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, 2022

OR

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

Commission File Number 001-33462

INSULET CORPORATION

(Exact name of Registrant as specified in its charter)

Delaware	**04-3523891**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification No.)**
100 Nagog Park Acton Massachusetts	**01720**
(Address of Principal Executive Offices)	**(Zip Code)**

Registrant's Telephone Number, Including Area Code: (978) 600-7000

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

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

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

Large accelerated filer	☒	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 ☒

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.001 Par Value Per Share	PODD	The NASDAQ Stock Market, LLC

As of October 27, 2022, the registrant had 69,448,703 shares of common stock outstanding.

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PART I - FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements (Unaudited)

INSULET CORPORATION

CONDENSED CONSOLIDATED BALANCE SHEETS

(UNAUDITED)

(in millions, except share and per share data)	September 30, 2022	December 31, 2021
ASSETS		
Current Assets		
Cash and cash equivalents	$ 722.0	$ 791.6
Accounts receivable trade, less allowance for credit losses of $2.9 and $2.7	153.1	135.2
Accounts receivable trade, net — related party	48.3	25.8
Inventories	327.6	303.2
Prepaid expenses and other current assets	78.1	74.0
Total current assets	1,329.1	1,329.8
Property, plant and equipment, net	553.1	536.5
Other intangible assets, net	53.7	36.6
Goodwill	51.6	39.8
Other assets	178.7	106.1
Total assets	$ 2,166.2	$ 2,048.8
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities		
Accounts payable	$ 62.1	$ 37.7
Accrued expenses and other current liabilities	241.7	164.3
Accrued expenses and other current liabilities — related party	3.5	1.7
Current portion of long-term debt	26.9	25.1
Total current liabilities	334.2	228.8
Long-term debt, net	1,379.8	1,248.8
Other liabilities	24.2	14.9
Total liabilities	1,738.2	1,492.5
Commitments and contingencies (Note 12)		
Stockholders' Equity		
Preferred stock, $.001 par value, 5,000,000 authorized; none issued and outstanding	—	—
Common stock, $.001 par value, 100,000,000 authorized; 69,431,159 and 69,178,691 issued and outstanding	0.1	0.1
Additional paid-in capital	1,022.4	1,207.9
Accumulated deficit	(601.3)	(649.5)
Accumulated other comprehensive income (loss)	6.8	(2.2)
Total stockholders' equity	428.0	556.3
Total liabilities and stockholders' equity	$ 2,166.2	$ 2,048.8

The accompanying notes are an integral part of these condensed consolidated financial statements.

INSULET CORPORATION

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(UNAUDITED)

(in millions, except share and per share data)	Three Months Ended September 30, 2022	Three Months Ended September 30, 2021	Nine Months Ended September 30, 2022	Nine Months Ended September 30, 2021
Revenue	$ 281.9	$ 261.8	$ 772.8	$ 771.8
Revenue from related party	58.9	13.8	162.8	19.3
Total revenue	340.8	275.6	935.6	791.1
Cost of revenue	152.5	86.9	347.3	252.2
Gross profit	188.3	188.7	588.3	538.9
Research and development expenses	45.0	37.5	130.7	118.3
Selling, general and administrative expenses	140.4	117.5	443.5	344.3
Operating income	2.9	33.7	14.1	76.3
Interest expense, net	(6.8)	(16.3)	(24.0)	(46.1)
Loss on extinguishment of debt	—	(1.5)	—	(41.6)
Other expense, net	(1.8)	(0.7)	(2.6)	(1.5)
(Loss) income before income taxes	(5.7)	15.2	(12.5)	(12.9)
Income tax benefit (expense)	0.5	(2.6)	0.1	0.5
Net (loss) income	$ (5.2)	$ 12.6	$ (12.4)	$ (12.4)
Net (loss) income per share:				
Basic	$ (0.08)	$ 0.18	$ (0.18)	$ (0.18)
Diluted	$ (0.08)	$ 0.18	$ (0.18)	$ (0.18)
Weighted-average number of common shares outstanding (in thousands):				
Basic	69,418	68,869	69,343	67,236
Diluted	69,418	69,619	69,343	67,236

The accompanying notes are an integral part of these condensed consolidated financial statements.

INSULET CORPORATION

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE (LOSS) INCOME

(UNAUDITED)

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in millions)	**2022**	**2021**	**2022**	**2021**
Net (loss) income	$ (5.2)	$ 12.6	$ (12.4)	$ (12.4)
Other comprehensive (loss) income, net of tax:				
Foreign currency translation adjustment	(11.6)	(4.4)	(24.9)	(8.3)
Unrealized gain (loss) on cash flow hedges	11.2	0.3	33.9	(0.3)
Unrealized loss on available-for-sale securities	—	—	—	(0.3)
Total other comprehensive (loss) income, net of tax	(0.4)	(4.1)	9.0	(8.9)
Comprehensive (loss) income	$ (5.6)	$ 8.5	$ (3.4)	$ (21.3)

The accompanying notes are an integral part of these condensed consolidated financial statements.

INSULET CORPORATION

CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

(UNAUDITED)

Three Months Ended September 30, 2022

(dollars in millions)	Common Stock Shares (in thousands)	Common Stock Amount	Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Shareholders' Equity
Balance at June 30, 2022	69,386	$ 0.1	$ 1,011.2	$ (596.1)	$ 7.2	$ 422.4
Exercise of options to purchase common stock	43	—	2.4	—	—	2.4
Stock-based compensation expense	—	—	9.0	—	—	9.0
Restricted stock units vested, net of shares withheld for taxes	2	—	(0.2)	—	—	(0.2)
Net loss	—	—	—	(5.2)	—	(5.2)
Other comprehensive loss	—	—	—	—	(0.4)	(0.4)
Balance at September 30, 2022	69,431	$ 0.1	$ 1,022.4	$ (601.3)	$ 6.8	$ 428.0

Three Months Ended September 30, 2021

(dollars in millions)	Common Stock Shares (in thousands)	Common Stock Amount	Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Shareholders' Equity
Balance at June 30, 2021	68,610	$ 0.1	$ 1,149.6	$ (691.3)	$ 0.7	$ 459.1
Exercise of options to purchase common stock	95	—	4.3	—	—	4.3
Stock-based compensation expense	—	—	8.2	—	—	8.2
Restricted stock units vested, net of shares withheld for taxes	2	—	(0.2)	—	—	(0.2)
Extinguishment of conversion feature on 1.375% Notes, net of issuance costs	—	—	(41.7)	—	—	(41.7)
Issuance of shares for debt extinguishment	215	—	59.7	—	—	59.7
Net income	—	—	—	12.6	—	12.6
Other comprehensive loss	—	—	—	—	(4.1)	(4.1)
Balance at September 30, 2021	68,922	$ 0.1	$ 1,179.9	$ (678.7)	$ (3.4)	$ 497.9

The accompanying notes are an integral part of these condensed consolidated financial statements.

Nine Months Ended September 30, 2022

(dollars in millions)	Common Stock Shares (in thousands)	Common Stock Amount	Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive (Loss) Income	Total Shareholders' Equity
Balance at December 31, 2021	69,179	$ 0.1	$ 1,207.9	$ (649.5)	$ (2.2)	$ 556.3
Adoption of ASU 2020-06 (Note 1)	—	—	(207.7)	60.6	—	(147.1)
Exercise of options to purchase common stock	95	—	4.3	—	—	4.3
Issuance of shares for employee stock purchase plan	27	—	4.9	—	—	4.9
Stock-based compensation expense	—	—	29.7	—	—	29.7
Restricted stock units vested, net of shares withheld for taxes	130	—	(16.7)	—	—	(16.7)
Net loss	—	—	—	(12.4)	—	(12.4)
Other comprehensive income	—	—	—	—	9.0	9.0
Balance at September 30, 2022	69,431	$ 0.1	$ 1,022.4	$ (601.3)	$ 6.8	$ 428.0

Nine Months Ended September 30, 2021

(dollars in millions)	Common Stock Shares (in thousands)	Common Stock Amount	Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Shareholders' Equity
Balance at December 31, 2020	66,017	$ 0.1	$ 1,264.3	$ (666.3)	$ 5.5	$ 603.6
Exercise of options to purchase common stock	259	—	10.5	—	—	10.5
Issuance of shares for employee stock purchase plan	17	—	3.9	—	—	3.9
Stock-based compensation expense	—	—	25.8	—	—	25.8
Restricted stock units vested, net of shares withheld for taxes	172	—	(27.6)	—	—	(27.6)
Extinguishment of conversion feature on 1.375% Notes, net of issuance costs	—	—	(779.4)	—	—	(779.4)
Issuance of shares for debt extinguishment	2,457	—	682.4	—	—	682.4
Net loss	—	—	—	(12.4)	—	(12.4)
Other comprehensive loss	—	—	—	—	(8.9)	(8.9)
Balance at September 30, 2021	68,922	$ 0.1	$ 1,179.9	$ (678.7)	$ (3.4)	$ 497.9

The accompanying notes are an integral part of these condensed consolidated financial statements.

