UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the Quarterly Period Ended September 30, 2023

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 x 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	x	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 October 26, 2023, there were 65,209,703 shares of the registrant's Common Stock outstanding.

TABLE OF CONTENTS

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements.

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

	September 30, 2023	December 31, 2022
Assets	(Unaudited)	(Note 1)
Current assets:		
Cash and cash equivalents	$ 79,611	$ 172,517
Short-term investments	418,547	444,384
Accounts receivable, net	100,318	114,717
Inventories	143,492	111,117
Prepaid and other current assets	16,176	7,241
Total current assets	758,144	849,976
Property and equipment, net	75,760	68,552
Operating lease right-of-use assets	89,434	110,626
Other long-term assets	16,571	23,631
Total assets	$ 939,909	$ 1,052,785
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 46,142	$ 55,730
Accrued expenses	14,073	9,595
Employee-related liabilities	43,735	38,682
Operating lease liabilities	17,618	13,121
Deferred revenue	31,610	18,837
Other current liabilities	33,932	29,325
Total current liabilities	187,110	165,290
Convertible senior notes, net - long-term	284,580	283,232
Operating lease liabilities - long-term	116,012	123,524
Deferred revenue - long-term	14,089	16,874
Other long-term liabilities	24,118	23,918
Total liabilities	625,909	612,838
Commitments and contingencies (Note 13)	—	—
Stockholders' equity:		
Common stock, $0.001 par value; 200,000 shares authorized, 65,191 and 64,513 shares issued and outstanding at September 30, 2023 and December 31, 2022, respectively.	65	65
Additional paid-in capital	1,237,939	1,170,888
Accumulated other comprehensive loss	(2,206)	(1,817)
Accumulated deficit	(921,798)	(729,189)
Total stockholders' equity	314,000	439,947
Total liabilities and stockholders' equity	$ 939,909	$ 1,052,785

See accompanying notes to unaudited condensed consolidated financial statements.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Sales	$ 185,622	$ 204,547	$ 550,922	$ 580,716
Cost of sales	95,869	100,122	276,527	283,252
Gross profit	89,753	104,425	274,395	297,464
Operating expenses:				
Selling, general and administrative	79,328	84,104	266,752	237,989
Research and development	41,970	36,798	127,063	103,529
Acquired in-process research and development expenses	—	31,016	78,750	31,016
Total operating expenses	121,298	151,918	472,565	372,534
Operating loss	(31,545)	(47,493)	(198,170)	(75,070)
Other income (expense), net:				
Interest income and other, net	5,656	1,720	17,305	2,961
Interest expense	(4,840)	(1,576)	(8,079)	(4,629)
Total other income (expense), net	816	144	9,226	(1,668)
Loss before income taxes	(30,729)	(47,349)	(188,944)	(76,738)
Income tax expense	2,232	1,621	3,665	2,003
Net loss	$ (32,961)	$ (48,970)	$ (192,609)	$ (78,741)
Other comprehensive income (loss):				
Unrealized gain (loss) on short-term investments	$ 349	$ (258)	$ 1,800	$ (3,899)
Foreign currency translation losses	(1,362)	(524)	(2,189)	(549)
Comprehensive loss	$ (33,974)	$ (49,752)	$ (192,998)	$ (83,189)
Net loss per share - basic	$ (0.51)	$ (0.76)	$ (2.97)	$ (1.23)
Net loss per share - diluted	$ (0.51)	$ (0.76)	$ (2.97)	$ (1.23)
Weighted average shares used to compute basic net loss per share	65,117	64,236	64,834	64,066
Weighted average shares used to compute diluted net loss per share	65,117	64,237	64,834	64,067

See accompanying notes to unaudited condensed consolidated financial statements.

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

Three Months Ended September 30, 2023

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

Nine Months Ended September 30, 2023

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

See accompanying notes to unaudited condensed consolidated financial statements.

Three Months Ended September 30, 2022

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at June 30, 2022	64,210	$ 64	$ 1,118,168	$ (4,282)	$ (664,366)	$ 449,584
Exercise of stock options	26	—	583	—	—	583
Vesting of restricted stock units, net of shares withheld for taxes	29	—	(952)	—	—	(952)
Stock-based compensation expense	—	—	22,359	—	—	22,359
Unrealized loss on short-term investments	—	—	—	(258)	—	(258)
Foreign currency translation losses	—	—	—	(524)	—	(524)
Net loss	—	—	—	—	(48,970)	(48,970)
Balance at September 30, 2022	64,265	$ 64	$ 1,140,158	$ (5,064)	$ (713,336)	$ 421,822

Nine Months Ended September 30, 2022

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2021	63,833	$ 64	$ 1,068,259	$ (616)	$ (634,595)	$ 433,112
Exercise of stock options	198	—	6,981	—	—	6,981
Vesting of restricted stock units, net of shares withheld for taxes	99	—	(3,527)	—	—	(3,527)
Issuance of common stock under Employee Stock Purchase Plan	129	—	7,915	—	—	7,915
Exercise of common stock warrants	6	—	83	—	—	83
Stock-based compensation expense	—	—	60,447	—	—	60,447
Unrealized loss on short-term investments	—	—	—	(3,899)	—	(3,899)
Foreign currency translation losses	—	—	—	(549)	—	(549)
Net loss	—	—	—	—	(78,741)	(78,741)
Balance at September 30, 2022	64,265	$ 64	$ 1,140,158	$ (5,064)	$ (713,336)	$ 421,822

See accompanying notes to unaudited condensed consolidated financial statements.

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

	Nine Months Ended September 30,	
	2023	**2022**
Operating Activities		
Net loss	$ (192,609)	$ (78,741)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation and amortization expense	11,684	10,689
Amortization of debt issuance costs	1,711	1,395
Provision for expected credit losses	4,066	2,955
Provision for inventory obsolescence	332	775
Operating lease impairment charge	14,099	—
Amortization of premium on short-term investments	3,177	3,381
Stock-based compensation expense	65,335	60,477
Acquired in-process research and development expenses	78,750	31,016
Other	(1,769)	(647)
Changes in operating assets and liabilities:		
Accounts receivable, net	9,872	(4,796)
Inventories	(32,714)	(37,062)
Prepaid and other current assets	(7,296)	1,364
Other long-term assets	(1,216)	(960)
Accounts payable and accrued expenses	(4,574)	28,038
Employee-related liabilities	5,571	(3,585)
Deferred revenue	10,042	4,998
Operating leases and other current liabilities	10,745	24,305
Other long-term liabilities	200	1,042
Net cash provided by (used in) operating activities	(24,594)	44,644
Investing Activities		
Purchases of short-term investments	(391,025)	(362,494)
Proceeds from maturities and redemptions of short-term investments	415,485	422,907
Purchases of property and equipment	(21,605)	(28,470)
Acquisitions, including in-process research and development, net of cash acquired	(69,496)	(25,697)
Purchases of intangible assets and strategic investments	(2,515)	(8,855)
Net cash used in investing activities	(69,156)	(2,609)
Financing Activities		
Proceeds from issuance of common stock under Company stock plans, net	1,567	11,369
Proceeds from exercise of common stock warrants	—	83
Other financing activities	(71)	(675)
Net cash provided by financing activities	1,496	10,777
Effect of foreign exchange rate changes on cash	(652)	(207)
Net increase (decrease) in cash and cash equivalents	(92,906)	52,605
Cash and cash equivalents at beginning of period	172,517	71,181
Cash and cash equivalents at end of period	$ 79,611	$ 123,786
Supplemental disclosures of cash flow information		
Income taxes paid	$ 1,771	$ 162
Supplemental schedule of non-cash investing and financing activities		
Operating lease right-of-use assets obtained in exchange for operating lease obligations	$ —	$ 110,980
Purchases of property and equipment included in accounts payable	$ 3,224	$ 4,319
Intangible costs in accounts payable	$ —	$ 515

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's manufacturing, sales and support activities principally focus on the t:slim X2 Insulin Delivery System (t:slim X2), the Company's flagship pump platform which has an advanced algorithm for managing insulin delivery, and is designed to display continuous glucose monitoring (CGM) sensor information directly on the pump home screen. The Company's insulin pump products are compatible with other complementary digital health offerings, such as the mobile application, cloud-based diabetes management applications and the Tandem Device Updater, a Mac- and PC-compatible tool that offers and supports remote updates of the Company's insulin pump software from a personal computer. 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 disposable 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, 2022 (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.

Reclassifications

The change in fair value of common stock warrants for the three and nine months ended September 30, 2022, which was previously reported separately, is now reported as a component of interest income and other, net on the condensed consolidated statements of operations. In addition, certain prior year balances on the condensed consolidated statement of cash flows have been reclassified to conform to the current year presentation.

2. Summary of Significant Accounting Policies

There have been no material changes to the Company's significant accounting policies during the nine months ended September 30, 2023, as compared to those disclosed in the Company's 2022 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.

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 measures the fair value of its convertible senior notes for disclosure purposes. The Company estimated the fair value of its convertible senior notes to be $273.9 million and $260.5 million at September 30, 2023 and December 31, 2022, respectively, based on Level 2 quoted market prices as of those dates.

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 entered into or reassessed after the adoption of ASC 842 *Leases*, the Company combines lease and non-lease components. 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 nine months ended September 30, 2023 and 2022.

Strategic Investments

The Company holds equity investments totaling $10.1 million in two separate private companies, each of which represented less than 5% of the outstanding equity of the respective company as of the date of investment. The investments are carried at cost minus impairment, if any, adjusted for changes in observable prices. The investments were included as a component of other long-term assets on the condensed consolidated balance sheets at September 30, 2023. The Company monitors these investments to evaluate whether a decline in value has occurred based on the implied value of recent company financings, public market prices of comparable companies and general market conditions.

Revenue Recognition

Revenue is generated primarily from sales of insulin pumps, disposable 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 returns.

Revenue Recognition for Arrangements with Multiple Performance Obligations

The Company considers the individual deliverables in its product offering 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 t:connect, Tandem Source and the Tandem Device Updater, 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 it becomes commercially available. Participating customers have the right to purchase the alternative Tandem pump for a fee, referred to as Choice Right. Tandem Choice expires on December 31, 2024. 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.

In the third quarter of 2023, the Company announced a reduction in the price of the Tandem Choice program whereby purchasers of the X2 pump can obtain the Tandem Mobi. The change in the program resulted in an increase to the amount of the transaction price allocated to the material right as the Company expects more customers to exercise the right as compared to the prior existing program price. The amount of revenue deferred in the third quarter of 2023 related to the Choice program was $8.2 million.

