UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2023

OR

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

For the transition period from to

Commission file number: 001-37474

Conformis, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**56-2463152**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)
600 Technology Park Drive Billerica, MA	**01821**
(Address of principal executive offices)	(Zip Code)

(781) 345-9001
(Registrant's telephone number, including area code)

(Former name, former address and former fiscal year, if changed since last report)

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, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer" and "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, $0.00001 par value	CFMS	The Nasdaq Capital Market

As of April 30, 2023, there were 7,495,960 shares of Common Stock, $0.00001 par value per share, outstanding. The number of shares outstanding takes in account the 1-for-25 reverse stock split that was consummated on November 9, 2022.

Conformis, Inc.

INDEX

PART I - FINANCIAL INFORMATION

Item 1. FINANCIAL STATEMENTS

CONFORMIS, INC. AND SUBSIDIARIES
Consolidated Balance Sheets
(in thousands, except share and per share data)

	March 31, 2023	December 31, 2022
	(unaudited)	
Assets		
Current Assets		
Cash and cash equivalents	$ 37,786	$ 48,667
Accounts receivable, net	8,552	9,773
Royalty and licensing receivable	120	134
Inventories, net	19,490	18,910
Prepaid expenses and other current assets	1,671	1,785
Total current assets	67,619	79,269
Property and equipment, net	8,060	8,154
Operating lease right-of-use assets	5,696	6,078
Other Assets		
Restricted cash	462	462
Other long-term assets	86	85
Total assets	$ 81,923	$ 94,048
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 4,164	$ 4,163
Accrued expenses	5,726	7,978
Operating lease liabilities	1,952	1,932
Total current liabilities	11,842	14,073
Other long-term liabilities	283	230
Long-term debt, less debt issuance costs	20,601	20,563
Operating lease liabilities	4,572	5,003
Total liabilities	37,298	39,869
Commitments and contingencies		
Stockholders’ equity		
Preferred stock, $0.00001 par value:		
Authorized: 5,000,000 shares authorized at March 31, 2023 and December 31, 2022; no shares issued and outstanding as of March 31, 2023 and December 31, 2022	—	—
Common stock, $0.00001 par value:		
Authorized: 20,000,000 shares authorized at March 31, 2023 and December 31, 2022; 7,497,138 and 7,502,462 shares issued and outstanding at March 31, 2023 and December 31, 2022, respectively	—	—
Additional paid-in capital	635,268	634,647
Accumulated deficit	(590,895)	(581,324)
Accumulated other comprehensive income	252	856
Total stockholders’ equity	44,625	54,179
Total liabilities and stockholders’ equity	$ 81,923	$ 94,048

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

CONFORMIS, INC. AND SUBSIDIARIES

Consolidated Statements of Operations
(unaudited)
(in thousands, except share and per share data)

	Three Months Ended March 31,	
	2023	**2022**
Revenue		
Product	$ 12,691	$ 14,884
Royalty and licensing	146	667
Total revenue	12,837	15,551
Cost of revenue	7,734	9,810
Gross profit	5,103	5,741
Operating expenses		
Sales and marketing	5,051	6,665
Research and development	2,458	4,479
General and administrative	7,023	9,333
Total operating expenses	14,532	20,477
Loss from operations	(9,429)	(14,736)
Other income and expenses		
Interest income	9	17
Interest expense	(637)	(451)
Foreign currency exchange transaction income (loss)	468	(827)
Total other expenses	(160)	(1,261)
Loss before income taxes	(9,589)	(15,997)
Income tax (benefit) provision	(18)	34
Net loss	$ (9,571)	$ (16,031)
Net loss per share		
Basic and diluted*	$ (1.32)	$ (2.24)
Weighted average common shares outstanding		
Basic and diluted*	7,253,645	7,167,171

*Adjusted for the 1-for-25 reverse stock split

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

CONFORMIS, INC. AND SUBSIDIARIES

Consolidated Statements of Comprehensive (Loss) Income
(unaudited)
(in thousands)

	Three Months Ended March 31,	
	2023	**2022**
Net loss	$ (9,571)	$ (16,031)
Other comprehensive (loss) income		
Foreign currency translation adjustments	(604)	737
Comprehensive loss	$ (10,175)	$ (15,294)

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

CONFORMIS, INC. AND SUBSIDIARIES

Consolidated Statements of Changes in Stockholders' Equity
(unaudited)
(in thousands, except share and per share data)

	Three Months Ended March 31, 2023					
	Common Stock					
	Shares*	Par Value	Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total
Balance, December 31, 2022	7,502,462	$ —	$ 634,647	$ (581,324)	$ 856	$ 54,179
Issuance of common stock—restricted stock	(5,324)	—	—	—	—	—
Compensation expense related to issued stock options and restricted stock awards	—	—	621	—	—	621
Net loss	—	—	—	(9,571)	—	(9,571)
Other comprehensive loss	—	—	—	—	(604)	(604)
Balance, March 31, 2023	7,497,138	$ —	$ 635,268	$ (590,895)	$ 252	$ 44,625

	Three Months Ended March 31, 2022					
	Common Stock					
	Shares*	Par Value	Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive (Loss) Income	Total
Balance, December 31, 2021	7,441,668	$ 2	$ 632,513	$ (530,851)	$ (1,112)	$ 100,552
Issuance of common stock—restricted stock	(28,387)	—	—	—	—	—
Compensation expense related to issued stock options and restricted stock awards	—	—	736	—	—	736
Net loss	—	—	—	(16,031)	—	(16,031)
Other comprehensive income	—	—	—	—	737	737
Balance, March 31, 2022	7,413,281	$ 2	$ 633,249	$ (546,882)	$ (375)	$ 85,994

*Adjusted for the 1-for-25 reverse stock split

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

CONFORMIS, INC. AND SUBSIDIARIES

Consolidated Statements of Cash Flows
(unaudited)
(in thousands)

	Three Months Ended March 31,	
	2023	2022
Cash flows from operating activities:		
Net loss	$ (9,571)	$ (16,031)
Adjustments to reconcile net loss income to net cash used in operating activities:		
Depreciation and amortization expense	921	1,107
Stock-based compensation expense	621	736
Unrealized foreign exchange (gain) loss	(476)	783
Non-cash lease expense	381	367
Provision for credit losses	84	77
Impairment of long-term assets	80	—
Non-cash interest expense	39	41
Changes in operating assets and liabilities:		
Accounts receivable	1,137	(1,136)
Royalty and licensing receivable	14	(372)
Inventories	(580)	(447)
Prepaid expenses and other assets	113	(120)
Accounts payable, accrued expenses and other liabilities	(2,610)	(2,107)
Net cash used in operating activities	(9,847)	(17,102)
Cash flows from investing activities:		
Acquisition of property and equipment	(907)	(692)
Net cash used in investing activities	(907)	(692)
Cash flows from financing activities:		
Net cash provided by financing activities	—	—
Foreign exchange effect on cash and cash equivalents	(127)	(45)
Decrease in cash, cash equivalents and restricted cash	(10,881)	(17,839)
Cash, cash equivalents and restricted cash beginning of period	49,129	101,118
Cash, cash equivalents and restricted cash end of period	$ 38,248	$ 83,279
Supplemental information:		
Cash paid for interest	545	356
Non cash investing and financing activities:		
Operating leases right-of-use assets obtained in exchange for lease obligations	—	63

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

Note A—Organization and Basis of Presentation

Conformis, Inc. (together with its subsidiaries, collectively, the "Company") is a medical technology company that uses its proprietary iFit Image-to-Implant technology platform to develop, manufacture and sell joint replacement implants that are individually sized and shaped, which the Company refers to as personalized, individualized, or sometimes as customized, to fit and conform to each patient's unique anatomy. The Company also offers Identity Imprint, a new line of total knee replacement products that utilizes a proprietary algorithm to select the implant size that most closely meets the geometric and anatomic requirements of the patient's knee. Conformis' sterile, just-in-time, Surgery-in-a-Box delivery system is available with all of its implants and personalized, single-use instruments. The Company's proprietary iFit technology platform is potentially applicable to all major joints.

