7 million for the second quarter of 2024, compared to $74.4 million in the second quarter of 2023. We also benefited from an increase in average selling prices. The scaled launch of Tandem Mobi has impacted, and may continue to impact, the timing of customer purchases. For example, Tandem Mobi became commercially available in the United States in February 2024 initially with Dexcom G6 sensor integration, followed by Dexcom G7 sensor integration in June 2024. Sales of pump-related supplies increased primarily due to a year-over-year increase in our installed base of customers in the United States, as well as an increase in average selling prices. Sales in the United States for the three months ended June 30, 2023 were reduced by deferrals related to Tandem Choice for which eligibility to participate ended in February 2024. The associated sales deferrals also ended in February 2024. We began Tandem Choice fulfillment in the second quarter of 2024, resulting in incremental sales of $0.2 million.

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

	Three Months Ended June 30,	
	2024	2023
Pump	$ 26,130	$ 27,317
Supplies and other	39,069	26,099
Total Sales Outside the United States	$ 65,199	$ 53,416

Our pump shipments outside the United States decreased by 6% to nearly 10,000 pumps for the second quarter of 2024 compared to the second quarter of 2023. Pump sales outside the United States were $26.1 million for the second quarter of 2024, compared to $27.3 million in the second quarter of 2023. Pump sales and shipments decreased slightly due to variable pump ordering and stocking patterns, partially offset by an increase in average selling prices due primarily to geographical mix. Sales of pump-related supplies increased due to a year-over-year increase in our installed base of customers outside the United States, as well as modest disruption related to an operational transition to a centralized European distribution center impacting orders in 2023.

Cost of Sales and Gross Profit

Our cost of sales for the three months ended June 30, 2024 was $109.1 million, resulting in gross profit of $112.8 million, compared to cost of sales of $94.2 million and gross profit of $101.7 million for the same period in 2023. The gross margin for the three-month periods ended June 30, 2024 and 2023 was 51% and 52%, respectively.

Gross profit for the three months ended June 30, 2023 was reduced by $2.3 million, or approximately one percentage point of gross margin due to Tandem Choice. The effect of our Tandem Choice program on gross profit and gross margin was negligible for the three months ended June 30, 2024. The impact on gross margin from Tandem Choice will continue to fluctuate through the end of the program based on the number of eligible customers who ultimately elect to participate.

Excluding the impact of Tandem Choice, gross margin decreased compared to the prior year period. Gross margin benefited from pricing improvement and lower materials cost, offset by higher labor and overhead on a per-unit basis as we scale volumes of Tandem Mobi in this initial launch phase. Gross margin was also impacted by product and geographical mix. Pump sales, which have the highest gross margin, were 49% of total worldwide sales, excluding the impact of Tandem Choice, in the second quarter of 2024, compared to 51% in the second quarter of 2023.

Operating Expenses

Our operating expenses for the three months ended June 30, 2024 were $143.6 million, compared to $140.5 million for the three months ended June 30, 2023. The $3.1 million increase was primarily driven by increased development efforts for pipeline products as well as the ramp up of sales and marketing for Mobi.

Selling, General and Administrative Expenses. SG&A expenses were $94.2 million for the three months ended June 30, 2024, compared to $97.6 million for the same period in 2023, which included a one-time lease impairment charge of $14.1 million. Due to cost reduction efforts in 2023, our facilities and IT equipment expenses decreased $1.8 million compared to the prior period. This was offset by a $7.6 million increase in employee-related spending. We also experienced an $4.9 million increase in outside services, supplies, and travel expenses largely related to the launch of multiple new products, as well as IT software and services.

Research and Development Expenses. R&D expenses increased to $49.3 million for the three months ended June 30, 2024, from $42.9 million for the same period in 2023. The increase in R&D expenses was primarily the result of an increase of $5.6 million in employee benefits and salaries due to an increase in personnel to support our product development efforts. We also experienced an increase in other non-employee discretionary spending, including clinical trial expenses, supplies and equipment costs.

Other Income (Expense), Net

Total other income (expense), net for the three months ended June 30, 2024 was $1.0 million income, compared to $4.2 million income in the same period in 2023. Other income, net for the three months ended June 30, 2024 primarily consisted of $5.3 million of interest income earned on our cash equivalents and short-term investments, partially offset by a $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 related to our convertible senior notes due 2025 and 2029 (the 2025 Notes and the 2029 Notes, respectively). Other income, net for the three months ended June 30, 2023 primarily consisted of $5.1 million of interest income earned on our cash equivalents and short-term investments and $0.7 million in foreign currency transaction gains, partially offset by $1.6 million of interest expense which included the amortization of debt issuance costs related to the 2025 Notes.

Income Tax Expense

We recognized income tax expense of $1.1 million on a pre-tax loss of $29.7 million for the three months ended June 30, 2024, compared to income tax expense of $1.1 million on a pre-tax loss of $34.6 million for the three months ended June 30, 2023. Income tax expense for the three months ended June 30, 2024 and 2023 was primarily attributable to federal, state and foreign income tax expense as a result of current taxable income in certain jurisdictions.

Comparison of the Six Months Ended June 30, 2024 and 2023

Sales

For the six months ended June 30, 2024, we shipped more than 55,000 pumps worldwide. Sales were $413.6 million, which included $127.1 million of sales outside the United States. For the six months ended June 30, 2024, our revenues were reduced by $1.0 million of pump sales as a result of sales deferrals related to our Tandem Choice program. Pump sales after February 2024 were not eligible for Tandem Choice. Sales were $365.3 million for the same period in 2023, which included $91.6 million of sales outside the United States. For the six months ended June 30, 2023, we deferred $4.3 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,	
	2024	2023
Pump	$ 143,465	$ 140,816
Supplies and other	143,999	137,259
Net revenue recognized (deferred) for Tandem Choice program	(992)	(4,332)
Total Sales in the United States	$ 286,472	$ 273,743

Our pump shipments in the United States decreased by 1% to nearly 36,000 pumps for the six months ended June 30, 2024, compared to the six months ended June 30, 2023. Pump sales in the United States were $143.5 million for the six months ended June 30, 2024, compared to $140.8 million for the same period in 2023. We also benefited from an increase in average selling prices. Sales of pump-related supplies increased primarily due to a year-over-year increase in our ending estimated installed base of customers in the United States, as well as increase in average selling prices. Sales in the United States for the six months ended June 30, 2024 and 2023 were reduced by $1.0 million and $4.3 million, respectively, as the result of net sales deferrals related to our Tandem Choice program. The decrease in the net revenue deferral for Tandem Choice in 2024 as compared to 2023 was primarily due to the cessation of the sales deferral period in February 2024, which coincided with the launch of Tandem Mobi. Pump sales that occurred after February 2024 were not eligible for Tandem Choice, nor subject to a sales deferral. We began Tandem Choice fulfillment in the second quarter of 2024 resulting in incremental sales of $0.2 million for the six months ended June 30, 2024.

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

	Six Months Ended June 30,	
	2024	2023
Pump	$ 51,697	$ 45,563
Supplies and other	75,415	45,994
Total Sales Outside the United States	$ 127,112	$ 91,557

Our pump shipments outside the United States increased by 17% to more than 19,000 pumps for the six months ended June 30, 2024 compared to the six months ended June 30, 2023. Pump sales outside the United States were $51.7 million for the six months ended June 30, 2024, compared to $45.6 million for the same period in 2023. Pump sales and shipments increased due primarily to an operational transition to a centralized European distribution center in the first half of 2023. Distributor ordering patterns were significantly disrupted during that transition period, which negatively affected pump and supply shipments and sales. The transition was completed by the second half of 2023. The increase in pump sales was offset by a slight decrease in average selling prices due primarily to geographical mix. In addition to the distribution center transition, sales of pump-related supplies outside the United States increased due to growth in our installed base of customers. Sales to distributors accounted for the overwhelming majority of our total sales outside the United States for the six-month periods ended June 30, 2024, and 2023.

Cost of Sales and Gross Profit

Our cost of sales for the six months ended June 30, 2024 was $206.1 million resulting in gross profit of $207.5 million, compared to cost of sales of $180.7 million and gross profit of $184.6 million for the same period in 2023. The gross margin for the six months ended June 30, 2024 was 50% compared to 51% in the same period in 2023.

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

Excluding the impact of Tandem Choice, gross margin for the six months ended June 30, 2024 was 50 percent compared to 51 percent in the same period of the prior year. Gross margin benefited from pricing improvement and lower materials cost, offset by higher labor and overhead costs on a per-unit basis as we scale volumes of Tandem Mobi in our initial launch phase. Gross margin was also impacted by product and geographical mix. Pump sales, which have the highest gross margin, were 47% of total worldwide sales, excluding the impact of Tandem Choice, in the first six months of 2024, compared to 50% in the first six months of 2023.

Operating Expenses

Our operating expenses for the six months ended June 30, 2024 were $279.9 million, compared to $351.3 million for the six months ended June 30, 2023. The $71.4 million decrease was primarily driven by $78.8 million of acquired in-process research and development expenses incurred in 2023 in connection with our acquisition of AMF Medical, for which there was no comparable expense in 2024. In 2023, we also incurred a non-recurring operating lease impairment charge in SG&A of $14.1 million as a result of a facilities consolidation (see Note 6, “Leases”), and employee severance costs of $2.7 million.

Selling, General and Administrative Expenses. SG&A expenses decreased 2% to $184.3 million for the six months ended June 30, 2024, from $187.4 million for the same period in 2023. Expenses decreased due to non-recurring expenses of $14.1 million related to lease impairment charges and $2.1 million in severance costs in 2023, offset by current year increases of $12.9 million in employee-related and marketing and consulting expenses which related to new product launches.

Research and Development Expenses. R&D expenses increased 12% to $95.6 million for the six months ended June 30, 2024, from $85.1 million for the same period in 2023. The increase in R&D expenses was primarily the result of an increase in salaries and related benefits from our acquisitions and an increase in personnel to support our product development efforts. We also experienced an increase in other non-employee discretionary spending, including clinical trials costs and equipment expenses.

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

Other Income (Expense), Net

Total other income (expense), net for the six months ended June 30, 2024 was $3.2 million income, compared to $8.4 million expense in the same period in 2023. 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 related to our 2025 Notes and 2029 Notes. Other income, net for the six months ended June 30, 2023 primarily consisted of $9.3 million of interest income earned on our cash equivalents and short-term investments, and $2.3 million in foreign currency transaction gains, partially offset by $3.2 million of interest expense which included the amortization of debt issuance costs related to our 2025 Notes.

Income Tax Expense

We recognized income tax expense of $4.3 million on a pre-tax loss of $69.3 million for the six months ended June 30, 2024, compared to income tax expense of $1.4 million on a pre-tax loss of $158.2 million for the six months ended June 30, 2023. Income tax expense for the six months ended June 30, 2024 and 2023 was primarily attributable to federal, state and foreign income tax expense as a result of current taxable income in certain jurisdictions.

Liquidity and Capital Resources

At June 30, 2024, we had $452.4 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 acquired assets, capital expenditures and debt service costs.

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

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

	Six Months Ended June 30,	
	2024	2023
Net cash provided by (used in):		
Operating activities	$ (13,271)	$ (24,649)
Investing activities	(8,596)	(20,631)
Financing activities	10,584	3,407
Effect of foreign exchange rate changes on cash	112	107
Net decrease in cash and cash equivalents	$ (11,171)	$ (41,766)

Operating Activities. Net cash used in operating activities was $13.3 million for the six months ended June 30, 2024, compared to $24.6 million cash used in the same period in 2023. For the six months ended June 30, 2024, net loss was $73.5 million, net non-cash adjustments were $63.8 million, and change in working capital balances was an increase of $3.6 million. For the six months ended June 30, 2023, net loss was $159.6 million, net non-cash adjustments were $150.3 million and change in working capital balances was a $15.3 million decrease. For the six months ended June 30, 2023, net non-cash adjustments included $78.8 million of acquired in-process research and development expenses related to our acquisition of AMF Medical.

Investing Activities. 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 of 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. Net cash used in investing activities was $20.6 million for the six months ended June 30, 2023, which was primarily related to $235.5 million of purchases of short-term investments, $69.5 million for the acquisition of AMF Medical, including transaction costs (see Note 12, "Acquisitions"), and $16.2 million in purchases of property and equipment, offset by $303.1 million in proceeds from maturities and redemptions of short-term investments.

Financing Activities. 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. Net cash provided by financing activities was $3.4 million for the six months ended June 30, 2023, which primarily consisted of proceeds from the issuance of common stock under our stock plans, net of payments for related tax withholdings.

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

- our ability to generate sales, the timing of those sales, the mix of products sold and the collection of receivables from period to period;
- contractual debt obligations, including periodic interest payments;
- the timing of any additional financings, and the net proceeds raised from such financings;
- the timing and amount of proceeds from the issuance of equity awards pursuant to employee stock plans;
- fluctuations in gross and operating margins; and
- fluctuations in working capital, including changes in accounts receivable, inventories, accounts payable, employee-related liabilities, and operating lease liabilities.

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

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

- payments under licensing, development and commercialization agreements; and
- integration costs related to acquisitions of businesses, products and technologies.

Critical Accounting Policies

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

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

Item 3. Quantitative and Qualitative Disclosures about Market Risk.

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

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

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

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

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

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

Changes in Internal Control over Financial Reporting

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

PART II. OTHER INFORMATION

Item 1. Legal Proceedings.

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

Item 1A. Risk Factors.

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

Risks Related to Our Business and Industry

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

Risks Related to Our International Operations

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

Risks Related to Macroeconomic Conditions and External Factors

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

Risks Related to Our Future Financings and Financial Results

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

Risks Related to Privacy and Security

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

Risks Related to Legal and Intellectual Property

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

Risks Related to Our Regulatory Environment

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

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

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

General Risks

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

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

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

Risks Related to Our Indebtedness

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

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

- We may take actions which could limit our ability to make payments on the Notes.

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

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

Risks Related to Our Business and Our Industry

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

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

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

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

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

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

We generate nearly all of our revenue from the sale of t:slim X2 insulin pumps and the related insulin cartridges and infusion sets. In addition, we recently launched our Tandem Mobi insulin pump. Sales of these products may be negatively impacted by many factors, including:

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

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

Because we currently rely on sales of our t:slim X2 insulin pump, and expect to rely on sales of our Tandem Mobi insulin pump, and related products to generate a significant majority of our revenue, any factors that negatively impact sales of these products (or negatively impact the products or components integrated with these products) could adversely affect our business, financial condition and operating results. Furthermore, any disruption in our supply chain could negatively impact our ability to manufacture or otherwise supply sufficient product quantities to meet current customer demand, or any unexpected increase in demand, which could also have the effect of magnifying the negative impact of any of the factors described above.

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

Our operations and performance depend in part on worldwide economic and political conditions. Many of the jurisdictions in which our products are sold have experienced and could continue to experience unfavorable general economic conditions, such as a recession or economic slowdown, which could negatively affect the affordability of, and consumer demand for, our products. Under difficult economic conditions, consumers may seek to modify spending priorities and reduce discretionary spending by delaying purchases of our products, which could reduce our profitability and could negatively affect our overall financial performance. Other financial uncertainties in our major markets and unstable political conditions in certain markets, including civil unrest and governmental changes, could undermine global consumer confidence and reduce consumers' purchasing power, thereby reducing demand for our products. We cannot predict the reoccurrence of any economic slowdown or the strength or sustainability of the economic recovery, worldwide, in the United States, or in our industry. These and other economic factors could have a material adverse effect on our business, financial condition, and results of operations.

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

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

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

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

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

Our primary competitors are major medical device companies, primarily Insulet, Medtronic, 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 may enjoy several competitive advantages over us, including:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

As part of our product development efforts, we expect to increasingly rely on clinical investigators and clinical sites to enroll participants in our clinical trials or users in our human factors testing and other third parties to manage such trials and testing and to perform related data collection and analysis. However, we may not be able to control the amount and timing of resources that clinical sites may devote to our clinical trials or other studies. If these clinical investigators and clinical sites fail to enroll a sufficient number of patients, fail to ensure compliance by patients with clinical protocols, or fail to comply with regulatory requirements, we may be unable to successfully complete our clinical trials or other studies, which could prevent us from obtaining regulatory clearances, certifications, or approvals for our products and commercializing our products, which would have an adverse impact on our business.

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

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

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

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

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

These risks include our ability to:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Our International Operations

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

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

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

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

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

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

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

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

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

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

Risks Related to Macroeconomic Conditions and External Factors

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

Our operations and performance depend in part on worldwide economic and political conditions. Many of the jurisdictions in which our products are sold have experienced and could continue to experience unfavorable general economic conditions, such as a recession or economic slowdown, including as a result of political instability and military hostilities in certain geographies, concerns over the potential downgrade of United States sovereign debt and continued sovereign debt, monetary and financial uncertainties in Europe and other geographies, and domestic and global inflationary trends, any of which could negatively affect the affordability of, and consumer demand for, our products. Under difficult economic conditions, consumers may seek to modify spending priorities and reduce discretionary spending by delaying purchases of our products, which could reduce our profitability and could negatively affect our overall financial performance. Other financial uncertainties in our major markets and unstable political conditions in certain markets, including civil unrest and governmental changes, could undermine global consumer confidence and reduce consumers' purchasing power, thereby reducing demand for our products. We cannot predict the reoccurrence of any economic slowdown or the strength or sustainability of the economic recovery, worldwide, in the United States, or in our industry. These and other economic factors could have a material adverse effect on our business, financial condition, and results of operations.

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

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

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

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

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

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

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

Risks Related to Our Future Financings and Financial Results

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

As of June 30, 2024, we had $452.4 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;
- our ability to maintain our existing infrastructure;
- the amount of, and the timing of the payment for, insurance deductibles required to be paid by our customers and potential customers under their existing insurance plans;
- interruption in the manufacturing or distribution of our products;
- our ability to simultaneously manufacture multiple products that meet quality, reliability and regulatory requirements;

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

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

Risks Related to Privacy and Security

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

If we or the third parties with whom we work fail, or are perceived to have failed to address or comply with applicable data privacy obligations, we could face significant consequences, including but not limited to: government enforcement actions (e.g., investigations, fines, penalties, audits, inspections, and similar); litigation (including class-action claims) and mass arbitration demands; additional reporting requirements and/or oversight; bans on processing of personal data; orders to destroy

or not use personal data; and imprisonment of company officials. In particular, plaintiffs have become increasingly more active in bringing data privacy-related claims against companies, including class claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis; if viable, these claims carry the potential for monumental statutory damages, depending on the volume of personal data and the number of violations.

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

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

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

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

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

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

In addition, our insulin pumps and other products rely on software and hardware, some of which is developed by third-party service providers or other third parties with whom we work, that could contain vulnerabilities. We take steps designed to detect, mitigate and remediate vulnerabilities in our information systems (such as our hardware and/or software, including that of third parties with whom we work), but we may not be able to detect, mitigate, and remediate such vulnerabilities, including on a timely basis. Further, we may experience delays in developing and deploying remedial measures and patches designed to address identified vulnerabilities. Our risks may increase significantly due to the use of mobile and cloud-based applications in our medical devices. For example, while use of our Tandem Device Updater is designed to give us the ability to quickly recover from certain risks and/or vulnerabilities, the use of mobile applications enables third parties to store their information on mobile devices that we do not control. Vulnerabilities could be exploited and result in a security incident.

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Legal and Intellectual Property

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

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

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

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

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

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

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

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

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

For example, in November 2023, at the Unified Patent Court (the "UPC"), we filed a revocation action and an action for a declaration of non-infringement of EP Patent No. 2 196 231 B1 (the "'231 patent") against Roche Diabetes Care GmbH. While Roche contends that Tandem's t:slim X2 pump infringes the '231 patent, we contend that our t:slim X2 pump does not infringe the '231 patent. Furthermore, we contend that the claims of the '231 patent are invalid over the prior art and should be revoked. In February 2024, Roche filed an infringement action against Tandem and one of its distributors at the UPC contending that Tandem's t:slim X2 pump infringes the '231 patent. On November 6, 2024, the UPC (Paris Central Division) will hold a hearing on Tandem's motion to revoke the claims of the '231 patent.

In December 2023, F. Hoffman-La Roche AG and Roche Diabetes Care GmbH (collectively, "Roche"), filed an infringement action at the UPC against multiple defendants including Tandem Diabetes Care, Inc. and Tandem Diabetes Care Europe B.V. Roche alleges our t:slim X2 insulin pump, and the offering, marketing, using, importing, possessing, and supplying of such devices, infringe EP Patent No. 1 970 677 B1 (the "'677 patent"). Roche seeks, among other things, damages and other monetary relief, costs and expenses of the legal proceedings, and an order to cease and desist the allegedly infringing activities. As the UPC is a new court system that came into effect in 2023, enforcement and litigation under the UPC is new and we cannot accurately predict the outcome of such proceedings.

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

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

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

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

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

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

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

Risks Related to Our Regulatory Environment

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- the federal and state Anti-Kickback Statutes, which prohibit, among other things, persons from knowingly and willfully soliciting, receiving, offering, paying or providing remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind in exchange for or to induce either the referral of an individual for, or the purchase, lease, order or recommendation of, any good or service for which payment may be made under federal healthcare programs such as the Medicare and state Medicaid programs;

- federal and state false claims laws which prohibit, among other things, persons from knowingly presenting, or causing to be presented, false or fraudulent claims for payment to Medicare, state Medicaid programs, or other third-party payors;

- federal and state physician self-referral laws, such as the Stark Law, which prohibit a physician from referring Medicare or Medicaid patients to an entity providing "designated health services," including a company that furnishes durable medical equipment, with which the physician or their immediate family member has a financial relationship unless that financial relationship meets an exception under the applicable law;

- federal and state laws, such as the Civil Monetary Penalties Law, that prohibit an individual or entity from offering or transferring remuneration to any person eligible for benefits under a federal or state health care program which such individual or entity knows or should know are likely to influence such eligible individual's choice of provider, practitioner or supplier of any item or service for which payment may be made under federal health care programs such as Medicare and state Medicaid programs;

- federal criminal laws enacted as part of HIPAA that prohibit, among other things, executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

- federal and state disclosure laws, such as the Physician Payments Sunshine Act, which require certain manufacturers, including medical device manufacturers, to submit annual data pertaining to payments or other transfers of value to covered recipients, including physicians and certain other healthcare providers, and teaching hospitals, as well as information regarding ownership and investment interests held by physicians and their immediate family members;

- federal and state laws governing the use, disclosure and security of personal information, including protected health information, such as HIPAA and the HITECH; and

- foreign and United States state law equivalents of each of the above federal laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

General Risks

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

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

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

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

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

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

- authorize the issuance of preferred stock with powers, preferences and rights that may be senior to our common stock, which can be created and issued by the board of directors without prior stockholder approval;
- provide for a staggered board of directors whereby the board is currently divided into three classes, although our board and stockholders have approved the phased declassification of the board of directors such that the board structure will be completely declassified by our 2024 annual meeting of stockholders;
- provide for the removal of a director only with cause and then by the affirmative vote of the holders of a majority of the outstanding shares;
- prohibit stockholders from calling special stockholder meetings;
- prohibit stockholders from acting by written consent without holding a meeting of stockholders;
- require the vote of at least two-thirds of the outstanding shares to approve amendments to the certificate of incorporation or bylaws; and
- require advance written notice of stockholder proposals and director nominations.

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Our Indebtedness

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

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

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

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

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

- a high level of indebtedness may limit our ability to obtain additional financing in the future or negatively impact the terms on which additional financing may be obtained.

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

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

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

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

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

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

The conversion of some or all of the Notes will dilute the ownership interests of existing stockholders to the extent we deliver shares upon conversion of any of the Notes. Any sales in the public market of the common stock issued upon the conversion of the Notes could adversely affect prevailing market prices of our common stock. In addition, the perception that some or all of the Notes may be converted into shares of our common stock in the future could have a negative impact on the trading price of our common stock.

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

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

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

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

The option counterparties or their respective affiliates may modify their hedge positions by entering into or unwinding various derivatives with respect to our common stock and/or purchasing or selling our common stock or other securities of ours in secondary market transactions before the applicable maturity of the Notes. This activity could also cause or avoid an increase or a decrease in the market price of our common stock or the Notes, which could affect a Note holder's ability to convert the Notes.

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

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

The option counterparties are financial institutions, and we will be subject to the risk that any or all of them may default under the Capped Call Transactions. If an option counterparty becomes subject to insolvency proceedings, we will become an unsecured creditor in those proceedings with a claim equal to our exposure at that time under the Capped Call Transaction with such option counterparty. Our exposure will depend on many factors but, in general, an increase in our exposure will be correlated to an increase in the market price and volatility of our common stock. In addition, upon a default by an option counterparty, we may suffer more dilution than we currently anticipate with respect to our common stock.

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

None.

Item 5. Other Information.

None.

Item 6. Exhibits.

Exhibit Number	Exhibit Description	Incorporated by Reference				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†‡	Amended and Restated Development Agreement, dated May 22, 2024, by and between the Company and DexCom, Inc.					X
10.2†‡	Amended and Restated Commercialization Agreement, dated May 22, 2024, by and between the Company and DexCom, Inc.					X
10.3	Employee Offer Letter, dated June 10, 2024, by and between Tandem Diabetes Care, Inc. and Jean-Claude Kyrillos.					X
10.4	Employment Severance Agreement, dated June 21, 2024, by and between Tandem Diabetes Care, Inc. and Jean-Claude Kyrillos.					X
10.5†‡	Amendment No. 1 to Distributor Agreement, dated May 10, 2024, by Unomedical a/s and the Company.					X
10.6	Tandem Diabetes Care, Inc. 2013 Employee Stock Purchase Plan, as amended.	S-8	333-279642	May 23, 2024	99.1	
10.7	Tandem Diabetes Care, Inc. 2023 Long-Term Incentive Plan, as amended.	S-8	333-279642	May 23, 2024	99.2	
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.

† Certain portions of this exhibit have been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K.

‡ Exhibits and/or schedules have been omitted pursuant to Item 601(a)(5) of Regulation S-K

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 1, 2024

By: /s/ John F. Sheridan

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

Dated: August 1, 2024

By: /s/ Leigh A. Vosseller

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

AMENDED AND RESTATED DEVELOPMENT AGREEMENT

This Amended and Restated Development Agreement (this "**Agreement**") is made and entered into effective as of May 21, 2024 ("Effective Date") by and between Tandem Diabetes Care, Inc, having a principal place of business at 12400 High Bluff Drive, San Diego, CA 92130 ("**Tandem**") and DexCom, Inc., a Delaware corporation having a principal place of business at 6340 Sequence Drive, San Diego, CA 92121 ("**DexCom**"). Tandem and DexCom may be referred to in this Agreement individually as a "**Party**" and collectively as the "**Parties.**"

RECITALS

A. DexCom is in the business of developing and commercializing continuous glucose monitoring systems;

B. Tandem is in the business of developing and commercializing insulin pump systems;

C. The Parties entered into that certain development agreement dated June 4, 2015, as amended, to enable the integration of Tandem's t:slim X2™ insulin pump with DexCom's G6® CGM device (the "**On-Market t-slim:G6 Implementation**" and such agreement, the "**Original G6 Development Agreement**");

D. On February 7, 2020, DexCom issued a notice of termination for (i) the development agreement dated January 4, 2013, which addressed the integration of Tandem's insulin pump with DexCom's G4® CGM device (the "**G4 Development Agreement**"), which termination became effective August 10, 2020 and (ii) the development agreement dated June 4, 2015, which addressed the integration of Tandem's insulin pump with DexCom's G5® CGM device (the "**G5 Development Agreement**" and collectively with the G4 Development Agreement, "**Legacy Development Agreements**"), which terminated on December 31, 2020 with respect to all countries other than Australia and terminated on December 31, 2021 with respect to Australia;

E. On January 23, 2023, Tandem completed its acquisition of AMF Medical SA (now known as Tandem Diabetes Care Switzerland Sàrl), the developer of the Sigi™ insulin pump ("**Sigi**");

F. The Parties previously entered into a Development Agreement (the "**Superseded Development Agreement**") effective as of November 20, 2020 (the "**Original Effective Date**"), which this Agreement amends and restates in its entirety effective as of the Effective Date; and

G. The Parties previously entered into a Commercialization Agreement effective as of November 20, 2020, which the Parties are also amending and restating in its entirety in connection with this Agreement pursuant to an amended and restated commercialization agreement (the "**Commercialization Agreement**") which sets forth the terms for the commercialization of both the integrated technology solutions developed hereunder and the integrated technology solutions developed under the Original G6 Development Agreement.

The Parties therefore agree as follows:

1. **DEFINITIONS**

1.1 "**Affiliate**" means any corporation or other entity that is directly or indirectly controlling, controlled by or under common control with a Party. For the purpose of this definition, "control" means: (i) the direct or indirect ownership of more than fifty percent (50%) of the capital stock of the subject entity; (ii) the direct or indirect control of more than fifty percent (50%) of the voting rights of the subject entity; or (iii) the possession, directly or indirectly, of the power to direct or cause the direction of the management or policies of the subject entity (whether through ownership of securities or other ownership interests, by contract or otherwise).

1.2 **"***"** means, (a) with respect to DexCom *** and (b) with respect to Tandem ***.

1.3 "**CGM**" means continuous glucose monitoring.

1.4 "**Change of Control**" means a transaction or a series of related transactions: (i) in which one or more related parties that did not previously own or control greater than a fifty percent (50%) equity interest in a Party obtains ownership or control of greater than a fifty percent (50%) equity interest in a Party; (ii) as a result of which one or more related parties that did not previously have the right or power to control the management or policies of a Party acquires such right or power; or (iii) in which a Party sells all or substantially all of its assets to a Third Party.