For purposes of evaluating Tandem Choice in accordance with ASC 606, the Company has 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. At September 30, 2023 and December 31, 2022, $18.4 million and $6.8 million, respectively, were allocated to the material right provided to customers and recorded in current deferred revenue on the condensed consolidated balance sheets.

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 disposable 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 may be insufficient; therefore, the Company's process relies on long-term historical averages until sufficient data are available. As actual experience becomes available, the Company uses the data to update the historical averages. The Company may make further adjustments to the warranty reserve when deemed appropriate, giving additional consideration to revised future expectations of performance based on enhanced hardware components, or new features and capabilities that may become available through Tandem Device Updater. Warranty expense is recorded as a component of cost of sales in the condensed consolidated statements of operations.

The following table provides a reconciliation of the changes in product warranty liabilities for the three and nine months ended September 30, 2023 and 2022 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Balance at beginning of the period	$ 38,917	$ 31,904	$ 36,537	$ 30,401
Provision for warranties issued during the period	9,601	8,744	26,889	23,224
Settlements made during the period	(8,986)	(6,148)	(24,054)	(17,856)
Increases (decreases) in warranty estimates	(1,775)	110	(1,615)	(1,159)
Balance at end of the period	$ 37,757	$ 34,610	$ 37,757	$ 34,610

As of September 30, 2023 and December 31, 2022, total product warranty reserves were included in the following condensed consolidated balance sheet accounts (in thousands):

	September 30, 2023	December 31, 2022
Other current liabilities	$ 18,370	$ 17,280
Other long-term liabilities	19,387	19,257
Total warranty reserve	$ 37,757	$ 36,537

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 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 plans, potential awards to be granted pursuant to the ESPP, and common stock warrants, each calculated using the treasury stock method; and shares issuable upon conversion of the convertible senior notes calculated using the if-converted method.

For the three and nine months ended September 30, 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. For the three and nine months ended September 30, 2022, the net loss used in the calculation of diluted net loss per share was increased by $12,000 and $103,000, respectively, to remove the gain recognized from the change in fair value of certain common stock warrants based on the dilutive effect of assumed exercise, and the denominator was increased by 937 shares and 959 shares, respectively, calculated under the treasury stock method.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Options to purchase common stock	135	1,080	135	1,250
Unvested restricted stock units	2,930	1,526	2,011	977
Warrants to purchase common stock	194	195	194	195
Awards granted under the ESPP	173	99	80	73
Convertible senior notes (if-converted)	2,554	2,554	2,554	2,554
	5,986	5,454	4,974	5,049

3. Short-Term Investments

The Company invests in marketable securities primarily consisting of debt instruments of the U.S. Government, U.S. Government-sponsored enterprises, and financial institutions and corporations with strong credit ratings. The following represents a summary of the estimated fair value of short-term investments at September 30, 2023 and December 31, 2022 (in thousands):

At September 30, 2023	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Estimated Fair Value
Available-for-sale securities:				
U.S. Government-sponsored enterprises	$ 163,806	$ 2	$ (751)	$ 163,057
U.S. Treasury securities	131,939	2	(196)	131,745
Commercial paper	109,853	—	(102)	109,751
Corporate debt securities	14,006	3	(15)	13,994
Total	$ 419,604	$ 7	$ (1,064)	$ 418,547

At December 31, 2022	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Estimated Fair Value
Available-for-sale securities:				
U.S. Government-sponsored enterprises	$ 100,602	$ 21	$ (615)	$ 100,008
U.S. Treasury securities	213,105	3	(1,947)	211,161
Commercial paper	112,812	6	(208)	112,610
Corporate debt securities	18,218	—	(104)	18,114
Supranational bonds	2,504	—	(13)	2,491
Total	$ 447,241	$ 30	$ (2,887)	$ 444,384

The contractual maturities of available-for-sale debt securities as of September 30, 2023, were as follows (in thousands):

	Years to Maturity		
At September 30, 2023	Within One Year	One to Two Years	Estimated Fair Value
U.S. Government-sponsored enterprises	$ 110,863	$ 52,194	$ 163,057
U.S. Treasury securities	98,898	32,847	131,745
Commercial paper	109,751	—	109,751
Corporate debt securities	7,074	6,920	13,994
Total	$ 326,586	$ 91,961	$ 418,547

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

The Company reviews the portfolio of available-for-sale debt securities quarterly to determine if any investment is impaired due to changes in credit risk or other potential valuation concerns. Unrealized losses on available-for-sale debt securities at September 30, 2023 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 September 30, 2023.

4. Composition of Certain Financial Statement Items

Accounts Receivable

Accounts receivable, net consisted of the following at September 30, 2023 and December 31, 2022 (in thousands):

	September 30, 2023	December 31, 2022
Accounts receivable	$ 105,673	$ 119,044
Less: allowance for credit losses	(5,355)	(4,327)
Accounts receivable, net	$ 100,318	$ 114,717

Allowance for Credit Losses

The following table provides a reconciliation of the changes in the allowance for estimated accounts receivable credit losses for the three and nine months ended September 30, 2023 and 2022 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Balance at beginning of the period	$ 4,842	$ 4,600	$ 4,327	$ 4,249
Provision for expected credit losses	1,308	965	4,066	2,955
Write-offs and adjustments, net of recoveries	(795)	(1,292)	(3,038)	(2,931)
Balance at end of the period	$ 5,355	$ 4,273	$ 5,355	$ 4,273

Inventories

Inventories consisted of the following at September 30, 2023 and December 31, 2022 (in thousands):

	September 30, 2023	December 31, 2022
Raw materials	$ 40,232	$ 39,207
Work-in-process	41,622	18,571
Finished goods	61,638	53,339
Total inventories	$ 143,492	$ 111,117

5. Fair Value Measurements

Authoritative guidance on fair value measurements defines fair value, and provides a consistent framework for measuring fair value and for disclosures of each major asset and liability category measured at fair value on either a recurring or a nonrecurring basis. Fair value is intended to reflect an assumed exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, the authoritative guidance establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

Level 1: Observable inputs such as unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities.

Level 2: Inputs, other than quoted prices in active markets, that are observable either directly or indirectly for substantially the full term of the asset or liability.

Level 3: Unobservable inputs in which there is little or no market data and that are significant to the fair value of the assets or liabilities, which require the reporting entity to develop its own valuation techniques that require input assumptions.

The following table presents information about the Company's financial assets and liabilities measured at fair value on a recurring basis as of September 30, 2023 and December 31, 2022, and indicates the fair value hierarchy of the valuation techniques used by the Company to determine such fair value (in thousands):

	Fair Value Measurements at September 30, 2023			
	Total	Level 1	Level 2	Level 3
Assets				
Cash equivalents[1]	$ 63,810	$ 63,810	$ —	$ —
U.S. Government-sponsored enterprises	163,057	—	163,057	—
U.S. Treasury securities	131,745	131,745	—	—
Commercial paper	109,751	—	109,751	—
Corporate debt securities	13,994	—	13,994	—
Total assets	$ 482,357	$ 195,555	$ 286,802	$ —

	Fair Value Measurements at December 31, 2022			
	Total	Level 1	Level 2	Level 3
Assets				
Cash equivalents[1]	$ 150,742	$ 150,742	$ —	$ —
U.S. Government-sponsored enterprises	100,008	—	100,008	—
U.S. Treasury securities	211,161	211,161	—	—
Commercial paper	112,610	—	112,610	—
Corporate debt securities	18,114	—	18,114	—
Supranational bonds	2,491	—	2,491	—
Total assets	$ 595,126	$ 361,903	$ 233,223	$ —

(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 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.

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. Leases with an initial term of 12 months or less (Short-term Lease) are expensed as incurred and are not recorded as right-of-use leased assets on the Company's condensed consolidated balance sheets. The Company is required to recognize operating lease right-of-use assets and liabilities, and begin recording lease expense when the Company takes possession of the leased property (Commencement Date). The Company recognizes lease expense for these leases on a straight-line basis over the lease term. Because the Company's leases do not provide an implicit interest rate, the Company uses its incremental borrowing rate based on the information available at the lease Commencement Date to determine the operating lease right-of-use assets and liabilities based on the present value of future lease payments over the lease term.

Certain leases include an option to renew, with renewal terms that can extend the lease term for additional periods. The exercise of lease renewal options is at the Company's sole discretion. For renewal options that are reasonably certain at the lease Commencement Date of being exercised, the Company includes the renewal option period in the lease term.

Headquarters Lease

In September 2021, the Company entered into a lease agreement for 181,949 square feet of general administrative, laboratory, and research and development office space (the Premises) located on High Bluff Drive in San Diego, California (Headquarters Lease), formerly referred to as the Tech Center Lease. Possession of the Premises will be tendered to the Company by the landlord in two phases, with Phase I consisting of 143,850 rentable square feet, and Phase II consisting of 38,099 rentable square feet. The Headquarters Lease also includes a first right of offer with respect to an additional 34,569 rentable square feet of general office space should the space become available.

The Phase I Commencement Date occurred in March 2022 when the Company was tendered possession of the Phase I portion of the Premises, and rent payments commenced in September 2022 (Phase I Rent Commencement Date). The Phase II Commencement Date is expected to occur upon the earlier of (i) the date upon which the Company first commences business in the Phase II portion of the Premises, and (ii) May 1, 2025 (Phase II Rent Commencement Date). The Headquarters Lease term expires in April 2035. The Company has two options to extend the term of the lease, with each option providing for an additional period of five years. The Headquarters Lease term was determined assuming the renewal options would not be exercised.

The initial base rent for the Headquarters Lease is approximately $906,000 per month beginning on the Phase I Rent Commencement Date, and the base rent increases by approximately $255,000 per month on the Phase II Rent Commencement Date. The monthly base rent will increase by 3.0% on each annual anniversary of the respective Rent Commencement Date. In addition to the monthly base rent, the Company is required to pay its proportionate share of certain ongoing operating expenses throughout the duration of the lease. No base rent, other than the proportionate share of operating expenses, will be due for the Phase I portion of the Premises for months two through nine following the Phase I Rent Commencement Date, and for the Phase II portion of the Premises for months two through five following the Phase II Rent Commencement Date. The Company recognized operating lease right-of-use assets and corresponding operating lease liabilities of $107.5 million on the condensed consolidated balance sheet on the Phase I Commencement Date in the first quarter of 2022.

In the second quarter of 2023, the Company began using Phase I of the Headquarters Lease for operations that previously occupied 77,458 square feet of leased space located on Roselle Street (Roselle leases) in San Diego, California. The Roselle leases expired in May 2023. Also in the second quarter of 2023, the Company relocated operations that occupied 73,929 square feet of leased space on Vista Sorrento Parkway in San Diego, California (Vista Sorrento Lease) to the new Headquarters Lease location.