The Company was incorporated in Delaware and commenced operations in 2004. The Company introduced its iUni and iDuo in 2007, its iTotal CR in 2011, its iTotal PS in 2015, its Conformis hip system in 2018, and its Identity Imprint in 2021. The Company has its corporate offices in Billerica, Massachusetts.

Liquidity and operations

These consolidated financial statements as of March 31, 2023 and for the three months ended March 31, 2023 and 2022, and related interim information contained within the notes to the Consolidated Financial Statements, have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business.

Since the Company's inception in June 2004, it has financed its operations primarily through private placements of preferred stock, its initial public offering in July 2015, other equity financings, debt and convertible debt financings, equipment purchase loans, patent licensing, and product revenue beginning in 2007. The Company has recurring losses for the three months ended March 31, 2023 and 2022. At March 31, 2023, the Company had an accumulated deficit of $590.9 million and cash and cash equivalents of $37.8 million, and $0.5 million in restricted cash allocated to a lease deposit.

The Company currently expects that its existing cash and cash equivalents as of the date hereof and anticipated revenue from operations will enable the Company to fund its operations, capital expenditure requirements and debt service for the 12 months following the date of this filing. However, for the Company to meet its long-term operating plan, the Company expects that revenue growth, margin improvements and leveraging operating expenses will be necessary. To enhance its liquidity position, the Company has taken measures to manage its expenses, will continue to monetize the Company's intellectual property, and will evaluate additional equity or debt financing opportunities. Whether the Company ultimately consummates such an additional equity and/or debt financing will depend on many factors, including market conditions. It cannot be assured that the Company will be successful in raising such additional financing, or in achieving the revenue growth, margin improvements and operating expense leverage.

On October 26, 2022, the Company's Board of Directors approved a 1-for-25 reverse stock split of the Company's common stock (the "Reverse Stock Split") which was implemented in November 2022. All share and per share information has been retroactively adjusted to give effect to the Reverse Stock Split for all periods presented, unless otherwise indicated. There were no fractional shares issued as a result of the Reverse Split. All fractional shares as a result of the Reverse Split were rounded up to the nearest whole number. The total number of the Company's authorized shares of preferred stock was not affected by the foregoing. However, the total number of the Company's authorized common stock was decreased to 20,000,000 after giving effect to the Reverse Stock Split. For further information regarding this Reverse Stock Split, see "Note J—Stockholders' Equity".

On November 22, 2021, the Company and its subsidiary, ImaTx, Inc., entered into a Credit and Security Agreement (the "New Credit Agreement") with MidCap Financial Trust ("MidCap"), as agent, and certain lender parties thereto. The New Credit Agreement provides for a five-year, $21 million secured term loan facility (the "Term Facility"). The New Credit Agreement refinanced and replaced the Company's prior 2019 secured credit facility with Innovatus (the "2019 Secured Loan Agreement").

The Company experienced significantly decreased demand for its products during the pandemic as healthcare providers and individuals de-prioritized and deferred medical procedures deemed to be elective, such as joint replacement procedures, which is expected to continue to have a significant negative effect on the Company's revenue. In the third and fourth quarters of 2021, the Company experienced higher levels of deferred and rescheduled knee and hip procedures as a result of the surge in COVID-19 cases associated with the Delta and Omicron variants. During the first quarter of 2022, United States case counts peaked in January and then trended downward for the remainder of the year. The future progression of the pandemic remains uncertain. To the extent that individuals in these markets continue to de-prioritize or delay deferrable procedures as a result of the COVID-19 pandemic or otherwise, our business, cash flows, financial condition and results of operations could continue to be negatively affected.

Basis of presentation and use of estimates

The preparation of consolidated financial statements in conformity with generally accepted accounting principles in the United States ("U.S. GAAP") requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements, and the reported amounts of revenue and expenses during the reporting periods. The most significant estimates used in these consolidated financial statements include revenue recognition, accounts receivable valuation, inventory reserves, impairment assessments, income tax reserves and related allowances, and the lives of property and equipment. Actual results may differ from those estimates. The interim financial statements should be read in conjunction with the audited financial statements and notes thereto included in the Company’s Annual Report on Form 10-K for the year ended December 31, 2022.

Unaudited Interim Financial Information

The accompanying Interim Consolidated Financial Statements as of March 31, 2023 and for the three months ended March 31, 2023 and 2022, and related interim information contained within the notes to the Consolidated Financial Statements are unaudited. These unaudited interim consolidated financial statements have been prepared in accordance with GAAP. In management’s opinion, the unaudited interim consolidated financial statements have been prepared on the same basis as the audited financial statements and include all adjustments (including normal recurring adjustments) necessary for the fair presentation of the Company’s financial position as of March 31, 2023, results of operations for and stockholders' equity for the three months ended March 31, 2023 and 2022, and comprehensive loss, and cash flows for the three months ended March 31, 2023 and 2022. The results for the three months ended March 31, 2023 are not necessarily indicative of the results expected for the full year or any interim period.

Note B—Summary of Significant Accounting Policies

The Company's financial results are affected by the selection and application of accounting policies and methods. There were no material changes in the three months ended March 31, 2023 to the application of significant accounting policies and estimates as described in its audited consolidated financial statements for the year ended December 31, 2022.

Concentrations of credit risk and other risks and uncertainties

Financial instruments that subject the Company to credit risk primarily consist of cash, cash equivalents, and accounts receivable. The Company maintains the majority of its cash with accredited financial institutions which mitigates potential risks related to concentration. The Company had $0.7 million as of March 31, 2023 and $1.2 million as of December 31, 2022 held in foreign bank accounts that are not federally insured. In addition, the cash held in U.S bank accounts exceeds the federally insured limits.

The Company and its contract manufacturers rely on sole source suppliers and service providers for certain components. A shortage or stoppage of shipments of the materials or components that the Company purchases could result in a delay in production or adversely affect the Company’s operating results.

For the three months ended March 31, 2023, no customer represented greater than 10% of total revenue. For the three months ended March 31, 2022, no customer represented greater than 10% of total revenue. As of March 31, 2023 and December 31, 2022, respectively, there was no customer that represented greater than 10% of the total net receivable balance.

Principles of consolidation

The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries including ImaTx, Inc., ConforMIS Europe GmbH, ConforMIS UK Limited, ConforMIS Hong Kong Limited, Conformis India LLP, and Conformis Cares LLC. All intercompany balances and transactions have been eliminated in consolidation.