1.5 "**Clinical Study**" means any pre or post approval clinical study involving the administration of and/or use of a Combined System with a human subject, whether conducted before or after Regulatory Approval of a Combined System, including clinical studies to support such Regulatory Approval process or as otherwise required by a Regulatory Authority.

1.6 "**Combined System**" means an integrated technology solution comprised of the DexCom System and the Tandem System that enables ***. The Parties agree that the integrated technology solution(s) developed by the Parties pursuant to the Legacy Development Agreements, and any improvements thereto, are not Combined Systems hereunder. The Parties agree that the On-Market t-slim:G6 Implementation developed by the Parties pursuant to the Original G6 Development Agreement is a Combined System hereunder.

1.7 **"Combined System Implementation"** means, as applicable, an implementation of the Combined System, involving the integration of Tandem's Mobi insulin pump with DexCom's G6® CGM device, the integration of Tandem's t:slim X2™ insulin pump with DexCom's G7® CGM device, the integration of Tandem's Mobi insulin pump with DexCom's G7® CGM device, and the integration of Tandem's Sigi insulin pump with DexCom's G7® CGM device, in each case, as developed under this Agreement. The Parties agree that the On-Market t-slim:G6 Implementation, including any improvement thereto, is not a Combined System Implementation. The current architecture for the Combined System Implementations is listed in **Exhibit A**.

1.8 "**Commercially Reasonable Efforts**" means the carrying out of a Party's obligations under this Agreement with the exercise of prudent scientific and business judgment and a level of effort and resources consistent with the efforts and resources that the Party who bears the performance obligation, but in any event at least the level of effort and resources of a similarly-sized comparable Third Party in the CGM or insulin delivery device industry, as applicable, would employ for products of similar strategic importance and commercial value that result from its own research efforts.

1.9 "**Committee**" means any of the Development Working Team, Commercial Working Team, Joint Steering Committee and any subordinate committee appointed by such Working Teams or the Joint Steering Committee.

1.10 "**Communication Protocol**" means a DexCom communication protocol that permits a DexCom CGM-Enabled Tandem Display Device to identify, receive and display DexCom CGM Data and to control the DexCom CGM Transmitter, which communication protocol will be developed by or on behalf of DexCom under the Development Plan, as may be amended or updated by DexCom from time to time in accordance with the Development Plan.

1.11 "**Development Plan**" means the written plan setting forth the activities and related obligations to be performed by the Parties with respect to the development and validation of the Combined System Implementations with respect to DexCom's G6® and G7® CGM devices, as such plan may be updated from time to time by the Development Working Team as set forth below, including the following:

1.11.1 Applicable specifications;

1.11.2 Applicable deliverables;

1.11.3 Assigned key personnel (which for clarity shall be for informational purposes only and each Party shall be free to change its key personnel at any time);

1.11.4 Applicable development milestones;

1.11.5 Applicable Regulatory Approvals; and

1.11.6 Any other matters related to the development of the Combined System Implementations that the Development Working Team deems material.

1.12 "**DexCom CGM App**" means any software (including any software application) of DexCom or its Affiliates designed to gather DexCom CGM Data in connection with a Combined System, which may include ***, depending on the configuration of such Combined System, as described in more detail in the Development Plan.

1.13 "**DexCom CGM Data**" means the continuous glucose monitoring data displayed on the receiver or other display device connected to a DexCom System (in each case solely to the extent such DexCom System is used as part of a Combined System in accordance with this Agreement or the Commercialization Agreement), as set forth in more detail in Exhibit B to the Commercialization Agreement. For clarity, DexCom CGM Data excludes any raw CGM sensor data.

1.14 "**DexCom CGM Device**" means DexCom's CGM devices known as DexCom G6® and DexCom G7®, including any Minor Release thereof.

1.15 "**DexCom CGM-Enabled Tandem Display Device**" means a Tandem Display Device comprising a receiver or other component of the Tandem Insulin Delivery Device configured to identify, Process and/or display DexCom CGM Data from a DexCom CGM Transmitter and control the DexCom CGM Transmitter, as described in more detail in the Development Plan. A DexCom CGM-Enabled Tandem Display Device will be independently developed by Tandem and is not, and will not be, a component of any DexCom System.

1.16 "**DexCom CGM Transmitter**" means the transmitter component of the DexCom System (which may be a standalone DexCom transmitter that operably couples to the DexCom Sensor or an embedded component of a DexCom Sensor) that is configured to transmit DexCom CGM Data from a DexCom Sensor to any receiver adapted to identify, receive, and display such information, and is also controlled from an authenticated receiver and the DexCom CGM App.

1.17 "**DexCom Sensor**" means the component of a DexCom System comprising a continuous glucose monitoring electrode sensor, adapted to (i) penetrate the patient's skin to come into contact with the patient's interstitial fluid, (ii) measure interstitial fluid glucose level, and (iii) be operably coupled to a DexCom CGM Transmitter to communicate the blood glucose value as measured by such sensor, to a separate receiver.

1.18 "**DexCom System**" means a CGM system comprised of a DexCom CGM Device and one or more DexCom CGM Apps, as described in more detail in the Development Plan.

1.19 "**EMA**" means the European Medicines Agency or any successor agency thereto.

1.20 "**EU**" means those countries that are members of the European Union as of the date on which the relevant determination is being made.

1.21 "**FDA**" means the United States Food and Drug Administration or any successor agency thereto.

1.22 "**Governmental Authority**" means any (i) international, regional, national, federal, state, or local government entity, authority, agency, instrumentality, court, tribunal, regulatory commission or other body, either foreign or domestic, whether legislative, judicial, administrative or executive; or (ii) arbitrator to whom a dispute has been presented under government rule or by agreement of the Parties with an interest in such dispute.

1.23 "**Intellectual Property**" means (collectively): any copyright, patent or patent application (including any foreign counterparts of any of the foregoing, as well as all continuations, continuations-in-part, divisionals, reissues, reexaminations, and all renewals and extensions thereof, regardless of whether such rights arise under the laws of the United States or any other state, country or jurisdiction), inventions, trade secrets, methods, know-how, technology, information, data and results (including pharmacological, biological, chemical, biochemical, toxicological, and clinical test data and results), software, algorithms, rights of publicity, authors' rights, goodwill and all other intellectual property rights as may exist now and/or hereafter come into existence. Intellectual Property shall include Software and Copyrights, but shall exclude all Trademarks.

1.24 "**Internal Compliance Policies**" means a Party's internal policies and procedures intended to ensure that a Party complies with Applicable Laws, Party-Specific Regulations, and such Party's internal ethical, medical and similar standards.

1.25 "**Major Release**" means a new generation of a product (*e.g.*, in the case of the DexCom System, G7® as compared to G6®) that adds material features and functionality improving overall performance, efficiency and/or usability, and designated by the provider as a replacement for a prior generation, excluding for clarity any Minor Release.

1.26 "**Minor Release**" means an intra-generational product release adding functionality in a backwards-compatible manner, or a patch version for such product making backwards-compatible bug fixes.

1.27 "**Party-Specific Regulations**" means all judgments, decrees, orders or similar decisions issued by any Governmental Authority specific to a Party, and all consent decrees, corporate integrity agreements, or other agreements or undertakings of any kind by a Party with any Governmental Authority, in each case as the same may be in effect from time to time and applicable to a Party's activities contemplated by this Agreement.

1.28 "**Personal Data**" means any information or set of information relating to an identified or identifiable individual Processed by either Party through a Combined System or provided or shared by or on behalf of one Party to the other Party under this Agreement, regardless of the medium in which such information is displayed or contained, which shall include (a) all information that identifies that individual or could reasonably be used to identify such individual, (b) all "personal information," "personal data," and/or "protected health information" under applicable Privacy Laws (including, as applicable, HIPAA, CCPA, GDPR, and APPI), and (c) all information to which any applicable Privacy Laws apply and shall, at a minimum, include any information which relates to an identified or identifiable natural person.

1.29 "**PMA**" means premarket approval.

1.30 "**Privacy Laws**" means all applicable foreign, federal, state, and local laws and regulations governing the Processing, sharing, safeguarding, security, disclosure or transfer of Personal Data (including electronic transaction sets, medical code sets, provider identifier, employer identifier, and patient identifier), as amended from time to time, including, as applicable, (i) HIPAA and the HITECH Act and all amendments to and further regulations of HIPAA and the HITECH Act, (ii) the EU General Data Protection Regulation 2016/679 ("**GDPR**"), (iii) California Consumer Privacy Act ("**CCPA**"), (iv) Japan's Act on the Protection of Personal Information ("**APPI**"), and (v) the CAN-SPAM Act, Canada's Anti-Spam Legislation and other laws or regulations governing telemarketing, including any such laws or regulations prohibiting unsolicited telephone calls to persons or entities listed on "Do Not Call" registries or similar lists or prohibiting unsolicited e-mails, spam or faxes to any person.

1.31 "**Processing**" (including "**Process**" and "**Processed**") means any operation or set of operations that is performed on Personal Data, DexCom CGM Data or Tandem Insulin Data, within an entity that maintains such information, including receipt, use, collection, recording, maintaining, organization, storage, adaptation, modification, retrieval, consultation, retention, alteration, dissemination, transmission, access, transfer, combination, erasure, destruction, deidentification, or pseudonymization. Processing does not include the release, transfer,

provision of, access to, or divulging in any other manner of Personal Data outside the Party maintaining such information (and its Affiliates) and not to the other Party or its Affiliates.

1.32 "**Regulatory Approval**" means, with respect to a country, any and all classifications, clearances, approvals, licenses, registrations or authorizations of any Regulatory Authority necessary to commercially distribute, sell or market a product in such country, including, as may be applicable, PMA, a premarket notification (510(k)) or a *de novo* application in the United States or analogous clearance or approval in other jurisdictions, including a CE marking approval in the EU; ***.

1.33 "**Regulatory Authority**" means the FDA, the EMA or any supranational, national or local agency, authority, department, inspectorate, ministry official, parliament or public or statutory person of any government of any country, including a notified body, having jurisdiction over any of the activities contemplated by this Agreement or the Parties, or any successor bodies thereto.

1.34 "**Regulatory Documentation**" means all (i) applications, registrations, licenses, authorizations and approvals (including Regulatory Approvals); and (ii) correspondence, reports and other submissions submitted to or received from Regulatory Authorities and all supporting documents with respect thereto, including all adverse event files and complaint files.

1.35 "**Representatives**" means a Party's and its Affiliates' employees, officers, directors, consultants and legal, technical and business advisors.

1.36 "**Software and Copyrights**" means software, code, works of authorship and copyrightable subject matter.

1.37 **"System**" means, (i) with respect to DexCom, the DexCom System as used in a Combined System, and (ii) with respect to Tandem, the Tandem System as used in a Combined System.

1.38 "**Tandem Development Tools**" means those application program interfaces and developer tools that Tandem provides or otherwise makes available to DexCom for use in connection with the Development Plan.

1.39 "**Tandem Diabetes Management App**" means any diabetes management software (including any software application), of Tandem or its Affiliates for use in connection with the Tandem Insulin Delivery Device, and associated data management software, which may include ***, depending on the configuration of such Combined System, as described in more detail in the Development Plan.

1.40 "**Tandem Display Device**" means a device used in connection with, or as a component of, the Tandem Insulin Delivery Device that communicates with and controls (fully or partially) the Tandem Insulin Delivery Device and which also Processes data related to the Tandem System.

1.41 "**Tandem Insulin Data**" means any insulin data generated by a Tandem System (solely to the extent such Tandem System is used as part of a Combined System in accordance with this Agreement or the Commercialization Agreement) and made available to DexCom through the Tandem Partner CID, as set forth in more detail in Exhibit D to the Commercialization Agreement. For clarity, Tandem Insulin Data does not include any data not specified in the Tandem Partner CID.

1.42 "**Tandem Insulin Delivery Device**" means Tandem's pump products known as t:slim X2™, Mobi and Sigi, with or without a dedicated controller, including any Minor Release thereof.

1.43 "**Tandem Partner CID**" means the communication interface description ("**CID**") that defines the messaging protocol used to allow the Tandem System to communicate *** Data to a DexCom CGM App.

1.44 "**Tandem Partner CID Documentation**" means written documentation, including any specifications, provided by or on behalf of Tandem to DexCom, sufficient to allow DexCom to build code such that

*** Data may be transferred into a DexCom CGM App from the Tandem System when a User uses the Tandem Partner CID.

1.45 "**Tandem System**" means a subcutaneous infusion system comprised of a Tandem Insulin Delivery Device, a Tandem Display Device and one or more Tandem Diabetes Management Apps, as described in more detail in the Development Plan.

1.46 "**Third Party**" means any entity or person other than DexCom or Tandem or their respective Affiliates.

1.47 "**Trademarks**" means all trade names, trademarks, service marks, logos and trade dress, including applications therefor, and all rights therein and thereto, together with all goodwill associated therewith.

1.48 "**Transaction Agreements**" means, collectively, this Agreement, the Commercialization Agreement and the Quality Agreement.

1.49 **Additional Definitions.** Any capitalized terms not defined in this Agreement have the meaning as defined in the Commercialization Agreement. The following table identifies the location of definitions set forth in various Sections of this Agreement (or, where applicable, the Commercialization Agreement):

Defined Term	Section Reference
***	***
***	***
"Agreement"	Preamble to this Agreement
***	***
"Alliance Manager"	Section 2.7
"Anti-Corruption Laws"	Commercialization Agreement
***	***
***	***
"Combined System Infringement Action"	Section 7.4
"Commercial Working Team"	Commercialization Agreement
"Commercialization Agreement"	Recitals to this Agreement
"Commercialization Plan"	Commercialization Agreement
***	***
"Confidential Information"	Section 6.1
"Development Working Team"	Section 2.3.1
"DexCom"	Preamble to this Agreement
"DexCom Indemnitees"	Section 7.2
***	***
"Disclosing Party"	Section 6.1
***	***
"G4 Development Agreement"	Recitals to this Agreement
"G5 Development Agreement"	Recitals to this Agreement
"Indemnitee"	Section 7.6
"Indemnitor"	Section 7.6
"Joint Steering Committee"	Section 2.4.1
"Legacy Development Agreements"	Recitals to this Agreement
"Losses"	Section 7.1

"Notifying Party"	Section 8.2.1
"On-Market t-slim:G6 Implementation"	Recitals to this Agreement
"Original G6 Development Agreement"	Recitals to this Agreement
"Original Effective Date"	Preamble to this Agreement.
"Party" and "Parties"	Preamble to this Agreement
***	***
"Publication"	Section 6.7
"Quality Agreement"	Commercialization Agreement
"Receiving Party"	Section 6.1
"Relevant DexCom Regulatory Meetings"	Section 4.2.4
"Relevant Tandem Regulatory Meetings"	Section 4.1.2
"Tandem"	Preamble to this Agreement
"Tandem Indemnitees"	Section 7.1
"Term"	Section 8.1
"Termination Support Services"	Section 8.6.3
"TypeZero License Agreement"	Section 3.1.2

2. **DEVELOPMENT, DEVELOPMENT WORKING TEAM, JOINT STEERING COMMITTEE, AND PARTY RESPONSIBILITIES**

2.1 Development Generally. Following the Original Effective Date, the Parties (through the Development Working Team) jointly developed and agreed on the Development Plan. Each Party shall use Commercially Reasonable Efforts to perform its designated responsibilities and work under the Development Plan; provided, that each Party acknowledges that there is no guarantee of any successful results from the performance of such Development Plan.

2.2 Conduct of Development Plan; Compliance with Law. The Parties shall conduct the Development Plan, or cause the same to be done, (i) using reasonable and customary good scientific practices and in accordance with all Applicable Laws, the provisions of this Agreement (including the Development Plan), and (ii) in accordance with, in the case of Tandem, Tandem's Internal Compliance Policies, and in the case of DexCom, DexCom's Internal Compliance Policies, to the extent such Internal Compliance Policies do not conflict with the Applicable Laws.

2.3 Development Working Team.

2.3.1 The Parties shall establish a management team for the implementation of the Development Plan that shall be comprised of *** for each Party ("**Development Working Team**") (who shall be employees of the appointing Party (or its Affiliate) and at least one of which shall be a member of the Joint Steering Committee). Each Party may replace its Development Working Team members at any time by notice to the other Party.

2.3.2 In accordance with the provisions and objectives of this Agreement and the Development Plan, the Development Working Team shall, subject to Section 2.5:

(i) develop, review and approve the Development Plan;

(ii) oversee, coordinate and manage the Parties' activities under, and implementation of, the Development Plan;

(iii) ensure communication between the Parties concerning the implementation, status and results of the Development Plan;

(iv) exercise decision-making authority over all Development Plan activities in accordance with this Section 2.3 and make all such decisions and take all such other actions as are delegated to it in this Agreement;

(v) review and approve updates or amendments to the Development Plan as the Development Working Team determines is appropriate for the Parties to achieve the Development Plan objectives;

(vi) coordinate continuous improvement and technology upgrades for the Combined System Implementations with the Commercial Working Team; and

(vii) perform such other functions as are appropriate to further the purposes of this Agreement as mutually determined in writing by the Parties.

2.3.3 The Development Working Team shall meet as needed but not less than ***, except as may otherwise be agreed in writing by the Parties. Development Working Team meetings shall be held at times and places or in such form, such as by telephone or video conference, as the Development Working Team determines, except that in-person meetings of the Development Working Team will alternate between the Parties' offices, unless otherwise agreed in writing by the Parties. Any Development Working Team member may designate by notice to the other members (which may be provided by e-mail) a qualified Representative of its Party as a substitute to attend and perform the functions of that Development Working Team member at any Development Working Team meeting that such member cannot attend.

2.3.4 The Development Working Team shall appoint one (1) of the Development Working Team members to act as the initial Development Working Team chairperson during such period as the Development Working Team shall designate. At the end of each such designated period during the Term, the Parties shall alternate in appointing the chairperson for the next such defined period. When the Development Working Team *** chairperson cannot attend a Development Working Team meeting, the other member having been previously designated by the same Party shall serve as the temporary Development Working Team chairperson for such meeting, unless neither of such Party's designated Development Working Team members can attend, in which case a qualified substitute designated by the Development Working Team chairperson for such purpose shall serve as the temporary Development Working Team chairperson for such meeting.

2.3.5 The Development Working Team chairperson shall be responsible for:

(i) calling and presiding over each Development Working Team meeting during his or her tenure as chairperson;

(ii) preparing and circulating the agenda for each such meeting; and

(iii) preparing draft minutes of each such meeting and providing a copy of the draft minutes to each Development Working Team member within *** after each such meeting for approval, which shall be deemed to have been given unless the Development Working Team member objects within *** after receipt of the draft minutes.

2.3.6 Each Party shall collectively have one (1) vote in any matter requiring the Development Working Team's action or approval. All Development Working Team decisions shall be unanimous and no Development Working Team vote may be taken unless at least one Development Working Team member of each Party (or properly designated substitute) is present. The Development Working Team shall make all decisions and take other actions in good faith and with due care, after consideration of the information that is reasonably available to it, with the intention that the resulting decision or action shall maintain or increase the likelihood that the Parties will achieve the purposes and goals of the Development Plan.

2.3.7 If the Development Working Team cannot reach a unanimous decision on any matter within its authority at a scheduled Development Working Team meeting or within *** thereafter, then either Party may, by notice to the other Party, refer such matter to the Joint Steering Committee for resolution by good faith discussions for a period of at least ***. In the event that the Joint Steering Committee is unable to reach agreement with respect to such matter within such ***, then the following shall apply:

(i) DexCom shall have the final decision-making authority with respect to (A) the technical specifications for the DexCom System and the Communication Protocol; provided, that such technical specifications are consistent with the general Combined System Implementation features and functionality set forth in the Development Plan and (B) DexCom's day-to-day implementation of its responsibilities under the Development Plan; and

(ii) Tandem shall have the final decision-making authority with respect to (A) the technical specifications for the Tandem System; provided, that such technical specifications are consistent with the general Combined System Implementation features and functionality set forth in the Development Plan and (B) Tandem's day-to-day implementation of its responsibilities under the Development Plan;

Provided, further, that neither Party may exercise its final decision-making authority in a manner that (A) goes beyond the JSC's authority, as limited by Section 2.5, (B) would unilaterally impose any additional or different obligation on the other Party (including for the other Party to incur or share any additional cost), (C) would cause a Party to assume additional regulatory responsibilities, including reporting requirements or (D) would require changes to quality management practices.

2.3.8 The Development Working Team shall keep each Party fully informed of the status and progress of the Development Plan. Except as otherwise provided in this Agreement or in the Development Plan, the Parties will make available and disclose to one another all results of material work conducted pursuant to the Development Plan in the prior period at least *** days prior to and in preparation for the Development Working Team meetings, and in any particular form and format, that is designated by the Development Working Team. For avoidance of doubt, the Parties are under no obligation to disclose information relating to any other research efforts not related to the Development Plan.

2.4 Joint Steering Committee.

2.4.1 The Parties shall establish a committee for oversight of the development and commercialization of the Combined Systems developed under this Agreement and the Original G6 Development Agreement that shall be comprised of two (2) employees of DexCom (or any of DexCom's Affiliates) and two (2) employees of Tandem (or any of Tandem's Affiliates) ("**Joint Steering Committee**"). Each Party may replace its Joint Steering Committee members at any time by notice to the other Party.

2.4.2 In accordance with the provisions and objectives of this Agreement, the Joint Steering Committee shall, subject to Section 2.5:

(i) Establish strategic objectives and general direction for the Development Working Team and Commercial Working Team and the Combined System Implementations;

(ii) monitor each Party's performance, progress and results with respect to the Development Plan and Commercialization Plan;

(iii) appoint and oversee additional subordinate committees or working groups responsible for certain specific matters (*e.g.*, an intellectual property committee, information security committee, etc.), as and to the extent necessary and appropriate;

(iv) decide on changes to Agreed Markets under a Commercialization Plan as proposed by the Commercial Working Team;

(v) resolve disputes referred to it by either the Development Working Team or the Commercial Working Team; and

(vi) perform such other functions as are appropriate to further the purposes of this Agreement as mutually determined in writing by the Parties.

2.4.3 The Joint Steering Committee shall meet as needed but not less than ***, except as may otherwise be agreed in writing by the Parties. Joint Steering Committee meetings shall be held at times and places or in such form, such as by telephone or video conference, as the Joint Steering Committee determines, except that in-person meetings of the Joint Steering Committee will alternate between the Parties' offices, unless otherwise agreed in writing by the Parties. Any Joint Steering Committee member may designate a qualified Representative of its Party as a substitute to attend and perform the functions of that Joint Steering Committee member at any Joint Steering Committee meeting.

2.4.4 Subject to such persons being bound by written agreement(s) or other legally enforceable obligations concerning confidentiality and proper assignment of Intellectual Property under the Development Plan consistent with the terms of this Agreement, each Party may invite additional Representatives to attend Joint Steering Committee meetings to make presentations, without any voting authority, on written notice to the other Party's members of the Joint Steering Committee (including notice sent via e-mail) before the Joint Steering Committee meeting that the Representative will attend.

2.4.5 Each Party shall collectively have one (1) vote in any matter requiring the Joint Steering Committee action or approval. All Joint Steering Committee decisions shall be unanimous and no Joint Steering Committee vote may be taken unless at least one Joint Steering Committee member of each Party (or properly designated substitute) is present. The Joint Steering Committee shall make all decisions and take other actions in good faith and with due care, after consideration of the information that is reasonably available to it.

2.4.6 If the Joint Steering Committee cannot reach a unanimous decision on any matter within its authority at a scheduled Joint Steering Committee, meeting or within *** thereafter, then the matter shall be resolved in accordance with Section 2.3.7 of this Agreement if the dispute relates to the Development Plan (or activities thereunder or related thereto), or Section 2.3.7 of the Commercialization Agreement if the dispute relates to the Commercialization Plan (or activities thereunder or related under), or if not subject to dispute resolution in accordance with either of such Sections, then the status quo shall be maintained until a unanimous decision can be reached.

2.5 Governance Limitations. Each of the Joint Steering Committee and the Development Working Team has only the powers specifically delegated to it by this Agreement (or with respect to the Joint Steering Committee, the Commercialization Agreement) and has no authority to act on behalf of any Party in connection with any Third Party. Without limiting the foregoing, and notwithstanding anything in this Agreement to the contrary, neither the Joint Steering Committee nor the Development Working Team has any authority to, and shall not purport to or attempt to:

(i) amend this Agreement or any other Transaction Agreement;

(ii) approve or take any action that would breach or conflict with any provision of this Agreement or of any other Transaction Agreement;

(iii) negotiate agreements on behalf of any Party;

(iv) make representations or warranties on behalf of any Party;

(v) determine compliance or non-compliance with any provision of this Agreement or of any other Transaction Agreement; provided, that the Joint Steering Committee shall have the right to discuss any such non-compliance;

(vi) waive any rights of any Party;

(vii) extend credit on behalf of any Party; or

(viii) take or grant licenses of, transfer ownership or otherwise encumber Intellectual Property on behalf of any Party.

2.6 Governance ***. Each Party shall *** of its respective Joint Steering Committee and Development Working Team members, and their designated substitutes, related to their participation on the Joint Steering Committee and Development Working Team and attendance at Joint Steering Committee and Development Working Team meetings.

2.7 Alliance Managers. Each of Tandem and DexCom shall appoint one (1) Representative who possesses a general understanding of development and commercialization issues to act as its alliance manager (each, an "**Alliance Manager**"). Each of Tandem and DexCom may change its designated Alliance Manager from time to time upon written notice to the other Party. Any Alliance Manager may designate another Representative of its Party as a substitute to temporarily perform the functions of that Alliance Manager upon written notice to the other Party's Alliance Manager. The Alliance Managers shall attend all meetings of the Joint Steering Committee, Development Working Team and Commercial Working Team (and each Alliance Manager may attend any other Committee meetings that he or she desires to attend) as non-voting participants and support the Committee members in the discharge of their responsibilities.

2.7.1 Responsibilities. In accordance with, and without limiting the terms of this Agreement and the Commercialization Agreement, each Alliance Manager shall:

(i) identify and bring disagreements and issues that may result in disputes (including any asserted occurrence of a material breach by a Party) to the attention of the Joint Steering Committee, Development Working Team and/or Commercial Working Team, as applicable, in a timely manner, and function as the point of first referral in all matters of conflict resolution;

(ii) provide a single point of communication for seeking consensus both internally within the Parties' respective organizations and between the Parties;

(iii) plan and coordinate cooperative efforts, internal communications and external communications between the Parties with respect to this Agreement and the Commercialization Agreement; and

(iv) take responsibility for ensuring that meetings and the production of meeting agendas and minutes occur as set forth in this Agreement and the Commercialization Agreement, and that relevant action items resulting from such meetings are appropriately carried out or otherwise addressed.

The Alliance Managers shall jointly be responsible for:

(A) calling each Joint Steering Committee meeting;
(B) preparing and circulating the agenda for each Joint Steering Committee meeting; and
(C) preparing draft minutes of each Joint Steering Committee meeting and providing a copy of the draft minutes to each Joint Steering Committee member within *** after each such meeting for approval, which shall be deemed to have been given unless any Joint Steering Committee member objects within

*** after receipt of the draft minutes. The Parties shall work in good faith to promptly resolve any dispute regarding such draft minutes.

2.8 Tandem's Development Related Responsibilities. Unless otherwise determined by the Development Working Team, or stated otherwise in the Development Plan, Tandem shall:

2.8.1 be solely responsible for all design and development activities associated with the development of the DexCom CGM-Enabled Tandem Display Devices and Tandem Diabetes Management Apps;

2.8.2 commit personnel and resources and formulate a plan to achieve the milestones set forth in the Development Plan. For the avoidance of doubt, such personnel may work on projects not related to the Combined System Implementations, provided they use Commercially Reasonable Efforts to achieve the milestones set forth in the Development Plan;

2.8.3 use Commercially Reasonable Efforts in the design and development of the Combined System Implementations to give such Combined Systems the ability to: (1) *** (2) ***, in compliance with all Privacy Laws, and (3) operate using commercially reasonable cybersecurity measures.

2.9 DexCom Development Related Responsibilities. Unless otherwise determined by the Development Working Team, or stated otherwise in the Development Plan, DexCom shall:

2.9.1 be solely responsible for the design and development of the DexCom CGM Devices and DexCom CGM Apps;

2.9.2 commit personnel and resources and formulate a plan to achieve the milestones set forth in the Development Plan. For the avoidance of doubt, such personnel may work on projects not related to the Combined System Implementations, provided they use Commercially Reasonable Efforts to achieve the milestones set forth in the Development Plan;

2.9.3 use Commercially Reasonable Efforts to support the integration of DexCom CGM Data into the Combined System Implementations in accordance with the Development Plan; and

2.9.4 use Commercially Reasonable Efforts in the design and development of the Combined System Implementations to give such Combined Systems the ability to operate using commercially reasonable cybersecurity measures and in compliance with all Privacy Laws.