Operating Lease Impairment Charge

During the second quarter of 2023, the Company consolidated facilities by moving the administrative functions and other operations from the Vista Sorrento Lease facility to the new Headquarters Lease location. In connection with permanently ceasing use of the Vista Sorrento facility, the Company recorded a $14.1 million impairment charge as the carrying amount of the assets related to the Vista Sorrento Lease exceeded its fair value based on the Company's estimate of future discounted cash flows related to the leased facility. Estimates used to determine the present value of future cash flows over the remaining lease term included projected sublease income and a discount rate. The $14.1 million charge was comprised of an $11.2 million impairment of operating lease right-of-use assets and a $2.9 million write-off of fixed assets consisting primarily of leasehold improvements, and was recorded as a component of selling, general and administrative expenses in the condensed consolidated statements of operations.

Supplemental Lease Disclosure Information

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Operating lease cost	$ 3,528	$ 5,097	$ 12,457	$ 13,286
Short-term lease cost	22	36	87	107
Right-of-use asset impairment charge	—	—	11,224	—
Total lease cost	$ 3,550	$ 5,133	$ 23,768	$ 13,393

Maturities of operating lease liabilities at September 30, 2023 were as follows (in thousands):

Years Ending December 31,	
2023 (remaining)	$ 4,641
2024	17,198
2025	17,023
2026	17,068
2027	17,333
Thereafter	103,844
Total undiscounted lease payments	177,107
Less: amount representing interest	(43,477)
Present value of operating lease liabilities	133,630
Less: current portion of operating lease liabilities	(17,618)
Operating lease liabilities - long-term	$ 116,012

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

	September 30, 2023	December 31, 2022
Weighted-average remaining lease term (in years)	10.4	10.8
Weighted-average discount rate used to determine operating lease liabilities	5.4 %	5.3 %

Cash paid for amounts included in the measurement of lease liabilities, representing operating cash flows from operating leases, was $9.2 million and $9.4 million for the nine months ended September 30, 2023 and 2022, respectively.

Lease For Which Accounting Has Not Yet Commenced

As of September 30, 2023, the Phase II Commencement Date for the Headquarters Lease had not yet occurred. Accordingly, the condensed consolidated balance sheet at September 30, 2023 does not include operating lease right-of-use assets and operating lease liabilities, and the condensed consolidated statements of operations for the three and nine months ended September 30, 2023 and 2022 do not include any lease costs, related to Phase II of the Headquarters Lease. In addition, the above disclosures of the Company's lease costs, maturities of operating lease liabilities, weighted-average remaining lease term, and weighted-average discount rate do not include any amounts related to Phase II of the Headquarters Lease.

The Company currently estimates that Phase II Commencement Date will occur in the first quarter of 2025, at which time the Phase II operating lease right-of-use assets and liabilities will be recorded. Future minimum payments for monthly base rent due under Phase II of the Headquarters Lease, are currently estimated to be $34.7 million in total from 2025 through 2035, subject to the actual Phase II Commencement Date. Because the incremental borrowing rate will not be available until the Phase II Commencement Date, we are not yet able to determine the Phase II operating lease right-of-use assets and liabilities.

7. Debt

Convertible Senior Notes

In May 2020, the Company entered into a purchase agreement with certain counterparties for the sale of an aggregate of $287.5 million principal amount of 1.50% Convertible Senior Notes due 2025 (Notes) in a private offering to qualified institutional buyers pursuant to Rule 144A under the Securities Act of 1933, as amended. 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.

The 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 Notes mature on May 1, 2025 unless repurchased, redeemed, or converted in accordance with their terms before the maturity date.

The 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 Notes, which is equivalent to an initial conversion price of $112.57 (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 Notes.

The Company has the option to redeem for cash all or any portion of the 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 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 Notes to be redeemed, plus accrued and unpaid interest. No sinking fund is provided for the Notes.

Holders of the Notes may convert all or a portion of their 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 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 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 Notes on such trading day;
- if the Company calls any or all of the Notes for redemption, at any time prior to the close of business on the scheduled trading day immediately preceding the redemption date; or
- 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.

Holders of the 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 Notes may require us to repurchase all or a portion of the 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 Notes on the condensed consolidated balance sheets consisted of the following (in thousands):

	September 30, 2023	December 31, 2022
Principal amount	$ 287,500	$ 287,500
Unamortized debt issuance costs	(2,920)	(4,268)
Net carrying amount	$ 284,580	$ 283,232

The Notes will have a dilutive effect to the extent the average market price per share of common stock for a given reporting period exceeds the conversion price of $112.57. As of September 30, 2023 and December 31, 2022, the if-converted value of the Notes did not exceed the principal amount.

As of September 30, 2023, the unamortized debt issuance costs of $2.9 million associated with the Notes will be amortized to interest expense, at an effective interest rate of 2.2% over the remaining period of approximately 1.6 years.

In October 2023, the Company was notified that additional interest beyond the 1.50% per annum has been accruing on the Notes since May 2021, pursuant to the terms of the indenture. This additional interest continues to accrue at a rate of 0.50% per annum on the outstanding principal amount of the Notes, and as of September 30, 2023 amounts to approximately $3.1 million in the aggregate. The overdue unpaid interest itself accrues interest at a rate of 2.50% per annum. The Company has deposited the full amount for these payments with the trustee for the Notes and are coordinating with the trustee for the payments to be completed as soon as reasonably practicable in the fourth quarter of 2023.

The following table details interest expense related to the Notes recognized for the three and nine months ended September 30, 2023 and 2022 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Contractual interest expense[(1)]	$ 4,138	$ 1,078	$ 6,368	$ 3,234
Amortization of debt issuance costs	702	498	1,711	1,395
Total interest expense	$ 4,840	$ 1,576	$ 8,079	$ 4,629

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

Capped Call Transactions

In connection with the issuance of the Notes, the Company entered into Capped Call Transactions in May 2020 with certain counterparties at a net cost of $34.1 million. The Capped Call Transactions are intended to reduce potential dilution to holders of the Company's common stock beyond the conversion price of $112.57, up to a conversion price of $173.18 on any conversion of the Notes, or to offset any cash payments the Company is required to make in excess of the principal amount of such converted Notes, as the case may be, with such reduction or offset subject to a cap. The cap price of the Capped Call Transactions is initially $173.18 per share of the Company's common stock, representing a premium of 100% above the last reported sale price of $86.59 per share of the Company's common stock on May 12, 2020, and is subject to certain adjustments under the terms of the Capped Call Transactions. Conditions that cause adjustments to the initial strike price of the Capped Call Transactions mirror conditions that result in corresponding adjustments for the Notes.

For accounting purposes, the Capped Call Transactions are separate transactions, and not part of the terms of the Notes, while they are integrated for federal tax purposes. As these transactions met certain criteria under the applicable accounting guidance, the Capped Call Transactions were recorded in stockholders' equity and were not accounted for as derivatives. The cost of the Capped Call 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.

Line of Credit

On May 18, 2022, the Company entered into a three-year Revolving Line of Credit Agreement that provided the Company with a maximum principal borrowing amount of $100.0 million (Line of Credit), reduced by any letters of credit issued and outstanding under a $15.0 million letter of credit sub-limit. On August 2, 2023, the Revolving Line of Credit Agreement was amended to reduce the maximum principal borrowing amount to $50.0 million for the remainder of the term, limited to a percentage of eligible accounts receivable during the third quarter of 2023. The Line of Credit allows the Company to request advances thereunder, and to use the proceeds of such advances for general corporate purposes, including working capital and capital expenditures. The Line of Credit matures on the earlier of (i) May 18, 2025 or (ii) the Springing Maturity Date, unless renewed at maturity upon approval by the Company's board of directors and the lender. The Springing Maturity Date is any date during the 91 days before the May 1, 2025 maturity date of the Company's Convertible Senior Notes, that the Company does not satisfy a predefined liquidity threshold. The Line of Credit is secured by a first priority security interest in substantially all of the assets of the Company and its subsidiaries.

During the term of the Line of Credit, the Company is required to maintain compliance with two financial maintenance covenants: a minimum consolidated interest coverage ratio and a maximum consolidated net leverage ratio. The Company was in compliance with the minimum consolidated interest coverage ratio covenant as of September 30, 2023. The maximum consolidated net leverage ratio will not be tested as of September 30, 2023, in accordance with the August 2, 2023 amendment to the Revolving Line of Credit Agreement. Without the amendment, the Company would have been non-compliant with the maximum consolidated net leverage ratio covenant for the trailing twelve month measurement period ended September 30, 2023. The Company is currently not entitled to borrow any amounts under the Line of Credit as a result of its inadvertent failure to timely pay additional interest under the Notes.

Advances drawn under the Line of Credit bear interest at an annual rate of (1) the SOFR Rate (as defined in the Line of Credit); plus (2) an applicable credit spread adjustment ranging from 0.10% to 0.25%; plus (3) an applicable margin ranging from 1.25% to 2.00%, and each advance will be payable on the Maturity Date with the interest on outstanding advances payable quarterly. The Credit Agreement also includes a commitment fee ranging from 0.20% to 0.35% per annum on the average daily unused amount of the Line of Credit, payable quarterly. The Company may, at its option, prepay any borrowings under the Line of Credit, in whole or in part at any time before the maturity date, without premium or penalty. As of September 30, 2023, the Company had no outstanding borrowings under the Line of Credit, and a $4.9 million outstanding standby letter of credit.

8. Stockholders' Equity

Shares Reserved for Future Issuance

The following shares of the Company's common stock were reserved for future issuance at September 30, 2023 (in thousands):

Shares reserved for issuance upon conversion of Convertible Senior Notes	2,554
Shares underlying outstanding warrants	194
Shares underlying outstanding stock options	4,085
Shares underlying unvested restricted stock units	3,049
Shares authorized for issuance pursuant to awards granted under the ESPP	704
Shares authorized for future equity award grants	1,031
Total	11,617

Common Stock Warrants

Warrants outstanding to purchase shares of the Company's common stock as of September 30, 2023 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 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.

The Company’s Employee Stock Purchase Plan (ESPP) was approved by the Board in October 2013. The ESPP enables eligible employees to purchase shares of the Company’s common stock using their after-tax payroll deductions, subject to certain conditions. The purchase price of common stock under the ESPP is the lesser of: (a) 85% of the fair market value of a share of the Company’s common stock on the first date of an offering or (b) 85% of the fair market value of a share of the Company’s common stock on the date of purchase. Generally, offerings under the ESPP consist of a two-year offering period with four six-month purchase periods which begin in May and November of each year.