INSULET CORPORATION

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(UNAUDITED)

(in millions)	Nine Months Ended September 30, 2022	2021
Cash flows from operating activities		
Net loss	$ (12.4)	$ (12.4)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation and amortization	47.0	42.5
Stock-based compensation expense	29.7	25.8
Non-cash interest expense	4.3	31.9
Loss on extinguishment of debt	—	41.6
Provision for credit losses	3.1	2.8
Other	1.1	0.2
Changes in operating assets and liabilities:		
Accounts receivable	(28.3)	(25.9)
Accounts receivable — related party	(22.5)	(14.1)
Inventories	(34.5)	(108.1)
Prepaid expenses and other assets	(32.1)	(28.2)
Accounts payable	23.3	6.0
Accrued expenses and other liabilities	87.8	(5.6)
Accrued expenses and other liabilities — related party	1.8	0.9
Net cash provided by (used in) operating activities	68.3	(42.6)
Cash flows from investing activities		
Capital expenditures	(58.5)	(80.1)
Acquisition of intangible assets	(10.4)	(5.7)
Acquisition	(26.0)	—
Cash paid for investments	(7.8)	—
Receipts from the maturity or sale of marketable securities	—	39.5
Net cash used in investing activities	(102.7)	(46.3)
Cash flows from financing activities		
Proceeds from issuance of convertible debt, net of issuance costs	—	489.5
Repayment of convertible debt	—	(460.8)
Proceeds from equipment financing, net	—	43.1
Repayment of equipment financings	(13.0)	(9.6)
Repayment of mortgage	(1.6)	(1.5)
Repayment of term loan	(3.7)	(1.3)
Payment of debt issuance costs	—	(4.0)
Proceeds from exercise of stock options	4.3	10.5
Proceeds from issuance of common stock under employee stock purchase plan	4.9	3.9
Payment of withholding taxes in connection with vesting of restricted stock units	(16.7)	(27.6)
Net cash (used in) provided by financing activities	(25.8)	42.2
Effect of exchange rate changes on cash	(9.1)	(3.9)
Net decrease in cash, cash equivalents and restricted cash	(69.3)	(50.6)
Cash, cash equivalents and restricted cash at beginning of period (Note 3)	806.4	922.0
Cash, cash equivalents and restricted cash at end of period (Note 3)	$ 737.1	$ 871.4
Supplemental noncash information:		
Purchases of property and equipment included in accounts payable and accrued expenses	$ 6.0	$ 3.2
Purchases of intangible assets included in accounts payable and accrued expenses	$ 0.8	$ 7.3
Lease liabilities arising from obtaining right-of-use assets	$ 12.1	$ 0.5

The accompanying notes are an integral part of these condensed consolidated financial statements.

INSULET CORPORATION

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

Note 1. Basis of Presentation and Summary of Significant Accounting Policies

Basis of Presentation

The accompanying financial statements reflect the consolidated operations of Insulet Corporation and its subsidiaries ("Insulet" or the "Company"). The unaudited consolidated financial statements have been prepared in United States dollars, in accordance with accounting principles generally accepted in the United States of America ("GAAP"). The preparation of the consolidated financial statements in conformity with GAAP requires management to make use of estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities, and the reported amounts of revenues and expenses. Actual results may differ from those estimates. In management's opinion, the unaudited consolidated financial statements contain all normal recurring adjustments necessary for a fair statement of the interim results reported. Operating results for the nine months ended September 30, 2022 are not necessarily indicative of the results that may be expected for the full year ending December 31, 2022, or for any other subsequent interim period.

The year-end balance sheet data was derived from audited consolidated financial statements. These unaudited consolidated financial statements do not include all of the annual disclosures required by GAAP; accordingly, they should be read in conjunction with the Company's audited consolidated financial statements contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2021.

Reclassification of Prior Period Amounts

Certain reclassifications have been made to prior period amounts to conform to the current period financial statement presentation. The Company reclassified the change in unbilled receivables from the change in prepaid expenses and other current assets to the change in accounts receivable in the prior year statement of cash flows in the amount of $4.5 million. There was no change to previously reported net cash used in operating activities.

Investments

The Company has investments in privately-held companies in which the Company's interest is less than 20%, the Company does not exercise significant influence over the investee, and the investment does not have a readily determinable fair value. These investments are carried at cost less impairment, if any. If an observable price change is identified, the investment is measured at its fair value as of the date that the observable transaction occurred with the adjustments reflected in other (expense) income in the Company's consolidated statements of operations.

In January and May 2022, the Company made strategic investments in two companies in the amount of $5.0 million and $2.8 million, respectively. As of September 30, 2022 and December 31, 2021, the total carrying value of the Company's investments was $8.7 million and $0.9 million, respectively.

Shipping and Handling Costs

Shipping and handling costs included in selling, general and administrative expenses were $3.5 million and $2.8 million for the three months ended September 30, 2022 and 2021, respectively, and were $9.7 million and $7.5 million for the nine months ended September 30, 2022 and 2021, respectively.

Fair Value Measurements

Fair value is defined as the price that would be received from the sale of an asset or paid to transfer a liability in the principal or most advantageous market in an orderly transaction between market participants on the measurement date. To measure fair value of assets and liabilities, the Company uses the following fair value hierarchy based on three levels of inputs:

Level 1—observable inputs, such as quoted prices in active markets for identical assets or liabilities;

Level 2—significant other observable inputs that are observable either directly or indirectly; and

Level 3—significant unobservable inputs for which there are little or no market data, which require the Company to develop its own assumptions.

Certain of the Company's financial instruments, including cash and cash equivalents, accounts receivable, accounts payable, accrued expenses and other liabilities are carried at cost, which approximates their fair value because of their short-term maturity. See Notes 3 and 10 for financial assets and liabilities held at carrying amount on the consolidated balance sheet and Note 11 for derivative instruments measured at fair value on a recurring basis.

Recently Adopted Accounting Standard

Effective January 1, 2022, the Company adopted Accounting Standards Update ("ASU") 2020-06, *Debt - Debt With Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging - Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity* using the modified retrospective method for convertible debt instruments outstanding as of the date of adoption. Under ASU 2020-06, a convertible debt instrument is generally reported as a single liability at its amortized cost with no separate accounting for embedded conversion features. Consequently, the effective interest rate of convertible debt instruments is closer to the coupon interest rate under the new guidance. The following table shows the adjustments made to the consolidated balance sheet as of January 1, 2022 as a result of adopting the new guidance.

(in millions)	As Reported Prior to ASU 2020-06	Adjustments	As Adjusted Under ASU 2020-06
	December 31, 2021	January 1, 2022	January 1, 2022
Long-term debt, net [1]	$ 1,248.8	$ 147.1	$ 1,395.9
Additional paid-in-capital [2]	$ 1,207.9	$ (207.7)	$ 1,000.2
Accumulated deficit [3]	$ (649.5)	$ 60.6	$ (588.9)

(1) The increase in debt resulted from the derecognition of the discount associated with the embedded conversion feature, offset by the remaining debt issuance costs reclassified out of equity.

(2) The decrease in additional paid-in-capital resulted from the derecognition of the embedded conversion feature and debt issuance costs bifurcated to equity.

(3) The decrease to accumulated deficit represents the cumulative interest expense recognized related to the amortization of the bifurcated conversion option and debt issuance costs.

In addition to the adjustments in the table above, the Company wrote-off the related deferred tax liabilities with a corresponding adjustment to the valuation allowance, resulting in no net impact to the cumulative adjustment recorded to accumulated deficit. Adoption of this standard had no impact on the Company's diluted earnings per share as the Company historically calculated earnings per share using the if-converted method.

Note 2. Revenue and Contract Acquisition Costs

The following table summarizes the Company's disaggregated revenue:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in millions)	**2022**	**2021**	**2022**	**2021**
U.S. Omnipod	$ 238.1	$ 167.2	$ 608.6	$ 461.0
International Omnipod	88.0	93.1	272.8	274.6
Total Omnipod	326.1	260.3	881.4	735.6
Drug Delivery	14.7	15.3	54.2	55.5
Total revenue	$ 340.8	$ 275.6	$ 935.6	$ 791.1

The percentages of total revenue for customers that represent 10% or more of total revenue were as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	**2021**	**2022**	**2021**
Distributor A	17%	*	18%	*
Distributor B	18%	14%	16%	12%
Distributor C	*	*	*	13%
Distributor D	17%	*	15%	*
Distributor E	10%	*	*	*

* Represents less than 10% of revenue for the period.

Deferred revenue related to unsatisfied performance obligations was included in the following consolidated balance sheet accounts in the amounts shown:

(in millions)	September 30, 2022	December 31, 2021
Accrued expenses and other current liabilities	$ 9.0	$ 3.5
Other liabilities	1.5	1.5
Total deferred revenue	$ 10.5	$ 5.0

Revenue recognized from amounts included in deferred revenue at the beginning of each respective period was as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in millions)	2022	2021	2022	2021
Deferred revenue recognized	$ 0.3	0.1	$ 1.8	4.0

Contract acquisition costs, representing capitalized commission costs related to new customers, net of amortization, were included in the following consolidated balance sheet captions in the amounts shown:

(in millions)	September 30, 2022	December 31, 2021
Prepaid expenses and other current assets	$ 14.2	$ 13.3
Other assets	28.2	26.1
Total capitalized contract acquisition costs, net	$ 42.4	$ 39.4

The Company recognized $3.7 million and $3.2 million of amortization of capitalized contract acquisition costs during the three months ended September 30, 2022 and 2021, respectively. The Company recognized $10.7 million and $9.1 million of amortization of capitalized contract acquisition costs during the nine months ended September 30, 2022 and 2021, respectively.