2.10 Costs. Unless otherwise mutually agreed by the Parties in the Development Plan, ***.

2.11 Clinical Studies.

2.11.1 Subject to this Section 2.11.1 and Section 2.11.2, Tandem shall have the sole right to (a) determine, in its sole discretion, the need for any Clinical Studies for the Combined System Implementations to the extent necessary or reasonably useful to obtain or maintain Regulatory Approval for such Combined System Implementations, and (b) to conduct, support or sponsor such Clinical Studies, provided that, in each instance in which Tandem conducts or is the sponsor (from a regulatory perspective) of any such Clinical Trial, ***. Tandem shall keep DexCom reasonably informed of Clinical Studies conducted, supported or sponsored by Tandem through regular updates to the JSC, which updates shall (i) address the nature, anticipated timing and progress with each such Clinical Study, and (ii) identify any and all contract research organizations engaged by or on behalf of Tandem to provide services in connection with such Clinical Study, and with respect to any Clinical Study sponsored by Tandem, Tandem shall consider in good faith any input timely received from DexCom. Without limiting the foregoing, Tandem shall ***. Upon request, DexCom will (i) provide reasonable assistance and reasonably cooperate with Tandem to ***, and (ii) ***. Notwithstanding anything to the contrary contained in this Agreement or any other Transaction Agreements, any and all non-public information provided by DexCom to Tandem relating

to (A) *** or (B) the *** constitute Confidential Information and trade secrets of DexCom, and shall be subject to the provisions of Section 6.

2.11.2 In no event shall a Party conduct any Clinical Studies that ***.

2.11.3 For clarity, nothing in this Agreement or the Commercialization Agreement shall prevent Tandem, as the sponsor of a Clinical Study hereunder, from undertaking in good faith any exigent action that it reasonably believes it is required to undertake as such sponsor to protect the safety of study subjects, to protect the integrity of study data or to comply with Applicable Laws.

2.12 Version Support. Beginning on the date of the first Regulatory Approval of each Combined System Implementation, each Party agrees, for the Term, to use Commercially Reasonable Efforts to conduct and support continuous development of such Combined System Implementation with respect to any Minor Release or Major Release of its System or component thereof, as set forth herein, ***.

2.13 DexCom Discontinuation. Notwithstanding Section 2.12, DexCom may, in its sole discretion,

(i) ***;

(ii) discontinue its support of the then-current DexCom CGM Device (a) in *** subsequent to *** or (b) in *** any time commencing ***; and

(iii) *** DexCom CGM Device *** at any time commencing *** after ***.

3. INTELLECTUAL PROPERTY OWNERSHIP AND LICENSES

3.1 Intellectual Property Ownership.

3.1.1 Except as set forth in Section 3.2 or as otherwise expressly set forth in herein, this Agreement does not comprise an assignment or license of any Intellectual Property by either Party to the other.

3.1.2 As between the Parties, DexCom (and/or its Affiliates) will solely own and retain all rights, title and interest to any Intellectual Property owned or Controlled by DexCom (and/or its Affiliates) as of the Original Effective Date or developed or acquired by DexCom (and/or its Affiliates) during the Term independently from this Agreement and the Commercialization Agreement or developed solely by or on behalf of DexCom (and/or its Affiliates) pursuant to this Agreement or the Commercialization Agreement, including for clarity any such Intellectual Property related to the Communication Protocol. As between the Parties, Tandem (and/or its Affiliates) will own and retain all rights, title and interest to any Intellectual Property owned or Controlled by Tandem (and/or its Affiliates) as of the Original Effective Date or developed or acquired by Tandem (and/or its Affiliates) during the Term independently from this Agreement and the Commercialization Agreement or solely developed by or on behalf of Tandem (and/or its Affiliates) pursuant to this Agreement or the Commercialization Agreement, including for clarity any such Intellectual Property related to the Tandem Partner CID or any Tandem Development Tool. This Agreement does not amend or modify the terms of the License Agreement between TypeZero Technologies LLC and Tandem dated July 14, 2016, as amended (the "**TypeZero License Agreement**").

3.1.3 The Parties do not intend for there to be any "joint inventions" under this Agreement. Notwithstanding the foregoing, to the extent any Intellectual Property is developed by employees or contractors of DexCom or its Affiliates jointly with employees or contractors of Tandem or its Affiliates in the course of their performance under this Agreement or the Commercialization Agreement, (i) such Intellectual Property shall be deemed to be both Parties' Confidential Information, such that each Party shall be deemed to be a Receiving Party with respect thereto; (ii) the Parties will jointly own such Intellectual Property, and each Party shall have the right to exploit such jointly owned Intellectual Property and freely grant licenses to Affiliates or Third Parties under its interest therein without the consent of or accounting to, the other Party, subject to Section 6; and (iii) at either

Party's request, the Parties shall discuss in good faith whether and where to file any patent applications covering such jointly owned Intellectual Property.

3.2 DexCom Granted Licenses in Intellectual Property.

3.2.1 License Grant. Subject to the terms and conditions in this Agreement and any other applicable Transaction Agreement, DexCom hereby grants Tandem ***, non-exclusive license to use the Communication Protocol solely for the purpose of developing and commercializing each DexCom CGM-Enabled Tandem Display Device for use as part of a Combined System Implementation, including the right to make, have made, use, sell, offer to sell, have sold and import such DexCom CGM-Enabled Tandem Display Devices.

3.2.2 Limitations on Use. Tandem agrees not to distribute, license, sublicense or otherwise transfer the Communication Protocol to any Third Party other than, subject to Section 10.2, subcontractors that have entered into written agreements (or are otherwise subject to legally enforceable obligations) (i) whereby all ownership rights in any Intellectual Property made or developed through such distribution, license, sublicense or transfer will be duly vested in Tandem (or its Affiliate); and (ii) containing obligations of nonuse and nondisclosure of Confidential Information consistent with the terms of this Agreement. Tandem shall have no right, under this Agreement to intercept, propagate, reverse engineer, disassemble, de-encrypt, or derive the source code for the software or bios included in any DexCom System, or any proprietary component thereof. Tandem is not granted any right to raw sensor data received or generated by any DexCom System and/or used by the DexCom System to produce the DexCom CGM Data or any other output beyond the data made available through the Communication Protocol, and will not try to derive, de-encrypt or intercept any of such data. Tandem shall not access or use any information within the DexCom System other than as set forth in this Agreement.

3.3 Tandem Granted Licenses in Intellectual Property.

3.3.1 License Grant. Subject to the terms and conditions in this Agreement and any other applicable Transaction Agreement, Tandem hereby grants DexCom a *** non-exclusive license to use the Tandem Partner CID Documentation, Tandem Partner CID and Tandem Development Tools solely for the purpose of accessing Tandem Insulin Data in accordance with the Combined System Implementations contemplated by the Development Plan.

3.3.2 Limitations on Use. DexCom agrees not to distribute, license, sublicense or otherwise transfer the Tandem Partner CID Documentation, Tandem Partner CID or any Tandem Development Tool to any Third Party other than, subject to Section 10.2, subcontractors that have entered into written agreements (or are otherwise subject to legally enforceable obligations) (i) whereby all ownership rights in any Intellectual Property made or developed through such distribution, license, sublicense or transfer will be duly vested in DexCom (or its Affiliate); and (ii) containing obligations of nonuse and nondisclosure of Confidential Information consistent with the terms of this Agreement. DexCom shall have no right under this Agreement to intercept, propagate, reverse engineer, disassemble, de-encrypt, or derive the source code for the software or bios included in any Tandem System, or any proprietary component thereof. DexCom is not granted any right to any data within the Tandem System beyond the data made available through the Tandem Partner CID, and will not try to derive, de-encrypt or intercept any of such data. DexCom shall not access or use any information within the Tandem System other than as set forth in this Agreement.

3.3.3 Agreements with Representatives. Each Party shall ensure that each Representative involved in any way with the development of the Combined System Implementations, including such Party's Alliance Manager and appointed members of the Joint Steering Committee and the Development Working Group, shall have entered into written agreements (or are otherwise subject to legally enforceable obligations) (i) whereby all ownership rights in any Intellectual Property made or developed by them under the Development Plan will be duly vested in such Party (or its Affiliate); and (ii) containing obligations of nonuse and nondisclosure of Confidential Information consistent with the terms of this Agreement.

3.3.4 Representations Regarding Licensed Intellectual Property. DexCom represents and warrants to Tandem that DexCom has the right to provide the Communication Protocol to Tandem for Tandem's use in accordance with the terms of this Agreement. Tandem represents and warrants to DexCom that Tandem has the right to provide the Tandem Partner CID, Tandem Partner CID Documentation, and Tandem Development Tools to DexCom for DexCom's use in accordance with the terms of this Agreement. Except as otherwise provided in this Agreement, all rights granted under this Section 3 are granted "as is" with no representations or warranties made regarding the validity, utility or performance of any Intellectual Property licensed hereunder.

3.4 All Rights Retained. Except as expressly set forth in this Agreement and any other applicable Transaction Agreement, neither Party grants to the other Party under this Agreement or any other applicable Transaction Agreement any rights or license in or to any Intellectual Property owned or Controlled by such Party or any of its Affiliates, whether by implication, estoppel, or otherwise.

4. REGULATORY MATTERS

4.1 Tandem's Testing and Regulatory Responsibilities.

4.1.1 Tandem will be responsible for performing and leading all regulatory testing and related tasks, including all Clinical Studies and all regulatory filings, for Combined System Implementations, including, as applicable the Tandem Diabetes Management Apps, but excluding DexCom CGM Apps, including all necessary related translations and all Clinical Studies required for all Regulatory Approvals, for the Combined Systems.

4.1.2 To the extent permitted by Applicable Laws and by the applicable Regulatory Authority, Tandem will, in the exercise of its commercially reasonable, good faith judgement and in a timely manner (and in any event with at least *** except where not reasonably feasible), *** with relevant Regulatory Authorities as necessary to support Regulatory Approval of the Combined System Implementations that are specific to *** ("**Relevant Tandem Regulatory Meetings**"). At the request of Tandem, DexCom shall ***. Where reasonably feasible with the Regulatory Authority, Tandem shall *** reasonably in advance of such Relevant Tandem Regulatory Meeting. Tandem will endeavor to ***. Furthermore, in any meeting or teleconference with Regulatory Authorities (or portion thereof) that ***, Tandem shall (i) ***, and (ii) promptly (and in any event within ***) following the Relevant Tandem Regulatory Meeting, (a) *** and (b) ***, to the extent pertaining to ***. As soon as practicable following ***, the Parties shall ***.

4.2 DexCom's Testing and Regulatory Responsibilities.

4.2.1 DexCom will be responsible for performing and leading all regulatory testing and related tasks for the DexCom CGM Devices, and the DexCom CGM App, including all necessary related translations, and for the avoidance of doubt, the DexCom System.

4.2.2 DexCom will designate personnel to provide reasonable support for Tandem in testing of the Combined System Implementations as related to performance of the DexCom CGM Devices and the DexCom CGM App.

4.2.3 Without limiting Section 4.1.2, upon Tandem's request, DexCom will participate in joint meetings with Tandem with relevant Regulatory Authorities as reasonably necessary to support Regulatory Approval of Combined System Implementations, including, as applicable the Tandem Diabetes Management Apps, but excluding DexCom CGM Apps.

4.2.4 To the extent permitted by Applicable Laws and by the applicable Regulatory Authority, DexCom will, in the exercise of its commercially reasonable, good faith judgement and in a timely manner (and in any event with at least *** prior notice to Tandem except where not reasonably feasible), *** any and all meetings and teleconferences with DexCom with relevant Regulatory Authorities as necessary to support Regulatory Approval of the Combined Systems that are specific to *** ("**Relevant DexCom Regulatory Meetings**"). At the request of DexCom, Tandem shall ***. Where reasonably feasible with the Regulatory Authority, DexCom shall *** reasonably in advance of such Relevant DexCom Regulatory Meeting. DexCom will endeavor to ***.

Furthermore, in any meeting or teleconference with Regulatory Authorities (or portion thereof) that ***, DexCom shall (i)***, and (ii) promptly (and in any event within ***) following the Relevant DexCom Regulatory Meeting, (a) *** and (b) ***, to the extent pertaining to ***. As soon as practicable following ***, the Parties shall ***.

4.3 Right to Reference. Each Party hereby has the right to cross reference, refer to, rely on, file, incorporate by reference, or otherwise use any regulatory submission or drug master file controlled by the other Party or its Affiliates (and any data contained therein) for the Combined System Implementations or any component thereof, made in any country in the Agreed Markets (including all Regulatory Approvals); provided, that (i) Tandem's right to cross-reference, refer to, rely on, file, incorporate by reference or otherwise use shall be limited to doing so in order to support regulatory submissions that Tandem makes under this Agreement or any other Transaction Agreement for the Combined System Implementations in the Agreed Markets and to enable Tandem to fulfill its obligations, or exercise its rights, under this Agreement or any other Transaction Agreement to develop and/or to commercialize the Combined System Implementations in the Agreed Markets, including doing so in order to conduct, support or sponsor Clinical Studies utilizing such DexCom CGM-Enabled Tandem Display Device, and (ii) DexCom's right to cross-reference, refer to, rely on, file, incorporate by reference or otherwise use shall be limited to doing so in order to support regulatory submissions that DexCom makes under this Agreement or any other Transaction Agreement for the DexCom System for use with the Combined System Implementations in the Agreed Markets. Each Party hereby agrees to promptly provide or have provided to the applicable Regulatory Authorities and/or the other Party or its designee a letter of consent to permit such referencing. In any case in which the Regulatory Authority for the applicable jurisdiction requires a Party to have copies of such filings in order to exercise its rights or perform its obligations hereunder, the other Party shall provide such copies to such requesting Party (provided that the requesting Party shall be responsible for any translation costs in connection therewith).

4.4 Regulatory Obligations and Expenses. In connection with obtaining or maintaining Regulatory Approvals , interacting with Regulatory Authorities, filing or maintaining Regulatory Documentation, or maintaining regulatory records (in each case in relation to its System or the Combined System Implementations), unless required to comply with Applicable Laws, in no instance shall either Party take any action or omit to take any action that, directly or indirectly, would be reasonably likely to result in the other Party incurring (i) additional responsibilities to Regulatory Authorities or otherwise under Applicable Laws that are not listed or described in the Development Plan or Commercialization Plan, or (ii) additional internal or out- of-pocket expenses (including expenses related to additional reporting obligations) that are not listed or described in the Development Plan or Commercialization Plan, in each case without prior written consent of such other Party; provided, that the foregoing shall not limit either Party's right to make any Minor Release or Major Release of, on the part of DexCom, any component(s) of the DexCom System, and on the part of Tandem, any component(s) of the Tandem System.

5. REPRESENTATIONS AND WARRANTIES

5.1 Each Party hereby represents, warrants and covenants, as applicable, to the other Party that:

(i) it is duly organized and validly existing under the laws of its jurisdiction of incorporation or formation;

(ii) it is duly authorized to execute and deliver this Agreement, the person or persons executing this Agreement on its behalf have been duly authorized to do so by all requisite corporate action, and this Agreement is legally binding upon it and enforceable in accordance with its terms;

(iii) it has full corporate right, power and authority to perform its respective obligations under this Agreement, including the right to grant the rights and licenses granted to the other Party hereunder;

(iv) it will obtain and maintain all licenses, permits and other authorizations necessary to perform its obligations hereunder, and will fully cooperate in obtaining and maintaining any approvals from Regulatory Authorities necessary to implement this Agreement;

(v) it will perform its obligations hereunder in compliance with all Applicable Laws, and it has in place a compliance program and internal policies and procedures for its employees and agents to comply with Applicable Laws (including Anti-Corruption Laws and Privacy Laws) as contemplated by Section 6, including training on such policies and procedures and reporting obligations for non-compliance.

(vi) it has not been:

(A) Debarred by the United States Food and Drug Administration under any provision of the Generic Drug Enforcement Act; or

(B) Excluded by the Office of the Inspector General of the United States Department of Health and Human Services, or by any other authority, from participating in any health care program (such as Medicare or Medicaid) funded by any Governmental Authority.

Each Party agrees that no person who has been debarred or excluded as described above will furnish any of the services or deliverables or perform any obligations on behalf of such Party under this Agreement. Neither Party shall subcontract any performance of this Agreement to any person or entity that is on the Specially Designated Nationals and Blocked Persons List (or any successor program) maintained by the United States Department of the Treasury Office of Foreign Assets Control. Each Party will promptly notify the other Party in writing (with a copy to legal counsel) of any formal actions taken or pending, of which the Party has knowledge, that could reasonably be construed to threaten or to confirm a debarment or exclusion of any person on the lists specified in Section 5.1(vi)(A) or (B).

5.2 Disclaimer of Warranties. EXCEPT AS EXPRESSLY SET FORTH IN THIS SECTION 5 OR ELSEWHERE IN THIS AGREEMENT, NEITHER TANDEM NOR DEXCOM MAKES ANY REPRESENTATIONS OR WARRANTIES UNDER THIS AGREEMENT, AND EXPRESSLY DISCLAIMS ANY WARRANTIES WHETHER EXPRESS, IMPLIED, STATUTORY OR OTHERWISE, INCLUDING ANY WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, VALIDITY, OR NON- INFRINGEMENT.

6. CONFIDENTIALITY

6.1 Confidential Information. Except as expressly provided in this Agreement or any other Transaction Agreement, during the Term and for ***, except with respect to Confidential Information constituting trade secrets (to the extent identified by the Disclosing Party in writing or to the extent reasonably identifiable as a trade secret based on the nature and content of the disclosure), which such obligations shall not expire, the Party or its Affiliates receiving Confidential Information (the "**Receiving Party**") from the Disclosing Party: (i) will maintain the Disclosing Party's Confidential Information in strict confidence, and protect and safeguard it using at least the same degree of care as it uses to protect the confidentiality of its own confidential information of similar importance, but no less than a commercially reasonable degree of care; (ii) will not publish or otherwise disclose such Confidential Information, except that the Receiving Party may disclose the Disclosing Party's Confidential Information to its Representatives who have a bona fide need to know such Confidential Information solely for, and only to the extent necessary to pursue, the Purpose, *provided that* each such Representative is bound by a written agreement with the Receiving Party that contains non-use and confidentiality obligations at least as protective of the Disclosing Party's Confidential Information as those set forth in this Agreement; and (iii) will not use such Confidential Information for any purpose other than carrying out Receiving Party's obligations and exercising its rights under this Agreement and any other Transaction Agreement (the "**Purpose**"). For purposes of this Agreement, "**Confidential Information**" means any information furnished by or on behalf of a Party or its Affiliates (the "**Disclosing Party**") in connection with this Agreement or any other Transaction Agreement (including in connection with the negotiation thereof) or either of the Legacy Development Agreements which is confidential or proprietary to the Disclosing Party, including research and development plans and results; processes; evaluation procedures (including clinical and field testing); manufacturing methods; applications to government authorities; pricing or cost information; construction plans; sales, marketing, and advertising studies and plans; customer lists; computer information and software; special techniques unique to a Party's business; information subject to a right of

privacy in favor of a Third Party; information the Disclosing Party maintains under a system of protection against unauthorized access; and, subject to the rights and obligations with respect to disclosure and use thereof contained in the Transaction Agreements (including any rights that users have therein), the DexCom CGM Data and the Tandem Insulin Data. Notwithstanding the foregoing, the Disclosing Party's Confidential Information will not include information that the Receiving Party can demonstrate with competent evidence:

6.1.1 was already known to the Receiving Party, other than under an obligation of confidentiality, at the time of disclosure;

6.1.2 was generally available to the public or otherwise part of the public domain at the time of its disclosure to the Receiving Party;

6.1.3 became generally available to the public or otherwise part of the public domain after its disclosure hereunder and other than through any act or omission of the Receiving Party in breach of this Agreement; or

6.1.4 was subsequently lawfully disclosed to the Receiving Party by a person without breaching a duty of confidentiality or developed by or for the Receiving Party without use of, reliance on, or reference to any Confidential Information of the Disclosing Party.

6.2 Permitted Disclosures. Notwithstanding Section 6.1, a Receiving Party may use or disclose the Disclosing Party's Confidential Information solely to the extent such use or disclosure is reasonably necessary in complying with an order of a court of law, prosecuting or defending litigation, complying with applicable governmental regulations, submitting information to tax or other Governmental Authorities, or conducting Clinical Studies; provided that, subject to Section 6.5, if a Receiving Party is required to make any such disclosure of Confidential Information, it will give the other Party reasonable advanced notice of the disclosure, and use its reasonable efforts to secure confidential treatment of the information prior to its disclosure (whether through protective orders or otherwise).

6.3 Unauthorized Disclosure of Confidential Information. If the Receiving Party becomes aware of an unauthorized disclosure of the Disclosing Party's Confidential Information, then such Receiving Party shall notify the Disclosing Party promptly in writing.

6.4 Return of Confidential Information. Following any expiration or termination of this Agreement and all other Transaction Agreements, within *** after receipt of the Disclosing Party's written request, the Receiving Party will return to the Disclosing Party (where practicable), or, at the Receiving Party's option, destroy and provide written certification of the destruction of, all tangible materials that contain the Disclosing Party's Confidential Information, other than such Confidential Information to which the Receiving Party retains a right to use under this Agreement or any other Transaction Agreement. Notwithstanding the foregoing, (i) the Receiving Party may retain one copy of the Disclosing Party's Confidential Information in the legal files of the Receiving Party for the sole purpose of determining the scope of obligations incurred under this Agreement or as otherwise required by Applicable Laws; (ii) the Receiving Party may retain any electronic copies of the Disclosing Party's Confidential Information held securely in the Receiving Party's electronic backup storage in accordance with its established document retention policies and (iii) the Receiving Party may retain the Disclosing Party's Confidential Information to the extent included in the Receiving Party's board of director or board committee materials or minutes or actions, quality systems, or regulatory history; subject in each case to the Receiving Party's continuing confidentiality and non-use obligations under this Agreement with respect to such Confidential Information.

6.5 Confidentiality Terms; Confidentiality of Agreement; Press Releases.

6.5.1 Except as explicitly permitted under this Section 6.5 or any other Transaction Agreement, neither Party will disclose to any Third Party the terms of this Agreement without the prior written consent of the other Party hereto, except each Party may disclose the terms of this Agreement and any other Transaction Agreement: (i) on a confidential basis to its Representatives, existing or potential investors (provided that such

investors are not ***) and others on a need to know basis, in each case under appropriate confidentiality provisions substantially equivalent to those in this Agreement, providing that such Party shall be responsible for any disclosure of information by any of the persons referred to in the preceding sentence in contravention of the terms of this Agreement; or (ii) to the extent necessary to comply with Applicable Laws; provided that the Disclosing Party shall promptly notify the other Party (other than in the case where such disclosure is necessary, in the reasonable opinion of the Disclosing Party's legal counsel, to comply with Applicable Laws) and allow the other Party a reasonable opportunity to oppose with the Governmental Authority initiating the process and, to the extent allowable by Applicable Laws, to seek limitations on the portion of the Agreement that is required to be disclosed.

6.5.2 The Parties shall not issue a press release disclosing the existence of this Agreement or any other Transaction Agreement, any specific term hereof, or any specific transaction contemplated herein unless required by Applicable Laws or as agreed in writing by the Parties. Where such a press release or other public disclosure is so required, no Party shall issue a press release without first giving the other Party reasonable opportunity to review and approve the proposed public disclosure or press release, such approval not to be unreasonably withheld, delayed or conditioned. For clarity, no such review and approval shall be required for any public disclosure or press release that restates information that has been previously approved for public disclosure or that is otherwise in the public domain without a breach of this Agreement or any Transaction Agreement, provided that such information remains accurate in all material respects.

6.6 Records. At its own expense, each Party will create and maintain and provide access to upon reasonable request all records that relate to this Agreement and to a Party's performance under this Agreement (i) to the extent required by this Agreement and Applicable Laws, (ii) sufficient to demonstrate that any and all amounts invoiced to a Party under this Agreement are accurate and proper in both kind and amount; (iii) sufficient to demonstrate the accuracy of reports submitted to either Party under this Agreement; and (iv) sufficient to enable a Party to comply with Applicable Laws and other legal obligations, to the extent that such Party has or reasonably should have knowledge of those Applicable Laws and other legal obligations. Each of the Parties will maintain all such records for the longer of (a) any period prescribed by Applicable Laws or stated expressly in this Agreement, (b) *** after the term of this Agreement.

6.7 Publication. If a Party desires to publish or present, whether in writing or by oral presentation, any methods, findings, results, or other matters arising out of the Development Plan that relate specifically to the non-publishing Party's System or include the non-publishing Party's Confidential Information (a "**Publication**"), such Party shall provide the non-publishing Party with ***. The non-publishing Party will have the right during such *** period to ***. If such non-publishing Party does not provide any comments during such period, it shall be ***. In addition, the Publication may be delayed at the non-publishing Party's written request received during such period for an additional *** if it contains ***. For clarity, this Section 6.7 shall not apply to any further disclosure that has been previously publicly disclosed pursuant to this Section 6.7, provided that further disclosure remains accurate in all material respects.

***

6.8 Personal Data; DexCom CGM Data and Tandem Insulin Data. To the extent any Personal Data, DexCom CGM Data and/or Tandem Insulin Data is collected, received or shared by a Party or its Affiliates with or from the other Party or its Affiliates in connection with activities contemplated by this Agreement, the use of such data shall be governed solely by Section 8 of the Commercialization Agreement (and not this Section 6).

7. INDEMNIFICATION AND DEFENSE OF INFRINGEMENT

7.1 DexCom will defend and indemnify Tandem, its Affiliates, and each of their respective directors, officers, employees, agents, successors and assigns (collectively, "**Tandem Indemnitees**"), against all Third Party claims, suits and proceedings, and will hold the Tandem Indemnitees harmless against all judgments, settlements, costs, liabilities and expenses (including reasonable attorneys' fees and litigation costs) (collectively, "**Losses**") payable to Third Parties in connection with such claims, suits and proceedings, to the extent arising from or

occurring as a result of: (i) DexCom's breach of its *** under this Agreement, (ii) the ***, (iii) the ***, or (iv) physical injury (including death) and/or property damage ***.

7.2 Tandem will defend and indemnify DexCom, its Affiliates, and each of their respective directors, officers, employees, agents, successors and assigns (collectively, "**DexCom Indemnitees**"), against all Third Party claims, suits and proceedings, and will hold the DexCom Indemnitees harmless against all Losses payable to Third Parties in connection with such claims, suits and proceedings, to the extent arising from or occurring as a result of: (i) Tandem's breach of its *** under this Agreement, (ii) the ***, (iii) the ***, or (iv) physical injury (including death) and/or property damage ***.

7.3 If the manufacture or use of the Combined System Implementations results in a claim, suit or proceeding in which DexCom and Tandem are both entitled to indemnification by the other Party pursuant to Sections 7.1 and 7.2, then the Parties will discuss in good faith their cooperation in connection with such matter, and shall ***.

7.4 If the manufacture or use of the Combined System Implementations results in a Third Party claim, suit, allegation, action or proceeding against Tandem or DexCom alleging infringement or misappropriation of the Intellectual Property of such Third Party and neither DexCom nor Tandem is entitled to indemnification pursuant to Sections 7.1 and 7.2 (a "**Combined System Infringement Action**"), such Party will promptly notify the other Party in writing. The Parties will *** in connection with the Combined System Infringement Action and shall *** of any Combined System Infringement Action. The Parties will *** concerning any Combined System Infringement Action and, in the *** that the ***, the Parties will ***.

7.5 At either Party's request, the Parties shall promptly enter into a common-interest agreement to protect any available attorney-client privileges and the like, on reasonable and customary terms.

7.6 A Party seeking indemnification hereunder (the "**Indemnitee**") will promptly notify the indemnifying Party (the "**Indemnitor**") of any claim, suit, proceeding, loss, or expense likely to lead to a claim for indemnification, along with all material related information in the Indemnitee's possession. The Indemnitor will have the right to manage the defense and settlement of any claim, except that the ***. The Indemnitee may not enter into any settlement of any such claim without the prior written consent of Indemnitor. The Indemnitee will ***. The Indemnitee may ***. In addition, the Indemnitee may ***.

7.7 Notwithstanding the foregoing in this Section 7, an Indemnitor under this Section 7 has no obligation for any Losses to the extent resulting from (i) ***, or (ii) ***.

7.8 In the event of any actual or alleged infringement of a valid claim of a patent or the actual or alleged infringement or misappropriation of any Third Party Intellectual Property by the Tandem System (or components thereof, including any DexCom CGM-Enabled Tandem Display Device, but excluding any Communication Protocol provided by DexCom), (a) Tandem shall have the right to *** to render such Tandem System non-infringing or to be no longer misappropriating such Third Party Intellectual Property and (b) if Tandem cannot reasonably modify the Tandem System to be non-infringing or to no longer be misappropriating such Third Party Intellectual Property, Tandem shall have the right to terminate this Agreement upon *** written notice to DexCom.

7.9 In the event of any actual or alleged infringement of a valid claim of a patent or the actual or alleged infringement or misappropriation of any Third Party Intellectual Property by the DexCom System (or components thereof), (a) DexCom shall have the right to modify the DexCom System (including any components thereof) to render such DexCom System non-infringing or to be no longer misappropriating such Third Party Intellectual Property and (b) if DexCom cannot reasonably modify the DexCom System to be non-infringing or to no longer be misappropriating such Third Party Intellectual Property, DexCom shall have the right to terminate this Agreement upon *** written notice to Tandem.

7.10 In the event that either Party is entitled to indemnification of any Third Party claim, suit or proceeding under both this Agreement and the Commercialization Agreement or the ***, then such Party shall only be entitled to seek indemnification for such claim, suit or proceeding (and only entitled to recover for a particular Loss) *** under either this Agreement or the Commercialization Agreement or the *** and in no event shall such Party be permitted to seek indemnification for such claim, suit or proceeding (or recover for any particular Loss) under both this Agreement and the Commercialization Agreement or under both this Agreement and the ***.