Stock-Based Compensation

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. RSUs granted before March 2022 generally vest over a four-year period based on continued service to the Company as to 25% of the underlying shares on the first anniversary of the award, with the balance of the RSUs vesting quarterly over the following three years. RSUs granted in March 2022 and thereafter vest over a three-year period based on continued service to the Company as to 33% of the underlying shares on the first anniversary of the award, with the balance of the RSUs vesting quarterly over the following two years. In addition, the Company granted 110,074 performance-based RSUs during the nine months ended September 30, 2023, and 53,662 performance-based RSUs during the nine months ended September 30, 2022. The performance-based RSUs have a grant value equal to the closing price of the Company’s common stock on the award date, and vest upon the Company’s actual performance relative to predefined performance metrics and subject to the awardee’s continuing service through the respective December 31, 2024 and 2025 measurement dates.

The total number of RSUs granted, which includes performance-based RSUs, and the respective weighted average grant date fair value were as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
RSUs granted	208,082	330,807	1,997,907	1,338,056
Weighted average grant date fair value (per share)	$ 29.19	$ 56.49	$ 28.94	$ 70.33

Stock Options

Stock options have an exercise price equal to the closing price of the Company's common stock on the applicable grant date, and have a maximum term of ten years. Stock options granted before the second quarter of 2022 generally vest over a four-year period as to 25% of the underlying shares on the first anniversary of the grant date, with the balance of the options vesting monthly over the following three years. Stock options granted during the second quarter of 2022 and thereafter vest over a three-year period as to 33% of the underlying shares on the first anniversary of the grant date, with the balance of the options vesting monthly over the following two years. There have been no common stock options granted since the second quarter of 2022. Common stock options granted during the nine months ended September 30, 2022, along with the assumptions used in the Black-Scholes option pricing model were as follows:

	Nine Months Ended September 30, 2022
Stock options granted	83,008
Weighted average grant date fair value (per share)	$ 42.16
Risk-free interest rate	2.7 %
Dividend yield	0.00 %
Expected volatility	72.0 %
Expected term (in years)	5.8

Employee Stock Purchase Plan

The Company records stock-based compensation expense associated with the ESPP using the Black-Scholes option pricing model. Valuations are performed on the grant date at the beginning of the purchase period, which generally occurs in May and November of each year. The assumptions used in the Black-Scholes option pricing model for the ESPP were as follows:

	Nine Months Ended September 30,	
	2023	2022
Weighted average grant date fair value (per share)	$ 12.52	$ 26.57
Risk-free interest rate	4.7 %	2.2 %
Dividend yield	0.0 %	0.0 %
Expected volatility	60.9 %	47.1 %
Expected term (in years)	1.3	1.3

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Cost of sales	$ 1,812	$ 1,920	$ 5,154	$ 5,666
Selling, general and administrative	12,466	15,125	41,448	40,711
Research and development	6,463	5,191	18,732	14,100
Total stock-based compensation expense	$ 20,741	$ 22,236	$ 65,334	$ 60,477

The total stock-based compensation expense capitalized as part of the cost of the Company’s inventories was $1.3 million at September 30, 2023, and $1.1 million at December 31, 2022.

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 rehire or entry date. Under the terms of the plan, employees may make voluntary contributions as a percent of compensation, and, starting in 2022, the Company matches a discretionary percentage of employee contributions.

10. Income Taxes

For the three and nine months ended September 30, 2023, the Company recognized income tax expense of $2.2 million and $3.7 million, respectively, on a pre-tax loss of $30.7 million and $188.9 million, respectively. For the three and nine months ended September 30, 2022, the Company recognized income tax expense of $1.6 million and $2.0 million, respectively, on a pre-tax loss of $47.3 million and $76.7 million, respectively. Income tax expense for the three and nine months ended September 30, 2023 and 2022, was primarily attributable to federal, state and foreign income tax expense as a result of current taxable income in certain jurisdictions.

For the three and nine months ended September 30, 2023, the Company calculated the provision for income taxes 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. For the three and nine months ended September 30, 2022, the Company calculated the provision for income taxes 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 September 30, 2023, 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, disposable 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 and by major sales channel as management believes these categories best depict how the nature, amount and timing of revenues and cash flows are affected by economic factors.

Revenues by Geographic Region and Customer Sales Channel

During the three and nine months ended September 30, 2023 and 2022, no individual country outside the United States generated revenue that represented more than 10% of total revenue. The table below sets forth revenues for the Company's two primary geographical markets, based on the geographic location to which its products are shipped (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
United States	$ 130,222	$ 146,035	$ 403,964	$ 422,985
Outside the United States	55,400	58,512	146,958	157,731
Total Sales	$ 185,622	$ 204,547	$ 550,922	$ 580,716

Sales to distributors accounted for 64% and 66% of the Company's United States sales for the three months ended September 30, 2023 and 2022, respectively, and 64% and 65% of the Company's United States sales for the nine-month periods ended September 30, 2023 and 2022, respectively. Sales to distributors accounted for 95% and 96% of the Company's sales outside the United States for the three and nine-month periods ended September 30, 2023 and 2022, respectively.

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 next two years, and a payment of up to CHF 91.2 million upon obtaining regulatory clearance from the United States Food and Drug Administration of an automated controller enabled (ACE) pump. The contingent consideration will be recognized as each contingency is resolved and the respective consideration is paid or becomes payable. As of September 30, 2023, 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 condensed consolidated balance sheet at September 30, 2023. The Company funded the initial closing payment using existing cash balances. As of December 31, 2022, the previous strategic investment was included as a component of other long-term assets on the condensed consolidated balance sheet.

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 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 for the three and nine months ended September 30, 2023 included the operating results of AMF Medical since the date of acquisition.

Capillary Biomedical Acquisition

On July 21, 2022, the Company acquired Capillary Biomedical, Inc. (Capillary Biomedical), an infusion set developer, for total cash consideration of $24.7 million, and the assumption of $4.7 million of long-term debt. The debt becomes due and payable upon the first sale or license of the commercialized product, and is included as a component of other long-term liabilities on the condensed consolidated balance sheets at September 30, 2023 and December 31, 2022. Capillary Biomedical's extended-wear infusion set technology is currently in development and is not yet commercially available. The Company funded the purchase price 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 $31.0 million charge 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 for the three and nine months ended September 30, 2023 included the operating results of Capillary Biomedical.

13. Commitments and Contingencies

Legal and Regulatory Matters

In May 2020, the Company was named as a defendant in three California state court class action lawsuits arising from a phishing incident that occurred in January 2020. Collectively, these lawsuits sought statutory, compensatory, actual, and punitive damages; equitable relief, including restitution; pre- and post-judgment interest; injunctive relief; and attorney fees, costs, and expenses from us. On July 24, 2020, these three lawsuits were consolidated into a single case in the Superior Court of the State of California in the County of San Bernardino entitled Joseph Deluna et al. v. Tandem Diabetes Care, Inc. The consolidated case alleged violations of the Confidentiality of Medical Information Act (CMIA), CCPA, California's Unfair Competition Law (UCL), and breach of contract. The Company filed a demurrer on all claims, which was heard by the Court on October 20, 2020, and the demurrer to the CCPA claim was sustained. The plaintiffs filed a motion for class certification on January 7, 2022 and we filed a motion for summary adjudication on the CMIA claim on April 7, 2022. On February 8, 2023, the Court granted plaintiffs' request to dismiss their remaining two claims with prejudice, and dismissed the motion for class certification, thereby terminating the case in 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.

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) in the United States District Court for the Southern District of California against the Company and certain of the Company's current executive officers. The complaint generally alleges that defendants violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended, by failing to properly account for and disclose the full impact that COVID-19, inflation, and the sales of competitors' products were having on the Company's sales and revenue. The complaint seeks unspecified monetary damages and other relief. Although the Company intends to vigorously defend against this claim, there is no guarantee that the Company will prevail. Accordingly, the Company is unable to determine the ultimate outcome of this lawsuit or determine the amount or range of potential losses associated with the lawsuit.

From time to time, the Company is involved in various other legal proceedings, regulatory matters, and other disputes or claims arising from or related to claims incident to the normal course of the Company's business activities, including actions with respect to intellectual property, data privacy, employment, regulatory, product liability and contractual matters. Although the results of such legal proceedings and claims cannot be predicted with certainty, as of September 30, 2023 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

In connection with one of the Company's operating leases (see Note 6, "Leases"), the Company has a $4.9 million unsecured irrevocable standby letter of credit arrangement with a bank (see Note 7, "Debt"), under which the landlord of the building is the beneficiary. The Company is required to maintain the standby letter of credit throughout the term of the lease, which expires in April 2035.

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

You should read the following discussion and analysis together with our financial statements and related notes in Part I, Item 1 of this Quarterly Report on Form 10-Q for the quarter ended September 30, 2023 (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, 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 in the section entitled "Risk Factors" in Part I, Item 1A, of our Annual Report on Form 10-K for the year ended December 31, 2022 (Annual Report), in the section entitled "Risk Factors" in Part II, Item 1A, of our Quarterly Report on Form 10-Q for the quarter ended June 30, 2023, and 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 lead in insulin therapy management across multiple of these market segments by providing a robust ecosystem and a portfolio of delivery devices, software, and data insight solutions to people living with diabetes, as well as their caregivers and healthcare providers.

Since our initial commercial launch, we have rapidly innovated and brought more products to market than our competitors. Today, the t:slim X2 Insulin Delivery System is our flagship technology solution. In the four-year period ended September 30, 2023, we shipped approximately 444,000 t:slim X2 insulin pumps, which is representative of our in-warranty global installed customer base assuming the typical four-year reimbursement cycle. Approximately 308,000 of these pumps were shipped to customers in the United States and approximately 136,000 were shipped to customers outside the United States. Our products are currently available in approximately 25 countries outside the United States. The vast majority of our customers worldwide are people living with type 1 diabetes.

In addition, in July 2023, the FDA provided clearance for the Tandem Mobi insulin pump, which 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. A limited release of Tandem Mobi in the United States began in the fourth quarter of 2023 with full commercial availability expected to begin in early 2024.

Our manufacturing, sales and support activities are scaling in anticipation of offering people living with diabetes a choice between the t:slim X2 and Tandem Mobi insulin pumps based on their individual needs and preferences.

The majority of our customers use their t:slim X2 with continuous glucose monitoring (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 have demonstrated that use of Control-IQ technology provides people across all demographics with improved clinical outcomes that are both immediate and sustained. It was the first system cleared by the U.S. Food and Drug Administration (FDA) to deliver automatic correction boluses in addition to adjusting insulin to help prevent high and low blood sugar.