Cash, cash equivalents and restricted cash

The Company considers all highly liquid investment instruments with original maturities of 90 days or less when purchased to be cash equivalents. The Company's cash equivalents consist of demand deposits and money market accounts. Demand deposits and money market accounts are carried at cost which approximates their fair value. The Company has recorded restricted cash of $0.5 million as of March 31, 2023 and December 31, 2022. Restricted cash consisted of security provided for lease obligations.

The following table provides a reconciliation of cash, cash equivalents, and restricted cash reported within the consolidated balance sheets that sum to the total of the same such amounts shown in the consolidated statements of cash flows.

	March 31, 2023	December 31, 2022
Cash and cash equivalents	$ 37,786	$ 48,667
Restricted cash	462	462
Total cash, cash equivalents, and restricted cash shown in the statement of cash flows	$ 38,248	$ 49,129

Fair value of financial instruments

Certain of the Company's financial instruments, including cash and cash equivalents (excluding money market funds), accounts receivable, accounts payable, accrued expenses and other liabilities are carried at cost, which approximates their fair value because of the short-term maturity. The carrying value of the debt approximates fair value because the interest rate under the obligation approximates market rates of interest available to the Company for similar instruments.

Accounts receivable and allowance for credit losses

Accounts receivable consist of billed and unbilled amounts due from medical facilities or independent distributors (the "Customer"). Upon completion of a procedure, revenue is recognized and an unbilled receivable is recorded. Under Accounting Standards Codification ("ASC") Topic 606, Revenue from Contracts with Customers ("ASC 606"), an enforceable contract is met either at or prior to the procedure being performed. Upon receipt of a purchase order from the Customer, the billed receivable is recorded and the unbilled receivable is reversed. As a result, the unbilled receivable balance fluctuates based on the timing of the Company's receipt of purchase orders from the medical facilities. In estimating whether accounts receivable can be collected, the Company performs evaluations of customers and continuously monitors collections and payments and estimates an allowance for credit losses based on the aging of the underlying invoices, collections experience to date and any specific collection issues that have been identified. The allowance for credit losses is recorded in the period in which revenue is recorded or when collection risk is identified.

Inventories

Inventories consist of raw materials, work-in-process components and finished goods. Inventories are stated at the lower of cost, determined using the first-in first-out method, or net realizable value. The Company regularly reviews its inventory quantities on hand and related cost and records a provision for any excess or obsolete inventory based on its estimated forecast of product demand and existing product configurations. The Company also reviews its inventory value to determine if it reflects the lower of cost or market, based on net realizable value. Appropriate consideration is given to inventory items sold at negative gross margin, purchase commitments and other factors in evaluating net realizable value. During the three months ended March 31, 2023, the Company recognized provisions of $0.3 million and $1.6 million, respectively, to adjust its inventory value to the lower of cost or net realizable value for excess and obsolete reserves, and estimated unused product related to known and potential cancelled cases, which is included in cost of revenue.

Property and equipment

Property and equipment is stated at cost less accumulated depreciation and is depreciated using the straight-line method over the estimated useful lives of the respective assets. Leasehold improvements are amortized over their useful life or the life of the lease, whichever is shorter. Assets capitalized under capital leases are amortized in accordance with the respective class of assets and the amortization is included with depreciation expense. Maintenance and repair costs are expensed as incurred.

Long-lived assets

The Company tests impairment of long-lived assets when events or changes in circumstances indicate that the assets might be impaired. If changes in circumstances lead the Company to believe that any of its long-lived assets may be impaired, the Company will test the asset group for recoverability, by evaluating whether the estimated undiscounted cash flows, including estimated residual value, generated from the asset group are sufficient to support the carrying value of the assets. During the quarter ended March 31, 2023, the Company had experienced a significant decrease in its stock price and incurred current-period operating losses associated with its asset group, and as such, an assessment for recoverability was performed. During the three months ended March 31, 2023, the Company recognized $0.1 million in impairment charges related to unused manufacturing equipment and building improvements.

Leases

The Company has elected not to separate non-lease components from all classes of leases. Non-lease components have been accounted for as part of the single lease component to which they are related.

Leases with an anticipated term, inclusive of renewals of 12 months or less are not recorded on the balance sheet; the Company recognizes lease expense for these leases on a straight-line basis over the lease term.

The Company has elected the hindsight practical expedient to determine the lease term for existing leases. This practical expedient enables an entity to use hindsight in determining the lease term when considering options to extend and terminate leases as well as purchase the underlying assets. The operating lease right-of-use assets are subsequently assessed for impairment in accordance with the Company's accounting policy for long-lived assets.

Revenue Recognition

Product Revenue Recognition

Revenue is recognized when, or as, obligations under the terms of a contract are satisfied, which occurs when control of the promised products or services is transferred to customers. Revenue is measured as the amount of consideration the Company expects to receive in exchange for transferring products or services to a customer (“transaction price”). When determining the transaction price of a contract, an adjustment is made if payment from a customer occurs either significantly before or significantly after performance, resulting in a significant financing component. Applying the practical expedient in paragraph 606-10-32-18, the Company does not assess whether a significant financing component exists if the period between when the Company performs its obligations under the contract and when the customer pays is one year or less. None of the Company’s contracts contained a significant financing component as of March 31, 2023. Payment is typically due between 30 and 60 days from invoice.

To the extent that the transaction price includes variable consideration, such as prompt-pay discounts or rebates, the Company estimates the amount of variable consideration that should be included in the transaction price utilizing the expected value to which the Company expects to be entitled. Variable consideration is included in the transaction price if, in the Company’s judgment, it is probable that a significant future reversal of cumulative revenue under the contract will not occur. Actual amounts of consideration ultimately received may differ from the Company's estimates. Estimates of variable consideration and determination of whether to include estimated amounts in the transaction price are based largely on an assessment of the Company’s anticipated performance and all information (historical, current and forecasted) that is reasonably available.

If the contract contains a single performance obligation, the entire transaction price is allocated to the single performance obligation. Contracts that contain multiple performance obligations require an allocation of the transaction price based on the estimated relative standalone selling prices of the promised products or services underlying each performance obligation. The Company determines standalone selling prices based on observable prices or a cost-plus margin approach when one is not available. Revenue is recognized at the time the related performance obligation is satisfied by transferring control of a promised good or service to a customer. The Company's performance obligations are satisfied at the same time, typically upon surgery, therefore, product revenue is recognized at a point in time upon completion of the surgery. Since the Company does not have contracts that extend beyond a duration of one year, there is no transaction price related to performance obligations that have not been satisfied.

Certain customer contracts include terms that allow the Company to bill for orders that are cancelled after the product is manufactured and could result in revenue recognition over time. However, the impact of adopting over time revenue recognition was deemed immaterial.

Under the long-term Distribution Agreement with Stryker, the Company supplies patient specific instrumentation to Stryker and revenue is recognized at a point in time, that is, when Stryker obtains control of the products.

Unconditional rights to consideration are reported as receivables. Incidental items that are immaterial in the context of the contract are recognized as expense. The Company records a contract liability when there is an obligation to transfer goods or services to a customer for which the Company has received consideration from the customer. As of January 1, 2023, the contract liability balance was $0.2 million. There was no contract liability balance recorded as of January 1, 2022. At March 31, 2023, the Company had $0.7 million of contract liabilities recorded on the Consolidated Balance Sheets derived from contracts with customers. There were no contract assets recorded at March 31, 2023. The Company did not have any contract assets or liabilities recorded at March 31, 2022.