8. TERM AND TERMINATION

Term. The term of this Agreement will begin on the Effective Date and continue in effect for as long as the Commercialization Agreement continues in effect, unless this Agreement is terminated earlier pursuant to the other provisions of this Agreement (the "**Term**").

8.1 Termination for Material Breach.

8.1.1 Either Party (the "**Notifying Party**") shall be entitled to terminate this Agreement upon written notice to the other Party if such other Party materially breaches this Agreement and fails to cure such breach *** following written notice from the Notifying Party specifying such breach in reasonable detail.

8.1.2 Notwithstanding the foregoing, if the allegedly breaching Party in good faith disputes such material breach or the failure to cure such material breach, then such Party shall provide the Notifying Party written notice of that dispute putting forward in reasonable detail the rationale for disputing the alleged breach or failure to cure to the Notifying Party. In such event, the Parties shall promptly undertake good faith efforts to resolve such dispute, in which case, such termination shall not be effective until *** after the resolution as to whether such material breach has occurred (and, if it is determined that there was a material breach that remains uncured at the expiration of such ***); provided, that, during the pendency of any such dispute resolution the Parties shall continue performing their respective obligations, and exercising their respective rights, under this Agreement. The Parties hereby agree to take such steps as may be reasonably necessary to complete such dispute resolution as expeditiously as possible given the circumstances.

8.2 Termination Without Cause. Either Party may terminate this Agreement at any time with *** written notice to the other Party.

8.3 Termination for Change of Control. Each Party shall provide to the other Party written notice within the later of *** after or as soon as permitted under Applicable Laws after undergoing a Change of Control. If such Change of Control is ***, then such other Party shall have the right (but not the obligation) to terminate this Agreement upon *** prior written notice, provided that such notice is given within *** following such other Party's receipt of the notice of such Change of Control. ***.

8.4 *** If a Party *** asserting that *** then the *** may, ***. Notwithstanding the foregoing, the *** shall not have the right to *** to the extent ***.

8.5 Effect of Termination.

8.5.1 General. In the case of expiration or termination of this Agreement, all rights and obligations of the Parties under this Agreement shall cease immediately, unless otherwise stated in this Agreement.

8.5.2 Accrued Rights and Obligations. Expiration or termination of this Agreement shall not relieve the Parties of any obligation accrued prior to such expiration or termination, nor shall expiration or any termination of this Agreement preclude either Party from pursuing all rights and remedies it may have under this Agreement, at law or in equity, with respect to breach of this Agreement nor prejudice any Party's right to obtain performance of any obligation.

8.5.3 Post-Termination Support. Upon any expiration or termination of this Agreement, the Parties will ensure continued provision of support services to the then-current Customers for the applicable System, as set forth in the then-current warranty terms covering such System (or such longer period as may be required under Applicable Laws) (hereinafter the "**Termination Support Services**"). If required to perform the Termination Support Services, the license grants set forth in Sections 3.2.1 and 3.2.2 relating to the Communication Protocol and the license grants set forth Sections 3.3.1 and 3.3.2 relating to the use of the Tandem Partner CID Documentation, Tandem Partner CID and Tandem Development Tools shall continue for the length of the Termination Support Services and shall be subject to the restrictions set forth therein, provided that upon any expiration or termination of this Agreement, the license grants set forth in Sections 3.2.1 and 3.2.2 relating to the Communication Protocol and the license grants set forth Sections 3.3.1 and 3.3.2 relating to the use of the Tandem Partner CID Documentation, Tandem Partner CID and Tandem Development Tools will immediately and automatically be limited to the extent necessary to support the units of the Combined Systems for such then-current Customers.

8.5.4 Survival. In addition, Sections 1, 3.1, 5.2, 6, 7, 8.6, 9 and 10, and the third sentence of Section 2.11.1 (but solely to the extent any relevant data results from such Clinical Studies commenced or initiated during the Term of this Agreement), will survive expiration or termination of this Agreement, provided that, in the event any Section identified above expressly sets forth a limited period of time with respect to the duration or survival of such right or obligation beyond the expiration or termination of this Agreement, then such right or obligation shall survive only for such expressly identified period of time.

9. LIMITATION OF LIABILITY

IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER OR ANY OTHER PERSON OR ENTITY FOR COSTS OF PROCUREMENT OF SUBSTITUTE GOODS, LOST PROFITS, OR ANY OTHER SPECIAL, CONSEQUENTIAL, OR INCIDENTAL DAMAGES, HOWEVER CAUSED AND UNDER ANY THEORY OF LIABILITY ARISING OUT OF THIS AGREEMENT WHETHER BASED IN CONTRACT, TORT (INCLUDING NEGLIGENCE), OR OTHERWISE. THESE LIMITATIONS SHALL APPLY WHETHER OR NOT THE BREACHING PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES AND NOTWITHSTANDING ANY FAILURE OF ESSENTIAL PURPOSE OF ANY LIMITED REMEDY PROVIDED HEREIN. IF EITHER PARTY TERMINATES THIS AGREEMENT IN ACCORDANCE WITH ANY OF ITS PROVISIONS, NEITHER PARTY SHALL BE LIABLE TO THE OTHER, BECAUSE OF SUCH TERMINATION, FOR COMPENSATION, REIMBURSEMENT OR DAMAGES ON ACCOUNT OF THE LOSS OF PROSPECTIVE PROFITS OR ANTICIPATED SALES OR ON ACCOUNT OF EXPENDITURES, INVENTORY, INVESTMENTS, LEASES OR COMMITMENTS IN CONNECTION WITH THE BUSINESS OR GOODWILL OF TANDEM OR DEXCOM.

THE FOREGOING EXCLUSION OF CERTAIN DAMAGES IN THIS SECTION DOES NOT APPLY TO DAMAGES FOR ANY OF THE FOLLOWING:

(I) BREACH OF AN OBLIGATION OF CONFIDENTIALITY UNDER SECTION 6 OR MISAPPROPRIATION OF INTELLECTUAL PROPERTY OR TRADE SECRETS; OR

(II) INDEMNIFICATION OBLIGATIONS UNDER SECTION 7, INCLUDING INDEMNIFICATION OBLIGATIONS UNDER SECTION 7 RELATED TO INFRINGEMENT OF INTELLECTUAL PROPERTY RIGHTS.

10. MISCELLANEOUS

10.1 No Exclusivity. This Agreement shall be non-exclusive for both Tandem and DexCom, and, subject to compliance with the terms and conditions of this Agreement, shall in no way prohibit either Party from working with any Third Party, including other insulin pump or CGM and/or data management companies, or acquiring, licensing, designing, developing, marketing, selling and/or distributing products that compete, directly or

indirectly, with the products contemplated by this Agreement. Each Party further acknowledges that the personnel assigned to the activities contemplated by this Agreement may also participate in other activities that may utilize technologies similar to or involve products competitive with those contemplated by this Agreement.

10.2 Subcontractors. Subject to the terms and conditions of this Agreement, either Party may subcontract the performance of its obligations under this Agreement to a Third Party ***, provided that (i) such subcontractor is bound by terms and conditions consistent, in all relevant respects, with this Agreement, including restrictions with respect to the protection and use of Confidential Information which are no less stringent than those set forth in this Agreement; (ii) such Party hereby expressly waives any requirement that the other Party exhaust any right or remedy (or otherwise proceed) against any such subcontractor for any obligation or performance hereunder prior to proceeding directly against such Party; and (iii) each Party shall be fully responsible for the performance of its subcontractors.

10.3 Contract Interpretation. The meaning of a provision of this Agreement will be considered in context with other provisions of the Agreement. The following principles apply to the construction of this Agreement unless the construction is plainly contrary to the intent of the Parties:

10.3.1 "Including" means "including but not limited to."

10.3.2 "Or" means "and/or."

10.3.3 "Will" and "shall" have the same meaning.

10.3.4 Language that has a generally prevailing meaning is given that meaning unless the Agreement expressly assigns a different one.

10.3.5 Technical terms used in the technical field of the subject of the Agreement are given their technical meaning.

10.3.6 Singular words may be treated as plural, and plural words may be treated as singular.

10.3.7 The masculine gender may be treated as feminine, and the feminine gender may be treated as masculine.

10.3.8 In computing any period of time under this Agreement, the day of the act, event, or default from which the designated period of time begins to run is not included. If the Agreement specifies that a period is to run for a certain number of business days, only business days are included in the count, and the period may not end on any day that is not a business day.

10.4 Force Majeure. Nonperformance of any Party will be excused to the extent that performance is prevented or delayed by strike, fire, earthquake, flood, governmental acts or orders or restrictions (other than due to a failure to comply with Applicable Laws), epidemic, pandemic, or any other reason where failure to perform is beyond the reasonable control of the nonperforming Party.

10.5 No Implied Waivers; Rights Cumulative. No failure on the part of DexCom or Tandem to exercise and no delay in exercising any right under this Agreement, or provided by statute or at law or in equity or otherwise, will impair, prejudice or constitute a waiver of any such right, nor will any partial exercise of any such right preclude any other or further exercise thereof or the exercise of any other right.

10.6 Independent Contractors. Nothing contained in this Agreement is intended implicitly, or is to be construed, to constitute DexCom or Tandem as partners in the legal sense. No Party hereto will have any express or implied right or authority to assume or create any obligations on behalf of or in the name of the other Party or to bind the other Party to any contract, agreement or undertaking with any Third Party.

10.7 Notices. All notices, requests and other communications hereunder will be in writing and will be personally delivered or sent by registered or certified mail, return receipt requested, postage prepaid, or via email (with delivery or receipt confirmation), in each case to the respective address specified below, or such other address as may be specified in writing to the other Parties hereto:

Tandem:	Tandem Diabetes Care, Inc. 12400 High Bluff Drive San Diego, CA 92130 Attn: CEO ***
With Copy to:	Tandem Diabetes Care, Inc. 12400 High Bluff Drive San Diego, CA 92121 Attn: Legal ***
DexCom:	DexCom, Inc. 6340 Sequence Drive San Diego, California 92121 Attn: Legal Department ***

10.8 Assignment. Except as otherwise expressly provided under this Agreement, neither Party may assign or otherwise transfer this Agreement or any right or obligation hereunder without the express prior written consent of the other Party; provided that: either Party shall be permitted to effect such an assignment or other transfer of this Agreement in its entirety, without the written consent of the other Party (i) to any of its then-existing Affiliates, or (ii) in connection with a merger or the transfer or sale of all or substantially all of its business or assets related to this Agreement, or (iii) subject to Section 8.4, in connection with a Change of Control.

10.9 Modifications. No amendment or modification of any provision of this Agreement will be effective unless in writing signed by each Party hereto. No provision of this Agreement will be varied, contradicted or explained by any oral agreement, course of dealing or performance or any other matter not set forth in an agreement in writing and signed by all Parties. In the event of a conflict between the provisions of the exhibits or the attachments to this Agreement and the provisions of this Agreement itself, the conflicting provision(s) of the Agreement shall control over the language in the exhibit or attachments, unless otherwise agreed by the Parties.

10.10 Severability. If any provision hereof should be held invalid, illegal or unenforceable in any jurisdiction, all other provisions hereof will remain in full force and effect in such jurisdiction and will be liberally construed in order to carry out the intentions of the Parties hereto as nearly as may be possible. Such invalidity, illegality or unenforceability will not affect the validity, legality or enforceability of such provision in any other jurisdiction.

10.11 Governing Law.

10.11.1 This Agreement and any dispute arising from the performance or breach hereof will be governed by and construed and enforced in accordance with the laws of the State of California without regard for conflicts of laws principles. Disputes as to matters within the authority of the Development Working Team will be

resolved as set forth in Section 2.3.7; provided that any dispute as to the application of such Section 2.3.7 shall be subject to this Section 10.11.

10.11.2 Notwithstanding any other provision of this Agreement, either Party may seek interim equitable relief in any court of competent jurisdiction in connection with any alleged breach or violation of Section 2.2, Section 6 or Intellectual Property rights.

10.12 Choice of Forum. The Parties hereby submit and consent to the exclusive jurisdiction of any state or federal court located in *** and irrevocably agree that all actions or proceedings relating to this Agreement shall be litigated in such courts, and each of the Parties waives any objection which it may have based on improper venue or forum non conveniens to the conduct of any such action or proceeding in such court.

10.13 Counterparts. This Agreement may be executed in two or more counterparts, each of which will be deemed an original, and all of which together, will constitute one and the same instrument.

10.14 Headings. Headings used herein are for convenience only and will not in any way affect the construction of or be taken into consideration in interpreting this Agreement.

10.15 Entire Agreement. This Agreement (including the exhibits attached hereto which are hereby incorporated into this Agreement by reference), together with the Transaction Agreements, constitutes the entire agreement with respect to the subject matter hereof, and supersedes all prior or contemporaneous understandings or agreements, whether written or oral, between DexCom and Tandem with respect to such subject matter (including the Superseded Development Agreement). For clarity, (i) the G4 Development Agreement was terminated effective August 10, 2020, (ii) the G5 Development Agreement was terminates effective December 31, 2020 with respect to all countries other than Australia and was terminated on December 31, 2021 with respect to Australia, (iii) the Original G6 Development Agreement shall remain in full force and effect subject to any amendments thereto and for clarity shall include the amendments in the Commercialization Agreement and (iv) the TypeZero License Agreement shall remain in full force and effect and shall not be amended or modified by this Agreement.

10.16 Performance by Affiliates. Either Party may discharge any obligation and exercise any right hereunder through any of its Affiliates. Each Party hereby guarantees the performance by its Affiliates of such obligations under this Agreement, and shall cause its Affiliates to comply with the provisions of this Agreement in connection with such performance. Any breach by a Party's Affiliate of any of such Party's obligations under this Agreement shall be deemed a breach by such Party, and the other Party may proceed directly against such first Party without any obligation to first proceed against such Affiliate.

10.17 [Intentionally Removed.]

[Signature Page Follows]

IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be signed by duly authorized officers or representatives as of the date first written above.

DEXCOM, INC.	**TANDEM DIABETES CARE, INC.**
By: /s/ Jereme Sylvain	By: /s/ Elizabeth Gasser
Print Name: Jereme Sylvain	Print Name: Elizabeth Gasser
Title: Executive Vice President and Chief Financial Officer	Title: Executive Vice President, Chief Strategy and Product Officer
Date: May 22, 2024	Date: May 22, 2024

Exhibit A: ***

***

AMENDED AND RESTATED COMMERCIALIZATION AGREEMENT

This Amended and Restated Commercialization Agreement (this "**Agreement**") is made and entered into effective as of May 21, 2024 ("Effective Date") by and between Tandem Diabetes Care, Inc, having a principal place of business at 12400 High Bluff Drive, San Diego, CA 92130 ("**Tandem**"), and DexCom, Inc., a Delaware corporation having a principal place of business at 6340 Sequence Drive, San Diego, CA 92121 ("**DexCom**"). Tandem and DexCom may be referred to in this Agreement individually as a "**Party**" and collectively as the "**Parties**".

RECITALS

A. DexCom is in the business of developing and commercializing continuous glucose monitoring systems;

B. Tandem is in the business of developing and commercializing insulin pump systems;

C. The Parties entered into a development agreement effective on November 20, 2020, to enable the integration of Tandem's Mobi (formerly known as t:sport) insulin pump with DexCom's G6® CGM device and enable the integration of Tandem's t:slim X2™, Mobi and Sigi insulin pumps with DexCom's G7® CGM device (as amended and restated, the "**Development Agreement**");

D. The Parties have amended that certain development agreement, dated June 4, 2015, as amended, for the integration of Tandem's t:slim X2™ insulin pump with DexCom's G6® CGM device (the "**On-Market t-slim:G6 Implementation**" and such agreement, the "**Original G6 Development Agreement**" and, together with the Development Agreement, "**Current Development Agreements**"), such that commercialization activities relating to this implementation of the Combined System are governed by the terms of this Agreement;

E. On February 7, 2020, DexCom issued a notice of termination for (i) the development agreement dated January 4, 2013, which addressed the integration of Tandem's insulin pump with DexCom G4® CGM device (the "**G4 Development Agreement**"), which termination became effective August 10, 2020 and (ii) the development agreement dated June 4, 2015, which addressed the integration of Tandem's insulin pump with DexCom G5® CGM device (the "**G5 Development Agreement**" and collectively with the G4 Development Agreement, "**Legacy Development Agreements**"), which terminated on December 31, 2020 with respect to all countries other than Australia and terminated on December 31, 2021 with respect to Australia; and

F. On January 23, 2023, Tandem completed its acquisition of AMF Medical SA (now known as Tandem Diabetes Care Switzerland Sàrl), the developer of the Sigi™ insulin pump ("**Sigi**").

The Parties previously entered into a Commercialization Agreement (the "**Original Commercialization Agreement**") effective as of November 20, 2020 (the "**Original Effective Date**"), which this Agreement amends and restates in its entirety effective as of the Effective Date.

G. The Parties desire to commercialize the integrated solutions developed under the Current Development Agreements on the terms and conditions set forth herein.

Accordingly, the Parties therefore agree as follows:

AGREEMENT

1. **DEFINITIONS**

1.1 "**Affiliates**" means any corporation or other entity that is directly or indirectly controlling, controlled by or under common control with a Party. For the purpose of this definition, "control" means: (i) the direct or indirect ownership of more than fifty percent (50%) of the capital stock of the subject entity; (ii) the direct or indirect control of more than fifty percent (50%) of the voting rights of the subject entity; or (iii) the possession, directly or indirectly, of the power to direct or cause the direction of the management or policies of the subject entity (whether through ownership of securities or other ownership interests, by contract or otherwise).

1.2 "**Agreed Markets**" means the countries or jurisdictions in which the Combined System will be commercialized in accordance with the Commercialization Plan and specifically including the countries and jurisdictions set forth on **Exhibit A**. The Parties may amend the Agreed Markets by executing an amendment to this Agreement in the form attached as **Exhibit A-1**.

1.3 *** means, (a) with respect to DexCom *** and (b) with respect to Tandem ***.

1.4 "**Anti-Corruption Laws**" means the United States Foreign Corrupt Practices Act, the United States Anti-Kickback Statute, the United Kingdom Bribery Act, and any other laws of a similar nature for the prevention of *inter alia*, fraud, corruption, racketeering, money laundering and terrorism, in each case as may be amended from time to time.

1.5 "**Applicable Laws**" means all applicable laws, rules and regulations, including any rules, regulations, guidance or other requirements of any Regulatory Authority, that may be in effect from time to time and are applicable to a particular activity hereunder, including, as applicable, (i) regulations and guidance documents of the FDA and EMA (and national implementations thereof) and, if and as appropriate under the circumstances, International Conference on Harmonization (ICH) guidance or other comparable regulation and guidance of any applicable Regulatory Authority in the Agreed Markets, (ii) Anti-Corruption Laws, (iii) Privacy Laws, (iv) Transparency Laws, (v) cGCP, (vi) cGDP, and (vii) cGMP.

1.6 "**cGCP**" means all applicable current Good Clinical Practice standards for the design, conduct, performance, monitoring, auditing, recording, analyses and reporting of Clinical Studies, including, as applicable, (a) as set forth in the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use ("**ICH**") Harmonised Tripartite Guideline for Good Clinical Practice (CPMP/ICH/135/95) and any other guidelines for good clinical practice for trials on medicinal products in the Agreed Markets, (b) the Declaration of Helsinki (2004) as last amended at the 52nd World Medical Association in October 2000 and any further amendments or clarifications thereto, (c) U.S. Code of Federal Regulations Title 21, Parts 50 (Protection of Human Subjects), 56 (Institutional Review Boards) and 312 (Investigational New Drug Application), as may be amended from time to time, and (d) the equivalent applicable laws in any relevant country, each as may be amended and applicable from time to time and in each case, that provide for, among other things, assurance that the clinical data and reported results are credible and accurate and protect the rights, integrity, and confidentiality of trial subjects.

1.7 "**cGDP**" means the then current standards for all good distribution practices relevant to any product hereunder, including, as applicable, (a) the principles detailed in the U.S. Current Good Manufacturing Practices, 21 C.F.R. Sections 210, 211, (b) European Directive 2013/C 68/01 and Eudralex 4, (c) WHO TRS 957 Annex 5, (d) USP <1079>, (e) any state or other local laws or regulations governing the licensing of distributors or manufacturers of pharmaceutical products or medical devices, and (f) the equivalent applicable laws in any relevant country, each as may be amended and applicable from time to time.

1.8 "**CGM**" means continuous glucose monitoring.

1.9 "**cGMP**" means the then-current Good Manufacturing Practices that apply to the manufacture (including clinical or commercial supply) of any product hereunder, including, as applicable, (a) the United States regulations set forth under Title 21 of the United States Code of Federal Regulations, parts 4, 210, 211 and 820, (b) applicable guidance published from time-to-time by the FDA, (c) the International Conference on Harmonisation Guidelines ICH Q7A Good Manufacturing Practice Guidance for the principles, guidelines of Good Manufacturing

Practices for Medicinal Products as defined with EC Directive 2003/94/EC and associated EC Guide to Good Manufacturing Practice, and (d) the equivalent applicable laws in any relevant country, each as may be amended and applicable from time to time.

1.10 "**Change of Control**" means a transaction or a series of related transactions: (i) in which one or more related parties that did not previously own or control greater than a fifty percent (50%) equity interest in a Party obtains ownership or control of greater than a fifty percent (50%) equity interest in a Party; (ii) as a result of which one or more related parties that did not previously have the right or power to control the management or policies of a Party acquires such right or power; or (iii) in which a Party sells all or substantially all of its assets to a Third Party.

1.11 "**Clinical Study**" means any pre or post approval clinical study involving the administration of and/or use of a Combined System with a human subject, whether conducted before or after Regulatory Approval of a Combined System, including clinical studies to support such Regulatory Approval process or as otherwise required by a Regulatory Authority.

1.12 "**Combined System**" means an integrated technology solution comprised of the DexCom System and the Tandem System that enables ***. The Parties agree that the integrated technology solution(s) developed by the Parties pursuant to the Legacy Development Agreements, and any improvements thereto, are not Combined Systems hereunder.

1.13 "**Combined System Implementation**" means, as applicable, an implementation of the Combined System involving the integration of Tandem's Mobi insulin pump with DexCom's G6® CGM device, the integration of Tandem's t:slim X2™ insulin pump with DexCom's G7® CGM device, the integration of Tandem's Mobi insulin pump with DexCom's G7® CGM device, or the integration of Tandem's Sigi insulin pump with DexCom's G7® CGM device, in each case, as developed under the Development Agreement. The Parties agree that the On-Market t-slim:G6 Implementation, including any improvement thereto, is not a Combined System Implementation. The current architecture for the Combined System Implementations is listed in Exhibit A to the Development Agreement.

1.14 "**Commercially Reasonable Efforts**" means the carrying out of a Party's obligations under this Agreement with the exercise of prudent scientific and business judgment and a level of effort and resources consistent with the efforts and resources that the Party who bears the performance obligation, but in any event at least the level of effort and resources of a similarly-sized comparable Third Party in the CGM or insulin delivery device industry, as applicable, would employ for products of similar strategic importance and commercial value that result from its own research efforts.

1.15 "**Communication Protocol**" means a DexCom communication protocol that permits a DexCom CGM-Enabled Tandem Display Device to identify, receive and display DexCom CGM Data and to control the DexCom CGM Transmitter, which communication protocol will be developed by or on behalf of DexCom under the Development Plan, as may be amended or updated by DexCom from time to time in accordance with the Development Plan.

1.16 "**Compliance**" means the adherence by the Parties in all material respects to all Applicable Laws and Party-Specific Regulations, in each case with respect to the activities to be conducted under this Agreement.

1.17 "**Control**", "**Controls**" or "**Controlled by**" means, with respect to any item of or right under Intellectual Property, the ability of the specified Party or any of its Affiliates, whether through ownership, license or other right (other than pursuant to this Agreement), to grant access to, license or sublicense such item or right without violating the terms of any agreement or other arrangement with any Third Party. Notwithstanding the foregoing, Intellectual Property held by a Third Party that is an acquirer in a Change of Control transaction of a Party or by any of such Third Party's Affiliates (such Third Party and Affiliates collectively, the "**Acquirer**") that exists immediately before the consummation of such Change of Control transaction or is or developed or acquired

by the Acquirer after such consummation independently of this Agreement shall not be deemed to be Controlled by such Party.

1.18 "**Customer**" means a customer that has purchased a Combined System, or a DexCom CGM Device or Tandem Insulin Delivery Device in connection with a Combined System, whether an end user, a distributor, a payor or a healthcare professional, as applicable.

1.19 "**DexCom CGM App**" means any software (including any software application) of DexCom or its Affiliates designed to gather DexCom CGM Data in connection with a Combined System, which may include software loaded onto a CGM device, cloud infrastructure, and/or Electronic Health Record (EHR) systems, depending on the configuration of such Combined System, as described in more detail in the Development Plan.

1.20 "**DexCom CGM Data**" means the continuous glucose monitoring data displayed on the receiver or other display device connected to a DexCom System (in each case solely to the extent such DexCom System is used as part of a Combined System in accordance with this Agreement or the Development Agreement), as set forth in more detail in **Exhibit B**. For clarity, DexCom CGM Data excludes any raw CGM sensor data.

1.21 "**DexCom CGM Device**" means DexCom's CGM devices known as DexCom G6® and DexCom G7®, including any Minor Release thereof.

1.22 "**DexCom CGM-Enabled Tandem Display Device**" means a Tandem Display Device comprising a receiver or other component of the Tandem Insulin Delivery Device configured to identify, Process and/or display DexCom CGM Data from a DexCom CGM Transmitter and control the DexCom CGM Transmitter, as described in more detail in the Development Plan. A DexCom CGM-Enabled Tandem Display Device will be independently developed by Tandem and is not, and will not be, a component of any DexCom System.

1.23 "**DexCom CGM Transmitter**" means the transmitter component of the DexCom System (which may be a standalone DexCom transmitter that operably couples to the DexCom Sensor or an embedded component of a DexCom Sensor) that is configured to transmit DexCom CGM Data from a DexCom Sensor to any receiver adapted to identify, receive, and display such information, and is also controlled from an authenticated receiver and the DexCom CGM App.

1.24 "**DexCom Sensor**" means the component of a DexCom System comprising a continuous glucose monitoring electrode sensor, adapted to (i) penetrate the patient's skin to come into contact with the patient's interstitial fluid, (ii) measure interstitial fluid glucose level, and (iii) be operably coupled to a DexCom CGM Transmitter to communicate the blood glucose value as measured by such sensor, to a separate receiver.

1.25 "**DexCom System**" means a CGM system comprised of a DexCom CGM Device and one or more DexCom CGM Apps, as described in more detail in the Development Plan. For clarity, with respect to the On-Market t-slim:G6 Implementation, "DexCom System" means the DexCom CGM Device known as the G6®, including any Minor Release thereof, and the corresponding DexCom CGM App.

1.26 "**DexCom Trademarks**" means the Trademarks set forth on **Exhibit C** and such other Trademarks as DexCom may designate in writing to Tandem from time to time.

1.27 "**EMA**" means the European Medicines Agency or any successor agency thereto.

1.28 "**EU**" means those countries that are members of the European Union as of the date on which the relevant determination is being made.

1.29 "**FDA**" means the United States Food and Drug Administration or any successor agency thereto.

1.30 "**First Commercial Launch**" means, with respect to each Combined System, the first date that such Combined System is (or was) made available for purchase by any Customer in any Agreed Market following Regulatory Approval in such Agreed Market.

1.31 "**Governmental Authority**" means any (i) international, regional, national, federal, state, or local government entity, authority, agency, instrumentality, court, tribunal, regulatory commission or other body, either foreign or domestic, whether legislative, judicial, administrative or executive; or (ii) arbitrator to whom a dispute has been presented under government rule or by agreement of the Parties with an interest in such dispute.

1.32 "**HIPAA**" means the Health Insurance Portability and Accountability Act of 1996, and the regulations thereunder, as they may be amended from time to time.

1.33 "**HITECH Act**" means the Health Information Technology for Economic and Clinical Health Act, and the regulations thereunder, as they may be amended from time to time.

1.34 "**Intellectual Property**" means (collectively): any copyright, patent or patent application (including any foreign counterparts of any of the foregoing, as well as all continuations, continuations-in-part, divisionals, reissues, reexaminations, and all renewals and extensions thereof, regardless of whether such rights arise under the laws of the United States or any other state, country or jurisdiction), inventions, trade secrets, methods, know-how, technology, information, data and results (including pharmacological, biological, chemical, biochemical, toxicological, and clinical test data and results), software, algorithms, rights of publicity, authors' rights, goodwill and all other intellectual property rights as may exist now and/or hereafter come into existence. Intellectual Property shall include Software and Copyrights, but shall exclude all Trademarks.

1.35 "**Internal Compliance Policies**" means a Party's internal policies and procedures intended to ensure that a Party complies with Applicable Laws, Party-Specific Regulations, and such Party's internal ethical, medical and similar standards.

1.36 "**Joint Steering Committee**" means the Joint Steering Committee formed pursuant to the Development Agreement.

1.37 "**Major Release**" means a new generation of a product (*e.g.*, in the case of the DexCom System, G7® as compared to G6®) that adds material features and functionality improving overall performance, efficiency and/or usability, and designated by the provider as a replacement for a prior generation, excluding for clarity any Minor Release.

1.38 "**Minor Release**" means an intra-generational product release adding functionality in a backwards-compatible manner, or a patch version for such product making backwards-compatible bug fixes.

1.39 "**Party-Specific Regulations**" means all judgments, decrees, orders or similar decisions issued by any Governmental Authority specific to a Party, and all consent decrees, corporate integrity agreements, or other agreements or undertakings of any kind by a Party with any Governmental Authority, in each case as the same may be in effect from time to time and applicable to a Party's activities contemplated by this Agreement.