Note 3. Cash and Cash Equivalents

The following table provides a summary of cash and cash equivalents:

(in millions)	September 30, 2022	December 31, 2021
Cash	$ 117.7	$ 159.3
Money market mutual funds	553.4	630.7
Time deposits	50.4	—
Restricted cash	0.5	1.6
Total cash and cash equivalents	722.0	791.6
Restricted cash included in other assets	15.1	14.8
Total cash, cash equivalents, and restricted cash shown in the consolidated statements of cash flows	$ 737.1	$ 806.4

The restricted cash included in other assets on the consolidated balance sheet is primarily held as a compensating balance against long-term borrowings.

All cash and cash equivalents are Level 1 in the fair value hierarchy.

Certain of the Company’s subsidiaries participate in a multi-currency, notional cash pooling arrangement with a third-party bank provider to manage global liquidity requirements. Under this arrangement, which began in August 2022, cash deposited by participating subsidiaries may be used to offset amounts owed to the bank by other participating subsidiaries to the extent the overall balance in the cash pool is at least zero, providing legal rights of offset. As of September 30, 2022, the Company had a net cash position of approximately $0.2 million, consisting of a gross cash position of approximately $43.2 million less cash borrowings of approximately $43.0 million by participating subsidiaries, which is reflected as cash and cash equivalents in the consolidated balance sheet.

Note 4. Accounts Receivable, Net

At the end of each period, net accounts receivable were comprised of the following:

(in millions)	September 30, 2022	December 31, 2021
Accounts receivable trade, net	$ 125.9	$ 101.2
Unbilled receivable	27.2	34.0
Accounts receivable, net	$ 153.1	$ 135.2

The percentages of total net accounts receivable trade for customers that represent 10% or more of total net accounts receivable trade were as follows:

	September 30, 2022	December 31, 2021
Distributor A	28%	21%
Distributor B	10%	*
Distributor D	24%	15%

* Represents less than 10% of net accounts receivable trade as of period end.

Note 5. Inventories

At the end of each period, inventories were comprised of the following:

(in millions)	September 30, 2022	December 31, 2021
Raw materials	$ 86.1	$ 70.0
Work in process	66.5	112.6
Finished goods	175.0	120.6
Total inventories	$ 327.6	$ 303.2

Note 6. Cloud Computing Costs

Capitalized costs to implement cloud computing arrangements at cost and accumulated amortization were as follows:

(in millions)	September 30, 2022	December 31, 2021
Short-term portion	$ 17.3	$ 18.4
Long-term portion	78.7	49.2
Total capitalized implementation costs	96.0	67.6
Less: accumulated amortization	(13.2)	(4.4)
Capitalized implementation costs, net	$ 82.8	$ 63.2

Amortization expense is recognized on a straight-line basis over the expected term of the hosting arrangements, which range from three to five years. Amortization expense was $3.8 million and $0.8 million for the three months ended September 30, 2022 and 2021, respectively, and was $8.8 million and $2.1 million for the nine months ended September 30, 2022 and 2021, respectively.

Note 7. Acquisition

On January 3, 2022, the Company acquired substantially all of the assets related to the manufacture and production of Shape-Memory Alloy (“SMA”) wire assemblies that are used in the production of Omnipods from Dynalloy, Inc., a maker of dynamic alloys. The aggregate purchase price was $29.0 million, of which $26.0 million was paid in cash upon closing. The Company retained the remaining $3.0 million as a holdback to satisfy any post-closing working capital adjustment and to secure the seller’s indemnification obligations under the purchase agreement. The Company will release any remaining holdback funds to the seller twelve months from the closing date. Transaction costs were expensed as incurred and were not material.

The following table summarizes the fair value allocation of the assets acquired at the date of acquisition:

(in millions)		
Inventories	$	0.5
Property, plant and equipment		0.9
Other assets		0.2
Goodwill (tax deductible)		12.0
Developed technology (15 year useful life)		15.4
Total assets acquired	$	29.0

The primary factor that contributed to an acquisition price in excess of the fair value of assets acquired and the establishment of goodwill was the expected cost savings resulting from the integration of a supplier.

Note 8. Goodwill and Other Intangible Assets, Net

The change in the carrying amount of goodwill for the period is as follows:

(in millions)		
Goodwill at December 31, 2021	$	39.8
Acquisition (Note 7)		12.0
Foreign currency translation		(0.2)
Goodwill at September 30, 2022	$	51.6

The gross carrying amount, accumulated amortization and net book value of intangible assets at the end of each period were as follows:

	September 30, 2022			December 31, 2021		
(in millions)	Gross Carrying Amount	Accumulated Amortization	Net Book Value	Gross Carrying Amount	Accumulated Amortization	Net Book Value
Customer relationships	$ 43.2	$ (26.4)	$ 16.8	$ 43.4	$ (23.4)	$ 20.0
Internal-use software	32.8	(11.6)	21.2	25.5	(10.2)	15.3
Developed technology	15.4	(0.8)	14.6	—	—	—
Intellectual property	1.4	(0.3)	1.1	1.6	(0.3)	1.3
Total intangible assets	$ 92.8	$ (39.1)	$ 53.7	$ 70.5	$ (33.9)	$ 36.6

Amortization expense for intangible assets was $1.9 million and $1.6 million for the three months ended September 30, 2022 and 2021, respectively. Amortization expense for intangible assets was $5.4 million and $5.1 million for the nine months ended September 30, 2022 and 2021, respectively.

Note 9. Accrued Expenses and Other Current Liabilities

The components of accrued expenses and other current liabilities were as follows:

(in millions)	September 30, 2022	December 31, 2021
Employee compensation and related costs	$ 68.5	$ 70.3
Accrued rebates	58.6	28.7
Warranty liability - current portion	39.5	2.4
Professional and consulting services	25.0	22.8
Other	50.1	40.1
Accrued expenses and other current liabilities	$ 241.7	$ 164.3

Product Warranty Costs

The Company provides a four-year warranty on Personal Diabetes Managers ("PDMs") and Controllers sold in the United States and PDMs sold in Europe, a five-year warranty on PDMs sold in Canada, and may replace Pods that do not function in accordance with product specifications. The Company estimates its warranty obligation at the time the product is shipped based on historical experience and the estimated cost to service the claims. Since the Company continues to introduce new products and versions, the anticipated performance of the product over the warranty period is also considered in estimating warranty reserves. Warranty expense is recorded in cost of revenue in the consolidated statements of operations. Cost to service the claims reflects the current product cost. Reconciliations of the changes in the Company's product warranty liability were as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in millions)	**2022**	**2021**	**2022**	**2021**
Product warranty liability at beginning of period	$ 11.6	$ 6.5	$ 6.8	$ 6.7
Warranty expense - other	3.4	3.0	14.5	7.9
Warranty expense - voluntary medical device correction	36.8	—	36.8	—
Change in estimate	(3.1)	—	(3.1)	—
Warranty claims settled	(3.9)	(2.8)	(10.2)	(7.9)
Product warranty liability at the end of period	$ 44.8	$ 6.7	$ 44.8	$ 6.7

In October 2022, the Company issued a voluntary medical device correction notice for its Omnipod DASH PDM relating to its battery. The Company accrued an estimated liability of $36.8 million related to this issue during the three and nine months ended September 30, 2022, the majority of which represents product, reclaim and shipping and handling costs and the remainder of which represents incremental distribution and customer service support costs.

Note 10. Debt

The components of debt consisted of the following:

(in millions)	**September 30, 2022**	**December 31, 2021**
0.375% Convertible Senior Notes due September 2026	$ 800.0	$ 800.0
Term loan due May 2028	493.8	497.5
Revolving Credit Facility expires May 2024	—	—
Equipment financing due May 2024	11.2	16.0
Equipment financing due November 2025	24.3	29.6
Equipment financing due July 2028	35.3	38.2
5.15% Mortgage due November 2025	66.1	67.7
Unamortized debt discount	(8.0)	(159.9)
Debt issuance costs	(16.0)	(15.2)
Total debt, net	1,406.7	1,273.9
Less: current portion	26.9	25.1
Total long-term debt, net	$ 1,379.8	$ 1,248.8

0.375% Convertible Senior Notes

The Company's 0.375% Convertible Senior Notes due September 2026 (the "Notes") have an effective interest rate of 0.76%. The Notes are convertible into the Company's common stock at an initial conversion rate of 4.4105 shares of common stock per $1,000 principal amount of the notes, which is equivalent to a conversion price of $226.73 per share, subject to adjustment under certain circumstances. The notes will be convertible June 1, 2026 through August 28, 2026 by its holders for any reason, and prior to then under certain circumstances, and be settled with cash, shares, or a combination of both.

Additional interest of 0.5% per annum is payable if the Company fails to timely file required documents or reports with the Securities and Exchange Commission ("SEC"). If the Company merges or consolidates with a foreign entity, the Company may be required to pay additional taxes. The Company determined that the higher interest payments and tax payments required in certain circumstances were embedded derivatives that should be bifurcated and accounted for at fair value. The Company assessed the value of the embedded derivatives at each balance sheet date and determined it had nominal value.