The t:slim X2 was the first pump on which remote software updates were made commercially available in the United States and Tandem Mobi will offer the same capability. Now available for t:slim X2 in the countries we serve worldwide, our Tandem Device Updater (TDU) has allowed hundreds of thousands of people to update their pump software from a personal computer. 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. In the third quarter of 2022, we launched a new pump software update through TDU to allow all t:slim X2 pump users in the United States to bolus insulin using our smartphone app that is available on compatible iOS and Android devices.

Our insulin pump products are generally considered durable medical equipment and have an expected lifespan of at least four years. In addition to insulin pumps, we sell disposable 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.

In the United States, we also offer a data management web application that provides users, their caregivers and their healthcare providers with a fast, easy and visual way to display diabetes therapy management data from our pumps, integrated CGMs and supported blood glucose meters. Our first-generation data management application, t:connect, was commercially introduced in the United States in 2013. In the second quarter of 2023, we began a scaled global launch of our second-generation data management application, Tandem Source.

Products Under Development

Our products under development support our strategy of developing insulin delivery systems as part of a therapy management portfolio that is designed to improve patient experience and outcomes. Our product development efforts fall into three pillars of innovation: delivery devices, device software including algorithms, and data and insights.

Delivery Devices

We are developing a family of delivery device solutions to meet the varying needs of people living with type 1 and type 2 diabetes by providing choice within our portfolio. Preferences in the size, shape, and mode of operation that comprise an insulin pump's hardware often impact a person's pump purchasing decision and overall user experience.

t:slim X3

Advancing our flagship t:slim platform, the t:slim X3 is being designed to provide a modernized user interface and even greater usability for our planned feature updates. It is also being designed to include enhanced technology, such as greater processing power and capacity to support our advanced algorithms, as well as increased battery life, improved durability, and wireless software update capabilities.

Mobi: Tubeless

This offering is being developed 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. 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

This ergonomic, rechargeable Sigi Patch Pump is being designed 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. Our goals for infusion set innovations focus on solutions that extend wear time and enhance user experience, while reducing occlusions, body burden and waste. In support of this effort, we are currently developing a unique extended wear infusion set technology.

Device Software

Our device software is used to control our pumps either directly through the pump's interface or through our mobile application. It also includes our AID technology and the software used to support remote pump updatability.

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. We recently began a pivotal study to support expanding indications to include people living with type 2 diabetes. We are also researching the use of different insulins with our Control-IQ technology.

Integration

Building a robust ecosystem and portfolio around our flagship insulin pumps requires product development efforts to integrate, add, and enhance complementary system components.

Dexcom CGM: We have agreements with Dexcom, Inc. (Dexcom) to extend our current collaboration to include integration with their G7 CGM technology. This will be the fourth generation of Dexcom CGM that we integrate with our devices. Integration of the t:slim X2 with Dexcom's G7 is in the release process, which we plan to scale for full availability in the United States, followed by a rolling launch in international markets.

Abbott CGM: We have an agreement with Abbott Laboratories (Abbott) to develop and commercialize integrated diabetes solutions that combine Abbott's FreeStyle Libre CGM technology with our insulin delivery systems. This will be the first-generation of the Abbott Freestyle Libre CGM integrated with our t:slim X2. We intend to launch in the United States, and expand to additional geographies after obtaining regulatory clearances or approvals, where required.

Data and Insights

Our goal is to innovate across our digital health platforms by using the vast amount of data that we collect, in combination with technology such as artificial intelligence or machine learning, to provide information and insights to people living with diabetes, their caregivers and healthcare providers and insurance payors. Our key objectives include making these insights easy to understand, making the data available in real time, and providing the information in a flexible format through mobile or web apps. In addition, we are working to integrate health-related information from third-party sources and to use our data to support current and future products under development.

Settings Automation

Our automation research and development activities center around opportunities for enhanced user and healthcare provider experience and improved clinical outcomes. In support of this effort, we are working to automate our pump settings adjustments to further enhance ease of use and expand adoption of our insulin pump products.

Pump Shipments

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 our t:slim X2 insulin pump in select geographies outside the United States and our technology solutions are now available in approximately 25 countries worldwide. We consider the number of insulin pump units shipped to be an important metric for managing our business.

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. In the four-year period ended September 30, 2023, we shipped approximately 444,000 insulin pumps worldwide, which is representative of our global in-warranty installed customer base. Our ending estimated worldwide installed base increased approximately 11% year over year.

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 typically take 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.

Approximately 308,000 pumps were shipped to customers in the United States in the four-year period ended September 30, 2023, which is representative of our U.S. installed customer base. Pump shipments to customers in the United States by fiscal quarter for the current year and each of the previous five years, which aligns more closely with our typical renewal cycle, were as follows:

	United States Pump Unit Shipments for Each of the Three Months Ended in Respective Years				
	March 31	**June 30**	**September 30**	**December 31**	**Total**
2018	4,444	5,447	7,379	12,935	30,205
2019	9,669	12,799	13,814	17,453	53,735
2020	13,158	14,735	18,380	24,552	70,825
2021	16,644	20,665	20,296	25,712	83,317
2022	18,658	20,818	20,394	23,684	83,554
2023	17,003	18,964	16,842	N/A	52,809

Since beginning sales outside the United States in the third quarter of 2018, we shipped approximately 136,000 pumps and our products are now available in approximately 25 countries. 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 U.S. market. We recently began completing a full four-year reimbursement cycle in an increasing number of our markets outside of the United States. Pump shipments to customers outside the United States by fiscal quarter for the current year and each of the previous five years, were as follows:

	Outside the United States Pump Unit Shipments for Each of the Three Months Ended in Respective Years				
	March 31	June 30	September 30	December 31	Total
2018	N/A	N/A	1,055	3,233	4,288
2019	5,063	8,459	4,025	2,149	19,696
2020	4,220	3,952	3,641	8,133	19,946
2021	8,708	13,152	11,262	11,873	44,995
2022	9,437	11,296	12,113	11,939	44,785
2023	6,052	10,530	7,989	N/A	24,571

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 recently announced FDA clearance of Tandem Mobi and its anticipated launch has impacted and may impact the future timing of purchasing decisions by our current and prospective customers as the full commercial launch date approaches, resulting in delays that are 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.

- 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.

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 is highly variable from period to period. We commenced operations of a European distribution center beginning in the third quarter of 2022, which led to downward adjustments of inventory levels at our distributors in late 2022 and in the 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, as well as the anticipated launch of new products.

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 have continued to disrupt our relationships with suppliers, third-party manufacturers, healthcare providers, distributors and our existing or potential customers. We are experiencing higher costs as we navigate these global macroeconomic challenges.

Components of Results of Operations

Sales

We offer products for people with insulin-dependent diabetes in approximately 25 countries. The t:slim X2 insulin pump is our flagship pump platform. Our other products include disposable insulin cartridges and infusion sets, as well as our complementary t:connect, TDU and mobile application products. 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—Product Launches and Reimbursement," above.

In September 2022, we began offering 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. Tandem Choice expires on December 31, 2024. The accounting treatment for Tandem Choice is complex (see Note 2, "Summary of Significant Accounting Policies"). Initially, the program requires the deferral of some portion of sales for shipments of eligible pumps, which began in the third quarter of 2022. No election is made by the customer at the time of the initial sale, nor does the right offered to the customer impact the economics associated with how or when the initial pump sale is reimbursed. If a customer elects to participate in Tandem Choice at a future date beginning with the launch of our next generation hardware platform, Tandem Mobi, we will recognize the existing deferral, incremental fees received and the associated costs of providing the new hardware, Tandem Mobi, at the time of fulfillment. Any remaining deferrals will be recognized at program expiration. At this time, we are not able to estimate the financial impact for the duration of Tandem Choice.

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. 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. We have approximately 110 sales territories in the United States, which 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 trial costs, payments under our licensing, development and commercialization agreements and other indirect costs.

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

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 1.50% Convertible Senior Notes due May 2025 (Notes) and our line of credit facility.

On or about October 24, 2023, we were notified that additional interest beyond the 1.50% per annum has been accruing on the Notes since May 2021, pursuant to the terms of the indenture. This additional interest continues to accrue at a rate of 0.50% per annum on the outstanding principal amount of the Notes, and as of November 1, 2023 amounts to approximately $3.2 million in the aggregate. The overdue unpaid interest itself accrues interest at a rate of 2.50% per annum. We are coordinating with the trustee for the Notes to pay all overdue amounts as soon as reasonably practicable in the fourth quarter of 2023. See “Risk Factors—An event of default has occurred under the indenture governing our 1.50% Convertible Senior Notes due 2025.”

Income Tax Expense (Benefit)

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

Results of Operations

(in thousands, except percentages)	Three Months Ended September 30, 2023	Three Months Ended September 30, 2022	Nine Months Ended September 30, 2023	Nine Months Ended September 30, 2022
Sales:				
United States	$ 130,222	$ 146,035	$ 403,964	$ 422,985
Outside the United States	55,400	58,512	146,958	157,731
Total sales	185,622	204,547	550,922	580,716
Cost of sales	95,869	100,122	276,527	283,252
Gross profit	89,753	104,425	274,395	297,464
Gross margin	48 %	51 %	50 %	51 %
Operating expenses:				
Selling, general and administrative	79,328	84,104	266,752	237,989
Research and development	41,970	36,798	127,063	103,529
Acquired in-process research and development	—	31,016	78,750	31,016
Total operating expenses	121,298	151,918	472,565	372,534
Operating loss	(31,545)	(47,493)	(198,170)	(75,070)
Other income (expense), net:				
Interest income and other, net	5,656	1,720	17,305	2,961
Interest expense	(4,840)	(1,576)	(8,079)	(4,629)
Total other income (expense), net	816	144	9,226	(1,668)
Loss before income taxes	(30,729)	(47,349)	(188,944)	(76,738)
Income tax expense	2,232	1,621	3,665	2,003
Net loss	$ (32,961)	$ (48,970)	$ (192,609)	$ (78,741)

Comparison of the Three Months Ended September 30, 2023 and 2022

Sales

For the three months ended September 30, 2023, sales were $185.6 million, which included $55.4 million of sales outside the United States. For the three months ended September 30, 2023, we deferred $8.2 million of pump sales as the result of Tandem Choice, which launched in the United States in September of 2022. Sales were $204.5 million for the same period in 2022, which included $58.5 million of sales outside the United States.