1.40 "**Personal Data**" means any information or set of information relating to an identified or identifiable individual Processed by either Party through a Combined System or provided or shared by or on behalf of one Party to the other Party under this Agreement, regardless of the medium in which such information is displayed or contained, which shall include (a) all information that identifies that individual or could reasonably be used to identify such individual, (b) all "personal information," "personal data," and/or "protected health information" under applicable Privacy Laws (including, as applicable, HIPAA, CCPA, GDPR, and APPI), and (c) all information to which any applicable Privacy Laws apply and shall, at a minimum, include any information which relates to an identified or identifiable natural person.

1.41 "**PMA**" means premarket approval.

1.42 ***

1.43 "**Privacy Laws**" means all applicable foreign, federal, state, and local laws and regulations governing the Processing, sharing, safeguarding, security, disclosure or transfer of Personal Data (including electronic transaction sets, medical code sets, provider identifier, employer identifier, and patient identifier), as amended from time to time, including, as applicable, (i) HIPAA and the HITECH Act and all amendments to and further regulations of HIPAA and the HITECH Act, (ii) the EU General Data Protection Regulation 2016/679 ("**GDPR**"), (iii) California Consumer Privacy Act ("**CCPA**"), (iv) Japan's Act on the Protection of Personal Information ("**APPI**"), and (v) the CAN-SPAM Act, Canada's Anti-Spam Legislation and other laws or regulations governing telemarketing, including any such laws or regulations prohibiting unsolicited telephone calls to persons or entities listed on "Do Not Call" registries or similar lists or prohibiting unsolicited e-mails, spam or faxes to any person.

1.44 "**Processing**" (including "Process" and "Processed") means any operation or set of operations that is performed on Personal Data, DexCom CGM Data or Tandem Insulin Data within an entity that maintains such information, including receipt, use, collection, recording, maintaining, organization, storage, adaptation, modification, retrieval, consultation, retention, alteration, dissemination, transmission, access, transfer, combination, erasure, destruction, deidentification, or pseudonymization. Processing does not include the release, transfer, provision of, access to, or divulging in any other manner of Personal Data outside the Party maintaining such information (and its Affiliates) and not to the other Party or its Affiliates.

1.45 "**Product Claims**" means assertions relating to the *** features and/or benefits of the Combined Systems excluding any assertions solely relating to the *** features and/or benefits of (i) a DexCom CGM Device and/or a DexCom CGM App, or (ii) a Tandem Insulin Delivery Device, a Tandem Display Device and/or a Tandem Diabetes Management App.

1.46 "**Promotion Materials**" mean all advertising, promotional and communication materials, in whatever form or medium, for marketing, advertising, promotion, labeling and/or education of all or part of the Combined Systems in the Agreed Markets approved by the Parties in accordance with Section 6.2.1. For clarity, "Promotion Materials" only includes such materials for each Party's discrete System to the extent such System is being promoted in the context of the Combined Systems.

1.47 "**Quality Agreement**" means the quality agreement effective as of December 1, 2021 between Tandem and DexCom, as amended from time to time.

1.48 "**Regulatory Approval**" means, with respect to a country, any and all classifications, clearances, approvals, licenses, registrations or authorizations of any Regulatory Authority necessary to commercially distribute, sell or market a product in such country, including, as may be applicable, PMA, a premarket notification (510(k)) or a de novo application in the United States or analogous clearance or approval in other jurisdictions, including a CE marking approval in the EU ***.

1.49 "**Regulatory Authority**" means the FDA, the EMA or any supranational, national or local agency, authority, department, inspectorate, ministry official, parliament or public or statutory person of any government of any country, including a notified body, having jurisdiction over any of the activities contemplated by this Agreement or the Parties, or any successor bodies thereto.

1.50 "**Regulatory Documentation**" means all (i) applications, registrations, licenses, authorizations and approvals (including Regulatory Approvals); and (ii) correspondence, reports and other submissions submitted to or received from Regulatory Authorities and all supporting documents with respect thereto, including all adverse event files and complaint files.

1.51 "**Representatives**" means a Party's and its Affiliates' employees, officers, directors, consultants and legal, technical and business advisors.

1.52 "**Sales Team**" means, with respect to each Party, all of such Party's employees or agents directly engaged in the promotion and sale of the Combined Systems, including any field-based commercial representatives.

1.53 "**Software and Copyrights**" means software, code, works of authorship and copyrightable subject matter.

1.54 "**System**" means (i) with respect to DexCom, the DexCom System as used in a Combined System, and (ii) with respect to Tandem, the Tandem System as used in a Combined System.

1.55 "**Tandem Diabetes Management App**" means any diabetes management software (including any software application), of Tandem or its Affiliates for use in connection with the Tandem Insulin Delivery Device, and associated data management software, which may include such software loaded onto a Tandem Insulin Delivery Device, mobile device, cloud infrastructure, and/or Electronic Health Record (EHR) systems, depending on the configuration of such Combined System, as described in more detail in the Development Plan.

1.56 "**Tandem Display Device**" means a device used in connection with, or as a component of, the Tandem Insulin Delivery Device that communicates with and controls (fully or partially) the Tandem Insulin Delivery Device and which also Processes data related to the Tandem System.

1.57 "**Tandem Insulin Data**" means any insulin data generated by a Tandem System (solely to the extent such Tandem System is used as part of a Combined System in accordance with this Agreement or the Development Agreement) and made available to DexCom through the Tandem Partner CID, as set forth in more detail in **Exhibit D**. For clarity, Tandem Insulin Data does not include any data not specified in the Tandem Partner CID.

1.58 "**Tandem Insulin Delivery Device**" means Tandem's pump products known as t:slim X2™, Mobi and Sigi, with or without a dedicated controller, including any Minor Release thereof.

1.59 "**Tandem Partner CID**" means the communication interface description ("**CID**") that defines the messaging protocol used to allow the Tandem System to communicate *** Data to a DexCom CGM App.

1.60 "**Tandem System**" means a subcutaneous infusion system comprised of a Tandem Insulin Delivery Device, a Tandem Display Device and one or more Tandem Diabetes Management Apps, as described in more detail in the Development Plan. For clarity, with respect to the On-Market t-slim:G6 Implementation, "Tandem System" means the Tandem Insulin Delivery Device known as t-slim X2™, including any Minor Release thereof, the corresponding Tandem Display Device and one or more Tandem Diabetes Management Apps.

1.61 "**Tandem Trademarks**" means the Trademarks set forth on **Exhibit E** and such other Trademarks as Tandem may designate in writing to DexCom from time to time.

1.62 "**Third Party**" means any entity or person other than DexCom or Tandem or their respective Affiliates.

1.63 "**Trademarks**" means all trade names, trademarks, service marks, logos and trade dress, including applications therefor, and all rights therein and thereto, together with all goodwill associated therewith.

1.64 "**Transaction Agreements**" means, collectively, this Agreement, the Development Agreement, and the Quality Agreement.

1.65 **Additional Definitions:** Any capitalized terms not defined in this Agreement have the meaning as defined in the Development Agreement. The following table identifies the location of definitions set forth in various Sections of this Agreement (or, where applicable, the Development Agreement):

Defined Term	Reference
***	***
"**Agreement**"	Preamble to this Agreement
***	***
"**Alliance Manager**"	Development Agreement
"**Combined System Infringement Action**"	Section 14.4
"**Commercial Working Team**"	Section 2.3.1
***	***
"**Confidential Information**"	Section 13.1
"**Commercialization Plan**"	Section 2.1.1
"**Current Development Agreements**"	Recitals to this Agreement
"**Data Breach**"	Section 8.9.2
"**Development Agreement**"	Recitals to this Agreement
"**Development Plan**"	Development Agreement
"**DexCom**"	Preamble to this Agreement
"**DexCom CGM Data IP**"	Section 8.3.1
"**DexCom Improvements**"	Section 8.2
***	***
"**DexCom Indemnitees**"	Section 14.2
"**DexCom Trademark Guidelines**"	Section 3.2.1
"**Disclosing Party**"	Section 13.1
***	***
"**G4 Development Agreement**"	Recitals to this Agreement
"**G5 Development Agreement**"	Recitals to this Agreement
"**Indemnitee**"	Section 14.6
"**Indemnitor**"	Section 14.6
"**Initial Term**"	Section 15.1
"**Legacy Development Agreements**"	Recitals to this Agreement
"**Licensed Data**"	Section 8.8
"**Licensee**"	Section 8.8
"**Licensor**"	Section 8.8
"**Losses**"	Section 14.1
"**Managed Care Reimbursement**"	Section 5.2.5
"**Marketing Team**"	Section 6.1.2
"**Notifying Party**"	Section 15.2.1
"**Original Effective Date**"	Preamble to this Agreement
"**Original G6 Development Agreement**"	Recitals to this Agreement
"**Original G6 Development Agreement Activities**"	Section 2.1.1
"**On-Market t-slim:G6 Implementation**"	Recitals to this Agreement
"**Party**" and "**Parties**"	Preamble to this Agreement
"**Receiving Party**"	Section 13.1
"**Relevant DexCom Regulatory Meetings**"	Section 4.2.4
"**Relevant Tandem Regulatory Meetings**"	Section 4.1.2
"**Scheduled Release**"	Section 11.2.1(ii)
"**Subcommittee**"	Section 2.3.2(viii)

"**System Labeling Guidelines**"	Section 5.2.4
"**Tandem**"	Preamble to this Agreement
"**Tandem Improvements**"	Section 8.1
***	***
"**Tandem Indemnitees**"	Section 14.1
"**Tandem Insulin Data IP**"	Section 8.3.2
"**Tandem Trademark Guidelines**"	Section 3.3.1
"**Term**"	Section 15.1
"**Transparency Laws**"	Section 7.4
"**Unauthorized Use or Unauthorized Access**"	Section 8.9.1
"**Unscheduled Release**"	Section 11.2.1(ii)

2. **COMMERCIALIZATION, COMMERCIAL WORKING TEAM, PARTY RESPONSIBILITIES**

2.1 Commercialization Generally.

2.1.1 Commercialization Plan. Following the Original Effective Date, the Parties jointly agreed on a detailed plan defining each Party's responsibilities for commercializing the Combined Systems in the Agreed Markets (the "**Commercialization Plan**"). ***, the Commercialization Plan will include for each Agreed Market each Party's respective responsibilities for, *inter alia*: (1) branding and promotion of the Combined Systems, (2) provision of Promotion Materials, as necessary, to enable the other Party's Sales Team to sell, market and train on the safe and effective utilization of the Combined Systems, and (3) provision of ongoing patient support for its System as used in the Combined Systems. Notwithstanding anything to the contrary in this Agreement, (a), with respect to the On-Market t-slim:G6 Implementation, the Commercialization Plan will (i) account for any existing commercialization activities that are or were agreed upon by the Parties under the Original G6 Development Agreement (the "**Original G6 Development Agreement Activities**"), and (ii) provide a reasonable time period agreed upon by the Parties for the Parties to implement any changes necessary to such existing commercialization activities and processes related thereto to bring them into conformance with the terms of this Agreement and the terms of the Commercialization Plan applicable to the Combined System Implementations and (b) any conduct of the Original G6 Development Agreement Activities with respect to the On-Market t-slim:G6 Implementation prior to such time period agreed upon by the Parties shall not be deemed a breach of this Agreement.

2.1.2 Efforts. The Parties will use Commercially Reasonable Efforts to commercialize the Combined Systems in the Agreed Markets, provided that neither Party shall be obligated to launch its System or any component thereof, or to support the Combined Systems, in countries or jurisdictions other than the Agreed Markets. Each Party will use Commercially Reasonable Efforts to (i) perform its obligations under the Commercialization Plan, (ii) obtain and maintain all Regulatory Approvals with respect to its System necessary to commercialize the Combined Systems in each Agreed Market, and (iii) maintain commercial scale manufacturing with respect to its System sufficient to support its obligations under the Commercialization Plan.

2.1.3 Costs. Unless otherwise mutually agreed to by the Parties in the Commercialization Plan, ***.

2.1.4 Commercialization of the On-Market t-slim:G6 Implementation. Section 4 (Commercialization) of the Original G6 Development Agreement is hereby deleted in its entirety, and the Parties agree that this Agreement shall govern the Parties respective rights, obligations and liabilities with respect to the commercialization of the On-Market t-slim:G6 Implementation.

2.2 Alliance Managers. Each Party shall appoint an Alliance Manager as set forth in the Development Agreement. Responsibilities of the Alliance Managers beyond those set forth herein are set forth in the Development Agreement and may be included in other Transaction Agreements.

2.3 Commercial Working Team.

2.3.1 The Parties shall establish a management team for the implementation of the Commercialization Plan that shall be comprised of an equal number of Representatives of each party (one (1) to three (3) members for each Party) ("**Commercial Working Team**") (who shall be employees of the appointing Party (or its Affiliate) and at least one of which shall be a member of the Joint Steering Committee). Each Party may replace its Commercial Working Team members at any time by notice to the other Party.

2.3.2 In accordance with the provisions and objectives of this Agreement and the Commercialization Plan, the Commercial Working Team shall:

(i) review and approve the Commercialization Plan for each new Agreed Market;

(ii) oversee, coordinate and manage the Parties' activities under, and implementation of, the Commercialization Plan;

(iii) ensure communication between the Parties concerning the implementation, status and results of the Commercialization Plan;

(iv) exercise decision-making authority over all Commercialization Plan activities in accordance with this Section 2.3 and make all such decisions and take all such other actions as are delegated to it in this Agreement including but not limited to allocation of commercialization costs;

(v) review, discuss and make proposals to the Joint Steering Committee regarding changes to Agreed Markets under a Commercialization Plan;

(vi) oversee the format for providing forecasts under Section 5.2.2, and receive such forecasts;

(vii) coordinate continuous improvement and technology upgrades for the Combined Systems with the Development Working Team (as defined in the Development Agreement);

(viii) establish such additional joint subcommittees as it deems necessary to achieve the objectives and intent of this Agreement (each a "**Subcommittee**"); and

(ix) oversee and perform such other functions as are appropriate to further the purposes of this Agreement as mutually determined by the Parties in writing.

2.3.3 The Commercial Working Team shall meet as needed but not less often than ***, except as may otherwise be agreed in writing by the Parties. Commercial Working Team meetings shall be held at times and places or in such form, such as by telephone or video conference, as the Commercial Working Team determines, except that in-person meetings of the Commercial Working Team will alternate between the Parties' offices, unless otherwise agreed in writing by the Parties. Subject to Section 2.3.4, any Commercial Working Team member may designate by notice to the other members (which may be provided by e-mail) a qualified Representative of such Party to attend and perform the functions of that Commercial Working Team member at any Commercial Working Team meeting that such member cannot attend.

2.3.4 The Commercial Working Team shall appoint one (1) of the Commercial Working Team members to act as the initial Commercial Working Team chairperson during such period as the Commercial Working Team shall designate. At the end of each such designated period during the Term, the Parties shall alternate in appointing the chairperson for the next such defined period. When the Commercial Working Team consists of more than one (1) Representative from each Party and when the Commercial Working Team chairperson cannot attend a Commercial Working Team meeting, the other member having been previously designated by the same

Party shall serve as the temporary Commercial Working Team chairperson for such meeting, unless neither of such Party's designated Commercial Working Team members can attend, in which case a qualified substitute designated by the Commercial Working Team chairperson for such purpose shall serve as the temporary Commercial Working Team chairperson for such meeting.

2.3.5 The Commercial Working Team chairperson shall be responsible for:

(i) calling and presiding over each Commercial Working Team meeting during his or her tenure as chairperson;

(ii) preparing and circulating the agenda for each such meeting; and

(iii) preparing draft minutes of each such meeting and providing a copy of the draft minutes to each Commercial Working Team member within *** after each such meeting for approval, which shall be deemed to have been given unless any Commercial Working Team member objects within *** after receipt of the draft minutes.

2.3.6 Each Party shall collectively have one (1) vote in any matter requiring the Commercial Working Team's (or any Subcommittee's) action or approval. All decisions of the Commercial Working Team and each Subcommittee shall be unanimous, and no vote may be taken unless at least one Representative of each Party (or properly designated substitute) is present. The Commercial Working Team and each Subcommittee shall make all decisions and take other actions in good faith and with due care, after consideration of the information that is reasonably available to it, with the intention that the resulting decision or action shall maintain or increase the likelihood that the Parties will achieve the purposes and goals of the Commercialization Plan.

2.3.7 If a Subcommittee cannot reach a unanimous decision on a matter at a regularly scheduled Subcommittee meeting, the Subcommittee shall refer such matter to the Commercial Working Team for resolution. If the Commercial Working Team cannot reach a unanimous decision on any matter at a regularly scheduled Commercial Working Team meeting or within *** thereafter, then either Party may, by notice to the other Party, have such matter referred to the Joint Steering Committee for resolution by good faith discussions for a period of at least ***. In the event that the Joint Steering Committee is unable to reach agreement with respect to such matter within such ***, then the following shall apply:

(i) DexCom shall have the final decision-making authority with respect to (A) countries in which to commercialize the DexCom System as part of the Combined Systems, provided that, DexCom shall not exercise its final decision-making authority to cease commercialization of the DexCom System as part of the On-Market t-slim:G6 Implementation in any country in which it is already being commercialized prior to the Original Effective Date unless doing so is consistent with DexCom using Commercially Reasonable Efforts to commercialize such Combined System in such country (which, for clarity, includes implementation of life cycle management consistent with the terms of Section 11), (B) any Regulatory Documentation and Regulatory Approvals *** for the DexCom System, (C) DexCom's day-to-day implementation of its responsibilities under the Commercialization Plan; and (D) those portions of the Promotional Materials specifically relating to the DexCom System; and

(ii) Tandem shall have the final decision-making authority with respect to (A) countries in which to commercialize the Tandem System as part of the Combined Systems, provided that, Tandem shall not exercise its final decision-making authority to cease commercialization of the Tandem System as part of the On-Market t-slim:G6 Implementation in any country in which it is already being commercialized prior to the Original Effective Date unless doing so is consistent with Tandem using Commercially Reasonable Efforts to commercialize such Combined System in such country (which, for clarity, includes implementation of life cycle management consistent with the terms of Section 11), (B) any Regulatory Documentation and Regulatory Approvals *** for the Tandem System; (C) Tandem's day-to-day implementation of its responsibilities under the Commercialization Plan; and (D) those portions of the Promotional Materials specifically relating to the Tandem System;

provided further, that neither Party may exercise its final decision-making authority in a manner that (A) goes beyond the Commercial Working Team or JSC's authority, as limited by Section 2.5, (B) would unilaterally impose any additional or different material obligation on the other Party (including for the other Party to incur or share any additional cost), (C) would cause a Party to assume additional regulatory responsibilities, including reporting requirements or (D) would require changes to quality management practices. ***.

2.3.8 The Commercial Working Team shall keep each Party fully informed of the status of the Parties' activities under the Commercialization Plan. For avoidance of doubt, the Parties are under no obligation to disclose information relating to any other commercial efforts not related to the Commercial Plan.

2.3.9 Each Party shall *** of its respective Commercial Working Team members and their designated substitutes related to their participation on the Commercial Working Team and attendance at Commercial Working Team meetings.

2.4 Responsibilities. Subject to the terms and conditions of this Agreement, the Commercialization Plan and Development Agreement, or unless otherwise agreed in writing by the Parties, each Party shall (i) *** for the design, development, verification and validation, Regulatory Approvals, ***, customer training, marketing, distribution, Managed Care Reimbursement, and on-going post First Commercial Launch support of its System or any component thereof, and (ii) use good faith efforts to support the other Party's Customer acquisition, on-boarding, and ordering of such other Party's System.

2.5 Governance Limitations. Each of the Joint Steering Committee and the Commercial Working Team has only the powers specifically delegated to it by this Agreement (or with respect to the Joint Steering Committee, the Development Agreement) and has no authority to act on behalf of any Party in connection with any Third Party. Without limiting the foregoing, and notwithstanding anything in this Agreement to the contrary, neither the Joint Steering Committee nor the Commercial Working Team has any authority to, and shall not purport to or attempt to:

(i) amend this Agreement or any other Transaction Agreement;

(ii) approve or take any action that would breach or conflict with any provision of this Agreement or of any other Transaction Agreement;

(iii) negotiate agreements on behalf of any Party;

(iv) make representations or warranties on behalf of any Party;

(v) determine compliance or non-compliance with any provision of this Agreement or of any other Transaction Agreement; provided, that the Joint Steering Committee shall have the right to discuss any such non-compliance;

(vi) waive any rights of any Party;

(vii) extend credit on behalf of any Party; or

(viii) take or grant licenses of, transfer ownership or otherwise encumber Intellectual Property on behalf of any Party.

3. INTELLECTUAL PROPERTY OWNERSHIP AND LICENSES

3.1 Intellectual Property Ownership. The Parties intend that all development activities related to the Combined System, including any Clinical Study or any continued technology upgrades to the Combined System will be conducted under the applicable Current Development Agreement and subject to the terms and conditions set forth

therein. For clarity, the ownership and rights of each Party with respect to Intellectual Property arising from the development of the Combined System or any component thereof, including development work resulting from any Clinical Study or any continued technology upgrades to the Combined System, will be governed by the applicable Current Development Agreement.

3.2 DexCom Granted Licenses.

3.2.1 DexCom Trademarks. Subject to terms, conditions, restrictions and approval rights set forth in this Agreement (as and to the extent applicable), DexCom hereby grants to Tandem a *** license to use the DexCom Trademarks solely to perform Tandem's obligations under the Commercialization Plan and to otherwise exercise its rights hereunder. Any such use of the DexCom Trademarks by Tandem will be in material accordance with DexCom's trademark usage guidelines, which may be updated from time to time by DexCom, in DexCom's reasonable discretion, upon at least *** prior written notice to Tandem (provided that Tandem shall not be required to conform to such updated guidelines during the *** period immediately following the provision of such guidelines to Tandem) (for clarity, Tandem shall be required to conform to either the guidelines as they existed immediately prior to or following such update), a current copy of which Tandem acknowledges and agrees has been delivered to, and received by, Tandem, except as the Parties may otherwise agree in writing ("**DexCom Trademark Guidelines**"). Notwithstanding the foregoing, unless otherwise agreed in writing by DexCom, Tandem's use of the DexCom Trademarks shall be limited ***. All goodwill arising from Tandem's use of the DexCom Trademarks pursuant to the license grant in this Section 3.2.1 shall inure to DexCom.

3.2.2 DexCom Copyrights. Subject to the terms, conditions, restrictions and approval rights set forth in this Agreement (as and to the extent applicable), DexCom hereby grants to Tandem under DexCom's copyright interests in the Promotion Materials a *** license for the Term to use, reproduce, display and distribute the Promotion Materials (including translations thereof) solely to perform its obligations under the Commercialization Plan and to otherwise exercise its rights hereunder.

3.3 Tandem Granted Licenses.

3.3.1 Tandem Trademarks. Subject to terms, conditions, restrictions and approval rights set forth in this Agreement (as and to the extent applicable), Tandem hereby grants to DexCom a *** license to use the Tandem Trademarks solely to perform DexCom's obligations under the Commercialization Plan and to otherwise exercise its rights hereunder. Any such use of the Tandem Trademarks by DexCom will be in material accordance with Tandem's trademark usage guidelines, which may be updated from time to time by Tandem, in Tandem's reasonable discretion, upon at least *** prior written notice to DexCom (provided that DexCom shall not be required to conform to such updated guidelines during the *** period immediately following the provision of such guidelines to DexCom) (for clarity, DexCom shall be required to conform to either the guidelines as they existed immediately prior to or following such update), a current copy of which DexCom acknowledges and agrees has been delivered to, and received by, DexCom, except as the Parties may otherwise agree in writing ("**Tandem Trademark Guidelines**"). Notwithstanding the foregoing, unless otherwise agreed in writing by Tandem, DexCom's use of the Tandem Trademarks shall be limited ***. All goodwill arising from DexCom's use of the Tandem Trademarks pursuant to the license grant in this Section 3.3.1 shall inure to Tandem.

3.3.2 Tandem Copyrights. Subject to the terms, conditions, restrictions and approval rights set forth in this Agreement (as and to the extent applicable), Tandem hereby grants to DexCom under Tandem's copyright interests in the Promotion Materials a *** license for the Term to use, reproduce, display and distribute the Promotion Materials (including translations thereof) solely to perform its obligations under the Commercialization Plan and to otherwise exercise its rights hereunder.

3.4 Sublicenses. Any sublicense of the rights licensed under Sections 3.2 and 3.3 shall be subject to the following requirements: (i) each Third Party sublicensee must agree in writing to be bound by terms and restrictions, including as to the protection of Confidential Information, at least as protective of DexCom and Tandem (as applicable) and its Intellectual Property rights as those contained in this Agreement, and (ii) any such license rights may only be sublicensed for the purposes of and subject to any restrictions contained in this Agreement.

4. REGULATORY MATTERS

4.1 Tandem's Testing and Regulatory Responsibilities.

4.1.1 Tandem will be responsible for performing and leading all regulatory testing and related tasks, including all Clinical Studies and all regulatory filings, for Combined Systems, including, as applicable the Tandem Diabetes Management Apps, but excluding DexCom CGM Apps, including all necessary related translations and all Clinical Studies required for all Regulatory Approvals for the Combined Systems.

4.1.2 To the extent permitted by Applicable Laws and by the applicable Regulatory Authority, Tandem will, in the exercise of its commercially reasonable, good faith judgement and in a timely manner (and in any event with at least *** except where not reasonably feasible), *** with relevant Regulatory Authorities as necessary to support Regulatory Approval of the Combined Systems that are specific to *** ("**Relevant Tandem Regulatory Meetings**"). At the request of Tandem, DexCom shall ***. Where reasonably feasible with the Regulatory Authority, Tandem shall *** reasonably in advance of such Relevant Tandem Regulatory Meeting. Tandem shall endeavor to ***. Furthermore, in any meeting or teleconference with Regulatory Authorities (or portion thereof) that ***, Tandem shall (i) ***, and (ii) promptly (and in any event within *** following the Relevant Tandem Regulatory Meeting, (a) *** and (b) ***, to the extent pertaining to ***. As soon as practicable following ***, the Parties shall ***.

4.2 DexCom's Testing and Regulatory Responsibilities.

4.2.1 DexCom will be responsible for performing and leading all regulatory testing and related tasks for the DexCom CGM Devices, and the DexCom CGM App, including all necessary related translations, and for the avoidance of doubt, the DexCom System.

4.2.2 DexCom will designate personnel to provide reasonable support for Tandem in testing of the Combined Systems as related to performance of the DexCom CGM Devices and the DexCom CGM App.

4.2.3 Without limiting Section 4.1.2, upon Tandem's request, DexCom will participate in joint meetings with Tandem with relevant Regulatory Authorities as reasonably necessary to support Regulatory Approval of Combined Systems, including, as applicable the Tandem Diabetes Management Apps, but excluding DexCom CGM Apps.

4.2.4 To the extent permitted by Applicable Laws and by the applicable Regulatory Authority, DexCom will, in the exercise of its commercially reasonable, good faith judgement and in a timely manner (and in any event with at least *** prior notice to Tandem except where not reasonably feasible), *** any and all meetings and teleconferences with DexCom with relevant Regulatory Authorities as necessary to support Regulatory Approval of the Combined Systems that are specific to *** ("**Relevant DexCom Regulatory Meetings**"). At the request of DexCom, Tandem shall ***. Where reasonably feasible with the Regulatory Authority, DexCom shall *** reasonably in advance of such Relevant DexCom Regulatory Meeting. DexCom shall endeavor to ***. Furthermore, in any meeting or teleconference with Regulatory Authorities (or portion thereof) that ***, DexCom shall (i) ***, and (ii) promptly (and in any event within *** following the Relevant DexCom Regulatory Meeting, (a) *** and (b) ***, to the extent pertaining to ***. As soon as practicable following ***, the Parties shall ***.

4.3 Right to Reference. Each Party hereby has the right to cross reference, refer to, rely on, file, incorporate by reference, or otherwise use any regulatory submission or drug master file controlled by the other Party or its Affiliates (and any data contained therein) for the Combined Systems or any component thereof, made in any country in the Agreed Markets (including all Regulatory Approvals and, ***; provided, that (i) Tandem's right to cross-reference, refer to, rely on, file, incorporate by reference or otherwise use shall be limited to doing so in order to support regulatory submissions that Tandem makes under this Agreement or any other Transaction Agreement for the Combined Systems in the Agreed Markets and to enable Tandem to fulfill its obligations, or exercise its rights, under this Agreement or any other Transaction Agreement to develop and/or to commercialize the

Combined Systems in the Agreed Markets, including doing so in order to conduct, support or sponsor Clinical Studies utilizing such DexCom CGM-Enabled Tandem Display Device, and (ii) DexCom's right to cross-reference, refer to, rely on, file, incorporate by reference or otherwise use shall be limited to doing so in order to support regulatory submissions that DexCom makes under this Agreement or any other Transaction Agreement for the DexCom System for use with the Combined Systems in the Agreed Markets. Each Party hereby agrees to promptly provide or have provided to the applicable Regulatory Authorities and/or the other Party or its designee a letter of consent to permit such referencing. In any case in which the Regulatory Authority for the applicable jurisdiction requires a Party to have copies of such filings in order to exercise its rights or perform its obligations hereunder, the other Party shall provide such copies to such requesting Party (provided that the requesting Party shall be responsible for any translation costs in connection therewith).