In conjunction with the issuance of the Notes, the Company paid $85.4 million to enter into capped call options ("Capped Calls") on the Company's common stock with certain counterparties, which was recorded as a reduction to additional paid-in capital on the consolidated balance sheet. By entering into the Capped Calls, the Company expects to reduce the potential dilution to its common stock (or, in the event the conversion is settled in cash, to provide a source of cash to settle a portion of its cash payment obligation) in the event that at the time of conversion its stock price exceeds the conversion price under the Notes. The Capped Calls have an initial strike price of $335.90 per share, which represents a premium of 100% over the last reported sale price of the Company's common stock of $167.95 per share on the date of the transaction. The Capped Calls cover 3.5 million shares of common stock.

Senior Secured Credit Agreement

In May 2022, the Company increased the borrowing capacity under the Revolving Credit Facility by $10.0 million bringing the total borrowing capacity to $70.0 million.

1.375% Convertible Senior Notes

During the three months ended June 30, 2021, the Company repurchased $370.4 million in principal ($305.7 million net of discount and issuance costs) of its 1.375% Convertible Senior Notes due November 2024 ("1.375% Notes") for $460.8 million in cash and the issuance of 2.2 million shares with a fair value of $622.7 million. The debt repurchase resulted in a $40.1 million loss on extinguishment, including cash paid to the note holders as an inducement to convert and transaction costs.

During the three months ended September 30, 2021, $20.0 million in principal of the 1.375% Notes were converted into approximately 215,000 shares with a fair value of $59.7 million. The conversion resulted in a $1.5 million loss on extinguishment of debt.

Fair Value of Debt

The carrying amount and the estimated fair value of the Company's debt were as follows:

	September 30, 2022		December 31, 2021	
(in millions)	**Carrying Value**	**Estimated Fair Value**	**Carrying Value**	**Estimated Fair Value [1]**
0.375% Convertible Senior Notes [1]	$ 788.1	$ 809.4	$ 638.8	$ 938.8
Term loan [2]	482.9	481.4	485.2	498.1
Equipment Financings [3]	70.8	70.8	83.7	83.7
5.15% Mortgage [3]	64.9	64.9	66.2	66.2
Total	$ 1,406.7	$ 1,426.5	$ 1,273.9	$ 1,586.8

[1] The Notes are classified as Level 2 in the fair value hierarchy. Fair value was determined using the Company's quoted stock price and the contractual conversion rate.

[2] Term debt is classified as Level 1 in the fair value hierarchy. Fair value was determined using quoted market prices.

[3] The equipment financings and mortgage are classified as Level 3 in the fair value hierarchy. The fair values were determined using the cost bases of the financial liabilities, which approximate their carrying values.

Note 11. Derivative Instruments

The Company manages interest rate exposure through the use of interest rate swap transactions with financial institutions acting as principal counterparties. Under the Company's interest rate swap agreements that expire on April 30, 2025, the Company receives variable rate interest payments and pays fixed interest rates of 0.95% and 0.96% on a total notional value of $480.0 million of its Term Loan. The Company has designated the interest rate swaps as cash flow hedges.

The fair value of interest rate swaps, which are classified as Level 2 in the fair value hierarchy, represent the estimated amounts the Company would receive or pay to terminate the contracts and is determined using industry standard valuation models and market-based observable inputs, including credit risk and interest rate yield curves. The fair value of the interest rate swaps was $38.4 million and $4.5 million at September 30, 2022 and December 31, 2021, respectively, and was included in other assets on the consolidated balance sheets.

Note 12. Commitments and Contingencies

Legal Proceedings

In June 2020, Roche Diabetes Care, Inc. ("Roche") filed a patent infringement lawsuit against the Company in the United States District Court for the District of Delaware alleging that the Company's manufacture and sale of its Omnipod Insulin Management System, including OmniPods, Personal Diabetes Managers, and other components of the system, and kits in the United States infringed Roche's expired U.S. Patent 7,931,613. Roche was seeking monetary damages and attorneys' fees and costs. In July 2022, the Company entered into a Settlement and License Agreement (the "Settlement Agreement") with Roche to settle the pending litigation. Pursuant to the Settlement Agreement, in exchange for a release of claims, mutual covenant not to sue for five years, and license to the patent in suit from Roche, the Company made a one-time payment of $20 million to Roche. On July 12, 2022, following the filing by the parties of a Stipulation of Dismissal, the Court ordered the case dismissed with prejudice. The $20 million charge is included in selling, general and administrative expenses for the nine months ended September 30, 2022.

The Company is, from time to time, involved in the normal course of business in various legal proceedings, including intellectual property, contract, employment and product liability suits. The Company does not expect the outcome of these proceedings, either individually or in the aggregate, to have a material adverse effect on its results of operations.

Contract Dispute

The Company is engaged in negotiations over a contractual dispute involving in-licensed intellectual property. Offers to settle the dispute have been made by both the Company and the other party ranging from $5.7 million to $36 million. In connection with discussions to resolve this matter, during the nine months ended September 30, 2022, the Company accrued an estimated liability of $5.7 million. The ultimate resolution of this matter is uncertain and could have a material effect on the Company's results of operations.

Note 13. Stock-Based Compensation Expense

Compensation expense related to stock-based awards was recorded as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in millions)	**2022**	**2021**	**2022**	**2021**
Cost of revenue	$ 0.1	$ 0.1	$ 0.3	$ 0.3
Research and development expenses	2.1	1.9	6.3	5.8
Selling, general and administrative expenses	6.8	6.2	23.1	19.7
Total	$ 9.0	$ 8.2	$ 29.7	$ 25.8

Note 14. Accumulated Other Comprehensive Income (Loss)

Changes in the components of accumulated other comprehensive income (loss), net of tax, were as follows:

	Three Months Ended September 30, 2022			Nine Months Ended September 30, 2022		
(in millions)	**Foreign Currency Translation Adjustment**	**Unrealized Gain on Cash Flow Hedges**	**Accumulated Other Comprehensive Income**	**Foreign Currency Translation Adjustment**	**Unrealized Gain on Cash Flow Hedges**	**Accumulated Other Comprehensive (Loss) Income**
Balance at beginning of period	$ (20.0)	$ 27.2	$ 7.2	$ (6.7)	$ 4.5	$ (2.2)
Other comprehensive (loss) income before reclassifications	(11.6)	12.7	1.1	(24.9)	34.7	9.8
Amounts reclassified to net loss	—	(1.5)	(1.5)	—	(0.8)	(0.8)
Balance at the end of period	$ (31.6)	$ 38.4	$ 6.8	$ (31.6)	$ 38.4	$ 6.8

	Three Months Ended September 30, 2021				Nine Months Ended September 30, 2021			
(in millions)	**Foreign Currency Translation Adjustment**	**Unrealized Gain on Available-for-sale Securities**	**Unrealized Loss on Cash Flow Hedges**	**Accumulated Other Comprehensive Income (Loss)**	**Foreign Currency Translation Adjustment**	**Unrealized Gain on Available-for-sale Securities**	**Unrealized Loss on Cash Flow Hedges**	**Accumulated Other Comprehensive Income (Loss)**
Balance at beginning of period	$ 1.3	$ —	$ (0.6)	$ 0.7	$ 5.2	$ 0.3	$ —	$ 5.5
Other comprehensive loss before reclassifications	(4.4)	—	(0.3)	(4.7)	(8.3)	(0.3)	(1.2)	(9.8)
Amounts reclassified to net income (loss)	—	—	0.6	0.6	—	—	0.9	0.9
Balance at the end of period	$ (3.1)	$ —	$ (0.3)	$ (3.4)	$ (3.1)	$ —	$ (0.3)	$ (3.4)

Note 15. Interest Expense, Net

Interest expense, net was as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in millions)	**2022**	**2021**	**2022**	**2021**
Cash interest, net of interest rate swaps	$ 7.9	$ 8.4	$ 23.9	$ 18.9
Accretion of debt discount	0.4	7.5	1.1	29.2
Amortization of debt issuance costs	1.1	0.9	3.2	2.7
Capitalized interest	(0.2)	(0.4)	(0.9)	(4.2)
Interest expense, net of portion capitalized	9.2	16.4	27.3	46.6
Interest income	(2.4)	(0.1)	(3.3)	(0.5)
Interest expense, net	$ 6.8	$ 16.3	$ 24.0	$ 46.1

Note 16. Income Taxes

The Company's effective tax rate for the three and nine months ended September 30, 2022 was 9.0% and 0.7%, compared with 16.9% and 4.4% for the three and nine months ended September 30, 2021, respectively. Income tax benefits have not been recorded for losses in jurisdictions where valuation allowances exist against net deferred tax assets. The Company had a full valuation allowance against its net deferred tax assets in the United Kingdom and the United States at September 30, 2022 and December 31, 2021. The Company had no uncertain tax positions at September 30, 2022 and December 31, 2021.