Royalty and Licensing Revenue Recognition

The Company receives ongoing sales-based royalties under its license agreement (the "MicroPort License Agreement") with MicroPort Orthopedics Inc., a wholly owned subsidiary of MicroPort Scientific Corporation, (collectively, "MicroPort"). Royalty revenue is recorded at the expected value of the royalty revenue.

On February 9, 2023, the Company entered into a Settlement and License Agreement with Bodycad Laboratories, Inc. ("Bodycad") and Exactech, Inc. ("Exactech"), collectively, (the "Defendants"), pursuant to which the parties have agreed to terms for resolving all of their existing patent disputes. In consideration of the licenses, releases, covenants and other immunities granted by the Company to the Defendants, the Company received an upfront payment following the execution of the Settlement and License Agreement, and will receive an additional payment by June 30, 2023. The agreement provides for the grant of the licenses, covenants-not-to-sue, releases, and other significant deliverables upon receipt of full payment from. These individual rights are not accounted for as separate performance obligations as (i) the nature of the promise, within the context of the agreement, is to transfer combined items to which the promised rights are inputs and (ii) the Company's promise to transfer each individual right described above to the Defendants is not separately identifiable from other promises in the agreement. As a result, the Company accounts for the promises in the agreement as a single performance obligation. The Defendants will legally obtain control of the licenses and other rights upon full payment to Conformis. As such, the earnings process will be completed and revenue will be recognized upon receipt of the full payment, and all other revenue recognition criteria had been met within the scope of ASC 606.

On April 8, 2021, the Company entered into a license agreement (the “License Agreement”) with Paragon 28, Inc. ("Paragon 28"), granting Paragon 28 a non-exclusive license under a subset of the Company's U.S. patents for the use of patient-specific instruments with off-the-shelf implants in Paragon 28’s APEX 3D Total Ankle Replacement System. In consideration for the license, the Company received $0.5 million upon execution of the License Agreement, another $0.5 million in October 2021, and received an additional $0.5 million from Paragon 28 on April 7, 2022. In connection with this License Agreement, the Company recognized revenue of $1.0 million during the quarter ended June 30, 2021. The remaining $0.5 million was recognized as revenue during the quarter ended March 31, 2022.

On November 8, 2022 the Company entered into a Settlement and License Agreement with Medacta USA, ("Medacta"), pursuant to which both parties have agreed to terms for resolving all of their existing patent disputes. In consideration of the licenses, releases, covenants and other immunities granted by the Company to Medacta, Medacta was required to pay the Company a fee promptly after execution of the Settlement and License Agreement, which was received in full on December 12, 2022. The agreement provides for the grant of the licenses, covenants-not-to-sue, releases, and other significant deliverables upon receipt of the payment from Medacta. These individual rights are not accounted for as separate performance obligations as (i) the nature of the promise, within the context of the agreement, is to transfer combined items to which the promised rights are inputs and (ii) the Company's promise to transfer each individual right described above to Medacta is not separately identifiable from other promises in the agreement. As a result, the Company accounts for the promises in the agreement as a single performance obligation. Medacta legally obtained control of the license and other rights upon payment to Conformis. As such, the earnings process is complete and revenue was recognized upon receipt of the payment, and all other revenue recognition criteria had been met within the scope of ASC 606. In connection with the Settlement and License Agreement, the Company recognized licensing revenue during the year ended December 31, 2022. See “Note H—Commitments and Contingencies, Legal proceedings” for further discussion of the Medacta settlement.

Disaggregation of Revenue

See "Note K—Segment and Geographic Data" for disaggregated product revenue by geography and product category.

Variable Consideration

Revenues from product sales are recorded at the net sales price (transaction price), which includes estimates of variable consideration for which reserves are established and which result from rebates that are offered within contracts between the Company and some of its customers. The amount of variable consideration which is included in the transaction price may be constrained, and is included in the net sales price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period.

The following table summarizes activity for rebate allowance reserve (in thousands):

	March 31, 2023	December 31, 2022
Beginning Balance	$ 108	$ 79
Provision related to current period sales	66	126
Payments or credits issued to customers	(66)	(97)
Ending Balance	$ 108	$ 108

Costs to Obtain and Fulfill a Contract

The Company currently expenses commissions paid for obtaining product sales. Sales commissions are paid following the manufacture and implementation of the implant. Due to the period being less than one year, the Company will apply the practical expedient, whereby the Company recognizes the incremental costs of obtaining contracts as an expense when incurred if the amortization period of the assets that the Company otherwise would have recognized is one year or less. These costs are included in sales and marketing expense. Further, the Company incurs costs to buy, build, replenish, restock, sterilize and replace the reusable instrumentation trays associated with the sale of its products and services. The reusable instrument trays are not contract specific and are used for multiple contracts and customers, therefore does not meet the criteria to capitalize under ASC 606.

Shipping and handling costs

Shipping and handling activities prior to the transfer of control to the customer (e.g., when control transfers after delivery) are considered fulfillment activities, and not performance obligations. Amounts invoiced to customers for shipping and handling are classified as revenue. Shipping and handling costs incurred are included in general and administrative expense. Shipping and handling expense was $1.1 million and $1.4 million for the three months ended March 31, 2023 and 2022, respectively.

Taxes collected from customers and remitted to government authorities

The Company's policy is to present taxes collected from customers and remitted to government authorities on a net basis and not to include tax amounts in revenue.

Research and development expense

The Company's research and development costs consist of engineering, product development, quality assurance, clinical and regulatory expense. These costs primarily relate to employee compensation, including salary, benefits and stock-based compensation. The Company also incurs costs related to consulting fees, revenue share, materials and supplies, and marketing studies, including data management and associated travel expense. Research and development costs are expensed as incurred.

Advertising expense

Advertising costs are expensed as incurred, which are included in sales and marketing. Advertising expense was $0.3 million and $0.1 million for the three months ended March 31, 2023 and 2022, respectively.

Segment reporting

Operating segments are defined as components of an enterprise about which separate financial information is available and is evaluated on a regular basis by the chief operating decision-maker, or decision-making group, in deciding how to allocate resources to an individual segment and in assessing performance of the segment. The Company's chief operating decision-maker is its chief executive officer. The Company's chief executive officer reviews financial information presented on an aggregate basis for purposes of allocating resources and evaluating financial performance. The Company has one business segment and there are no segment managers who are held accountable for operations, operating results and plans for products or components below the aggregate Company level. Accordingly, in light of the Company's current product offerings, management has determined that the primary form of internal reporting is aligned with the offering of the Conformis personalized joint replacement products and that the Company operates as one segment. See "Note K—Segment and Geographic Data."

Foreign currency translation and transactions

The assets and liabilities of the Company's foreign operations are translated into U.S. dollars at current exchange rates at the balance sheet date, and income and expense items are translated at average rates of exchange prevailing during the quarter. Net translation gains and losses are recorded in accumulated other comprehensive loss. Gains and losses from foreign currency transactions denominated in foreign currencies, including intercompany balances not of a long-term investment nature, are included in the Consolidated Statements of Operations.

Income taxes

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the consolidated financial statement carrying amounts of existing assets and liabilities and their respective tax bases, operating losses and tax credit carry forwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized as income in the period that includes the enactment date.