4.4 Regulatory Obligations and Expenses. In connection with obtaining or maintaining Regulatory Approvals and ***, interacting with Regulatory Authorities, filing or maintaining Regulatory Documentation, or maintaining regulatory records (in each case in relation to its System or the Combined Systems), unless required to comply with Applicable Laws, in no instance shall either Party take any action or omit to take any action that, directly or indirectly, would be reasonably likely to result in the other Party incurring (i) additional responsibilities to Regulatory Authorities or otherwise under Applicable Laws that are not listed or described in the Development Plan or Commercialization Plan, or (ii) additional internal or out-of-pocket expenses (including expenses related to additional reporting obligations) that are not listed or described in the Development Plan or Commercialization Plan, in each case without prior written consent of such other Party; provided, that the foregoing shall not limit either Party's right to make any Minor Release or Major Release of, on the part of DexCom, any component(s) of the DexCom System, and on the part of Tandem, any component(s) of the Tandem System.

5. MANUFACTURING AND DISTRIBUTION

5.1 Manufacturing. Each Party shall be solely responsible, at its own cost, for manufacturing its System, or components thereof, in connection with commercialization of the Combined Systems. Each Party shall manufacture its System for use in the Combined Systems in accordance with any specifications for the Combined Systems agreed upon in writing, all Applicable Laws (including cGMP) and the Quality Agreement.

5.2 Distribution.

5.2.1 General. Subject to the terms and conditions herein and the Commercialization Plan, each Party shall be responsible for the pricing, sale and distribution of its System or components thereof to Customers in the Agreed Markets in connection with commercialization of the Combined Systems. In particular, Customers will order the DexCom System or any component thereof directly from DexCom, through DexCom's established distribution channels, and Customers will order the Tandem System or any component thereof directly from Tandem, through Tandem's established distribution channels. To the extent contemplated by the Commercial Plan, DexCom and Tandem agree to collaborate reasonably on ways to optimize distribution ***. For clarity, unless otherwise agreed to in a Commercialization Plan, neither Party will be obligated to identify and establish new distribution channels for its System in any Agreed Market.

5.2.2 Reporting.

(i) Combined Systems Forecasts. At least *** prior to the First Commercial Launch of the Combined System Implementations, Tandem shall deliver to DexCom a non-binding *** forecast of shipments of such implementation of the Combined System Implementations for the *** period following such projected First Commercial Launch, which forecast shall be updated *** on a rolling basis for the following *** period until such First Commercial Launch and provided to DexCom within *** of ***. After such First Commercial Launch, Tandem shall provide DexCom on a rolling basis, within *** of the ***, with *** forecasts of shipments of the Combined System Implementations for the following *** period. Tandem shall also provide non-binding *** forecasts of shipments for the On-Market t-slim:G6 Implementation, within *** of the end of each *** for the following *** period. All forecasts provided under this Section 5.2.2 shall be separately provided for the DexCom G6® CGM Device and the DexCom G7® CGM Device, ***, and shall be non-binding on Tandem, and

shall be in a format, subject to approval by the Commercial Working Team, that is sufficiently detailed to allow DexCom to adjust the manufacturing requirements of its System as appropriate (*e.g.*, manufacturing ramp up or ramp down). Any change to the timing of such forecasts shall be (i) subject to approval by the Commercial Working Team and (ii) permitted only following the date that is *** following the First Commercial Launch of a Combined System Implementation.

(ii) ***

5.2.3 Ordering Process. As part of the Commercialization Plan, Tandem and DexCom agree to establish a process whereby each Party will deliver its System or components thereof to Customers ***. For clarity, with respect to the On-Market t-slim:G6 Implementation, the Commercialization Plan will reflect the existing process for delivering the DexCom G6® CGM Device and related customer services practices that are in effect prior to the Original Effective Date. Each Party shall promptly notify the other Party of any anticipated supply shortage or supply delay with respect to its System or components thereof that is reasonably likely to impact its ability to timely deliver its System or components to Customers. Upon receipt of any such notification, the Parties will discuss in good faith how to mitigate and remediate such supply shortage or supply delay.

5.2.4 Labeling and Packaging. Subject to all Applicable Laws and conditions of Regulatory Approval, each Party will be solely responsible for packing its System for distribution to Customers in accordance with its normal shipping practices. Except as may be set forth in the Commercialization Plan, each Party shall be solely responsible for determining the labeling and packaging of its System, provided that to the extent any labeling (including any user guides) relates to the other Party's System (or any components thereof), such labeling shall (a) be in accordance with labeling language provided by the other Party ("**System Labeling Guidelines**") or (b) if not in accordance with the other Party's System Labeling Guidelines, be subject to the review and written approval of the other Party, which approval will not be unreasonably withheld, conditioned or delayed.

5.2.5 Reimbursement.

(i) ***. Each Party will be solely responsible for ***, provided that, upon request each Party shall reasonably support the other Party with respect to the other Party's ***. Each Party agrees that it ***.

(ii) Combined System Reimbursement.

(A) Neither Party shall ***. In addition, the responsible employees and authorized consultants or agents of either Party ***.

(B) ***.

(I) ***

(II) ***

(III) ***

6. MARKETING

6.1 Marketing Plan. The Parties agree to collaborate reasonably and in good faith to support the commercial launch and marketing of the Combined Systems in the Agreed Markets. In connection therewith, the Parties will include details in the Commercialization Plan setting forth each Party's responsibilities in connection with launching and promoting the Combined Systems in the Agreed Markets, including details for the Parties to collaborate ***. The Commercialization Plan will also set forth the Parties' joint promotion efforts to be undertaken with respect to the Combined Systems in the Agreed Markets, which joint efforts may include but are not limited to:

(i) ***;

(ii) ***;

(iii) ***;

(iv) ***;

(v) ***;

(vi) ***;

(vii) public communications and press releases regarding the Combined Systems (*e.g.*, "approved uses"), communications for investor relations, conferences, etc.;

(viii) joint presentations at trade shows; and

(ix) other aspects as jointly determined to be of benefit by the Parties.

6.2 Promotion Materials.

6.2.1 Approval. The Parties shall prepare the Promotion Materials in accordance with the Commercialization Plan with oversight by the Commercial Working Team. All Promotion Materials of a Party (solely to the extent such materials of a Party relate to the other Party's discrete System) will be subject to review and approval of the Commercial Working Team or its delegates and pursuant to each Party's internal policies and procedures. Each Party shall and shall cause its Representatives to (i) use, reproduce, display and distribute only Promotion Materials reviewed and approved as set forth in this Agreement (as may be translated for an Agreed Market, provided that neither Party may translate the other Party's Trademarks); and (ii) not modify, alter, amend, adjust or mask any portion of such Promotion Materials in any way (except to the extent required to comply with Applicable Laws, including requirements of any Regulatory Authority). Each Party will promptly notify the other Party and take all reasonably necessary corrective action in the event such Party learns that any such modification, alteration, amendment, adjustment or masking, or any such use or distribution of unapproved marketing materials has taken place by it or its Representatives. Promotion Materials will not contain Product Claims unless such claims (a) have been approved by the Commercial Working Team, (b) ***, and (c) ***.

6.2.2 Other Materials. Except as provided in Section 6.2.1 with respect to Promotion Materials, prior to a Party's usage of the other Party's Trademarks in connection with the marketing of its System, the Party that has created such materials shall submit them to the other Party for review and written approval, which may be given or withheld in the other Party's sole discretion. Each Party shall conduct its review of any materials submitted to it pursuant to this Section 6.2.2 within *** of receipt. If such approval is given, the Party that has created such materials may use them solely in the manner that has been approved, until such time as it receives a written notice from the other Party stating that such use must stop or be modified. ***.

6.3 Branding.

6.3.1 Tandem agrees ***, in each case (i) through (iii), in accordance with the DexCom Trademark Guidelines and subject to Section 6.2. DexCom agrees to ***, in each case (x)-(z), in accordance with the Tandem Trademark Guidelines and subject to Section 6.2.

6.3.2 Subject to all Applicable Laws and the conditions of any applicable Regulatory Approval, Tandem agrees ***.

6.4 ***. Without limiting Section 6.3:

6.4.1 *** Marketing Opportunities.

(i) ***.

(ii) ***.

6.4.2 New Markets. ***.

6.4.3 ***.

6.5 Training. The Parties shall, in accordance with the Commercialization Plan, collaborate reasonably and in good faith to continually update and provide Promotion Materials for training the Parties' respective Sales Teams with respect to promoting the Combined System in the Agreed Markets in compliance with Applicable Laws. In connection therewith, each Party agrees to reasonably make its relevant Sales Team available for training from time to time.

6.6 Third Party Products.

(i) During the Term and any Wind-Down Period, Tandem shall not directly encourage, or accept any consideration from any Third Party to ***, provided that such restriction shall not prevent Tandem from facilitating such replacement if made (a) in connection with a general advertisement not specifically targeting such replacement or (b) upon the request of a patient or such patient's health care professional.

(ii) During the Term and any Wind-Down Period, DexCom shall not directly encourage, accept any consideration from any Third Party to ***, provided that such restriction shall not prevent DexCom from facilitating such replacement if made (a) in connection with a general advertisement not specifically targeting such replacement or (b) upon the request of a patient or such patient's health care professional.

(iii) Notwithstanding the foregoing, both Parties may engage in development and commercialization activities, including research and development activities, marketing and educational activities, with Third Parties for which they may receive a monetary or other consideration, as long as such activities are general in nature and not specifically targeting at the replacement of either Party's device with that of a Third Party.

7. COMPLIANCE WITH LAWS

7.1 General. Each of DexCom and Tandem shall perform, and shall procure that their respective Affiliates and its and their Representatives perform, their obligations and other activities under this Agreement in accordance with Applicable Laws and the provisions of this Agreement.

7.2 Compliance with Party-Specific Regulations. Each Party agrees to cooperate with the other Party as may reasonably be required to ensure that such other Party is able to fully meet its obligations with respect to the Party-Specific Regulations applicable to it. Neither Party shall be obligated to pursue any course of conduct that would result in such Party being in breach of any Party-Specific Regulation applicable to it, and shall give the other Party prompt written notice of any such actual or potential conflict. All Party-Specific Regulations are binding only in accordance with their terms and only upon the Party to which they relate.

7.3 Compliance with Internal Compliance Policies. All Internal Compliance Policies shall apply only to the Party to which they relate. Each Party agrees to cooperate reasonably with the other Party to ensure that such other Party is able to comply with the substance of its respective Internal Compliance Policies and, to the extent practicable, to operate in a manner consist with its usual Compliance-related processes.

7.4 Transparency Reporting. Each Party will comply with Applicable Laws relating to the tracking and reporting of payments and transfers of value provided to health care professionals, health care organizations, and other relevant individuals and entities, including the Physician Payments Sunshine Act (Section 6002 of the Patient

Protection and Affordable Care Act) (collectively, "**Transparency Laws**"). Each Party agrees to cooperate with the other in good faith to provide to the other Party with all information necessary for such Party to comply with any Transparency Laws.

7.5 Privacy Laws. Each Party agrees to collect, Process and transfer cross borders Personal Data in its System in compliance with Privacy Laws. Without limiting the generality of the foregoing, each Party agrees to: (i) obtain and store all authorizations and/or lawful bases necessary to Process and share Personal Data (identified and de-identified) in connection with the Combined System, (ii) timely enter into legally required agreements with Third Parties regarding the processing of Personal Data (*e.g.*, "Business Associate" agreements as defined by HIPAA and processor agreements as defined by GDPR); (iii) implement and maintain appropriate organizational and technical security measures to protect Personal Data; (iv) only transfer Personal Data from any jurisdiction to any other jurisdiction (the European Economic Area constituting a single jurisdiction for this purpose) pursuant to an appropriate data transfer agreement or other mechanism appropriate to comply with Applicable Laws; (v) provide end-users with a mechanism to withdraw their consent for or otherwise object to/opt-out of processing for Personal Data that it controls or possesses as required by Applicable Laws.

8. COLLECTION, PROCESSING, STORAGE AND SHARING OF DATA.

8.1 Tandem ***. Subject to the restrictions set forth in this Section 8.1 and Section 8.7, Tandem will have the right to *** for any and all lawful purposes, including in and for *** and/or for the purposes of ***. Tandem may not *** (1) in connection with ***, *provided*, *however*, that the foregoing shall not ***; (2) to ***; (3) to ***; or (4) to ***. To the extent ***; (b) ***; and (c) to the extent Tandem ***; and (d) Tandem shall ***. Notwithstanding the foregoing and subject to the provisions of Section 8.7, ***, except ***.

8.2 DexCom ***. Subject to the restrictions set forth in this Section 8.2 and Section 8.7, DexCom will have the *** for any and all lawful purposes, ***. DexCom may not ***(1) in connection with ***; (2) to ***; (3) to ***; or (4) to ***. To the extent ***, (a) ***; (b) ***, and (c) to the extent DexCom ***; and (d) DexCom shall ***. Notwithstanding the foregoing and subject to the provisions of Section 8.7, *** (i) ***; (ii) ***; (iii) to ***; (iv) to ***; (v) to *** or (vi) as ***.

8.3 Data ***. DexCom (or its Affiliates, as applicable) ***, and Tandem (or its Affiliates, as applicable) ***.

8.3.1 Tandem hereby acknowledges that, ***. Tandem acknowledges and agrees that ***.

8.3.2 DexCom hereby acknowledges that, ***. DexCom acknowledges and agrees that ***.

8.3.3 With respect to Personal Data (as defined in the GDPR) collected from a Party's Customers located in the European Economic Area, ***. Under no circumstances will the Parties ***.

8.4 Delivery of Data. The Parties shall use Commercially Reasonable Efforts to cooperate and collaborate ***, as applicable.

8.5 Data Reconciliation. The Parties shall use Commercially Reasonable Efforts to cooperate and collaborate to ***.

8.6 Customer Consents. The Parties shall use Commercially Reasonable Efforts to cooperate and collaborate to ***, as applicable, from its *** and for complying with subsequent ***.

8.7 Data ***.

8.7.1 Each Party may share or transfer, or allow the sharing or transfer of, *** data (*i.e.*, the *** or the ***, as applicable), solely in the following circumstances: (i) ***, (ii) ***, in each case (a) solely ***, and (b) *** and (iii) ***. In addition, for purposes of clarity, current *** patient-directed sharing of data from the

Tandem System or the DexCom System with ***, and research institutions may continue, provided that ***. The data sharing restrictions in this Section 8.7.1 shall apply with respect to all of the Combined Systems, provided that, ***, and provided that (in each of the foregoing cases) ***, Tandem shall ***.

8.7.2 Except as set forth in Sections 8.1, 8.2 and 8.7.1, neither Party may share or transfer *** (*i.e.*, the *** or the *** (*i.e.*, ***) prior written consent, not to be unreasonably withheld, it being understood that to the extent a Party wishes to ***(other than as set forth in Section 8.7.1), such Party shall (i) *** and (ii) ***.

8.7.3 Each Party shall use good faith efforts to *** with respect to the sharing or transferring of data (*i.e.*, the *** or the ***, as applicable) from ***.

8.8 No Re-identification. Each Licensee shall not re-identify any person reflected in ***, including without limitation: (a) re-identifying, or attempting to re-identify, or allowing to be re-identified any patient or individual who is the subject of Protected Health Information (as defined by HIPAA) within such ***; (b) re-identifying, or attempting to re-identify, or allowing to be re-identified any relative, family or household member of any patient or individual reflected in such ***; or (c) linking any of the facial or direct identifiers set forth in 45 C.F.R. 164.514 to any other information. In addition, each *** that directly or indirectly involves developing a plan to or actually attempting to reidentify an individual. Each ***. For the purposes of this Section 8.8, the remainder of Section 8, and Section 12.2, "**Licensee**" means (i) with respect to ***, and (ii) with respect to ***; "**Licensor**" means (i) with respect to ***, and (ii) with respect to ***; "**Licensed Data**" means (i) where ***, and (ii) where ***.

8.9 Security Requirements.

8.9.1 Each Licensee shall use Commercially Reasonable Efforts to employ procedures and processes as appropriate to *** and to ***. Licensee shall promptly notify Licensor of any actual Unauthorized Use or Unauthorized Access identified by the Licensee. As used herein, "**Unauthorized Use or Unauthorized Access**" means any use or access that results from *** which shall mean *** or ***.

8.9.2 Each Licensee shall implement and maintain administrative, physical, and technical safeguards to ensure protection of the security, confidentiality, and integrity of any data (including Personal Data) collected through, or generated by, its System or any component thereof (or the other Party's System or any component thereof). Licensee's security measures shall be designed *** and against *** (a "**Data Breach**");

8.9.3 Each Licensee shall maintain written risk management and security policies that cover data center operations and desktop computer use related to the ***;

8.9.4 Each Licensee shall *** on any *** that are in its direct control or that it manages on behalf of its employees, consultants or agents; Each Party's product software to be utilized on patient mobile devices will require ***. *** on ***.

8.9.5 Each Licensee shall conduct or have conducted on its behalf by a Third Party, ***, an evaluation of its processes and systems to *** with respect to the confidentiality, integrity, and security of the Licensed Data. Upon request, Licensee will provide to Licensor a copy of the most recent evaluation ***;

8.9.6 Each Licensee shall transmit Licensed Data on patient mobile devices via ***. Licensee will use protections such as *** when transmitting Licensed Data via the internet or encryption or other secure means; Patient directed data transmission (including download) is excluded as patient will direct the means of such export.

8.9.7 The Parties agree to execute and undertake such compliance mechanisms as may be required by Applicable Laws in order for a party to transfer or receive Personal Data from countries outside the United States, including, but not limited to, the European Economic Area, the United Kingdom and Switzerland;

8.9.8 In addition to the expressly permitted data sharing provisions in this Agreement, each Party shall make the *** available only to *** who have a need to access the Licensed Data and Personal Data in order to perform the Party's obligations or exercise its rights under the Agreement; and

8.9.9 Each Licensee shall maintain security incident management policies and procedures and shall promptly notify Licensor *** of any *** in accordance with Section 8.11 below.

8.10 Audit. During the Term and for *** thereafter, Licensee agrees to permit an independent Third Party auditor designated by Licensor (provided, that such Third Party auditor is reasonably acceptable to Licensee and has entered into a confidentiality agreement directly with Licensee containing obligations of confidentiality and non-use at least as restrictive as those contained herein), upon reasonable advance notice, during regular business hours and ***, to inspect and examine Licensee's *** as reasonably necessary for Licensor to verify Licensee's compliance with Sections 7.5, 8, and 12.2; *provided*, that, such Third Party auditor shall not *** and shall only be permitted to *** of the *** and a *** of any ***.

8.11 Data Breaches. In the event of a Data Breach of Personal Data, the affected Party will *** of any Data Breach or use or disclosure of Personal Data. The affected Party shall promptly notify the other Party (***) upon discovery of any suspected Data Breach. The affected Party will promptly work to *** as required by Applicable Laws, and respond to *** inquiries. The affected Party shall be solely responsible for (i) notifying appropriate Governmental Authorities, affected individuals and any other entity required by Applicable Laws of any Data Breach experienced by it, and (ii) all ***. If a Data Breach affects both Parties, the Parties agree ***. In the event of a dispute or claim brought by an individual or any Government Authority concerning Licensed Data against either or both Parties, the Parties will inform each other about any such disputes or claims, and will ***.

8.12 General Obligations.

8.12.1 The Parties will not process or otherwise use or disclose any Personal Data for any purpose other than performing their respective obligations and exercising of their respective rights under this Agreement.

8.12.2 The Parties agree (i) that any sharing of Personal Data between the Parties is not a "sale" of Personal Data pursuant to Privacy Laws, and (ii) to take such steps as may be necessary in order to avoid any sharing of Personal Data between the Parties from being characterized as a "sale" of Personal Data pursuant to Privacy Laws.

8.13 Suspension. Each Licensor reserves the right to suspend delivery of or access to the applicable Licensed Data or any portion thereof upon its reasonable belief that tortious, criminal or otherwise improper or prohibited activity may be associated with Licensee's utilization of such Licensed Data or in the event that Licensee is in default of any obligation under Sections 7.5, 8, and 12.2. Licensor shall provide written notice to Licensee explaining the reason for any such suspension and Licensee shall immediately suspend such access. Licensor may condition any restoration of access upon satisfaction of such conditions directly associated with the suspension of service as Licensor reasonably determines are appropriate.

8.14 Termination. In the event of any termination of this Agreement, the rights of a Party with respect to DexCom CGM Data and Tandem Insulin Data set forth in Sections 8.1, 8.2 and 8.7 (as applicable) will continue in effect ***, but will be ***. Notwithstanding the foregoing, in the event of termination of this Agreement under Section 15.2 (Termination for Breach), (i) the rights of the terminating Party with respect to DexCom CGM Data or Tandem Insulin Data set forth in Sections 8.1, 8.2 and 8.7 (as applicable) will continue in effect ***, subject to this Section 8.14; and (ii) except with respect to ***, the rights of the other non-terminating Party with respect to DexCom CGM Data or Tandem Insulin Data set forth in Section 8.1, 8.2 or 8.7 (as applicable) will automatically terminate, and such other non-terminating Party shall cease all use of the DexCom CGM Data or Tandem Insulin Data (as applicable).

9. QUALITY AGREEMENT. The Parties entered into a Quality Agreement, effective December 1, 2021. To the extent there is any conflict between the terms and conditions of the Quality Agreement and this Agreement with respect to quality matters, the Quality Agreement shall control and this Agreement shall control with respect to all other matters.

10. CUSTOMER SERVICE.

10.1 Responsibility. Each Party shall be solely responsible, ***, for providing support to Customers of its System or any component thereof in accordance with the terms of the Quality Agreement. As part of this Agreement, the Parties may also establish customer service satisfaction metrics (including, but not limited to, complaint rates and customer satisfaction scores), as agreed to by the Commercial Working Team, for maintaining a minimum level of customer service satisfaction and requirements for each Party to implement adjustments to its customer service practices should such metrics fall below the agreed upon threshold.

10.2 Coordination. The Parties shall jointly review and update the system used to evaluate, triage, and transfer customer support calls (or other methods of inquiry) relating to the Combined System to the appropriate Party, as outlined in the Quality Agreement. At least *** prior to the projected First Commercial Launch of the first Combined System Implementation, the heads of each Party's customer team will meet to agree on such updates. The Parties will cooperate to successfully complete all testing of such system prior to such First Commercial Launch of the first Combined System Implementation.

10.3 Training. Tandem shall lead Customer support training for all of the Combined Systems beginning with First Commercial Launch of any Combined System Implementation, provided that DexCom shall provide to Tandem (i) existing training materials, and (ii) ***, at no cost to Tandem. ***. DexCom agrees to provide Tandem with a reasonable quantity of samples of its System (or components thereof) for Customer support training.

10.4 Supply. Each Party shall, in accordance with the Commercialization Plan, collaborate in good faith to ***. For clarity, (i) ***; and (ii) ***.

11. LIFECYCLE MANAGEMENT

11.1 Improvements and Technology Upgrades. During the Term, the Parties will cooperate on the (i) on-going development, maintenance, and support of the Combined Systems, and (ii) continuous improvement and technology upgrades for the Combined Systems or any component thereof, under and in accordance with the Current Development Agreements. Following execution of this Agreement, Tandem will implement ***. Tandem will implement such data transfer as soon as reasonably practicable ***. The Parties shall amend the Development Agreement, Development Plan and this Agreement as necessary to account for any licensing, Privacy Law or other terms necessary for the implementation of such data transfer.

11.2 Version Support. Each Party agrees ***. In addition:

(i) ***, each Party shall provide the other Party with at least *** advance written notice with respect to ***. ***, then the releasing Party will ensure ***, including ***. The Parties will use their Commercially Reasonable Efforts to cause such agreements to be amended to substitute the applicable Major Release for the obsolesced version of the applicable System.

(ii) DexCom may ***. DexCom shall provide Tandem with at least *** written notice prior to ***. DexCom shall provide ***.

11.3 DexCom Discontinuation. Notwithstanding Section 11.2, DexCom may, in its sole discretion,

(i) discontinue its support for the DexCom CGM Device G6® any time after March 14, 2026;

(ii) discontinue its support of the then-current DexCom CGM Device (a) *** any time commencing *** subsequent to ***, or (b) in *** any time commencing *** subsequent to ***, and

(iii) discontinue its support of features of its then-current DexCom CGM Device *** at any time commencing *** after ***.

11.4 Notwithstanding anything to the contrary herein, the Parties acknowledge and agree that the Parties will work together in good faith to modify the approach set forth in Sections 11.2 and 11.3 to the extent necessary to efficiently roll-out any release that is required under Applicable Laws or by a Regulatory Authority.

12. REPRESENTATIONS AND WARRANTIES

12.1 Each Party hereby represents, warrants and covenants, as applicable, to the other Party that:

(i) it is duly organized and validly existing under the laws of its jurisdiction of incorporation or formation;

(ii) it is duly authorized to execute and deliver this Agreement, the person or persons executing this Agreement on its behalf have been duly authorized to do so by all requisite corporate action, and this Agreement is legally binding upon it and enforceable in accordance with its terms;

(iii) it has full corporate right, power and authority to perform its respective obligations under this Agreement, including the right to grant the rights and licenses granted to the other Party hereunder

(iv) it will obtain and maintain all licenses, permits and other authorizations necessary to perform its obligations hereunder, and will fully cooperate in obtaining and maintaining any approvals from Regulatory Authorities necessary to implement this Agreement;

(v) it will perform its obligations hereunder in compliance with all Applicable Laws, and it has in place a compliance program and internal policies and procedures for its employees and agents to comply with Applicable Laws (including Anti-Corruption Law and Privacy Law) as contemplated by Section 7, including training on such policies and procedures and reporting obligations for non-compliance;

(vi) it will not violate rights of any third party in performing obligations under this Agreement;

(vii) it has obtained or will obtain all necessary institutional and regulatory approvals necessary to perform its obligations under this Agreement, including, without limitation, any institutional review board approval;

(viii) it has not been:

(A) Debarred by the United States Food and Drug Administration under any provision of the Generic Drug Enforcement Act; or

(B) Excluded by the Office of the Inspector General of the United States Department of Health and Human Services, or by any other authority, from participating in any health care program (such as Medicare or Medicaid) funded by any Governmental Authority.

Each Party agrees that no person who has been debarred or excluded as described above will furnish any of the services or deliverables or perform any obligations on behalf of such Party under this Agreement. Neither Party shall subcontract any performance of this Agreement to any person or entity that is on the Specially Designated Nationals and Blocked Persons List (or any successor program) maintained by the United States Department of the

Treasury Office of Foreign Assets Control. Each Party will promptly notify the other Party in writing (with a copy to legal counsel) of any formal actions taken or pending, of which the Party has knowledge, that could reasonably be construed to threaten or to confirm a debarment or exclusion of any person on the lists specified in sub-clause (A) or (B) above.

12.2 Representations and Warranties regarding Licensed Data. Each Licensor represents and warrants that: (a) it has or will obtain all rights, power and authority that are necessary for its collection, use, processing, and disclosure of its Licensed Data as contemplated under Section 8; and (b) Licensee's use of the applicable Licensed Data pursuant to this Agreement will not violate any Intellectual Property Rights, rights of publicity or privacy, other proprietary rights, or any applicable local, state or federal laws, regulations, orders or rules.

12.3 Disclaimer of Warranties. EXCEPT AS EXPRESSLY SET FORTH IN THIS SECTION 12 OR ELSEWHERE IN THIS AGREEMENT, NEITHER TANDEM NOR DEXCOM MAKES ANY REPRESENTATIONS OR WARRANTIES UNDER THIS AGREEMENT, AND EXPRESSLY DISCLAIMS ANY WARRANTIES WHETHER EXPRESS, IMPLIED, STATUTORY OR OTHERWISE, INCLUDING ANY WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, VALIDITY, OR NON-INFRINGEMENT.

12.4 Non-Disparagement.

12.4.1 Neither Party shall make any statement or take any action to disparage the other Party's System (or any component thereof or services related thereto) or engage in any unfair, misleading or deceptive practices regarding the same.

12.4.2 Neither Party shall make any statement (i) comparing the other Party's System (or any component thereof or services related thereto) with respect to performance, quality or clinical benefits, with the products of any Third Party, or (ii) that could reasonably be expected to adversely affect the goodwill of the other Party or its products, except in the case of (i) and (ii), to the extent such public statements are based on (x) published (in any industry recognized scientific publication) peer-reviewed studies; *provided*, *however*, that any peer-reviewed studies shall be *** or (y) are specifically included in a product registration with a Regulatory Authority or in response to a product safety or quality issue or (z) relate to the other Party's material breach of its obligations under either this Agreement or any other Transaction Agreement.

12.4.3 The Parties shall educate and train their employees regarding acceptable public communications regarding the other Party's System consistent with this Section 12.4.