Note 17. Net (Loss) Income Per Share

Basic net (loss) income per share is computed by dividing net (loss) income by the weighted average number of common shares outstanding for the period. Diluted net (loss) income per share is computed using the weighted average number of common shares outstanding and, when dilutive, common share equivalents. The weighted-average number of common shares used in the computation of basic and diluted net loss per share were as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	**2022**	**2021**	**2022**	**2021**
Weighted average number of common shares outstanding, basic	69,418	68,869	69,343	67,236
Stock options	—	650	—	—
Restricted stock units	—	100	—	—
Weighted average number of common shares outstanding, diluted	69,418	69,619	69,343	67,236

The number of common share equivalents excluded from the computation of diluted net (loss) income per share because either the effect would have been anti-dilutive, or the performance criteria related to the units had not yet been met, were as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	**2022**	**2021**	**2022**	**2021**
1.375% Convertible Senior Notes due November 2024	—	147	—	2,690
0.375% Convertible Senior Notes due September 2026	3,528	3,528	3,528	3,528
Restricted stock units	227	177	314	327
Stock options	595	60	602	776
Total	4,350	3,912	4,444	7,321

Note 18. Subsequent Events

In October 2022, the Company entered into an agreement to acquire real estate in Malaysia, including land and building to be constructed thereon ("the Malaysia Purchase Agreement"). The building is expected to be completed no later than January 1, 2024, at which time the Company will have the option to purchase or lease the real estate. If the Company decides to lease the real estate, it will have the option to purchase the property at any point after the commencement date of the lease and is contractually obligated to purchase the property nine months after the commencement date of the lease. Upon entering into the Malaysia Purchase Agreement, the Company made an upfront payment of $4.0 million. Total undiscounted future lease payments, including the price to purchase the asset, are approximately $15.9 million.

In August 2022, the Company entered into a $20 million uncommitted letter of credit facility. In October 2022, concurrently with the execution of the Malaysia Purchase Agreement, a $16.1 million letter of credit was issued under this facility to backstop a bank guarantee for the same amount. The bank guarantee serves as security for the building while under construction until the Company purchases the property. The Company pays interest on outstanding borrowings and commitment fees on the maximum amount available to be drawn under the letter of credit at a rate of between 1.65% and 2.25%, depending on the Company's credit rating. The letter of credit includes customary covenants, none of which are considered restrictive to the Company's operations.

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our consolidated financial statements and the accompanying notes included in this quarterly report. The following discussion may contain forward-looking statements that reflect our plans, estimates and beliefs, which are subject to risks, uncertainties and assumptions. Our actual results could differ materially from those discussed in these forward-looking statements. Factors that could cause or contribute to these differences include those discussed under the headings "Risk Factors" and "Forward-Looking Statements" in both our annual report on Form 10-K for the year ended December 31, 2021 and in this quarterly report.

Overview

We are primarily engaged in the development, manufacture and sale of our proprietary Omnipod System, a continuous insulin delivery system for people with insulin-dependent diabetes. The Omnipod System features a small, lightweight, self-adhesive disposable tubeless Omnipod (the "Pod") device that is worn on the body for up to three days at a time; and its wireless companion, the handheld PDM/Controller. The Omnipod System, which features discreet and easy-to-use devices, communicates wirelessly, provides for virtually pain-free automated cannula insertion and eliminates the need for MDI therapy or the use of pump and tubing. We believe that the Omnipod System's unique proprietary design and features allow people with insulin-dependent diabetes to manage their diabetes with unprecedented freedom, comfort, convenience and ease.

In addition to the diabetes market space, we have partnered with pharmaceutical and biotechnology companies to tailor the Omnipod System technology platform for the delivery of subcutaneous drugs across other therapeutic areas. Most of our drug delivery revenue currently consists of sales of pods to Amgen for use in the Neulasta® Onpro® kit, a delivery system for Amgen's Neulasta to help reduce the risk of infection after intense chemotherapy.

Our mission is to improve the lives of people with diabetes. To assist in achieving this mission, we are focused on the following key strategic imperatives:

- expanding access and awareness;
- delivering consumer-focused innovation;
- growing our global addressable market; and
- driving operational excellence.

Our long-term financial objective is to sustain profitable growth. To achieve this goal, our efforts have been focused on launching our Omnipod 5® Automated Insulin Delivery System ("Omnipod 5"), which in January 2022, received U.S. Food and Drug Administration ("FDA") clearance for individuals aged six years and older with type 1 diabetes. Our limited market release of Omnipod 5 began in February and in August we launched our full market release. Accordingly, Omnipod 5 is now available through retail pharmacies. Additionally, during the quarter, the indication for Omnipod 5 was expanded to include individuals aged two to five. We are also working to bring Omnipod 5 to our international markets. We recently received CE Mark approval under the European Medical Device Regulation and we are currently focused on further building our international teams and advancing our regulatory, reimbursement and market development efforts. We expect to launch Omnipod 5 in our first international market in 2023 and to continue our international roll out more broadly in 2024.

Additionally, we continue to increase our presence within our existing markets and expand internationally in a targeted and strategic manner. We opened an office in Dubai to serve as our primary local presence and regional infrastructure in the Middle East, launched Omnipod in Saudi Arabia, and expanded into the United Arab Emirates.

Further, we have been taking steps to further strengthen our global manufacturing capabilities. We are optimizing our operations in China by consolidating our production in that region into one location. We also broke ground on a new manufacturing plant in Malaysia to support our international expansion strategy, further ensure product supply and drive higher gross margins over time.

Finally, we plan to continue to expand awareness of and access to our products, while also focusing on our product development efforts. Our direct to consumer advertising programs continue to drive increased awareness of Omnipod. To accelerate our efforts to secure reimbursement for Omnipod 5, we are currently enrolling individuals in a randomized control trial in France and the U.S. Our product development efforts include focusing on automated insulin delivery ("AID") offerings, including choice of continuous glucose monitor and smartphone integration. In addition, we continue to focus on enhancing the customer experience through digital product and data capabilities. We have also developed a basal-only Pod for individuals with type 2 diabetes and expect to submit our 510(k) application to the FDA in the fourth quarter. Achieving the above strategic imperatives is expected to require additional investments in certain initiatives and personnel, as well as enhancements to our supply chain operation capacity, efficiency and effectiveness.

Results of Operations

Factors Affecting Operating Results

Our Pods are intended to be used continuously for up to three days, after which it may be replaced with a new disposable Pod. The Omnipod System's unique patented design allow us to provide pump therapy at a relatively low or no up-front investment, which reduces the risk to third-party payors in the U.S., compared to tubed insulin pumps. As we grow our customer base, we expect to generate an increasing portion of our revenues through recurring sales of our disposable Pods, which provides predictable recurring revenue.

We continue to experience constrained supply and supply chain disruption; however, to date we have been able to successfully mitigate this disruption and ensure uninterrupted supply to our customers by increasing our inventory levels and taking other measures. While our mitigation efforts and inflation are expected to negatively impact gross margins and net income throughout the year, we intend to continue to work to improve productivity to help offset these costs.

Revenue

	Three Months Ended September 30,				
(dollars in millions)	2022	2021	Percent Change	Currency Impact	Constant Currency [1]
U.S. Omnipod	$ 238.1	$ 167.2	42.4 %	— %	42.4 %
International Omnipod	88.0	93.1	(5.5)%	(14.4)%	8.9 %
Total Omnipod	326.1	260.3	25.3 %	(5.2)%	30.5 %
Drug Delivery	14.7	15.3	(3.9)%	— %	(3.9)%
Total revenue	$ 340.8	$ 275.6	23.7 %	(4.8)%	28.5 %

	Nine Months Ended September 30,				
(dollars in millions)	2022	2021	Percent Change	Currency Impact	Constant Currency [1]
U.S. Omnipod	$ 608.6	$ 461.0	32.0 %	— %	32.0 %
International Omnipod	272.8	274.6	(0.7)%	(10.8)%	10.1 %
Total Omnipod	881.4	735.6	19.8 %	(4.0)%	23.8 %
Drug Delivery	54.2	55.5	(2.3)%	— %	(2.3)%
Total revenue	$ 935.6	$ 791.1	18.3 %	(3.7)%	22.0 %

[1] Constant currency revenue growth is a non-GAAP financial measure which should be considered supplemental to, and not a substitute for, our reported financial results prepared in accordance with GAAP. See "Management's Use of Non-GAAP Measures."

Total revenue for the three months ended September 30, 2022 increased $65.2 million, or 23.7%, to $340.8 million, compared with $275.6 million for the three months ended September 30, 2021. Constant currency revenue growth of 28.5% was primarily driven by higher volume and, to a lesser extent, favorable sales channel mix.

Total revenue for the nine months ended September 30, 2022 increased $144.5 million, or 18.3%, to $935.6 million, compared with $791.1 million for the nine months ended September 30, 2021. Constant currency revenue growth of 22.0% was primarily driven by higher volume and, to a lesser extent, favorable sales channel mix.

U.S. Omnipod

U.S. Omnipod revenue for the three months ended September 30, 2022 increased $70.9 million, or 42.4%, to $238.1 million, compared with $167.2 million for the three months ended September 30, 2021. This increase was primarily due to higher volumes driven by growing our customer base and, to a lesser extent, growth through the pharmacy channel, where Pods have a higher average selling price due in part to the fact that we offer the PDM/Controller for no charge. This increase was also driven by conversions to Omnipod 5 as users generally fill both their starter kit and their first month of refills simultaneously.

U.S. Omnipod revenue for the three months ended September 30, 2022 includes $58.9 million of related party revenue, compared with $13.8 million for the three months ended September 30, 2021. The $45.1 million increase primarily resulted from growth through the pharmacy channel, and to a lesser extent, a shift in certain revenues from one distributor to another.