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

	Three Months Ended September 30, 2023	Three Months Ended September 30, 2022	% Change
Pump	$ 66,365	$ 81,295	(18)%
Supplies and other	72,093	65,339	10%
Deferral for Tandem Choice program	(8,236)	(599)	(1,275)%
Total Sales in the United States	$ 130,222	$ 146,035	(11)%

Pump sales in the United States were $66.4 million for the third quarter of 2023, compared to $81.3 million in the third quarter of 2022 as pump shipments decreased 17% compared to the same period in 2022. We continued to face challenging marketplace dynamics and economic conditions similar to recent quarters, with inflation and the threat of recession impacting pump purchasing decisions. Additionally, we believe the anticipation for the full release of the Dexcom G7 sensor integration with t:slim X2 and the recent FDA clearance of Tandem Mobi have begun to impact the timing of purchasing decisions for those who prefer those offerings, resulting in some customers delaying current purchases until full commercial availability of each product in future periods. Sales of pump-related supplies increased 10% primarily due to a 10% year-over-year increase in our ending estimated installed base of customers in the United States. Sales to distributors accounted for 64% and 66% of our total sales in the United States for the three months ended September 30, 2023 and 2022, respectively. Sales in the United States for the three months ended September 30, 2023 and 2022 were reduced by a deferral of $8.2 million and $0.6 million, respectively, as the result of our Tandem Choice program which launched in September of 2022. The increase in the revenue deferral for Tandem Choice in 2023 as compared to 2022, was primarily a result of a reduction in the Tandem Choice program price which became effective in the third quarter of 2023, resulting in an increase to our estimate of the future customer participation rate and, therefore, a higher deferral per pump sold, coupled with the Tandem Choice program being in effect for the entire third quarter of 2023.

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

	Three Months Ended September 30,		
	2023	2022	% Change
Pump	$ 21,672	$ 27,385	(21)%
Supplies and other	33,728	31,127	8%
Total Sales Outside the United States	$ 55,400	$ 58,512	(5)%

Pump sales outside the United States were $21.7 million for the third quarter of 2023, compared to $27.4 million in the third quarter of 2022. Pump shipments decreased 34% compared to the same period in the prior year. The decrease in pump sales was offset by an increase in average selling prices due primarily to geographical mix. Sales of pump-related supplies increased 8% primarily due to a 13% year-over-year increase in our ending estimated installed base of customers outside the United States. The year-over-year changes in pump and supply shipments were not necessarily indicative of actual customer demand, as they were heavily influenced by variability in historical ordering patterns of our distributors prior to commencement of operations at our centralized European distribution center in late 2022. Sales to distributors accounted for 95% and 96% of our total sales outside the United States for the three-month periods ended September 30, 2023 and 2022, respectively.

Cost of Sales and Gross Profit

Our cost of sales for the three months ended September 30, 2023 was $95.9 million, resulting in gross profit of $89.8 million, compared to cost of sales of $100.1 million and gross profit of $104.4 million for the same period in 2022. The gross margin for the three months ended September 30, 2023 and 2022 was 48% and 51%, respectively.

Gross profit for the three months ended September 30, 2023 was reduced by $8.2 million from the impact of Tandem Choice, resulting in a gross margin reduction of more than two percentage points. The impact on gross margin from our Tandem Choice program will fluctuate through the expiration of the program based on the timing of availability of a new hardware platform, Tandem Mobi, and the number of eligible customers who ultimately elect to participate.

Excluding the impact of Tandem Choice, gross margin was consistent with the prior year. Gross margin benefited from progress in underlying fundamentals, including an increase in average selling prices and manufacturing efficiencies, as well as leverage of fixed overhead. Gross margin further benefited from reduction in the impact of certain high-cost raw materials acquired in the prior year. More specifically, the higher cost of raw materials acquired in the prior year stemmed from supply chain challenges during the COVID-19 global pandemic, where certain pump materials were sourced from alternative suppliers to reduce the risk of component shortages. The impact in the quarter of these high-cost raw materials was reduced to less than one percent of sales. These benefits were offset by the impact of product and geographical mix. Pump sales, which have the highest gross margin, were 43% of total worldwide sales, excluding the impact of Tandem Choice, in the third quarter of 2023, compared to 53% in the third quarter of 2022.

Operating Expenses

Our operating expenses for the three months ended September 30, 2023 were $121.3 million, compared to $151.9 million for the three months ended September 30, 2022. The $30.6 million decrease was primarily driven by $31.0 million of acquired in-process research and development expenses incurred in 2022 in connection with our acquisition of Capillary Biomedical (see Note 12, “Acquisitions”).

Selling, General and Administrative Expenses. SG&A expenses decreased 6% to $79.3 million for the three months ended September 30, 2023, from $84.1 million for the same period in 2022. The decrease of $4.8 million was largely driven by lower employee-related expenses of $2.3 million, as well as reduced costs pertaining to certain facilities expense savings from our facilities consolidation initiatives.

Research and Development Expenses. R&D expenses increased 14% to $42.0 million for the three months ended September 30, 2023, from $36.8 million for the same period in 2022. The increase in R&D expenses was primarily the result of a $3.2 million increase in salaries and related benefits due to our acquisitions and an increase in personnel to support our product development efforts. We also experienced a $2.0 million increase in other non-employee discretionary spending, including supplies, outside services and equipment costs.

Acquired In-Process Research and Development Expenses. Acquired IPR&D expenses of $31.0 million for the three months ended September 30, 2022 represented the value of assets acquired, and acquisition related expenses, in connection with our acquisition of Capillary Biomedical.

Other Income (Expense), Net

Total other income (expense), net for the three months ended September 30, 2023 was $0.8 million income, compared to $0.1 million expense in the same period in 2022. Other income, net for the three months ended September 30, 2023 primarily consisted of $5.9 million of interest income earned on our cash equivalents and short-term investments, partially offset by $4.8 million of interest expense which included $3.1 million of additional interest as discussed above and the amortization of debt issuance costs related to our Convertible Senior Notes. Other expense, net for the three months ended September 30, 2022 primarily consisted of $1.7 million of interest income earned on our cash equivalents and short-term investments, partially offset by $1.6 million of interest expense which included the amortization of debt issuance costs related to our Notes.

Income Tax Expense

We recognized income tax expense of $2.2 million on a pre-tax loss of $30.7 million for the three months ended September 30, 2023, compared to income tax expense of $1.6 million on a pre-tax loss of $47.3 million for the three months ended September 30, 2022. Income tax expense for the three months ended September 30, 2023 and 2022 was primarily attributable to federal, state and foreign income tax expense as a result of current taxable income in certain jurisdictions.

Comparison of the Nine Months Ended September 30, 2023 and 2022

Sales

For the nine months ended September 30, 2023, sales were $550.9 million, which included $147.0 million of sales outside the United States. For the nine months ended September 30, 2023, we deferred $12.6 million of pump sales as a result of Tandem Choice, which launched in the United States in September of 2022. For the nine months ended September 30, 2022, sales were $580.7 million, which included $157.7 million of sales outside the United States.

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

	Nine Months Ended September 30,		
	2023	2022	% Change
Pump	$ 207,180	$ 236,448	(12)%
Supplies and other	209,352	187,136	12%
Deferral for Tandem Choice program	(12,568)	(599)	(1,998)%
Total Sales in the United States	$ 403,964	$ 422,985	(4)%

Pump sales in the United States were $207.2 million for the first nine months of 2023, compared to $236.4 million in the first nine months of 2022, as pump shipments decreased 12% compared to the same period in the prior year. We continued to face challenging marketplace dynamics and economic conditions, with inflation and the threat of recession impacting pump purchasing decisions. Additionally, we believe the anticipation for the full release of the Dexcom G7 sensor integration with t:slim X2 and the FDA clearance of Tandem Mobi in the third quarter of 2023 have begun to impact the timing of purchasing decisions for those who prefer those offerings, resulting in some customers delaying current purchases until full commercial availability of those products in future periods. Sales of pump-related supplies increased primarily due to a 10% year-over-year increase in our ending estimated installed base of customers in the United States. Sales to distributors accounted for 64% and 65% of our total sales in the United States for the nine months ended September 30, 2023 and 2022, respectively. Sales in the United States for the nine months ended September 30, 2023 and 2022 were reduced by a deferral of $12.6 million and $0.6 million, respectively, as the result of our Tandem Choice program which launched in September of 2022. The increase in the revenue deferral for Tandem Choice in 2023 as compared to 2022, was primarily a result of a reduction in the Tandem Choice program price which became effective in the third quarter of 2023, resulting in an increase to our estimate of the future customer participation rate and, therefore, a higher deferral per pump sold, coupled with the Tandem Choice program being in effect for the full nine months of 2023.

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

	Nine Months Ended September 30,		
	2023	2022	% Change
Pump	$ 67,235	$ 75,515	(11)%
Supplies and other	79,723	82,216	(3)%
Total Sales Outside the United States	$ 146,958	$ 157,731	(7)%

Pump sales outside the United States were $67.2 million for the first nine months of 2023, compared to $75.5 million in the first nine months of 2022. We commenced operations of a centralized European distribution center in late 2022, which resulted in a material disruption to distributor ordering patterns in the first half of 2023 as affected distributors reduced their pump and supply inventory levels to adjust for the reduced transit time. As a result, pump shipments decreased 25% compared to the same period in the prior year and supply orders declined as well. The decrease in pump sales was offset by an increase in average selling prices due primarily to geographical mix. The year-over-year changes in pump and supply shipments were not necessarily indicative of actual customer demand, as they were heavily influenced by variability in historical ordering patterns of our distributors prior to commencement of operations at our centralized European distribution center in late 2022. Sales to distributors accounted for 94% of our total sales outside the United States for the nine-month period ended September 30, 2023, and 96% for the same period in 2022.

Cost of Sales and Gross Profit

Our cost of sales for the nine months ended September 30, 2023 was $276.5 million resulting in gross profit of $274.4 million, compared to cost of sales of $283.3 million and gross profit of $297.5 million for the same period in 2022. The gross margin for the nine months ended September 30, 2023 was 50% compared to 51% in the same period in 2022.

Gross profit for the nine months ended September 30, 2023 was reduced by $12.6 million from the impact of Tandem Choice, resulting in a gross margin reduction of approximately one percentage point, as well as the decrease in sales in the first half of 2023 associated with the European distribution center transition. The impact on gross margin from our Tandem Choice program will fluctuate through the expiration of the program based on the timing of availability of Tandem Mobi and the number of eligible customers who ultimately elect to participate.