13. CONFIDENTIALITY

13.1 Confidential Information. Except as expressly provided in this Agreement or any other Transaction Agreement, during the Term and for ***, except with respect to Confidential Information constituting trade secrets (to the extent identified by the Disclosing Party in writing or to the extent reasonably identifiable as a trade secret based on the nature and content of the disclosure), which such obligations shall not expire, the Party or its Affiliates receiving Confidential Information (the "**Receiving Party**") from the Disclosing Party : (i) will maintain the Disclosing Party's Confidential Information in strict confidence, and protect and safeguard it using at least the same degree of care as it uses to protect the confidentiality of its own confidential information of similar importance, but no less than a commercially reasonable degree of care; (ii) will not publish or otherwise disclose such Confidential Information, except that the Receiving Party may disclose the Disclosing Party's Confidential Information to its Representatives who have a bona fide need to know such Confidential Information solely for, and only to the extent necessary to pursue, the Purpose, *provided that* each such Representative is bound by a written agreement with the Receiving Party that contains non-use and confidentiality obligations at least as protective of the Disclosing Party's Confidential Information as those set forth in this Agreement; and (iii) will not use such Confidential Information for any purpose other than carrying out Receiving Party's obligations and exercising its rights under this Agreement and any other Transaction Agreement (the "**Purpose**"). For purposes of this Agreement, "**Confidential Information**" means any information furnished by or on behalf of a Party or its Affiliates (the

"**Disclosing Party**") in connection with this Agreement or any other Transaction Agreement or either of the Legacy Development Agreements (including in connection with the negotiation thereof) which is confidential or proprietary to the Disclosing Party, including research and development plans and results; processes; evaluation procedures (including clinical and field testing); manufacturing methods; applications to government authorities; pricing or cost information; construction plans; sales, marketing, and advertising studies and plans; customer lists; computer information and software; special techniques unique to a Party's business; information subject to a right of privacy in favor of a Third Party; information the Disclosing Party maintains under a system of protection against unauthorized access; and, subject to the rights and obligations with respect to disclosure and use thereof contained in the Transaction Agreements, the DexCom CGM Data and the Tandem Insulin Data. Notwithstanding the foregoing, the Disclosing Party's Confidential Information will not include information that the Receiving Party can demonstrate with competent evidence:

13.1.1 was already known to the Receiving Party, other than under an obligation of confidentiality, at the time of disclosure;

13.1.2 was generally available to the public or otherwise part of the public domain at the time of its disclosure to the Receiving Party;

13.1.3 became generally available to the public or otherwise part of the public domain after its disclosure hereunder and other than through any act or omission of the Receiving Party in breach of this Agreement; or

13.1.4 was subsequently lawfully disclosed to the Receiving Party by a person without breaching a duty of confidentiality or developed by or for the Receiving Party without use of, reliance on, or reference to any Confidential Information of the Disclosing Party.

13.2 Permitted Disclosures. Notwithstanding Section 13.1, a Receiving Party may use or disclose the Disclosing Party's Confidential Information solely to the extent such use or disclosure is reasonably necessary in complying with an order of a court of law, prosecuting or defending litigation, complying with applicable governmental regulations, submitting information to tax or other Governmental Authorities, or conducting Clinical Studies; *provided* that, subject to Section 13.5, if a Receiving Party is required to make any such disclosure of Confidential Information, it will give the other Party reasonable advanced notice of the disclosure, and use its reasonable efforts to secure confidential treatment of the information prior to its disclosure (whether through protective orders or otherwise).

13.3 Unauthorized Disclosure of Confidential Information. If the Receiving Party becomes aware of an unauthorized disclosure of the Disclosing Party's Confidential Information, then such Receiving Party shall notify the Disclosing Party promptly in writing.

13.4 Return of Confidential Information. Following any expiration or termination of this Agreement and all other Transaction Agreements, within *** after receipt of the Disclosing Party's written request, the Receiving Party will return to the Disclosing Party (where practicable), or, at the Receiving Party's option, destroy and provide written certification of the destruction of, all tangible materials that contain the Disclosing Party's Confidential Information, other than such Confidential Information to which the Receiving Party retains a right to use under this Agreement or any other Transaction Agreement. Notwithstanding the foregoing, (i) the Receiving Party may retain one copy of the Disclosing Party's Confidential Information in the legal files of the Receiving Party for the sole purpose of determining the scope of obligations incurred under this Agreement or as otherwise required by Applicable Laws; (ii) the Receiving Party may retain any electronic copies of the Disclosing Party's Confidential Information held securely in the Receiving Party's electronic backup storage in accordance with its established document retention policies and (iii) the Receiving Party may retain the Disclosing Party's Confidential Information to the extent included in the Receiving Party's board of director or board committee materials or minutes or actions, quality systems, or regulatory history; subject in each case to the Receiving Party's continuing confidentiality and non-use obligations under this Agreement with respect to such Confidential Information.

13.5 Confidentiality Terms; Confidentiality of Agreement; Press Releases.

13.5.1 Except as explicitly permitted under this Section 13.5 or any other Transaction Agreement, neither Party will disclose to any Third Party the terms of this Agreement without the prior written consent of the other Party hereto, except each Party may disclose the terms of this Agreement and any other Transaction Agreement: (i) on a confidential basis to its Representatives, existing or potential investors (provided that such investors are not ***) and others on a need to know basis, in each case under appropriate confidentiality provisions substantially equivalent to those in this Agreement, providing that such Party shall be responsible for any disclosure of information by any of the persons referred to in the preceding sentence in contravention of the terms of this Agreement; or (ii) to the extent necessary to comply with Applicable Laws; provided that the Disclosing Party shall promptly notify the other Party (other than in the case where such disclosure is necessary, in the reasonable opinion of the Disclosing Party's legal counsel, to comply with Applicable Laws) and allow the other Party a reasonable opportunity to oppose with the Governmental Authority initiating the process and, to the extent allowable by Applicable Laws, to seek limitations on the portion of the Agreement that is required to be disclosed.

13.5.2 The Parties shall not issue a press release disclosing the existence of this Agreement or any other Transaction Agreement, any specific term hereof, or any specific transaction contemplated herein unless required by Applicable Laws or as agreed in writing by the Parties. Where such a press release or other public disclosure is so required, no Party shall issue a press release without first giving the other Party reasonable opportunity to review and approve the proposed public disclosure or press release, such approval not to be unreasonably withheld, delayed or conditioned. For clarity, no such review and approval shall be required for any public disclosure or press release that restates information that has been previously approved for public disclosure or that is otherwise in the public domain without a breach of this Agreement or any Transaction Agreement, provided that such information remains accurate in all material respects.

13.6 Records. At its own expense, each Party will create and maintain and provide access to upon reasonable request all records that relate to this Agreement and to a Party's performance under this Agreement (i) to the extent required by this Agreement and Applicable Laws, (ii) sufficient to demonstrate that any and all amounts invoiced to a Party under this Agreement are accurate and proper in both kind and amount; (iii) sufficient to demonstrate the accuracy of reports submitted to either Party under this Agreement; and (iv) sufficient to enable a Party to comply with Applicable Laws and other legal obligations, to the extent that such Party has or reasonably should have knowledge of those Applicable Laws and other legal obligations. Each of the Parties will maintain all such records for the longer of (a) any period prescribed by Applicable Laws or stated expressly in this Agreement, (b) *** after the term of this Agreement.

13.7 Personal Data; DexCom CGM Data and Tandem Insulin Data. To the extent any Personal Data, DexCom CGM Data and/or Tandem Insulin Data is collected, received or shared by a Party or its Affiliates with or from the other Party or its Affiliates in connection with activities contemplated by this Agreement or the Development Agreement, the use of such data shall be governed solely by Section 8 of this Agreement (and not this Section 13).

14. INDEMNIFICATION AND DEFENSE OF INFRINGEMENT

14.1 DexCom will defend and indemnify Tandem, its Affiliates, and each of their respective directors, officers, employees, agents, successors and assigns (collectively, "**Tandem Indemnitees**"), against all Third Party claims, suits and proceedings, and will hold the Tandem Indemnitees harmless against all judgments, settlements, costs, liabilities and expenses (including reasonable attorneys' fees and litigation costs) (collectively, "**Losses**") payable to Third Parties in connection with such claims, suits and proceedings, to the extent arising from or occurring as a result of: (i) DexCom's breach of its *** under this Agreement, (ii) the ***, (iii) ***, or (iv) physical injury (including death) and/or property damage actually or allegedly caused by any DexCom System (or components thereof), excluding physical injury (including death) and property damage ***.

14.2 Tandem will defend and indemnify DexCom, its Affiliates, and each of their respective directors, officers, employees, agents, successors and assigns (collectively, "**DexCom Indemnitees**"), against all Third Party

claims, suits and proceedings, and will hold the DexCom Indemnitees harmless against all Losses payable to Third Parties in connection with such claims, suits and proceedings, to the extent arising from or occurring as a result of: (i) Tandem's breach of its *** under this Agreement, (ii) ***, (iii) ***, or (iv) physical injury (including death) and/or property damage ***.

14.3 If the manufacture or use of the Combined Systems results in a claim, suit or proceeding in which DexCom and Tandem are both entitled to indemnification by the other Party pursuant to Sections 14. 1 and 14.2, then the Parties will discuss in good faith their cooperation in connection with such matter, and shall discuss in good faith an equitable allocation of each Party's indemnification obligations under this Section 14.

14.4 If the manufacture or use of the Combined Systems results in a Third Party claim, suit, allegation, action or proceeding against Tandem or DexCom alleging infringement or misappropriation of the Intellectual Property of such Third Party and neither DexCom nor Tandem is entitled to indemnification pursuant to Sections 14.1 and 14.2 (a "**Combined System Infringement Action**"), such Party will promptly notify the other Party in writing. The Parties will *** in connection with the Combined System Infringement Action and shall *** of any Combined System Infringement Action. The Parties will *** concerning any Combined System Infringement Action and, in the ***, the Parties will ***.

14.5 At either Party's request, the Parties shall promptly enter into a common-interest agreement to protect any available attorney-client privileges and the like, on reasonable and customary terms.

14.6 A Party seeking indemnification hereunder (the "**Indemnitee**") will promptly notify the indemnifying Party (the "**Indemnitor**") of any claim, suit, proceeding, loss, or expense likely to lead to a claim for indemnification, along with all material related information in the Indemnitee's possession. The Indemnitor will have the right to manage the defense and settlement of any claim, except that ***. The Indemnitee may not enter into any settlement of any such claim without the prior written consent of Indemnitor. The Indemnitee will ***. The Indemnitee may ***. In addition, the Indemnitee may ***.

14.7 Notwithstanding the foregoing in this Section 14, an Indemnitor under this Section 14 has no obligation for any Losses to the extent resulting from (i) ***, or (ii) ***.

14.8 In the event of any actual or alleged infringement of a valid claim of a patent or the actual or alleged infringement or misappropriation of any Third Party Intellectual Property by the Tandem System (or components thereof, including any DexCom CGM-Enabled Tandem Display Device, but excluding any Communication Protocol provided by DexCom), (a) Tandem shall have the right to modify the Tandem System *** to render such Tandem System non-infringing or to be no longer misappropriating such Third Party Intellectual Property and (b) if Tandem cannot reasonably modify the Tandem System to be non-infringing or to no longer be misappropriating such Third Party Intellectual Property, Tandem shall have the right to terminate this Agreement upon *** written notice to DexCom.

14.9 In the event of any actual or alleged infringement of a valid claim of a patent or the actual or alleged infringement or misappropriation of any Third Party Intellectual Property by the DexCom System (or components thereof), (a) DexCom shall have the right to modify the DexCom System *** to render such DexCom System non-infringing or to be no longer misappropriating such Third Party Intellectual Property and (b) if DexCom cannot reasonably modify the DexCom System to be non-infringing or to no longer be misappropriating such Third Party Intellectual Property, DexCom shall have the right to terminate this Agreement upon *** written notice to Tandem.

14.10 In the event that either Party is entitled to indemnification of any Third Party claim, suit or proceeding under both (a) this Agreement and (b) either of the Current Development Agreements, then such Party shall only be entitled to seek indemnification for such claim, suit or proceeding (and only entitled to recover for a particular Loss) *** under either this Agreement or the applicable Current Development Agreement and in no event shall such Party be permitted to seek indemnification for such claim, suit or proceeding (or recover for any particular Loss) under both this Agreement and the applicable Current Development Agreement.

15. TERM AND TERMINATION

Term. The initial term of this Agreement will commence on the Effective Date and will continue for a period of five (5) years from the Effective Date (the "**Initial Term**"), unless terminated earlier pursuant to the other provisions of this Section 15. Following the Initial Term, this Agreement shall automatically renew for successive two (2) year periods (the Initial Term and any renewal terms, collectively, the "**Term**"), unless either Party delivers to the other Party a termination notice *** before the expiration of the Initial Term or the then-current renewal term.

15.1 Termination for Material Breach.

15.1.1 Either Party (the "**Notifying Party**") shall be entitled to terminate this Agreement upon written notice to the other Party if such other Party materially breaches this Agreement and fails to cure such breach within *** following written notice from the Notifying Party specifying such breach in reasonable detail.

15.1.2 Notwithstanding the foregoing, if the allegedly breaching Party in good faith disputes such material breach or the failure to cure such material breach, then such Party shall provide the Notifying Party written notice of that dispute putting forward in reasonable detail the rationale for disputing the alleged breach or failure to cure to the Notifying Party. In such event, the Parties shall promptly undertake good faith efforts to resolve such dispute, in which case, such termination shall not be effective *** after the resolution as to whether such material breach has occurred (and, if it is determined that there was a material breach that remains uncured at the expiration of such *** period); provided, that, during the pendency of any such dispute resolution the Parties shall continue performing their respective obligations, and exercising their respective rights, under this Agreement. The Parties hereby agree to take such steps as may be reasonably necessary to complete such dispute resolution as expeditiously as possible given the circumstances.

15.2 Termination for Change of Control. Each Party shall provide to the other Party written notice within the later of *** after or as soon as permitted under Applicable Laws after undergoing a Change of Control. If such Change of Control is ***, then such other Party shall have the right (but not the obligation) to terminate this Agreement upon ***, provided that such notice is given within *** following such other Party's receipt of the notice of such Change of Control. ***.

15.3 ***. If a Party *** asserting that *** then the *** may, ***. Notwithstanding the foregoing, the *** shall not have the right to *** to the extent ***.

15.4 Effect of Termination.

15.4.1 General. In the case of expiration or termination of this Agreement, all rights and obligations of the Parties under this Agreement shall cease immediately, unless otherwise stated in this Agreement.

15.4.2 Accrued Rights and Obligations. Expiration or termination of this Agreement shall not relieve the Parties of any obligation accrued prior to such expiration or termination, nor shall expiration or any termination of this Agreement preclude either Party from pursuing all rights and remedies it may have under this Agreement, at law or in equity, with respect to breach of this Agreement nor prejudice any Party's right to obtain performance of any obligation.

15.4.3 Post-Termination Support. Upon any expiration or termination of this Agreement, the Parties will (a) ensure continued provision of support services to the then-current Customers for the applicable System, as set forth in the then-current warranty terms covering such System (or such longer period as may be required under Applicable Laws) (collectively, the "**Termination Support Services**") and (b) agree upon a commercially reasonable plan to effect the orderly wind-down of the activities contemplated under this Agreement with respect to the Combined Systems; *provided* that in no event shall such wind-down activities under subsection (b) continue for more than *** after termination (or such longer period as may be required under Applicable Laws) (collectively, the "**Wind-Down Period**"). Subject to the requirements of any Applicable Laws, ***. The license

grants set forth in this Agreement shall continue for the length of the Termination Support Services, provided that upon any expiration or termination of this Agreement, all such license grants (subject to Section 8.14) will immediately and automatically be limited to the extent necessary to support the units of the Combined Systems for such then-current Customers. ***.

15.4.4 Survival. In addition, Sections 1, 3.1, 8.1 (subject to Section 8.14), 8.2 (subject to Section 8.14), 8.3, 8.5, 8.6, 8.7 (subject to Section 8.14), 8.8, 8.9, 8.10, 8.11, 8.12, 8.13, 8.14, 12.3, 13, 14, 15.5, 16 and 17 will survive expiration or termination of this Agreement, provided that, in the event any Section identified above expressly sets forth a limited period of time with respect to the duration or survival of such right or obligation beyond the expiration or termination of this Agreement, then such right or obligation shall survive only for such expressly identified period of time.

16. LIMITATION OF LIABILITY. IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER OR ANY OTHER PERSON OR ENTITY FOR COSTS OF PROCUREMENT OF SUBSTITUTE GOODS, LOST PROFITS, OR ANY OTHER SPECIAL, CONSEQUENTIAL, OR INCIDENTAL DAMAGES, HOWEVER CAUSED AND UNDER ANY THEORY OF LIABILITY ARISING OUT OF THIS AGREEMENT WHETHER BASED IN CONTRACT, TORT (INCLUDING NEGLIGENCE), OR OTHERWISE. THESE LIMITATIONS SHALL APPLY WHETHER OR NOT THE BREACHING PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES AND NOTWITHSTANDING ANY FAILURE OF ESSENTIAL PURPOSE OF ANY LIMITED REMEDY PROVIDED HEREIN. IF EITHER PARTY TERMINATES THIS AGREEMENT IN ACCORDANCE WITH ANY OF ITS PROVISIONS, NEITHER PARTY SHALL BE LIABLE TO THE OTHER, BECAUSE OF SUCH TERMINATION, FOR COMPENSATION, REIMBURSEMENT OR DAMAGES ON ACCOUNT OF THE LOSS OF PROSPECTIVE PROFITS OR ANTICIPATED SALES OR ON ACCOUNT OF EXPENDITURES, INVENTORY, INVESTMENTS, LEASES OR COMMITMENTS IN CONNECTION WITH THE BUSINESS OR GOODWILL OF TANDEM OR DEXCOM.

THE FOREGOING EXCLUSION OF CERTAIN DAMAGES IN THIS SECTION DOES NOT APPLY TO DAMAGES FOR ANY OF THE FOLLOWING:

(I) BREACH OF AN OBLIGATION OF CONFIDENTIALITY UNDER SECTION 13 OR MISAPPROPRIATION OF INTELLECTUAL PROPERTY OR TRADE SECRETS; OR

(II) INDEMNIFICATION OBLIGATIONS UNDER SECTION 14, INCLUDING INDEMNIFICATION OBLIGATIONS UNDER SECTION 14 RELATED TO INFRINGEMENT OF INTELLECTUAL PROPERTY RIGHTS.

17. MISCELLANEOUS

17.1 No Exclusivity. This Agreement shall be non-exclusive for both Tandem and DexCom, and, subject to compliance with the terms and conditions of this Agreement, shall in no way prohibit either Party from working with any Third Party, including other insulin pump or CGM and/or data management companies, or acquiring, licensing, designing, developing, marketing, selling and/or distributing products that compete, directly or indirectly, with the products contemplated by this Agreement. Each Party further acknowledges that the personnel assigned to the activities contemplated by this Agreement may also participate in other activities that may utilize technologies similar to or involve products competitive with those contemplated by this Agreement.

17.2 Subcontractors. Subject to the terms and conditions of this Agreement, either Party may subcontract the performance of its obligations under this Agreement to a Third ***, provided that (i) such subcontractor is bound by terms and conditions consistent, in all relevant respects, with this Agreement, including restrictions with respect to the protection and use of Confidential Information which are no less stringent than those set forth in this Agreement; (ii) such Party hereby expressly waives any requirement that the other Party exhaust any right or remedy (or otherwise proceed) against any such subcontractor for any obligation or performance hereunder

prior to proceeding directly against such Party; and (iii) each Party shall be fully responsible for the performance of its subcontractors.

17.3 Force Majeure. Nonperformance of any Party will be excused to the extent that performance is prevented or delayed by strike, fire, earthquake, flood, governmental acts or orders or restrictions (other than due to a failure to comply with Applicable Laws), epidemic, pandemic, or any other reason where failure to perform is beyond the reasonable control of the nonperforming Party.

17.4 No Implied Waivers; Rights Cumulative. No failure on the part of DexCom or Tandem to exercise and no delay in exercising any right under this Agreement, or provided by statute or at law or in equity or otherwise, will impair, prejudice or constitute a waiver of any such right, nor will any partial exercise of any such right preclude any other or further exercise thereof or the exercise of any other right.

17.5 Independent Contractors. Nothing contained in this Agreement is intended implicitly, or is to be construed, to constitute DexCom or Tandem as partners in the legal sense. No Party hereto will have any express or implied right or authority to assume or create any obligations on behalf of or in the name of the other Party or to bind the other Party to any contract, agreement or undertaking with any Third Party.

17.6 Notices. All notices, requests and other communications hereunder will be in writing and will be personally delivered or sent by registered or certified mail, return receipt requested, postage prepaid, or via email (with delivery or receipt confirmation), in each case to the respective address specified below, or such other address as may be specified in writing to the other Parties hereto:

Tandem:	Tandem Diabetes Care, Inc. 12400 High Bluff Drive. San Diego, CA 92130 Attn: CEO ***
With Copy to:	Tandem Diabetes Care, Inc. 12400 High Bluff Drive San Diego, CA 92121 Attn: ***
DexCom:	DexCom, Inc. 6340 Sequence Drive San Diego, California 92121 Attn: Legal Department ***

17.7 Assignment. Except as otherwise expressly provided under this Agreement, neither Party may assign or otherwise transfer this Agreement or any right or obligation hereunder without the express prior written consent of the other Party; provided that: either Party shall be permitted to effect such an assignment or other transfer of this Agreement in its entirety, without the written consent of the other Party (i) to any of its then-existing Affiliates, or (ii) in connection with a merger or the transfer or sale of all or substantially all of its business or assets related to this Agreement, or (iii) subject to Section 15.3, in connection with a Change of Control.

17.8 Modifications. No amendment or modification of any provision of this Agreement will be effective unless in writing signed by each Party hereto. No provision of this Agreement will be varied, contradicted or explained by any oral agreement, course of dealing or performance or any other matter not set forth in an agreement in writing and signed by all Parties. In the event of a conflict between the provisions of the exhibits or the attachments to this Agreement and the provisions of this Agreement itself, the conflicting provision(s) of the Agreement shall control over the language in the exhibit or attachments, unless otherwise agreed by the Parties.

17.9 Severability. If any provision hereof should be held invalid, illegal or unenforceable in any jurisdiction, all other provisions hereof will remain in full force and effect in such jurisdiction and will be liberally construed in order to carry out the intentions of the Parties hereto as nearly as may be possible. Such invalidity, illegality or unenforceability will not affect the validity, legality or enforceability of such provision in any other jurisdiction.

17.10 Governing Law.

17.10.1 This Agreement and any dispute arising from the performance or breach hereof will be governed by and construed and enforced in accordance with, the laws of the State of California without regard for conflicts of laws principles. Disputes as to matters within the authority of the Commercial Working Team will be resolved as set forth in Section 2.3.7; provided that any dispute as to the application of such Section 2.3.7 shall be subject to this Section 17.10.

17.10.2 Notwithstanding any other provision of this Agreement, either Party may seek interim equitable relief in any court of competent jurisdiction in connection with any alleged breach or violation of Section 7.1, Section 13 or Intellectual Property rights.

17.11 Choice of Forum. The Parties hereby submit and consent to the exclusive jurisdiction of any state or federal court located in ***, and irrevocably agree that all actions or proceedings relating to this Agreement shall be litigated in such courts, and each of the Parties waives any objection which it may have based on improper venue or forum non conveniens to the conduct of any such action or proceeding in such court.

17.12 Counterparts. This Agreement may be executed in two or more counterparts, each of which will be deemed an original, and all of which together, will constitute one and the same instrument.

17.13 Contract Interpretation. The meaning of a provision of this Agreement will be considered in context with other provisions of the Agreement. The following principles apply to the construction of this Agreement unless the construction is plainly contrary to the intent of the Parties:

17.13.1 “Including” means “including but not limited to.”

17.13.2 “Or” means “and/or.”

17.13.3 “Will” and “shall” have the same meaning.

17.13.4 Language that has a generally prevailing meaning is given that meaning unless the Agreement expressly assigns a different one.

17.13.5 Technical terms used in the technical field of the subject of the Agreement are given their technical meaning.

17.13.6 Singular words may be treated as plural, and plural words may be treated as singular.

17.13.7 The masculine gender may be treated as feminine, and the feminine gender may be treated as masculine.

17.13.8 In computing any period of time under this Agreement, the day of the act, event, or default from which the designated period of time begins to run is not included. If the Agreement specifies that a period is to run for a certain number of business days, only business days are included in the count, and the period may not end on day that is not a business day.

17.14 Headings. Headings used herein are for convenience only and will not in any way affect the construction of or be taken into consideration in interpreting this Agreement.

17.15 Entire Agreement. This Agreement (including the exhibits attached hereto which are hereby incorporated into this Agreement by reference), together with the Transaction Agreements, constitutes the entire agreement with respect to the subject matter hereof, and supersedes all prior or contemporaneous understandings or agreements, whether written or oral, between DexCom and Tandem with respect to such subject matter, including the Original Commercialization Agreement. For clarity, (i) the Original G6 Development Agreement (as amended herein) shall remain in full force and effect except to the extent expressly stated otherwise herein and (ii) the License Agreement between TypeZero Technologies LLC and Tandem dated July 14, 2016, as amended, shall remain in full force and effect and shall not be amended or modified by this Agreement.

17.16 Performance by Affiliates. Either Party may discharge any obligation and exercise any right hereunder through any of its Affiliates. Each Party hereby guarantees the performance by its Affiliates of such obligations under this Agreement, and shall cause its Affiliates to comply with the provisions of this Agreement in connection with such performance. Any breach by a Party's Affiliate of any of such Party's obligations under this Agreement shall be deemed a breach by such Party, and the other Party may proceed directly against such first Party without any obligation to first proceed against such Affiliate.

17.17 [Intentionally Removed.]

17.18 Termination of Standstill pursuant to Original G6 Development Agreement. The Original G6 Development Agreement is hereby amended to delete the entirety of Section 10.7 (which provided for a standstill provision).

[**Signature Page Follows**]

IN WITNESS WHEREOF the Parties hereto have caused this Agreement to be signed by duly authorized officers or representatives as of the date first written above.

DEXCOM, INC.

By: /s/ Jereme Sylvain

Print Name: Jereme Sylvain

Title: Executive Vice President and Chief Financial Officer

Date: May 22, 2024

TANDEM DIABETES CARE, INC.

By: /s/ Elizabeth Gasser

Print Name: Elizabeth Gasser

Title: Executive Vice President, Chief Strategy and Product Officer

Date: May 22, 2024

[Signature page to Amended and Restated Commercialization Agreement]

Exhibit A: Agreed Markets

***

Exhibit A1: Form of Amendment Regarding Agreed Markets

This Amendment (this "**Amendment**") is entered into as of [_____] (the "**Amendment Effective Date**") by and between Tandem Diabetes Care, Inc, having a principal place of business at 12400 High Bluff Drive, San Diego, CA 92130 ("**Tandem**"), and DexCom, Inc., having a principal place of business at 6340 Sequence Drive, San Diego, CA 92121 ("**DexCom**", and together with Tandem, the "**Parties**," and each, a "**Party**"), with respect to that certain Commercialization Agreement dated as of January __, 2024 (as amended from time to time, the "**Agreement**"). The Parties agree as follows:

As of the Amendment Effective Date, the definition of "**Agreed Markets**" set forth in the Agreement is hereby amended by [adding] the following countries or jurisdictions to the existing definition of Agreed Markets (and Exhibit A to the Agreement is correspondingly amended):

- [_____]

Except as expressly provided in this Amendment, all of the terms and provisions of the Agreement are and will remain in full force and effect. From and after the Amendment Effective Date, each reference in the Agreement to "this Agreement," "the Agreement," "hereunder," "hereof," "herein," or words of like import will mean and be a reference to the Agreement as amended by this Amendment. This Amendment is governed by and construed in accordance with the laws of the State of California, without regard to the conflict of laws provisions of such State. This Amendment may be executed in counterparts, each of which is deemed an original, but all of which constitute one and the same agreement. Delivery of an executed counterpart of this Amendment electronically shall be effective as delivery of an original executed counterpart of this Amendment.

The Parties have executed this Amendment as of the Amendment Effective Date.

DEXCOM, INC.	**TANDEM DIABETES CARE, INC.**
By:	By:
Print Name:	Print Name:
Title:	Title:

Exhibit B: DexCom CGM Data

***

Exhibit C: DexCom Trademarks

***

Exhibit D: Tandem Insulin Data

***

Exhibit E: Tandem Trademarks

TANDEM DIABETES CARE TRADEMARK KEY

***

06/10/2024

Jean-Claude Kyrillos

Dear Jean-Claude Kyrillos:

Tandem Diabetes Care, Inc. (“Tandem” or the “Company”) is pleased to offer you employment on the terms and conditions set forth below.

1. **Position:** You will serve in a full-time capacity as Executive Vice President & Chief Operating Officer**.** You will report to John Sheridan, President & CEO. By signing this offer letter, you represent and warrant to the Company that you are under no contractual commitments that would limit your ability to work for the Company.

2. **Salary:** You will be paid at rate of **$17,315.53 USD Biweekly**, which is equivalent to **$450,203.73 Annually**, less required payroll taxes and withholdings. This is payable in accordance with the company’s standard payroll practices and in accordance with applicable laws for exempt employees. As an exempt employee, you will not be entitled to overtime pay. Tandem’s annual compensation review process occurs in April each year. Employees hired on or after December 1st will become eligible to participate in the compensation review process that occurs following their one-year anniversary.

3. **Corporate Bonus.** Your target bonus under the Cash Bonus Plan established by the Company is **60%** of regular wages, less required payroll taxes and withholdings. The actual bonus payout under the Cash Bonus Plan, if any, will be determined at the discretion of our Board of Directors and is conditioned on your employment on any payment date. Your target bonus is not a promise of compensation and is not intended to create any obligation on the part of the Company.

4. **Employee Benefits.** As a full-time employee of the Company, you will be eligible to participate in a number of Company-sponsored benefits in accordance with the terms of the Company’s benefit plans. In addition, you will be entitled to Flexible Vacation time off and Paid Sick Leave in accordance with the Company’s policy set forth in the Employee Handbook. Under the Flexible Vacation program, you will be afforded the flexibility to take planned time off as needed and as approved by your manager so long as you are able to fulfill your job duties and responsibilities. The Company reserves the right to change or eliminate these benefits on a prospective basis at any time.