In evaluating the need for a valuation allowance, the Company considers all reasonably available positive and negative evidence, including recent earnings, expectations of future taxable income and the character of that income. In estimating future taxable income, the Company relies upon assumptions and estimates of future activity including the reversal of temporary differences. Presently, the Company believes that a full valuation allowance is required to reduce deferred tax assets to the amount expected to be realized.

The tax benefit from an uncertain tax position is only recognized if it is more likely than not that the tax position will be sustained on examination by the taxing authorities, based on the technical merits of the position. The tax benefits recognized in the consolidated financial statements from these positions are measured based on the largest benefit that has a greater than fifty percent likelihood of being realized upon ultimate resolution. The Company reviews its tax positions on an annual basis and more frequently as facts surrounding tax positions change. Based on these future events, the Company may recognize uncertain tax positions or reverse current uncertain tax positions, the impact of which would affect the consolidated financial statements.

The Company has operations in the U.S., Germany, the United Kingdom, and India. The operating results of German operations will be permanently reinvested in that jurisdiction. As a result, the Company has only provided for income taxes at local rates when required.

The Company is subject to U.S. federal, state, and foreign income taxes. The Company recorded a provision for income taxes of $18,000 and $34,000 for the three months ended March 31, 2023 and 2022, respectively. The Company recognizes interest and penalties related to income taxes as a component of income tax expense. As of March 31, 2023 and 2022, a cumulative balance of $6,000 and $79,000 of interest and penalties had been accrued, respectively. Please note that as result of the conclusion of a 2017 - 2019 Germany tax audit, the Company has reversed the respective uncertain tax positions for those years, resulting in a reduction of interest and penalties, as they now apply to only tax years 2020 - 2022.

The Inflation Reduction Act (IRA) was enacted on August 16, 2022. Based on review of the IRA, the Company does not expect any impact to its tax provision. In particular, the Company does not expect to pay Corporate Alternative Minimum Tax (CAMT) in future years based on its projected losses and not reaching the income thresholds. The IRA introduces a 15% CAMT for corporations whose average annual adjusted financial statement income for any consecutive three-tax-year period preceding the tax year exceeds $1 billion starting in 2023.

Stock-based compensation

The Company accounts for stock-based compensation in accordance with ASC 718, Stock Based Compensation ("ASC 718"). ASC 718 requires all stock-based payments to employees and consultants, including grants of stock options, to be recognized in the consolidated statements of operations based on their fair values. The Company uses the Black-Scholes option pricing model to determine the weighted-average fair value of options granted and recognizes the compensation expense of stock-based awards on a straight-line basis over the vesting period of the award.

The determination of the fair value of stock-based payment awards utilizing the Black-Scholes option pricing model is affected by the stock price, exercise price, and a number of assumptions, including expected volatility of the stock, expected life of the option, risk-free interest rate and expected dividends on the stock. The Company evaluates the assumptions used to value the awards at each grant date and if factors change and different assumptions are utilized, stock-based compensation expense may differ significantly from what has been recorded in the past. If there are any modifications or cancellations of the underlying unvested securities, the Company may be required to accelerate, increase or cancel any remaining unearned stock-based compensation expense.

Net loss per share

The Company calculates net loss per share in accordance with ASC 260, "Earnings per Share." Basic earnings per share (“EPS”) is calculated by dividing the net income or loss for the period by the weighted average number of common shares outstanding for the period, without consideration for common stock equivalents. Diluted EPS is computed by dividing the net income or loss for the period by the weighted average number of common shares outstanding for the period and the weighted average number of dilutive common stock equivalents outstanding for the period determined using the treasury stock method.

The following table sets forth the computation of basic and diluted earnings per share attributable to stockholders (in thousands, except share and per share data):

(in thousands, except share and per share data)	Three Months Ended March 31, 2023	2022
Numerator:		
Basic and diluted loss per share		
Net loss	$ (9,571)	$ (16,031)
Denominator:		
Basic and diluted weighted average shares*	7,253,645	7,167,171
Loss per share attributable to Conformis, Inc. stockholders:		
Basic and diluted*	$ (1.32)	$ (2.24)

*Adjusted for the 1-for-25 reverse stock split

The following table sets forth potential shares of common stock equivalents that are not included in the calculation of diluted net loss per share because to do so would be anti-dilutive as of the end of each period presented:

	Three Months Ended March 31, 2023	2022
Stock options and restricted stock awards*	933	27,401

*Adjusted for the 1-for-25 reverse stock split

Recently Adopted Accounting Standards

In June 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2016-13, “Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments,” which modifies the measurement approach for credit losses on financial assets measured on an amortized cost basis from an 'incurred loss' method to an 'expected loss' method. In November 2019, the FASB issued ASU 2019-11, “Codification Improvements to Topic 326, Financial Instruments – Credit Losses.” ASU 2019-11 is an accounting pronouncement that amends ASU 2016-13. The ASU 2019-11 amendment provides clarity and improves the codification to ASU 2016-13. The Company adopted these ASUs as of January 1, 2023. The adoption of these ASUs has not had a material impact on the Company's consolidated financial statements or related disclosures.

Note C—Accounts Receivable

Accounts receivable consisted of the following (in thousands):

	March 31, 2023	December 31, 2022
Total receivables	$ 9,249	$ 10,383
Allowance for credit losses	(697)	(610)
Accounts receivable, net	$ 8,552	$ 9,773

The beginning accounts receivable balance as of January 1, 2023 and 2022, was $9.8 million and $9.1 million, respectively. All activity within accounts receivables relate to normal operational activity from the period. Accounts receivable included unbilled receivable of $1.2 million and $1.4 million at March 31, 2023 and December 31, 2022, respectively. Write-offs related to accounts receivable were approximately $0 and $13,000 for the three months ended March 31, 2023 and 2022, respectively.

Summary of allowance for credit losses and returns activity was as follows (in thousands):

	March 31, 2023	December 31, 2022
Beginning balance	$ (610)	$ (257)
Provision for expected credit losses	(83)	(396)
Other allowances	(4)	(7)
Accounts receivable write offs	—	50
Ending balance	$ (697)	$ (610)

Note D—Inventories

Inventories consisted of the following (in thousands):

	March 31, 2023	December 31, 2022
Raw Material	$ 9,931	$ 9,699
Work in process	1,931	2,118
Finished goods	7,628	7,093
Total inventories, net	$ 19,490	$ 18,910

Note E—Property and Equipment

Property and equipment consisted of the following (in thousands):

	Estimated Useful Life (Years)	March 31, 2023	December 31, 2022
Equipment	5-7	$ 20,490	$ 20,490
Furniture and fixtures	5-7	765	765
Computer and software	3	11,090	11,037
Leasehold improvements	3-7	2,445	2,295
Reusable instruments	5	7,771	7,147
Molding and Tooling	5	489	489
Total property and equipment		43,050	42,223
Accumulated depreciation		(34,990)	(34,069)
Property and equipment, net		$ 8,060	$ 8,154

Depreciation expense related to property and equipment was $0.9 million and $1.1 million for the three months ended March 31, 2023 and 2022, respectively. For the three months ended March 31, 2023, the Company recognized $0.1 million in impairment charges related to unused manufacturing equipment and building improvements.