Excluding the impact of Tandem Choice, gross margin for the nine months ended September 30, 2023 was consistent with the same period in 2022. Gross margin benefited from progress in underlying fundamentals, including an increase in average selling prices and manufacturing efficiencies, as well as leverage of fixed overhead. Gross margin further benefited from the lower impact of certain high-cost raw materials acquired during the pandemic. These benefits were offset by the impact of product mix and geographical mix.

Operating Expenses

Our operating expenses for the nine months ended September 30, 2023 were $472.6 million, compared to $372.5 million for the nine months ended September 30, 2022. A significant portion of the increase was driven by certain unique or non-recurring transactions. In 2023, we incurred $78.8 million of acquired in-process research and development expenses in connection with our recent acquisition of AMF Medical, compared to $31.0 million of acquired IPR&D expenses in connection with our acquisition of Capillary Biomedical in 2022 (see Note 12, "Acquisitions"). As a part of continued operating efficiency measures, 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. Additionally, incremental personnel and discretionary spending attributable to our recent acquisitions in both SG&A and R&D was $15.2 million.

Selling, General and Administrative Expenses. SG&A expenses increased 12% to $266.8 million for the nine months ended September 30, 2023, from $238.0 million for the same period in 2022. Excluding the impact of the $14.1 million lease impairment charge and $2.1 million in severance costs, the increase of $12.6 million was largely driven by $9.8 million in employee-related expenses. This was primarily the result of higher salaries and related benefits to provide continued support services for our growing installed customer base.

Research and Development Expenses. R&D expenses increased 23% to $127.1 million for the nine months ended September 30, 2023, from $103.5 million for the same period in 2022. The increase in R&D expenses was primarily the result of a $17.4 million increase in salaries and related benefits from our acquisitions and an increase in personnel to support our product development efforts. We also experienced a $6.2 million increase in other non-employee discretionary spending, including equipment, supplies and clinical trials costs.

Acquired In-Process Research and Development Expenses. Acquired IPR&D expenses of $78.8 million for the nine months ended September 30, 2023 represented the value of assets acquired, and acquisition related expenses, in connection with our acquisition of AMF Medical. Acquired IPR&D expenses of $31.0 million for the nine months ended September 30, 2022 represented the value of IPR&D assets acquired, and acquisition related expenses, in connection with our acquisition of Capillary Biomedical.

Other Income (Expense), Net

Total other income (expense), net for the nine months ended September 30, 2023 was $9.2 million income, compared to $1.7 million expense in the same period in 2022. Other income, net for the nine months ended September 30, 2023 primarily consisted of $15.2 million of interest income earned on our cash equivalents and short-term investments, and $2.0 million in foreign currency transaction gains, partially offset by $8.1 million of interest expense which included $3.1 million of additional interest as discussed above and the amortization of debt issuance costs related to our Notes. Other expense, net for the nine months ended September 30, 2022 primarily consisted of $4.6 million of interest expense which included the amortization of debt issuance costs related to our Notes, partially offset by $2.9 million of interest income earned on our cash equivalents and short-term investments.

Income Tax Expense

We recognized income tax expense of $3.7 million on a pre-tax loss of $188.9 million for the nine months ended September 30, 2023, compared to income tax expense of $2.0 million on a pre-tax loss of $76.7 million for the nine months ended September 30, 2022. Income tax expense for the nine months ended September 30, 2023 and 2022 was primarily attributable to federal, state and foreign income tax expense as a result of current taxable income in certain jurisdictions.

Liquidity and Capital Resources

At September 30, 2023, we had $498.2 million in cash and cash equivalents and short-term investments. In addition, we have a Revolving Line of Credit (Line of Credit), which expires in May 2025 (see Note 7, "Debt"), under which we may borrow up to $50.0 million, less the amount of our standby letter of credit, provided we are currently not entitled to borrow any amounts under the Line of Credit as a result of our inadvertent failure to timely pay additional interest under the Notes. See above under "Other Income and Expense". We believe that our cash and cash equivalents, short-term investments, borrowing availability under the Line of Credit, and future cash flows from operations will be sufficient to fund our ongoing core business activities for at least the next twelve months.

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.

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.

The following table shows a summary of our cash flows for the nine months ended September 30, 2023 and 2022 (in thousands):

	Nine Months Ended September 30,	
	2023	2022
Net cash provided by (used in):		
Operating activities	$ (24,594)	$ 44,644
Investing activities	(69,156)	(2,609)
Financing activities	1,496	10,777
Effect of foreign exchange rate changes on cash	(652)	(207)
Net increase (decrease) in cash and cash equivalents	$ (92,906)	$ 52,605

Operating Activities. Net cash used in operating activities was $24.6 million for the nine months ended September 30, 2023, compared to $44.6 million cash provided by operating activities in the same period in 2022. The reduction in net cash provided by operating activities for 2023 compared to 2022 was primarily a result of the increase in net loss, which included $78.8 million of acquired in-process research and development expenses and a $14.1 million operating lease impairment charge in 2023, as well as working capital changes. Working capital changes during the first nine months of 2023 primarily consisted of increases in inventories and prepaids and other current assets, partially offset by a decrease in accounts receivable and an increase in deferred revenue. Accounts receivable decreased to $100.3 million at September 30, 2023, from $114.7 million at December 31, 2022. Inventories increased to $143.5 million at September 30, 2023, from $111.1 million at December 31, 2022 primarily due to a return to target stocking levels post-pandemic as supply chain constraints subsided, as well as the scaling up of inventory to meet anticipated demand for Tandem Mobi.

Investing Activities. Net cash used in investing activities was $69.2 million for the nine months ended September 30, 2023, which primarily consisted of $391.0 million of purchases of short-term investments, $69.5 million for the acquisition of AMF Medical, including transaction costs (see Note 12, “Acquisitions”), and $21.6 million in purchases of property and equipment of which $8.7 million was associated with improvements to the new Headquarters lease facility which is now complete (see Note 6, “Leases”), offset by $415.5 million in proceeds from maturities and redemptions of short-term investments. Net cash used in investing activities was $2.6 million for the nine months ended September 30, 2022, which primarily consisted of $362.5 million of purchases of short-term investments, $28.5 million in purchases of property and equipment, and $25.7 million paid for the acquisition of Capillary Biomedical, including transaction costs (see Note 12, “Acquisitions”), offset by $422.9 million in proceeds from maturities and redemptions of short-term investments.

Financing Activities. Net cash provided by financing activities was $1.5 million for the nine months ended September 30, 2023, which primarily consisted of proceeds from the issuance of common stock under our stock plans, net of payments for related tax withholdings. Net cash provided by financing activities was $10.8 million for the nine months ended September 30, 2022, 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 margins 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, 2022.

Item 3. Quantitative and Qualitative Disclosures about Market Risk.

Credit and Interest Rate Risks

We invest our excess cash in marketable securities consisting primarily of U.S. Treasury securities, U.S. Government-sponsored enterprise securities, commercial paper and corporate debt securities. Some of the financial instruments in which we invest subject us to market risk, in that a change in prevailing interest rates may cause the principal amount of the instrument to fluctuate. Other financial instruments in which we invest subject us to credit risk, in that the value of the instrument may fluctuate based on the issuer's ability to pay. Credit rating agencies have, from time to time, issued downgrades or revised outlooks to negative for certain issuers of the debt securities held in our short-term investment portfolio. We review our portfolio of available-for-sale debt securities quarterly to determine if any investment is impaired due to changes in credit risk or other potential valuation concerns. Unrealized losses on available-for-sale debt securities at September 30, 2023 were primarily due to an increase in market interest rates after certain debt securities were purchased. Based on the credit quality of the available-for-sale debt securities in an unrealized loss position, and our current estimates of future cash flows to be collected from those securities, we believe the unrealized losses were not credit losses (see Note 3, "Short-Term Investments").

The primary objectives of our investment activities are to maintain liquidity and preserve principal while maximizing the income we receive from our financial instruments without significantly increasing risk. We have established guidelines regarding approved investments and maturities of investments, which are primarily designed to maintain liquidity and preserve principal.

Because of the short-term maturities of our financial instruments, we do not believe that an increase or decrease in market interest rates would have a significant impact on the realized value of our investment portfolio. If a 10% change in interest rates were to have occurred on September 30, 2023, it would not have had a material effect on the fair value of our investment portfolio as of that date.

In May 2020, we issued $287.5 million principal amount of Convertible Senior Notes, which bear interest at a fixed rate of 1.50% per year. Accordingly, we are not subject to interest rate risk related to the Convertible Senior Notes (see Note 7, "Debt").

Foreign Currency Exchange Rate Risk

Our operations are primarily located in the United States. In addition, we have a sales and marketing office in Canada, a distribution center in the Netherlands and, beginning in 2023, a research and development facility in Switzerland associated with the acquisition of AMF Medical. Our sales to customers in the United States are made in U.S. dollars. Sales from our distribution center in the Netherlands are made to independent distributors under agreements denominated in Euros. In addition, a portion of our sales in Canada are denominated in Canadian dollars. Accordingly, we believe our exposure to foreign currency rate fluctuations is primarily related to our operations in Canada and Europe, and acquisition related contingent earnout payments (see Note 12, "Acquisitions"), where fluctuations in the rate of exchange between the U.S. dollar and the local currency could adversely affect our financial results.

As we expand and further develop our operations in markets outside the United States, particularly in Europe, we will be exposed to additional foreign currency exchange rate risk. In addition, from time to time, we may have foreign currency exchange risk related to existing assets and liabilities, other committed transactions and forecasted future cash flows. In certain circumstances, we may seek to manage such foreign currency exchange risk by using derivative instruments such as foreign currency exchange forward contracts to hedge our risk. However, we may choose not to hedge some exposures for a variety of reasons, including prohibitive economic costs.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

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

As of September 30, 2023, we carried out an evaluation, under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures. Based on this evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective at a reasonable assurance level as of September 30, 2023.

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

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act) during the quarter ended September 30, 2023 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, Subsection 13 of this Quarterly Report, as of September 30, 2023, we do not believe we are currently a party to any material legal proceedings, regulatory matters, or other disputes or claims. Regardless of the merits of the claims raised or the outcome, legal proceedings, regulatory matters, and other disputes and claims 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.

Item 1A. Risk Factors.

Except as set forth below, we are not aware of any material changes to the risk factors set forth under the caption “Risk Factors” in Part II, Item 1A of the Annual Report and Part II, Item 1A of the Quarterly Report for the quarterly period ended June 30, 2023, which are incorporated herein by reference. The risks described in the Annual Report, in the Quarterly Report for the period ended June 30, 2023, and 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.