U.S. Omnipod revenue for the nine months ended September 30, 2022 increased $147.6 million, or 32.0%, to $608.6 million, compared with $461.0 million for the nine months ended September 30, 2021. This increase was primarily due to higher volumes driven by growing our customer base and, to a lesser extent, growth through the pharmacy channel, where Pods have a higher average selling price due in part to the fact that we offer the PDM/Controller for no charge. This increase was also driven by conversions to Omnipod 5 as users generally fill both their starter kits and their first month of refills simultaneously.

U.S. Omnipod revenue for the nine months ended September 30, 2022 includes $162.8 million of related party revenue, compared with $19.3 million for the nine months ended September 30, 2021. The $143.5 million increase primarily resulted from a shift in certain revenues from one distributor to another, and to a lesser extent, growth through the pharmacy channel.

For full year 2022, we expect strong U.S. Omnipod revenue, primarily driven by new customer starts and conversions to Omnipod 5, and, to a lesser extent, the continued increase in Omnipod DASH sales volume, both of which are sold through the pharmacy channel.

International Omnipod

International Omnipod revenue for the three months ended September 30, 2022 decreased $5.1 million, or 5.5%, to $88.0 million, compared with $93.1 million for the three months ended September 30, 2021. Excluding the 14.4% unfavorable impact of currency exchange, the remaining 8.9% increase in revenue was primarily due to higher volumes as we continue to expand awareness and access to Omnipod DASH, partially offset by increased competition from AID systems.

International Omnipod revenue for the nine months ended September 30, 2022 decreased $1.8 million, or 0.7%, to $272.8 million, compared with $274.6 million for the nine months ended September 30, 2021. Excluding the 10.8% unfavorable impact of currency exchange, the remaining 10.1% increase in revenue was primarily due to higher volumes as we continue to expand awareness and access to Omnipod DASH, partially offset by increased competition from AID systems.

For full year 2022, we expect International Omnipod revenue to be relatively level. The unfavorable impacts of currency exchange and competition from AID systems are expected to be offset by continued volume growth and market penetration aided by the ongoing adoption of Omnipod DASH throughout our international markets.

Drug Delivery

Drug Delivery revenue for the three months ended September 30, 2022 of $14.7 million was relatively level compared with $15.3 million for the three months ended September 30, 2021.

Drug Delivery revenue for the nine months ended September 30, 2022 of $54.2 million was relatively level compared with $55.5 million for the nine months ended September 30, 2021. For full year 2022, we expect Drug Delivery revenue to decline as production levels were elevated during the pandemic.

Operating Expenses

	Three Months Ended September 30,			
	2022		2021	
(dollars in millions)	**Amount**	**Percent of Revenue**	**Amount**	**Percent of Revenue**
Cost of revenue	$ 152.5	44.7 %	$ 86.9	31.5 %
Research and development expenses	$ 45.0	13.2 %	$ 37.5	13.6 %
Selling, general and administrative expenses	$ 140.4	41.2 %	$ 117.5	42.6 %

	Nine Months Ended September 30,			
	2022		2021	
(dollars in millions)	**Amount**	**Percent of Revenue**	**Amount**	**Percent of Revenue**
Cost of revenue	$ 347.3	37.1 %	$ 252.2	31.9 %
Research and development expenses	$ 130.7	14.0 %	$ 118.3	15.0 %
Selling, general and administrative expenses	$ 443.5	47.4 %	$ 344.3	43.5 %

Cost of Revenue

Cost of revenue for the three months ended September 30, 2022 increased $65.6 million, or 75.5%, to $152.5 million, compared with $86.9 million for the three months ended September 30, 2021. Gross margin was 55.3% for the three months ended September 30, 2022, compared with 68.5% for the three months ended September 30, 2021. The 13.2 point decrease in gross margin was primarily driven by a $36.8 million charge, or 10.8 points, associated with the voluntary medical device correction notice we issued in October for the Omnipod DASH PDM relating to its battery. The decrease was also driven by higher expected production costs in the U.S. as manufacturing continues to ramp and become a larger portion of our total production and increased costs associated with the manufacture of Drug Delivery pods. To a lesser extent, higher costs associated with Omnipod 5 production also contributed to the decline in margin. These decreases were partially offset by higher average selling price due to growth in the pharmacy channel.

Cost of revenue for the nine months ended September 30, 2022 increased $95.1 million, or 37.7%, to $347.3 million, compared with $252.2 million for the nine months ended September 30, 2021. Gross margin was 62.9% for the nine months ended September 30, 2022, compared with 68.1% for the nine months ended September 30, 2021. The 520 basis point decrease in gross margin was primarily driven by a $36.8 million charge, or 390 basis points, related to the voluntary medical device correction. The decrease was also driven by higher expected production costs in the U.S. as manufacturing continues to ramp and become a larger portion of our total production. To a lesser extent higher costs associated with Omnipod 5 production contributed to the decline in margin. These decreases were partially offset by higher average selling price due to growth in the pharmacy channel and improved manufacturing efficiencies.

For full year 2022, we expect gross margin to be in the range of 63% to 64%, including the $36.8 million charge related to the voluntary medical device correction. We anticipate gross margin will also be negatively impacted by higher costs in the U.S. as manufacturing continues to ramp and become a larger portion of our total production, higher costs associated with Omnipod 5, and unfavorable product line mix from lower Drug Delivery revenue. We believe these higher costs will be partially offset by increased volume in the pharmacy channel and improved manufacturing efficiencies.

Research and Development Expenses

Research and development expenses for the three months ended September 30, 2022 increased $7.5 million, or 20.0%, to $45.0 million, compared with $37.5 million for the three months ended September 30, 2021. The increase was primarily due to year-over-year headcount additions to support our continued investment in development of Omnipod products.

Research and development expenses for the nine months ended September 30, 2022 increased $12.4 million, or 10.5%, to $130.7 million, compared with $118.3 million for the nine months ended September 30, 2021. The increase was primarily due to year-over-year headcount additions to support our continued investment in development of Omnipod products, partially offset by lower outside services used for clinical activities. We expect research and development spending in 2022 to increase compared with 2021 as we continue to invest in advancing our innovation and contend with inflation.

Selling, General and Administrative Expenses

Selling, general and administrative expenses for the three months ended September 30, 2022 increased $22.9 million, or 19.5%, to $140.4 million, compared with $117.5 million for the three months ended September 30, 2021. The increase was primarily attributable to year-over-year headcount additions, mainly to support information technology and commercial operations, higher amortization of cloud computing implementation costs, and higher travel and entertainment expenses due to increased activity as COVID-19 restrictions have lifted. These increases were partially offset by lower litigation costs during the quarter compared to prior year.

Selling general and administrative expenses for the nine months ended September 30, 2022 increased $99.2 million, or 28.8%, to $443.5 million, compared with $344.3 million for the nine months ended September 30, 2021. The increase was primarily attributable to year-over-year headcount additions, mainly to support information technology and commercial operations and $27.3 million of legal costs related to the settlement of a patent infringement lawsuit, associated legal fees, and an estimated liability to settle a contract dispute. To a lesser extent, these increases were due to higher travel and entertainment expenses due to increased activity as COVID-19 restrictions have lifted, an increase in investments to expand market acceptance and access to the Omnipod, and higher amortization of cloud computing implementation costs. Additionally, selling, general and administrative expenses include $3.4 million of costs associated with the retirement and advisory services of our former chief executive officer.

We expect selling, general and administrative expenses to increase in 2022 compared with 2021 primarily due to investments in our sales and marketing efforts, including the launch of Omnipod 5.

Non-Operating Items

Interest Expense, Net

Net interest expense decreased $9.5 million to $6.8 million for the three months ended September 30, 2022, compared with $16.3 million for the three months ended September 30, 2021. This decrease was primarily driven by the adoption of Accounting Standards Update 2020-06, *Accounting for Convertible Debt Instruments and Contracts in an Entity's Own Equity* (“ASU 2020-06”), which eliminated most of the non-cash interest expense associated with our convertible notes. Refer to *Recently Adopted Accounting Standard* in Note 1 to the consolidated financial statements for additional information.

Net interest expense decreased $22.1 million to $24.0 million for the nine months ended September 30, 2022, compared with $46.1 million for the nine months ended September 30, 2021. This decrease was primarily driven by the adoption of ASU 2020-06 as discussed above.

Loss on Extinguishment of Debt

During the three months ended September 30, 2021, we incurred a $1.5 million loss on extinguishment of debt related to the conversion of a portion of our 1.375% Notes. During the nine months ended September 30, 2021, we incurred a $41.6 million loss on extinguishment of debt related to the repurchase and conversion of a portion of our 1.375% Notes.

Other Expense, Net

Other expense net increased $1.1 million to $1.8 million for three months ended September 30, 2022, compared with $0.7 million for the three months ended September 30, 2021. The increase was primarily driven by net realized foreign currency losses.

Other expense net increased $1.1 million to $2.6 million for the nine months ended September 30, 2022, compared with $1.5 million for the nine months ended September 30, 2021. The increase was primarily driven by net realized foreign currency losses.