Note F—Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	March 31, 2023	December 31, 2022
Accrued employee compensation	$ 1,926	$ 4,279
Accrued legal expense	1,129	397
Accrued vendor charges	445	903
Accrued revenue share expense	302	791
Accrued clinical trial expense	149	342
Deferred revenue	716	215
Accrued other	1,059	1,051
	$ 5,726	$ 7,978

Note G—Leases

The Company maintains its corporate headquarters in a leased building located in Billerica, Massachusetts. The Company maintains its design and manufacturing facilities in leased buildings located in Wilmington, Massachusetts, Wallingford, Connecticut and Hyderabad, India.

The Company's leases have remaining lease terms of approximately one-to-five years, some of which include one or more options to extend the leases for up to five years per renewal. The exercise of lease renewal options is at the sole discretion of the Company. The amounts disclosed in the Consolidated Balance Sheet pertaining to right-of-use assets and lease liabilities are measured based on management's current expectations of exercising its available renewal options.

On May 11, 2021, the Company executed an amendment to extend the term of the Wilmington lease through September 30, 2027.

The Company's existing leases are not subject to any restrictions or covenants which preclude its ability to pay dividends, obtain financing, or enter into additional leases.

As of March 31, 2023, the Company had not entered into any leases which have not yet commenced which would entitle the Company to significant rights or create additional obligations.

The Company uses either its incremental borrowing rate or the implicit rate in the lease agreement as the basis to calculate the present value of future lease payments at lease commencement. The incremental borrowing rate represents the rate the Company would have to pay to borrow funds on a collateralized basis over a similar term and in a similar economic environment.

The components of lease expense and related cash flows were as follows (in thousands):

	Three Months Ended March 31,	
	2023	2022
Rent expense	$ 489	$ 479
Variable lease cost [1]	41	108
	$ 530	$ 587

(1) Variable operating lease expenses consist primarily of common area maintenance and real estate taxes for the three months ended March 31, 2023 and 2022.

As of March 31, 2023, the remaining weighted-average lease term of the operating leases was 3.6 years and the weighted-average discount rate was 6.0%.

The future minimum rental payments under these agreements as of March 31, 2023 were as follows (in thousands):

Year	Minimum Lease Payments
2023	1,816
2024	2,126
2025	1,872
2026	972
2027	741
Total lease payments	$ 7,527
Present value adjustment	(1,003)
Present value of lease liabilities	$ 6,524

Note H—Commitments and Contingencies

License and revenue share agreements

Revenue share agreements

The Company is party to revenue share agreements with certain past and present members of its scientific advisory board under which these advisors agreed to participate on a scientific advisory board and to assist with the development of the Company's personalized implant products and related intellectual property. These agreements provide that the Company will pay the advisor a specified percentage of the Company's net revenue, ranging from 0.1% to 1.33%, with respect to the Company's products on which the advisor made a technical contribution or, in some cases, products covered by one or more claims of one or more Company patents on which the advisor is a named inventor. The specific percentage is determined by reference to product classifications set forth in the agreement and is often tiered based on the level of net revenue collected by the Company on such product sales. The Company's payment obligations under these agreements typically expire a fixed number of years after expiration or termination of the agreement or a fixed number of years after the first sale of a product, but in some cases expire on a product-by-product basis or expiration of the last to expire of the Company's patents where the advisor is a named inventor that claims the applicable product.

The Company incurred aggregate revenue share expense including all amounts payable under the Company's scientific advisory board revenue share agreements of $0.3 million during the three months ended March 31, 2023, representing 2.3% of product revenue and $0.6 million during the three months ended March 31, 2022, representing 4.0% of product revenue. Revenue share expense is included in research and development.

Other obligations

In the ordinary course of business, the Company is a party to certain non-cancellable contractual obligations typically related to product royalty and research and development. The Company accrues a liability for such matters when it is probable that future expenditures will be made and such expenditures can be reasonably estimated. There have been no contingent liabilities requiring accrual at March 31, 2023 or December 31, 2022.

Legal proceedings

In the ordinary course of the Company's business, the Company is subject to routine risk of litigation, claims and administrative proceedings on a variety of matters, including patent infringement, product liability, securities-related claims, and other claims in the United States and in other countries where the Company sells its products. In the case of matters below in which the Company is a defendant, adverse outcomes of these lawsuits could have a material adverse effect on the Company's business, financial condition or results of operations. The Company is presently unable to predict the outcome of these lawsuits or to reasonably estimate a range of potential losses, if any, related to the lawsuits. Legal costs associated with legal proceedings are accrued as incurred.

Settlement and License Agreement with Medacta

On August 29, 2019, the Company filed a lawsuit against Medacta USA, Inc. in the United States District Court for the District of Delaware. The Company amended its complaint on December 23, 2019, and again on October 14, 2020, adding Medacta International SA (Medacta USA, Inc.'s parent company) as a defendant (Medacta USA, Inc. and Medacta International SA are referred to, together, as "Medacta"). The Company is seeking damages for Medacta's infringement of certain of the Company's patents related to patient-specific instrument and implant systems, alleging that Medacta's multiple lines of patient-specific instruments, as well as the implant components used in conjunction with them, infringe four of the Company's patents. The accused product lines include Medacta patient-specific instrument and implant systems for knee and shoulder replacement procedures. On January 6, 2020, Medacta filed its answer to the Company's complaint, denying that its patient-specific instrument and implant systems infringe the patents asserted by the Company. Medacta's answer also alleges the affirmative defense that the Company's asserted patents are invalid. On January 21, 2021, Medacta International SA filed a partial motion to dismiss; on February 16, 2021, the Company filed its opposition to the motion; and on March 2, 2021, Medacta International SA filed its reply. On March 4, 2021, the court issued its opinion on claim construction, ruling in the Company's favor on the construction of all of the disputed terms. On June 3, 2022, the

court denied Medacta International SA's motion to dismiss. On September 8, 2022, the parties notified the court that an agreement in principle to settle the case had been reached. The trial schedule and case deadlines were canceled, pending the parties' preparation of and agreement to a definitive settlement agreement.

On October 20, 2021, the Company filed a lawsuit against Medacta Germany GmbH and Medacta International SA (together, "Medacta Europe") in the Regional Court of Düsseldorf ("German Court"). We are seeking damages for Medacta Europe's infringement of one of our German patents related to patient-specific instrument and implant systems through Medacta Europe's sales of multiple lines of PSI, as well as the implant components used in conjunction with them, in Germany. The accused product lines include Medacta Europe's patient-specific instrument and implant systems for knee, hip, and shoulder replacement procedures. Medacta Europe filed its statement of defense on January 31, 2022. The Company filed its reply to Medacta's statement of defense on April 28, 2022. As of July 28, 2022, the Company delivered security deposits in the amount of EUR 146,000 to the German Court in order to maintain the action. On September 1, 2022, an oral hearing on infringement and liability was held. On September 9, 2022, the parties notified the court that an agreement in principle to settle the case had been reached, and the issuance of further rulings by the court was delayed, pending the parties' preparation of and agreement to a definitive settlement agreement.

On November 8, 2022, the Company entered into a non-exclusive, fully paid up, worldwide settlement and license agreement with Medacta, resolving the matters described in the two preceding paragraphs. Under the terms of this agreement, the Company granted a perpetual, irrevocable, non-exclusive license to Medacta to use patient-specific instrument technology covered by the Company's patents and patent applications with off-the-shelf implants for the knee and shoulder. This license does not extend to patient-specific implants. This license agreement provided for a single lump-sum payment by Medacta to the Company upon entering into the license agreement, which was paid in the fourth quarter of 2022.