Risks Related to Our Indebtedness

An event of default has occurred under the indenture governing our 1.50% Convertible Senior Notes due 2025

On or about October 24, 2023, we were notified that additional interest has been accruing on the Convertible Senior Notes (“Notes”) since May 2021 pursuant to the terms of the indenture, as a result of our failure to timely remove the restrictive legends on the Notes and switch the Notes to an unrestricted CUSIP. This additional interest continues to accrue at a rate of 0.50% per annum on the outstanding principal amount of the Notes, and as of November 1, 2023 amounts to approximately $3.2 million in the aggregate. The overdue unpaid interest itself accrues interest at a rate of 2.50% per annum. We have deposited the full amount for these payments with the trustee for the Notes and are coordinating with the trustee for the payments to be completed as soon as reasonably practicable in the fourth quarter of 2023. However, the failure to pay these overdue amounts constitutes an event of default under the indenture, and the trustee or the holders of at least 25% of the outstanding principal amount of Notes can elect to declare all outstanding amounts under the Notes immediately due and payable while this event of default is continuing. Early repayment of the Notes would likely significantly impact our liquidity and financial condition, which could have a material adverse effect on our business. In addition, we cannot access funds under our $50.0 million Line of Credit due to the event of default under the indenture governing the Notes.

Risks Related to Legal and Intellectual Property

We are the subject of a putative securities class action lawsuit, and additional securities litigation may be brought against us in the future.

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) in the United States District Court for the Southern District of California against us and certain of our current executive officers. The complaint generally alleges that defendants violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended, by failing to properly account for and disclose the full impact that COVID-19, inflation, and the sales of competitors’ products were having on our sales and revenue. The complaint seeks unspecified monetary damages and other relief. It is possible that additional lawsuits will be filed, or allegations made by stockholders, with respect to these same or other matters and also naming us and/or our officers and directors as defendants. Although we intend to vigorously defend against this claim, there is no guarantee that we will prevail. Accordingly, we are unable to determine the ultimate outcome of this lawsuit or determine the amount or range of potential losses associated with the lawsuit. While we carry liability insurance, there is no assurance that any losses we incur in connection with the current lawsuit or any future lawsuit will be covered or that coverage, if any, will be sufficient. In addition, the current lawsuit and similar future litigation could result in substantial costs and a diversion of management’s attention and resources, which could harm our business.

Risks Related to Our Business and Industry

Competitive 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 competitive 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 competitive 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 embarrassment 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.

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.

Risks Related to Privacy and Security

A security breach or other significant disruption to our information technology systems or data, or those of our third-party business partners, or failures of our software used with our pumps to perform as we anticipate, could materially disrupt our operations or compromise sensitive information relating to our customers, suppliers, employees or other individuals, which could damage our relationships, expose us to litigation or regulatory proceedings, or harm our reputation.

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-party business partners. We rely on such systems to effectively store, process 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 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. Threat actors may continue to develop and use more sophisticated tools and techniques (including AI) that are specifically designed to circumvent security controls, evade detection, and obfuscate forensic evidence, making it more difficult for us to identify, investigate and recover from incidents. Notably, severe ransomware attacks are becoming increasingly prevalent and can lead to significant interruptions in our operations, 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. Additionally, to offer our products to our customers and operate our business, we use a number of products and services, such as IT networks and systems, including those we own and operate as well as others provided by third-party providers. Our ability to provide our products could be interrupted if these systems were impacted by a ransomware or other cyber-attack.

Should any of the risks described herein occur, it could also result in the loss, theft, misuse, unauthorized disclosure, or unauthorized access of such sensitive information, which could lead to significant reputational or competitive harm, litigation involving us or our business partners, regulatory proceedings, or substantial liabilities, fines, penalties or expenses. Further, many of our third-party service providers are subject to similar risks. We rely on third-party service providers 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 these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. If our third-party service providers experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if our third-party service providers 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 third parties' infrastructure in our supply chain or our third-party partners' supply chains have not been compromised.

In addition to the risks regarding information technology systems and processing of sensitive information, our insulin pumps and other products rely on software, some of which is developed by third-party service providers, that could contain vulnerabilities. We take steps to detect and remediate vulnerabilities, but we may not be able to detect and remediate all vulnerabilities because the threats and techniques used to exploit the vulnerability change frequently and are often sophisticated in nature. Therefore, such vulnerabilities could be exploited but may not be detected until after a security incident has occurred. These vulnerabilities pose material risks to our business. Further, we may experience delays in developing and deploying remedial measures designed to address any such identified vulnerabilities. These risks significantly increased when we began use of our Tandem Device Updater, which enables customers to remotely update software on their insulin pumps and may be higher after we launched our new mobile application in the second half of 2020. These risks may have further increased in the second half of 2022 when we enabled users to control insulin boluses through the mobile app.

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 our third-party service providers 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 to notify relevant stakeholders of security incidents. Such disclosures are costly, and the disclosure or the failure to comply with such requirements could lead to adverse consequences. If we (or a third party upon whom we rely) experience a security incident (such as the incident described below) 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); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; 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, 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 or our service providers' information technology systems or 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 may allow 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, errors 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 employee's, personnel's, or vendor's 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 ingests 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 may be subject to stringent and evolving U.S. and foreign laws, regulations, 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 collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, process (or processing)) sensitive information. 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 privacy and security policies, contractual requirements, and other obligations relating to data privacy and security.

There are a number of laws in the United States governing the privacy and security of personal information, including data breach notification laws, personal data privacy laws, consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), and other similar laws (e.g., wiretapping laws). For example, the U.S. 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, security, and transmission of individually identifiable protected health information.

For 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 per violation imposed through private litigation or by state authorities.

As another example, the California Consumer Privacy Act of 2018 (CCPA), as amended by the California Privacy Rights Act of 2020 (CPRA) (collectively, "CCPA"), applies to personal information of consumers, business representatives, and employees who are California residents, and requires businesses to provide specific disclosures in privacy notices and honor requests of such individuals to exercise certain privacy rights. The CCPA provides for administrative fines of up to $7,500 per violation and allows private litigants affected by certain data breaches to recover significant statutory damages. Although the CCPA exempts some data processed in the context of clinical trials, the CCPA increases compliance costs and potential liability with respect to other personal data we maintain about California residents. In addition, the CPRA expanded the CCPA's requirements, including by adding a new right for individuals to correct their personal information and establishing a new regulatory agency to implement and enforce the law. Other states, such as Virginia and Colorado, have also passed comprehensive privacy laws, and similar laws are being considered in several other states, as well as at the federal and local levels. These state laws and the CCPA provide individuals with certain rights over their personal information, including the right to access, correct, or delete certain personal information, and 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. While these states, like the CCPA, also exempt some data processed in the context of clinical trials, these developments further complicate compliance efforts, and increase legal risk and compliance costs for us, the third parties upon whom we rely, and our customers.

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 GDPR ("UK 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 EU GDPR, companies may face temporary or definitive bans on data processing and other corrective actions; fines of up to 20 million Euros / 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 and CPRA, other U.S. state comprehensive privacy laws, the EU and UK GDPR, and the UK Age Appropriate Design Code, impose various obligations on companies that process children data, including by requiring certain consents to process such data and extending certain rights to children and their parents with respect that 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 subject to legal challenges and changing interpretations, which may further complicate our efforts to comply with these laws.

Our employees and personnel use generative AI technologies to perform their work, and the disclosure and use of personal information in generative AI technologies is subject to various privacy laws and other 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 consumer lawsuits. If we are unable to use generative AI, it could make our business less efficient and result in competitive disadvantages.

The development and use of generative AI/ML technologies present various privacy and security risks that may impact our business. AI/ML are subject to privacy and data security laws, as well as increasing regulation and scrutiny. Several jurisdictions around the globe, including Europe and certain U.S. states, have proposed or enacted laws governing AI/ML. For example, European regulators have proposed a stringent AI regulation, and we expect other jurisdictions will adopt similar laws. Additionally, certain privacy laws extend rights to consumers (such as the right to delete certain personal data) and regulate automated decision making, which may be incompatible with our use of AI/ML. These obligations may make it harder for us to conduct our business using AI/ML, lead to regulatory fines or penalties, require us to change our business practices, retrain our AI/ML, or prevent or limit our use of AI/ML. 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 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 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 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 privacy laws it generally believes are 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 and UK's 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 for relevant organizations based in the United States who self-certify compliance and participate in the Framework), these mechanisms are subject to legal challenges, and 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 manner 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 limitations. 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.

In addition to data privacy and security laws, we are contractually subject to industry standards adopted by industry groups and we are, or may become subject to such obligations in the future. For example, we may also be 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 per month by credit card companies, litigation, damage to our reputation, and revenue losses. We are also bound by contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful. For example, certain privacy laws, such as the GDPR and the CCPA, require our customers to impose specific contractual restrictions on their service providers. Additionally, some of our customer contracts require us to host personal data locally. We publish privacy policies, marketing materials and other statements, such as compliance with certain certifications or self-regulatory principles, regarding data privacy and security. 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 and security are quickly changing, becoming increasingly stringent, and creating regulatory 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 that process personal data on our behalf. 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 and security obligations. Moreover, despite our efforts, our personnel or third parties on whom we rely 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 on which we rely fail, or are perceived to have failed to address or comply with applicable data privacy and security 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 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 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 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.

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	Separation Agreement, executed as of August 18, 2023, entered into by and between Tandem Diabetes Care, Inc. and Brian Hansen.	8-K	001-36189	August 18, 2023	10.1	
31.1	Certification of John F. Sheridan, Chief Executive Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
31.2	Certification of Leigh A. Vosseller, Chief Financial Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
32.1*	Certification of John F. Sheridan, Chief Executive Officer, pursuant to U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					X
32.2*	Certification of Leigh A. Vosseller, Chief Financial Officer, pursuant to U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					X
101.INS	Inline XBRL Instance Document.					X
101.SCH	Inline XBRL Taxonomy Extension Schema Document.					X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.					X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.					X
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.					X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.					X
104	Cover Page Interactive Data File (embedded within the Inline XBRL Document contained in Exhibit 101).					X

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

SIGNATURES

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

Tandem Diabetes Care, Inc.

Dated: November 1, 2023

By: /s/ John F. Sheridan

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

Dated: November 1, 2023

By: /s/ Leigh A. Vosseller

Leigh A. Vosseller
Executive Vice President, Chief Financial Officer and Treasurer
(on behalf of the registrant and as the registrant's Principal Financial and Accounting Officer)

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: November 1, 2023

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: November 1, 2023

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 September 30, 2023, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, John F. Sheridan, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company as of the dates and for the periods presented.

Date: November 1, 2023

/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 September 30, 2023, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Leigh A. Vosseller, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company as of the dates and for the periods presented.

Date: November 1, 2023

/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.