Income Tax Benefit (Expense)

Income tax benefit was $0.5 million for the three months ended September 30, 2022, compared with income tax expense of $2.6 million for the three months ended September 30, 2021, resulting in effective tax rates of 9.0% and 16.9%, respectively. The decrease in the effective tax rates was primarily driven by the jurisdictional distribution of profits and losses.

Income tax benefit was $0.1 million for the nine months ended September 30, 2022, compared with an income tax benefit of $0.5 million for the nine months ended September 30, 2021, resulting in effective tax rates of 0.7% and 4.4%, respectively. The decrease in the effective tax rates was primarily driven by the jurisdictional distribution of profits and losses.

Adjusted EBITDA

The table below presents reconciliations of Adjusted EBITDA, a non-GAAP financial measure, to net (loss) income, the most directly comparable financial measure prepared in accordance with accounting principles generally accepted in the United States of America (“GAAP”):

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in millions)	**2022**	**2021**	**2022**	**2021**
Net (loss) income	$ (5.2)	$ 12.6	$ (12.4)	$ (12.4)
Interest expense, net	6.8	16.3	24.0	46.1
Income tax (benefit) expense	(0.5)	2.6	(0.1)	(0.5)
Depreciation and amortization	15.9	14.5	47.0	42.5
Stock-based compensation	9.0	8.2	27.4	25.8
Voluntary medical device correction (1)	36.8	—	36.8	—
Legal costs (2)	—	—	27.3	—
CEO transition costs (3)	—	—	3.4	—
Loss on extinguishment of debt	—	1.5	—	41.6
Adjusted EBITDA	$ 62.8	$ 55.7	$ 153.4	$ 143.1

(1) Represents total estimated costs associated with the voluntary medical device correction issued in October to replace Omnipod DASH PDMs, all of which are included in cost of revenue. Refer to Note 9 to the consolidated financial statements for additional information.

(2) Includes a $20.0 million charge in the second quarter of 2022 to settle patent infringement litigation with Roche Diabetes Care, Inc., associated legal fees, and an estimated liability to settle a contract dispute. Refer to Note 12 to the consolidated financial statements for additional information.

(3) Represents costs in the second quarter of 2022 associated with the retirement and advisory services of the former chief executive officer, including $2.3 million of accelerated stock-based compensation expense.

Non-GAAP Financial Measures

Management uses the following non-GAAP financial measures:

Constant currency revenue growth represents the change in revenue between current and prior year periods using the exchange rate in effect during the applicable prior year period. We present constant currency revenue growth because we believe it provides meaningful information regarding our results on a consistent and comparable basis. Management uses this non-GAAP financial measure, in addition to financial measures in accordance with GAAP, to evaluate our operating results. It is also one of the performance metrics that determines management incentive compensation.

Adjusted EBITDA represents net income (loss) plus net interest expense, income tax expense (benefit), depreciation and amortization, stock-based compensation and other significant transactions or events, such as legal settlements and medical device corrections, that affect the period-to-period comparability of our operating performances, as applicable. We present Adjusted EBITDA because management uses it as a supplemental measure in assessing our operating performance, and we believe that it is helpful to investors, and other interested parties as a measure of our comparative operating performance from period to period. Adjusted EBITDA is a commonly used measure in determining business value and we use it internally to report results.

These non-GAAP financial measures should be considered supplemental to, and not a substitute for, our reported financial results prepared in accordance with GAAP. In addition, the above definitions may differ from similarly titled measures used by others. Non-GAAP financial measures exclude the effect of items that increase or decrease our reported results of operations; accordingly, we strongly encourage investors to review our consolidated financial statements in their entirety.

Liquidity and Capital Resources

As of September 30, 2022, we had $722.0 million in cash and cash equivalents. Additionally, we have a $70.0 million three-year senior secured revolving credit facility (the "Credit Facility"), which expires in 2024. At September 30, 2022, no amount was outstanding under the Credit Facility. The Credit Facility contains a covenant to maintain a specified leverage ratio under certain conditions when there are amounts outstanding under the facility. It also contains other customary covenants, none of which are considered restrictive to our operations. We believe that our current liquidity will be sufficient to meet our projected operating, investing and debt service requirements for at least the next twelve months.

Debt

To finance our operations and global expansion, we have periodically issued convertible senior notes, which are convertible into our common stock. As of September 30, 2022, the following notes were outstanding:

Issuance Date	Coupon	Principal Outstanding (in millions)		Due Date	Conversion Rate [1]	Conversion Price per Share of Common Stock	
September 2019	0.375%	$	800.0	September 2026	4.4105	$	226.73

[1] Per $1,000 face value of notes

Additional information regarding our debt is provided in Note 10 to the consolidated financial statements.

Summary of Cash Flows

	Nine Months Ended September 30,			
(in millions)	**2022**		**2021**	
Cash provided by (used in):				
Operating activities	$	68.3	$	(42.6)
Investing activities		(102.7)		(46.3)
Financing activities		(25.8)		42.2
Effect of exchange rate changes on cash		(9.1)		(3.9)
Net decrease in cash, cash equivalents and restricted cash	$	(69.3)	$	(50.6)

Operating Activities

Net cash provided by operating activities of $68.3 million for the nine months ended September 30, 2022 was primarily attributable to net loss, as adjusted for depreciation and amortization, stock-based compensation expense and non-cash interest expense, partially offset by a $4.5 million working capital cash outflow. The working capital outflow was driven by a $50.8 million increase in accounts receivable, a $34.5 million increase in inventories and a $32.1 million increase in prepaid expenses and other assets, partially offset by an $89.6 million increase in accrued expenses and other liabilities and a $23.3 million increase in accounts payable. The increase in accounts receivable was primarily due to an increase in sales in the U.S. pharmacy channel, which has longer payment terms. The increase in inventories was driven by a planned inventory build. The increase in prepaid expenses and other assets was driven by the capitalization of cloud computing implementation costs and new right-of-use assets. The increase in accrued expenses and other liabilities was primarily driven by a $36.8 million estimated liability accrued during the quarter related to the voluntary medical device correction and a $30.7 million increase in rebates due to growth in the pharmacy channel and the launch of Omnipod 5. Finally, the increase in accounts payable was primarily driven by the timing of payments.

Investing Activities

Net cash used in investing activities was $102.7 million for the nine months ended September 30, 2022, compared with net cash used in investing activities of $46.3 million for the nine months ended September 30, 2021.

Capital Spending—Capital expenditures were $58.5 million and $80.1 million for the nine months ended September 30, 2022 and 2021, respectively. The $21.6 million decrease was primarily driven by less spend on manufacturing equipment, due to the addition of manufacturing capacity in the prior year. We expect capital expenditures for 2022 to remain relatively level with 2021 as we continue to invest in our global manufacturing capabilities to support our growth. We expect to fund our capital expenditures using existing cash.

Purchases and Sales of Marketable Securities—The $39.5 million decrease in cash receipts from maturities of marketable securities was driven by the prior year shift of a portion of our investment portfolio to investments classified as cash equivalents.

Acquisition of Intangible Assets—Intangible asset acquisitions were $10.4 million and $5.7 million for the nine months ended September 30, 2022 and 2021, respectively. The $4.7 million increase was primarily driven by additional investments in internal-use software projects.

Acquisition and Investments—During the nine months ended September 30, 2022, we paid $26.0 million to acquire of substantially all the assets related to the manufacture and production of SMA wire assemblies that are used in the production of Omnipods from Dynalloy, Inc. In addition, we paid $7.8 million for strategic investments in two private companies.

Financing Activities

We had $25.8 million of net cash used in financing activities for the nine months ended September 30, 2022, compared with $42.2 million cash provided by financing activities for nine months ended September 30, 2021.

Debt Issuance and Repayments—During the nine months ended September 30, 2022, we made $18.3 million in aggregate principal payments on our equipment financings, mortgage, and term loan, compared with $12.4 million for the nine months ended September 30, 2021. The $5.9 million increase is due to entering the term loan and an additional equipment financing in the second and third quarter of 2021, respectively. During the nine months ended September 30, 2021, we received net proceeds of $489.5 million from the issuance of the term loan and used $460.8 million of cash to partially fund the repurchase of a portion of our 1.375% Notes. In addition, we received net proceeds of $43.1 million from an equipment financing transaction.

Option Exercises and Employee Stock Purchase Plan Proceeds—Total proceeds from option exercises and issuance of employee stock purchase plan shares were $9.2 million and $14.4 million for the nine months ended September 30, 2022 and 2021, respectively. The $5.2 million decrease was primarily driven by option exercises in the prior year by our former chief executive officer who retired in 2018.

Payment of Taxes for Restricted Stock Net Settlements—Payments for taxes related to net restricted and performance stock unit settlements were $16.7 million and $27.6 million for the nine months ended September 30, 2022 and 2021, respectively. The $10.9 million decrease was primarily driven by vesting of performance stock units in the prior year by our former chief executive officer who retired in 2018.

Commitments and Contingencies

We are engaged in negotiations over a contractual dispute involving in-licensed intellectual property. Offers to settle the dispute have been made by both parties ranging from $5.7 million to $36 million. In connection with discussions to resolve this matter, during the nine months ended September 30, 2022, we accrued an estimated liability of $5.7 million. The ultimate resolution of this matter is uncertain and could have a material effect on our results of operations.