Litigation with Osteoplastics

On March 20, 2020, Osteoplastics LLC ("Osteoplastics"), filed a lawsuit against the Company in the United States District Court for the District of Delaware, and Osteoplastics amended its complaint on April 2, 2020. Osteoplastics alleges that the Company's proprietary software, including the Company's iFit software platform, and the Company's use of its proprietary software for designing and manufacturing medical devices, including implants, infringes seven patents owned by Osteoplastics. On June 15, 2020, the Company filed a motion to dismiss Osteoplastics' complaint, and on October 21, 2020, the court denied the motion. On November 2, 2020, the Company filed its answer to the amended complaint, denying that it infringes the patents asserted by Osteoplastics. The Company's answer also alleges the affirmative defense that Osteoplastics' asserted patents are invalid. Trial is currently set to begin on July 24, 2023.

Litigation against DePuy

On April 30, 2021, the Company filed a lawsuit against DePuy Synthes, Inc., DePuy Synthes Products, Inc., and DePuy Synthes Sales, Inc. (collectively, "DePuy") in the United States District Court for the District of Delaware, seeking damages for DePuy's infringement of certain of the Company's patents related to patient-specific instrument and implant systems. The complaint alleges that DePuy's multiple lines of PSI, as well as the implant components used in conjunction with them, infringe seven of the Company's patents. The accused product lines include DePuy's patient-specific instrument and implant systems for knee and shoulder replacement procedures. On October 25, 2021, DePuy filed a partial motion to dismiss. On November 15, 2021, the Company filed an amended complaint. On December 6, 2021, DePuy filed a second partial motion to dismiss. The Company opposed the partial motion to dismiss on December 20, 2021, and DePuy filed a reply in support of its partial motion to dismiss on December 27, 2021. On February 14, 2022, the court denied DePuy's partial motion to dismiss. On February 28, 2022, DePuy filed its answer to the Company's amended complaint, denying that its patient-specific instrument and implant systems infringe the patents asserted by the Company. A claim construction hearing was held on February 6, 2023. Discovery in the lawsuit is ongoing.

Litigation against Exactech

On June 3, 2021, the Company filed a lawsuit against Exactech, Inc. ("Exactech") in the United States District Court for the Middle District of Florida seeking damages for Exactech's infringement of certain of the Company's patents related to patient-specific instrument and implant systems. The complaint alleges that Exactech's line of patient-specific instruments for use with its ankle implant systems, as well as the ankle implant

components used in conjunction with them, infringe five of the Company's patents. Discovery in the lawsuit is ongoing.

Litigation against Bodycad Laboratories

On June 3, 2021, the Company filed a lawsuit against Bodycad Laboratories, Inc., Bodycad USA Corp. (together, “Bodycad”), and Exactech (collectively, “Defendants”), in the United States District Court for the Middle District of Florida seeking damages for Defendants’ infringement of certain of the Company's patents related to patient-specific instrument and implant systems. The complaint alleges that Defendants’ line of patient-specific surgical systems for unicondylar knee replacement surgery and Bodycad’s line of patient-specific surgical systems for knee osteotomy surgery infringe six of the Company's patents. On August 2, 2021, Exactech filed its answer to the complaint, denying that it infringed our asserted patents and also alleging that our asserted patents are invalid. On August 20, 2021, Bodycad filed a motion to dismiss and for a more definite statement. On September 10, 2021, the Company filed an amended complaint that continued to accuse the same products of infringing six of the Company's patents. On September 24, 2021, Defendants filed a motion to dismiss, and the Company opposed the motion to dismiss on October 15, 2021. On March 30, 2022, the court denied Defendants motion to dismiss. Discovery in the lawsuit is ongoing. On February 9, 2023, the parties entered into a settlement and license agreement that resolves the patent infringement dispute filed by the Company in June of 2021. The parties agreed to an undisclosed amount for the dismissal of all patent litigation between the companies along with a release and license to certain Company patents related to patient-specific instrumentation and knee implants.

Litigation against Aetna

On May 8, 2020, the Company and an individual plaintiff filed a lawsuit against Aetna, Inc. and Aetna Life Insurance Company (together, “Aetna”) in the United States District Court for the District of Massachusetts seeking damages for Aetna’s improper denial of coverage for personalized knee implants under its health plans and the ones it administers. The Company amended its complaint on August 13, 2020, alleging that Aetna violated its duties under state and federal law, including the Employee Retirement Income Security Act. On March 31, 2021, the court dismissed the Company’s claims against Aetna, but allowed the individual plaintiff’s claims to survive. The individual plaintiff settled his claims against Aetna in October 2021 and the Company subsequently filed a notice of appeal. The Company filed its appeal brief on April 15, 2022. Aetna filed its response to our appeal brief on June 15, 2022. The court is scheduled to hear oral arguments from the parties on the appeal briefs on November 8, 2022.

On January 23, 2023, the United States Court of Appeals for the First Circuit revived the Company's trade libel claims against Aetna, finding that Aetna’s policy claims that the Company's knee implants are “experimental” and “investigational” can plausibly be considered actionable product disparagement, and that the district court had erred in dismissing these claims. The court found that the Company has plausibly claimed that Aetna's policy decision caused orthopedic surgeons to stop prescribing its knee replacement implants. The court also revived the Company's related claims for unfair trade practice and interference with advantageous relations. The court issued a scheduling order on March 2, 2023 and discovery in the lawsuit has commenced. The Company intends to continue pursuing these claims against Aetna, and expects to incur additional legal expenses in 2023 (and potentially thereafter) in connection with doing so. The Company is seeking an award of monetary damages and equitable relief. The Company is not presently able to predict the ultimate outcome of this matter or to reasonably estimate a range of potential damages the Company may be awarded, if successful.

Indemnification

In the normal course of business, the Company enters into contracts and agreements that contain a variety of representations and warranties and provide for general indemnifications. The Company’s exposure under these agreements is unknown because it involves claims that may be made against the Company in the future, but have not yet been made. To date, the Company has not paid any claims or been required to defend any action related to its indemnification obligations. However, the Company may record charges in the future as a result of these indemnification obligations. In accordance with its bylaws, the Company has indemnification obligations to its officers and directors for certain events or occurrences, subject to certain limits, while they are serving at the Company’s request in such capacity. There have been no claims to date and the Company has a director and officer insurance policy that would be expected to enable it to recover a portion of any amounts paid for future claims.

Note I—Debt and Notes Payable

Long-term debt consisted of the following (in thousands):

	March 31, 2023	December 31, 2022
MidCap, Term Loan	21,000	21,000
Less unamortized debt issuance costs	(399)	(437)
Long-term debt, less debt issuance costs	$ 20,601	$ 20,563

Principal payments due as of March 31, 2023 consisted of the following (in thousands):

	Principal Payment
2023 (remainder of the year)	—
2024	1,750
2025	10,500
2026	8,750
Total	$ 21,000

MidCap Term Loan

On November 22, 2021, the Company and its subsidiary, ImaTx, Inc., entered into the New Credit Agreement with MidCap, as agent, and certain lender parties thereto. The New Credit Agreement provides for a five-year, $21 million secured Term Facility. The New Credit Agreement refinanced and replaced the prior secured loan agreement with Innovatus that the Company entered into in June 2019 (the "2019 Secured Loan Agreement"), which agreement has been terminated. The full amount of the $21 million Term Facility was borrowed on the date of entering into the New Credit Agreement, and the Company used these proceeds to repay all outstanding obligations under the 2019 Secured Loan Agreement.