5. **Equity**. In connection with the commencement of your employment, the Company will recommend that the Board of Directors grant you Restricted Stock Units (RSUs) with a value equal to approximately **400%** of your base salary. The actual number of RSUs granted will be at the discretion of the Board. The RSUs will be issued pursuant to the Company’s 2023 Long-Term Incentive Plan, which may be amended from time to time (the “2023 Plan”). Awards are issued on or around the 15th of the month following your employment start date. The RSUs will vest based on the following schedule: 33.3% on the first anniversary of the grant date (as specified in the grant agreement), and in 8 equal quarterly installments thereafter such that all of the RSUs will have vested on the three-year anniversary of the grant date, subject to your continued employment with the Company and in accordance with the equity agreement approved by the Board for use with the 2023 Plan. The grant of such RSUs by the Company is subject to the Board’s approval, and this recommendation is not a promise of compensation and is not intended to create any obligation on the part of the Company. The grant of RSUs is not a guarantee of continued employment for any specific period of time and is subject to the terms and conditions outlined in the 2023 plan. Further details on the 2023 Plan will be provided upon approval of such grant by the Board.

6. **Payroll Taxes and Withholdings.** All forms of compensation referred to in this letter are subject to applicable payroll taxes and withholdings.

7. **Employment At-Will.** The Company is an at-will employer and cannot guarantee employment for any specific duration. You are free to quit, and the Company is entitled to terminate your employment at any time, with or without cause or prior warning. This provision supersedes all prior agreements and understandings concerning termination of employment, whether oral, written or implied. Although your job duties, title, reporting structure, compensation and benefits, as well as the Company's personnel policies and procedures may change from time to time, the "at-will" nature of your employment may only be changed in an express written agreement signed by you and a duly authorized officer of the Company.

8. **Employee Proprietary Information Agreement.** As a condition of your employment, you are required to sign the Company's Employee Proprietary Information Agreement, which includes an Assignment of Inventions provision.

9. **Pre-Employment Screening.** Your employment is contingent on successfully passing a drug test, background check, and satisfactory references check. The drug test and background and reference checks will be conducted through our 3rd party vendor in accordance with applicable laws and may be conducted before or after your employment begins.

10. **Conflicts of Interest.** Conflicts of interest exist where an individual's actions or activities, on behalf of Tandem or otherwise, involve the obtaining of an improper personal gain or advantage, or an adverse effect upon the interest of Tandem. For this reason, employees must refrain from engaging in any activity, practice, act, other employment or outside activities which conflict or interfere with the interests of Tandem, its corporate entities, or those it serves.

11. **Company Policies.** You agree to abide by the Company's policies and procedures, including those set forth in the Company's Employee Handbook and other Company documents, except to the extent they are inconsistent with the terms of this letter. You will be required to sign the signature page of the Employee Handbook and associated policies at the commencement of your employment with the Company.

12. **Employment Eligibility**. Your employment is contingent on you providing the Company with the legally required proof of your identity and authorization to work in the United States. You must also maintain your eligibility to work in the United States throughout your employment.

13. **Prior Employer Confidential Information/Restrictions**. You understand that you are expected to abide by all confidentiality agreements you may have signed at your previous employer(s). Thus, by your acceptance of this offer, you acknowledge and agree to the following:

a. You have taken no documents, information (whether hard copy or electronic), or any other property belonging to a prior employer that you are prohibited from taking, and will not do so; and

b. You have kept and will keep in confidence proprietary information, knowledge, or data acquired by you in confidence during your employment at prior employers, and you will not disclose to the Company or induce the Company to use any confidential or proprietary information belonging to a prior employer or other third parties.

This letter and attachments supersede any prior understandings or agreements, whether oral or written, between you and the Company.

Jean-Claude, we are very enthusiastic about you joining the team. We are impressed with your experience and abilities, and believe that your skills and background provide an excellent match for Tandem.

This offer will remain valid until the close of business on 06/11/2024 with an anticipated start date of 06/21/2024. If the terms are agreeable, please sign, date and return one copy of this letter indicating your acceptance, retaining the second copies for your records.

If you have questions or just wish to discuss things further, please don't hesitate to contact me.

Sincerely,

Tom Fox
Chief Human Resources Officer
Tandem Diabetes Care, Inc.

I have read and accept this employment offer:

By: /s/ JEAN-CLAUDE KYRILLOS
Jean-Claude Kyrillos

Dated: 6/10/2024

**Tandem Diabetes Care reserves the right to review all compensation plans and make changes, additions, and/or deletions at any time.*

EMPLOYMENT SEVERANCE AGREEMENT

This Employment Severance Agreement (the "Agreement") is made and entered into effective as of June 21, 2024 (the "Effective Date"), by and between Jean-Claude Kyrillos (the "Employee") and Tandem Diabetes Care, Inc. (the "Company").

RECITALS

A. The Board of Directors of the Company (the "Board") believes the Company should provide the Employee with certain severance benefits should the Employee's employment with the Company terminate under certain circumstances, such benefits to provide the Employee with enhanced financial security and sufficient incentive and encouragement to remain with the Company.

B. Certain capitalized terms used in the Agreement are defined in Section 4 below.

AGREEMENT

In consideration of the mutual covenants herein contained, and in consideration of the continuing employment of the Employee by the Company, the parties agree as follows:

1. At-Will Employment. The Company and the Employee acknowledge that the Employee's employment is and shall continue to be at-will, as defined under applicable law. If the Employee's employment terminates for any reason, the Employee shall not be entitled to any payments, benefits, damages, awards or compensation other than as provided by this Agreement, or as may otherwise be available in accordance with the Company's established employee plans and practices or in accordance with other agreements between the Company and the Employee.

2. Severance and Change of Control Benefits.

(a) Benefits upon Termination in Connection with a Change of Control. If, on or within three (3) months prior to a Change of Control or within twelve (12) months after a Change of Control, the Employee's employment terminates as a result of an Involuntary Termination or a Resignation For Good Reason and the Employee signs, complies with and does not revoke a Release of Claims, then the Employee shall receive the following severance benefits:

(i) the Employee will receive during the eighteen (18) month period immediately following the date of the Involuntary Termination or the Resignation For Good Reason (if such termination or resignation occurred after the Change of Control) or on the date of the Change of Control (if such termination or resignation occurred on or before the Change of Control), as applicable (the "Severance Period"), a guarantee of salary continuation equal to the Employee's monthly portion of Base Compensation on the date of termination, less applicable withholdings and deductions;

(ii) (A) the Employee will vest in and have the right to exercise all of the Employee's outstanding options, restricted stock units and stock appreciation rights that were otherwise unvested as of the date of such Involuntary Termination or Resignation For Good Reason, (B) all of the Company's rights to repurchase vested and unvested restricted stock or restricted stock units from the Employee shall lapse as to that number of shares in which such repurchase rights have yet to lapse and (C) any right of the Company to repurchase any common stock of the Company shall terminate including under any right of first refusal.

(b) Voluntary Resignation; Termination for Cause. If the Employee's employment with the Company terminates other than as a result of an Involuntary Termination or Resignation For Good Reason, then the Employee will not be entitled to receive severance change in control benefits as defined in this Section 2 or other severance or benefits except for those (if any) as may then be established under the Company's then existing severance and benefits plans and practices or pursuant to other written agreements with the Company.

(c) Disability; Death. If the Company terminates the Employee's employment as a result of the Employee's Disability, or the Employee's employment terminates due to the Employee's death, then the Employee will not be entitled to receive severance or other benefits except for those (if any) as may then be established under the Company's then existing written severance and benefits plans and practices or pursuant to other written agreements with the Company.

(d) Miscellaneous. Upon the termination of the Employee's employment for any reason, (i) the Company shall pay the Employee any unpaid base salary due for periods prior to the Termination Date; (ii) the Company shall pay the Employee all of the Employee's accrued and unused paid time off through the Termination Date; and (iii) following submission of proper expense reports by the Employee, the Company shall reimburse the Employee for all expenses reasonably and necessarily incurred by the Employee in connection with the business of the Company prior to the Termination Date. These payments shall be made promptly upon termination and within the period of time mandated by applicable law.

3. Limitations on Payments.

(a) Code Section 409A.

(i) Notwithstanding anything to the contrary in this Agreement, if the Employee is a "specified employee" within the meaning of Section 409A at the time of the Employee's termination (other than due to death), then the severance payable to the Employee, if any, pursuant to this Agreement, together with any other severance payments or separation benefits that are considered deferred compensation under Section 409A (together, the "Deferred Compensation Separation Benefits"), that are payable within the first six (6) months following the Employee's termination of employment will become payable on the first payroll date that occurs on or after the date six (6) months and one (1) day following the date of the Employee's termination of employment. All subsequent Deferred Compensation Separation Benefits, if any, will be payable in accordance with the payment schedule applicable to each payment or benefit. Notwithstanding anything herein to the contrary, if the Employee dies following the Employee's termination but prior to the six (6) month anniversary of the Employee's termination, then any payments delayed in accordance with this paragraph will be payable in a lump sum as soon as administratively practicable after the date of the Employee's death and all other Deferred Compensation Separation Benefits will be payable in accordance with the payment schedule applicable to each payment or benefit. Each payment and benefit payable under this Agreement is intended to constitute separate payments for purposes of Section 1.409A-2(b)(2) of the Treasury Regulations.

(ii) Any amount paid under this Agreement that satisfies the requirements of the "short-term deferral" rule set forth in Section 1.409A-1(b)(4) of the Treasury Regulations shall not constitute Deferred Compensation Separation Benefits for purposes of clause (i) above.

(iii) Any amount paid under this Agreement that qualifies as a payment made as a result of an involuntary separation from service pursuant to Section 1.409A-1(b)(9)(iii) of the Treasury Regulations that do not exceed the Section 409A Limit shall not constitute Deferred Compensation Separation Benefits for purposes of clause (i) above. For purposes of this Agreement, "Section 409A Limit" shall mean the lesser of two (2) times: (i) the Employee's annualized compensation based upon the annual rate of pay paid to the Employee during the Company's taxable year preceding the Company's taxable year of the Employee's termination of employment as determined under Treasury Regulation 1.409A-1(b)(9)(iii)(A)(1) and any Internal Revenue Service guidance issued with respect thereto; or (ii) the maximum amount that may be taken into account under a qualified plan pursuant to Section 401(a)(17) of the Code for the year in which the Employee's employment is terminated.

(iv) The foregoing provisions are intended to comply with the requirements of Section 409A so that none of the severance payments and benefits to be provided hereunder will be subject to the additional tax imposed under Section 409A, and any ambiguities herein will be interpreted to so comply. The Company and the Employee agree to work together in good faith to consider amendments to this Agreement and to take such reasonable actions which are necessary, appropriate or desirable to avoid imposition of any additional tax or income recognition prior to actual payment to the Employee under Section 409A.

(b) Code Section 280G. In the event that the severance and other benefits provided for in this Agreement or otherwise payable to the Employee (i) constitute "parachute payments" within the meaning of Section 280G of the Code and (ii) but for this Section 3(b), would be subject to the excise tax imposed by Section 4999 of the Code, then the Employee's benefits under Section 2 of this Agreement shall be either:

(i) delivered in full, or

(ii) delivered as to such lesser extent which would result in no portion of such severance and other benefits being subject to excise tax under Section 4999 of the Code, whichever of the foregoing amounts, taking into account the applicable federal, state and local income taxes and the excise tax imposed by Section 4999 of the Code, results in the receipt by the Employee on an after-tax basis, of the greatest amount of severance benefits, notwithstanding that all or some portion of such severance benefits may be taxable under Section 4999 of the Code. Unless the Company and the Employee otherwise agree in writing, any determination required under this Section 3(b) shall be made in writing by the Company's independent public accountants immediately prior to the Change of Control (the "Accountants"), whose determination shall be conclusive and binding upon the Employee and the Company for all purposes. For purposes of making the calculations required by this Section 3(b), the Accountants may make reasonable assumptions and approximations concerning applicable taxes and may rely on reasonable, good faith interpretations concerning the application of Sections 280G and 4999 of the Code. The Company and the Employee shall furnish to the Accountants such information and documents as the Accountants may reasonably request in order to make a determination under this Section 3(b). The Company shall bear all costs the Accountants may reasonably incur in connection with any calculations contemplated by this Section 3(b).

4. Definition of Terms. The following terms referred to in this Agreement shall have the following meanings:

(a) Base Compensation. "Base Compensation" means the Employee's (i) annual base salary paid by the Company for services performed as in effect on the Termination Date; and (ii) target cash bonus and/or other forms of cash incentive compensation for the fiscal year in which the Change of Control is effective.

(b) Cause. "Cause" means:

(i) the Employee's continued intentional and demonstrable failure to perform his or her duties customarily associated with the Employee's position as an employee of the Company or its respective successors or assigns, as applicable (other than any such failure resulting from the Employee's mental or physical Disability) after the Employee has received a written demand of performance from the Company which specifically sets forth the factual basis for the Company's belief that the Employee has not devoted sufficient time and effort to the performance of his or her duties and has failed to cure such non-performance within thirty (30) days after receiving such notice (it being understood that if the Employee is in good faith performing his or her duties, but is not achieving results the Company deems satisfactory for the Employee's position, it will not be considered to be grounds for termination of the Employee for "Cause");

(ii) the Employee's conviction of, or plea of nolo contendere to, a felony that the Board reasonably believes has had or will have a material detrimental effect on the Company's reputation or business;

(iii) the Employee's commission of an act of fraud, embezzlement, misappropriation, willful misconduct, or breach of fiduciary duty against, and causing material harm to, the Company or its respective successors or assigns, as applicable;

(iv) the Employee's unauthorized use of the Company's material confidential information; or

(v) the Employee's prohibited or unauthorized competitive activity.

The Employee will receive notice and an opportunity to be heard before the Board with the Employee's own attorney before any termination for Cause is deemed effective. Notwithstanding anything to the contrary, the Board may immediately place the Employee on administrative leave (with full pay and benefits to the extent legally permissible) but will allow reasonable access to Company information, employees and business should the Employee wish to avail himself and prepare for his or her opportunity to be heard before the Board prior to the Board's termination for Cause. If the Employee avails himself or herself of the Employee's opportunity to be heard before the Board, and then fails to make himself or herself available to the Board within thirty (30) days of such request to be heard, the Board may thereafter cancel the administrative leave and terminate the Employee for Cause. Likewise, if the Board fails to make itself available to the Employee and his or her counsel within thirty (30) days of the Employee's request to be heard, Employee will be entitled to terminate his or her employment with the Company and such termination will be treated as a resignation by Employee for Involuntary Termination.

(c) Change of Control. "Change of Control" means (A) the acquisition of the Company by another entity by means of any transaction or series of related transactions (including, without limitation, any merger, consolidation or other form of reorganization in which outstanding shares of the Company are exchanged for securities or other consideration issued, or caused to be issued, by the acquiring entity or its subsidiary, but excluding any transaction effected primarily for the purpose of changing the Company's jurisdiction of incorporation), *unless* the Company's stockholders of record as constituted immediately prior to such transaction or series of related transactions will, immediately after such transaction or series of related transactions hold at least a majority of the voting power of the surviving or acquiring entity, except that any change in the ownership of the stock of the Company as a result of a private financing of the Company that is approved by the Board and in which the Board determines is not a Change of Control for the purposes of this Agreement will not be considered a Change of Control, or (B) a sale, lease, transfer or other disposition of all or substantially all of the assets of the Company.

Notwithstanding the foregoing provisions of this definition, a transaction will not be deemed a Change of Control unless the transaction qualifies as a change in control event within the meaning of Section 409A.

(d) Disability. "Disability" means the Employee has been unable to perform his or her Company duties as the result of his or her incapacity due to physical or mental illness, and such inability, at least twenty-six (26) weeks after its commencement or 180 days in any consecutive twelve (12) month period, is determined to be total and permanent by a physician selected by the Company or its insurers and acceptable to the Employee or the Employee's legal representative (such agreement as to acceptability not to be unreasonably withheld). Termination resulting from Disability may only be effected after at least thirty (30) days' written notice by the Company of its intention to terminate the Employee's employment. In the event that the Employee resumes the performance of substantially all of his or her duties hereunder before the termination of his or her employment becomes effective, the notice of intent to terminate will automatically be deemed to have been revoked.

(e) Involuntary Termination. "Involuntary Termination" means termination of the Employee's employment, without the Employee's consent, by the Company for any reason other than Cause.

(f) Release of Claims. "Release of Claims" shall mean a waiver by the Employee, in a form satisfactory to the Company, of all employment-related obligations of and claims and causes of action against the Company, and a non-disparagement agreement by the Employee in a form satisfactory to the Company. Whenever in this Agreement a payment or benefit is conditioned on Employee's execution of a Release of Claims, such Release of Claims must be executed, and all applicable revocation periods shall have expired, within sixty (60) days after the date of termination, failing which such payment or benefit shall be forfeited. If such payment or benefit constitutes non-exempt "deferred compensation" for purposes of Section 409A of the Code, and if such 60-day period begins in one calendar year and ends in the next calendar year, the payment or benefit shall not be made or commence before the second such calendar year, even if the Release of Claims becomes irrevocable in the first such calendar year.

(g) Resignation for Good Reason. "Resignation for Good Reason" shall mean a resignation by Employee following a Change of Control and following the occurrence of one of the following:

(i) a material reduction in the Employee's Base Compensation;

(ii) any material breach by the Company of any material provision of this Agreement which continues uncured for thirty (30) days following notice thereof;

(iii) a material reduction in the Employee's duties, responsibilities or authority; or

(iv) a change of fifty (50) miles or more of the geographic location at which the Employee must primarily perform services for the Company.

Any purported Resignation for Good Reason pursuant to Section 4(g)(i) through (g)(iv) above will not be effective until the Employee has delivered to the Company, within sixty (60) days of the initial existence of the Good Reason condition, a written explanation that describes the basis for the Employee's belief that the Employee should be permitted to terminate the Employee's employment and have it treated as a Resignation for Good Reason and the Company has been given thirty (30) days following delivery of such notice to cure any curable violation. In no instance will a resignation by Employee be deemed to be a Resignation for Good Reason if it is made more than twelve (12) months following the initial existence of one or more of the conditions that constitute Good Reason hereunder.

(h) Termination Date. "Termination Date" shall mean the date on which an event that would constitute an Involuntary Termination or a Resignation for Good Reason occurs, or the later of (i) the date on which a notice of termination is given, or (ii) the date (which shall not be more than thirty (30) days after the giving of such notice) specified in such notice.

5. Successors.

(a) Company's Successors. Any successor to the Company (whether direct or indirect and whether by purchase, lease, merger, consolidation, liquidation or otherwise) to all or substantially all of the Company's business and/or assets shall assume the obligations under this Agreement and agree expressly to perform the obligations under this Agreement in the same manner and to the same extent as the Company would be required to perform such obligations in the absence of a succession. For all purposes under this Agreement, the term "Company" shall include any successor to the Company's business and/or assets which executes and delivers the assumption agreement pursuant to this subsection (a) or which becomes bound by the terms of this Agreement by operation of law.

(b) Employee's Successors. The terms of this Agreement and all rights of the Employee hereunder shall inure to the benefit of, and be enforceable by, the Employee's personal or legal representatives, executors, administrators, successors, heirs, distributees, devisees and legatees.

6. Notice.

(a) General. Notices and all other communications contemplated by this Agreement shall be in writing and shall be deemed to have been duly given when personally delivered or when mailed by U.S. registered or certified mail, return receipt requested and postage prepaid. In the case of the Employee, mailed notices shall be addressed to the Employee at the home address that the Employee most recently communicated to the Company in writing. In the case of the Company, mailed notices shall be addressed to its corporate headquarters, and all notices shall be directed to the attention of its Chief Executive Officer or principal human resources person.

(b) Notice of Termination. Any termination by the Company for Cause or by the Employee as a result of a voluntary resignation or an Involuntary Termination or Resignation for Good Cause shall be communicated by a notice of termination to the other party hereto given in accordance with Section 6(a) of this Agreement. Such notice shall indicate the specific termination provision in this Agreement relied upon, shall set forth in reasonable detail the facts and circumstances claimed to provide a basis for termination under the provision

so indicated, and shall specify the termination date (which shall be not more than thirty (30) days after the giving of such notice). The failure by the Employee to include in the notice any fact or circumstance which contributes to a showing of Involuntary Termination or Resignation for Good Cause shall not waive any right of the Employee hereunder or preclude the Employee from asserting such fact or circumstance in enforcing the Employee's rights hereunder.

7. Term and Termination. The term of this Agreement shall be one year from the Effective Date; provided, however, that this Agreement shall automatically renew for successive 1-year periods unless either party gives the other party notice, at least 60 days in advance of the next renewal date, of such party's intent that this Agreement terminate effective as of such next renewal date, in which case the Agreement shall terminate as of such next renewal date; provided further, however, that in the event a Change of Control that precedes the effective date of any such termination, the term of this Agreement shall extend at least until the one (1)-year anniversary of such Change of Control. Notwithstanding the foregoing, if the Employee becomes entitled to benefits pursuant to Section 2(a) or 2(b) of this Agreement, this Agreement will not terminate until, but will terminate at, such time that all of the obligations of the parties hereto with respect to this Agreement have been satisfied.

8. Miscellaneous Provisions.

(a) No Duty to Mitigate. The Employee shall not be required to mitigate the amount of any payment contemplated by this Agreement.

(b) Waiver and Amendment. No provision of this Agreement shall be modified, amended, waived or discharged unless the modification, amendment, waiver or discharge is agreed to in writing and signed by the Employee and by an authorized officer of the Company (other than the Employee). No waiver by either party of any breach of, or of compliance with, any condition or provision of this Agreement by the other party shall be considered a waiver of any other condition or provision or of the same condition or provision at another time.

(c) Whole Agreement. No agreements, representations or understandings (whether oral or written and whether express or implied) which are not expressly set forth in this Agreement or in the Existing Agreements have been made or entered into by either party with respect to the subject matter hereof.

(d) Severance Provisions in Other Agreements. The Employee acknowledges and agrees that the severance provisions set forth in this Agreement shall supersede any such provisions in any other agreement entered into between the Employee and the Company.

(e) Choice of Law. The validity, interpretation, construction and performance of this Agreement shall be governed by the laws of the State of California.

(f) Severability. The invalidity or unenforceability of any provision or provisions of this Agreement shall not affect the validity or enforceability of any other provision hereof, which shall remain in full force and effect.

(g) No Assignment of Benefits. The rights of any person to payments or benefits under this Agreement shall not be made subject to option or assignment, either by voluntary or involuntary assignment or by operation of law, including (without limitation) bankruptcy, garnishment, attachment or other creditor's process, and any action in violation of this subsection shall be void.

(h) Withholding. All payments made pursuant to this Agreement will be subject to withholding of applicable income, employment and other taxes. If the Company does not make such withholdings on Employee's behalf, Employee shall pay when due all such taxes (and any related penalties and interest) imposed on Employee and shall indemnify the Company for Employee's failure to do so.

(i) Assignment by Company. The Company may assign its rights under this Agreement to an affiliate, and an affiliate may assign its rights under this Agreement to another affiliate of the Company or to the

Company; provided, however, that no assignment shall be made if the net worth of the assignee is less than the net worth of the Company at the time of assignment. In the case of any such assignment, the term "Company" when used in a section of this Agreement shall mean the corporation that actually employs the Employee.

(j) Counterparts. This Agreement may be executed in counterparts, each of which shall be deemed an original, but all of which together will constitute one and the same instrument.

IN WITNESS WHEREOF, each of the parties has executed this Agreement, in the case of the Company by its duly authorized officer, as of the day and year first above written.

COMPANY: TANDEM DIABETES CARE, INC.

By: /s/ JOHN F. SHERIDAN
John F. Sheridan
President and Chief Executive Officer

EMPLOYEE: By: /s/ JEAN-CLAUDE KYRILLOS
Jean-Claude Kyrillos

Amendment No. 1 to Distributor Agreement

Unomedical a/s and Tandem Diabetes Care, Inc.

This amendment ("**Amendment No. 1**") is entered into effective as of May 8, 2024 (the "Amendment **Effective Date**") by and between Unomedical a/s, a Danish corporation having its principal place of business at Aaholmvej 1-3, Osted, 4320 Lejre, Denmark ("**Company**"), and Tandem Diabetes Care, Inc., a Delaware corporation having its principal place of business at 12400 High Bluff Drive, San Diego, California, 92130, USA ("**Distributor**") (each individually a "**Party**" and collectively the "**Parties**").

Capitalised terms not defined in this Amendment No. 1 shall have the meaning ascribed to them in the Agreement (as defined below).

WHEREAS

A. Company and Distributor have entered into a Distributor Agreement dated 14 January, 2022 (the "**Agreement**");
B. The Parties now wish to make certain amendments and updates to the Agreement;

As such, the Parties agree to amend the Agreement as set forth below:

1. DEFINITIONS

The definition of "Products" is deleted in its entirety and amended and restated as follows:

"**Products**" means AutoSoft™ 90 infusion sets, AutoSoft™ XC infusion sets, AutoSoft™ 30 infusion sets, TruSteel™ infusion sets, VariSoft™ infusion sets and AutoSoft+ infusion sets ("AutoSoft+") which are included in Company's published Price List, as amended or supplemented from time to time during the term of this Agreement by Company and listed in Exhibit A. Products as delivered to Distributor will have markings and instructions for use in English and other languages required in accordance with applicable laws and regulations. The Products are marked with the Company trademarks and Distributor's trademarks set out in Exhibit A.

2. TERM AND TERMINATION
Section 2.1 is deleted in its entirety and amended and restated as follows:

2.1. Term. The term of this Agreement **("Term")** shall be from the Amendment Effective Date until such time when it is terminated by either Party in accordance with the provisions of this Agreement. Subject to any other provisions in this Agreement, which give either Party a right of termination, the Agreement may be terminated by either Party with *** written termination notice to the other Party, however the earliest effective date of termination resulting from a termination shall be *** from the Amendment Effective Date.

3. DISTRIBUTORSHIP
Section 3.4.j is added as follows:

j. Company shall use commercially reasonable efforts to Launch AutoSoft+ ***. Launch means the first sale of AutoSoft+ by Company to Distributor to be distributed by or on behalf of Distributor for commercial purposes (i.e. revenue generating for Distributor) ("Launch"). Company shall provide at least the following capacity for production of AutoSoft+, always provided that Company shall not be required to build any additional manufacturing capacity:

***

***

Section 3.7.d.2 is deleted in its entirety and amended and restated as follows:

2. Company shall not discontinue manufacture of any Product covered by this Agreement without providing Distributor with at least *** and good faith negotiations by the Parties ***.

Section 3.8 is added as follows:

3.8. Addition of New Product. Company has developed and Distributor has expressed desire to distribute a new Product under the brand name "AutoSoft+", the Specifications for which are included in Exhibit B-1 (AutoSoft+). *** Company shall manufacture and supply AutoSoft+ to Distributor, and Distributor shall purchase AutoSoft+ from Company, on the terms and conditions of this Agreement. For the avoidance of doubt, Company shall obtain and maintain all regulatory approvals required for the marketing, sale and distribution of AutoSoft+ ***.

5. PURCHASE OF PRODUCT BY DISTRIBUTOR: PRICING AND PAYMENTS
Section 5.1 is deleted in its entirety and amended and restated as follows:

5.1. Minimum Order and Minimum Volumes.
(a) Distributor agrees to acquire from Company in minimum order quantities ("**Minimum Order**") as described in Exhibit C for each Product SKU per Purchase Order**.**

(b) Distributor also agrees to acquire from Company ***.

(c) ***

A new sentence is added to the end of Section 5.2

Notwithstanding anything in this Section 5.2, any Purchase Order submitted to Company for AutoSoft+ that is in accordance with the most recent forecast provided under Section 3.3(h) and which does not exceed the total capacity allocated for the applicable twelve (12) month period, shall be deemed an Accepted Purchase Order.

EXHIBIT A – PRODUCTS AND TRADEMARK LABELING
Exhibit A is deleted in its entirety and replaced with attached Exhibit A

EXHIBIT B-1 – SPECIFICATIONS – INFUSION SETS
The attached Exhibit B-1 (AutoSoft+) shall be added to the existing Exhibit B-1

EXHIBIT C – PRICING AND MINIMUM VOLUMES
The following is added to Exhibit C:

***

EXHIBIT D – SHELF LIFE/WARRANTY PERIODS
Exhibit D is deleted in its entirety and amended and restated as follows:
***

[SIGNATURES ON THE NEXT PAGE]

The Parties have caused this Amendment No. 1 to be executed as of the Amendment Effective Date.

Unomedical
For and on behalf of Unomedical a/s:

/s/ Kjersti Grimsrud
Name: Kjersti Grimsrud
President and COO Infusion Care
Date: May 10, 2024

Tandem
For and on behalf of Tandem Diabetes Care, Inc:

/s/ Elizabeth Gasser
Name: Elizabeth Gasser
Title: EVP, Chief Strategy & Product Officer
Date: May 10, 2024

EXHIBIT A

***

EXHIBIT B-1

***

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 1, 2024

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 1, 2024

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, 2024, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, John F. Sheridan, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company as of the dates and for the periods presented.

Date: August 1, 2024

/s/ John F. Sheridan
John F. Sheridan
President, Chief Executive Officer and Director

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

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, 2024, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Leigh A. Vosseller, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company as of the dates and for the periods presented.

Date: August 1, 2024

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

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