Legal Proceedings

The significant estimates and judgments related to establishing litigation reserves are discussed under “Legal Proceedings” in Note 12 to the consolidated financial statements included in this Form 10-Q.

Off-Balance Sheet Arrangements

As of September 30, 2022, we had various letters of credit totaling $1.6 million, none of which is individually significant.

In August 2022, the Company entered into a $20 million uncommitted letter of credit facility. In October 2022, in conjunction with the execution of an agreement to acquire real estate in Malaysia, including land and building, a letter of credit of $16.1 million was issued under this facility to backstop a bank guarantee for the same amount. The bank guarantee serves as security for the building while under construction. Additional information regarding our debt is provided in Note 18 to the consolidated financial statements.

Critical Accounting Policies and Estimates

The preparation of our consolidated financial statements in conformity with GAAP requires management to use judgment in making estimates and assumptions that affect the reported amounts of assets, liabilities, revenue and expenses, and related disclosure of contingent assets and liabilities.

Our accounting policies for revenue recognition and contingencies are based on, among other things, judgments and assumptions made by management that include inherent risks and uncertainties. There have been no significant changes to the above critical accounting policies or in the underlying accounting assumptions and estimates used in such policies from those disclosed in our annual consolidated financial statements and accompanying notes included in our Annual Report on Form 10-K for the year ended December 31, 2021, except as described below.

Product Warranty

We provide a four-year warranty on our PDMs sold in the United States and Europe and a five-year warranty on PDMs sold in Canada and may replace Pods that do not function in accordance with product specifications. We estimate our warranty obligation at the time the product is shipped based on historical experience and the estimated cost to service the claims. Warranty expense is recorded in cost of goods sold in the consolidated statements of operations. Costs to service the claims reflect the current product cost. Since we continue to introduce new products and versions, the anticipated performance of the product over the warranty period is also considered in estimating warranty reserves. Changes to the actual replacement rates, which are evaluated quarterly, could have a material impact on our estimated warranty reserve.

In October 2022, we issued a voluntary medical device correction notice for the Omnipod DASH PDM related to its battery. In connection with this issue, we accrued a warranty reserve of $36.8 million, of which $10.5 million is based on replacing all Omnipod DASH PDMs older than 18 months. These older PDMs have an increased likelihood of experiencing a battery issue before we have an updated Omnipod DASH PDM ready to ship to all DASH customers. Changes to the number of Omnipod DASH PDMs replaced prior to the shipment of updated Omnipod DASH PDMs could have a material impact on our estimated warranty reserve related to this issue.

FORWARD-LOOKING STATEMENTS

This quarterly report on Form 10-Q contains forward-looking statements. Forward-looking statements relate to future events or our future financial performance. We generally identify forward looking statements by terminology such as “may,” “will,” “should,” “expects,” “plans,” “anticipates,” “could,” “intends,” “targets,” “projects,” “contemplates,” “believes,” “estimates,” “predicts,” “potential” or “continue” or the negative of these terms or other similar words. These statements are only predictions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, results of operations and financial condition.

The outcomes of the events described in these forward-looking statements are subject to risks, uncertainties and assumptions. These risks and uncertainties include, but are not limited to:

- adverse changes in general economic conditions as well as risks associated with public health crises and pandemics, such as the COVID-19 global pandemic, government actions and restrictive measures implemented in response, supply chain disruptions, delays in clinical trials, and other impacts to the business;
- dependence on a principal product platform;
- ability to maintain and grow our customer base, scale our business to support revenue growth, maintain an effective sales force and expand our distribution network;
- ability to secure and retain adequate coverage or reimbursement from third-party payors;
- impact of healthcare reform laws;
- impact of competitive products, technological change, product innovation and ability to design, develop, manufacture and commercialize future products;
- changes to or termination of our license to incorporate a blood glucose meter into the Omnipod System or inability to enter into new license or other agreements with respect to the Omnipod System’s current or future features;
- challenges to the future development of our non-insulin drug delivery product line;
- international business risks, including regulatory, commercial and logistics risks;
- supply problems or price fluctuations with sole source or third-party suppliers on which we are dependent;
- failure to retain key suppliers and/or supplier pricing discounts and achieve satisfactory gross margins;
- ability to protect our intellectual property and other proprietary rights and potential conflicts with the intellectual property of third parties;
- adverse regulatory or legal actions relating to the Omnipod System or future products;
- failure of our contract manufacturer or component suppliers to comply with the FDA’s quality system regulations;
- potential adverse impacts resulting from a recall, or discovery of serious safety issues, product liability lawsuits relating to off-label use, the potential violation of anti-bribery/anti-corruption laws, laws and regulations regarding privacy and data protection, and breaches or failures of our product or information technology systems, including by cyberattack;
- unfavorable results of clinical studies or future publication of articles or announcement of positions by diabetes associations or other organizations that are unfavorable;
- the concentration of manufacturing operations and storage of inventory in a limited number of locations;

- loss of employees or inability to identify and recruit new employees;
- risks associated with potential future acquisitions or investments in new businesses;
- ability to generate sufficient cash to service our indebtedness or raise additional funds on acceptable terms or at all;
- the volatility of the trading price of our common stock;
- risks related to the conversion of any of outstanding Convertible Senior Notes; and
- potential limitations on our ability to use our net operating loss carryforwards.

The risk factors discussed in “Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2021 and in this Quarterly Report could cause our results to differ materially from those expressed in forward-looking statements. In addition, there may be other risks and uncertainties that we are unable to predict at this time or that we currently do not expect to have a material adverse effect on our business. Actual results could differ materially from those projected in the forward-looking statements; accordingly, you should not rely upon forward-looking statements as predictions of future events. We expressly disclaim any obligation to update these forward-looking statements other than as required by law.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Refer to “Part II. Item 7A. Quantitative and Qualitative Disclosures About Market Risk” in our Annual Report on Form 10-K for the year ended December 31, 2021 for a discussion of our market price sensitive instruments and foreign currency exchange risk.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures designed to ensure that information required to be disclosed in reports filed under the Securities Exchange Act of 1934 (“the Exchange Act”), as amended, is recorded, processed, summarized and reported within the specified time periods, and that such information is accumulated and communicated to management, including our chief executive officer and chief financial officer, as appropriate, to allow timely decisions regarding required disclosure.

Our management, with the participation of our chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of September 30, 2022. Based on the evaluation, our chief executive officer and chief financial officer concluded that, as of that date, our disclosure controls and procedures were effective.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting during the three months ended September 30, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings

Information regarding our material pending legal proceedings, which is incorporated herein by reference, is provided in Note 12 to the condensed consolidated financial statements in this Form 10-Q.

Item 1A. Risk Factors

Refer to the “Risks Factors” section in our Annual Report on Form 10-K for the year ended December 31, 2021 for a discussion of risks to which our business, financial condition, results of operations and cash flows are subject. There have been no material changes to the risk factors disclosed in the aforementioned Annual Report.

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

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

Number	Description
31.1	Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 by Chief Executive Officer.
31.2	Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 by Chief Financial Officer.
32.1*	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, by Chief Executive Officer and Chief Financial Officer.
101	The following materials from Insulet Corporation’s Quarterly Report on Form 10-Q for the quarter ended September 30, 2022 formatted in iXBRL (Inline eXtensible Business Reporting Language), as follows:
	(i) Condensed Consolidated Balance Sheets (Unaudited) as of September 30, 2022 and December 31, 2021
	(ii) Condensed Consolidated Statements of Operations (Unaudited) for the Three and Nine Months Ended September 30, 2022 and 2021
	(iii) Condensed Consolidated Statements of Comprehensive (Loss) Income (Unaudited) for the Three and Nine Months Ended September 30, 2022 and 2021
	(iv) Condensed Consolidated Statements of Stockholders’ Equity (Unaudited) for the Three and Nine Months Ended September 30, 2022 and 2021
	(v) Condensed Consolidated Statements of Cash Flows (Unaudited) for the Nine Months Ended September 30, 2022 and 2021
	(vi) Condensed Notes (Unaudited) to Consolidated Financial Statements
*	Furnished herewith.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

	INSULET CORPORATION (Registrant)
Date: November 3, 2022	/s/ James R. Hollingshead James R. Hollingshead Chief Executive Officer (Principal Executive Officer)
Date: November 3, 2022	/s/ Wayde McMillan Wayde McMillan Chief Financial Officer (Principal Financial Officer)

EXHIBIT 31.1

CERTIFICATION

I, James R. Hollingshead, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Insulet Corporation;
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 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.

/s/ James R. Hollingshead
James R. Hollingshead
Chief Executive Officer

Date: November 3, 2022

EXHIBIT 31.2

CERTIFICATION

I, Wayde McMillan, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Insulet Corporation;
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 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.

/s/ Wayde McMillan
Wayde McMillan
Chief Financial Officer

Date: November 3, 2022

EXHIBIT 32.1

**CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

Pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, each of the undersigned officers of Insulet Corporation, a Delaware corporation (the "Company"), does hereby certify with respect to the Quarterly Report of the Company on Form 10-Q for the period ended September 30, 2022, as filed with the Securities and Exchange Commission (the "Report") that, to their knowledge:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ James R. Hollingshead
James R. Hollingshead
Chief Executive Officer

Date: November 3, 2022

/s/ Wayde McMillan
Wayde McMillan
Chief Financial Officer

Date: November 3, 2022