The New Credit Agreement has a maturity date of November 1, 2026 and requires interest only payments through October 31, 2024, and thereafter, 24 monthly payments of principal and interest resulting in the Term Facility being fully paid by the maturity date. Interest is payable monthly in arrears at a rate of 5.7% per annum plus one month LIBOR subject to a LIBOR floor of 1%. In addition to the interest charged on the Term Facility, the Company is also obligated to pay certain fees, including an origination fee of 0.5% of the term loan due at closing and a final payment fee of 4.0% of the term loan at the time of final payment. On August 1, 2022, the Company entered into a New Credit Agreement, which replaced references to the LIBOR rate within the existing agreement, with the SOFR interest rate, such that interest will be payable monthly in arrears at a rate of 5.7% per annum plus one month SOFR subject to a SOFR floor of 1%. All other terms under the New Credit agreement remain the same.

The obligation of the Company with respect to the New Credit Agreement are secured by a security interest over substantially all of the personal property assets of the Company, including accounts receivable, deposit accounts, intellectual property, investment property, inventory, equipment and equity interests in its subsidiaries. The New Credit Agreement contains customary affirmative and negative covenants, including limitations on our ability to incur additional debt, grant or permit additional liens, make investments and acquisitions, merge or consolidate with others, dispose of assets, pay dividends and distributions, pay subordinated indebtedness and enter into affiliate transactions. In addition, the New Credit Agreement contains a minimum liquidity covenant requiring the Company to maintain unrestricted cash and cash equivalents in excess of $4.0 million. The New Credit Agreement also includes events of default customary for facilities of this type and upon the occurrence of such events of default, subject to customary cure rights, all outstanding loans under the Term Facility may be accelerated. As of March 31, 2023, the Company was not in breach of covenants under the New Credit Agreement.

The prepayment of the debt was accounted for as a debt extinguishment and the Company incurred a loss on the extinguishment of $1.1 million. This amount consisted of final payment fee, prepayment penalty and the write-off of unamortized debt issuance costs. The loss on extinguishment of debt was recognized as interest expense within the consolidated statement of operations during the year ended December 31, 2021.

Note J—Stockholders' Equity

Common stock

Common stockholders are entitled to dividends as and when declared by the board of directors, subject to the rights of holders of all classes of stock outstanding having priority rights as to dividends. There have been no dividends declared to date.

On March 30, 2021, the Company's board of directors adopted a resolution approving a Certificate of Amendment to the Company's Restated Certificate of Incorporation to increase the Company's number of authorized shares of Common Stock from 200,000,000 to 300,000,000 (the “Certificate of Amendment”). The Company's stockholders approved the Certificate of Amendment at the 2021 Annual Meeting. The total number of the Company's authorized common stock was decreased to 20,000,000 after giving effect to the Reverse Stock Split.

Reverse Stock Split

At the Company’s 2022 Annual Meeting of Stockholders, the Company’s stockholders approved a proposed amendment to the Company’s Restated Certificate of Incorporation to effect a reverse stock split of all of the Company’s outstanding shares of common stock by one of several fixed ratios between 1-for-2 and 1-for-10 and to correspondingly decrease the number of authorized shares of the Company’s common stock as disclosed in the Company’s proxy statement for the 2022 Annual Meeting of Stockholders. The reverse stock split was proposed to address the Company’s current non-compliance with Nasdaq’s $1.00 per share minimum bid price requirement.

On October 26, 2022, the Company held a Special Meeting of Stockholders and the Company’s stockholders approved an additional proposed amendment to the Company’s Restated Certificate of Incorporation to effect a reverse stock split of all of the Company’s outstanding shares of common stock by one of three fixed ratios, 1-for-15, 1-for-20 and 1-for-25, and to correspondingly adjust the number of authorized shares of the Company’s common stock by the approved ratio, 1-for-9, 1-for-12 and 1-for-15, respectively (the “Updated Reverse Stock Split Proposal”), as disclosed in the Company’s proxy statement for the October 26, 2022 Special Meeting of Stockholders. The Updated Reverse Stock Split Proposal amendment was proposed to address the Company’s current non-compliance at such time with Nasdaq’s $1.00 per share minimum bid price requirement.

The Company’s Board of Directors determined to proceed with implementing the 1-for-25 reverse stock split that was approved by shareholder on October 26, 2022, and such 1-for-25 reverse stock split was implemented in November 2022 (the “Reverse Stock Split”) . As a result of the Reverse Stock Split, each of the holders of the Company’s Common Stock received one (1) new share of Common Stock for every twenty-five (25) shares such shareholder held immediately prior. Fractional shares as a result of the Reverse Stock Split were paid in cash. The Reverse Stock Split also affected the Company’s outstanding stock options and warrants and resulted in the number of shares underlying such instruments being reduced and the exercise price being increased proportionately to the Reverse Stock Split ratio.

All share and per share information in this report has been retroactively adjusted to give effect to the Reverse Stock Split for all periods presented, unless otherwise indicated. The total number of the Company’s authorized shares of preferred stock was not affected by the foregoing. However, the total number of the Company's authorized common stock was decreased to 20,000,000. In connection with the Reverse Stock Split, there was no change in the par value per share of $0.00001.

Preferred stock

The Company’s Restated Certificate of Incorporation authorizes the Company to issue 5,000,000 shares of preferred stock, $0.00001 par value, all of which is undesignated. No shares were issued and outstanding at March 31, 2023 and December 31, 2022.

Demand registration rights

In conjunction with a private placement, on June 25, 2019, the Company entered into a registration rights agreement (the "Registration Rights Agreement") with Innovatus, Innovatus Life Science Offshore Fund I, LP and Innovatus Life Sciences Offshore Fund I-A, LP (collectively, the "Innovatus Investors") pursuant to which the Company agreed to register for resale the shares held by the Innovatus Investors (the “Shares”) under certain circumstances. Under the Registration Rights Agreement, in the event that the Company receives a written request

from the Innovatus Investors that the Company file with the SEC a registration statement covering the resale of all of the Shares, the Company shall promptly but no later than 120 days after the date of such request prepare and file with the SEC such registration statement. The Innovatus Investors have agreed to use best efforts not to make such a request, including by effecting any planned sales of Shares under Rule 144 under the Securities Act. The Company has agreed to use commercially reasonable efforts to cause such registration statement to become effective and to keep such registration statement effective until the date the Shares covered by such registration statement have been sold or may be resold pursuant to Rule 144 without restriction. The Company has agreed to be responsible for all fees and expenses incurred in connection with the registration of the Shares. The Company has granted the Innovatus Investors customary indemnification rights in connection with the registration statement. The Innovatus Investors have also granted the Company customary indemnification rights in connection with the registration statement.

Incidental registration rights

If the Company proposes to file a registration statement in connection with a public offering of its common stock, subject to certain exceptions, the holders of registrable shares are entitled to notice of registration and, subject to specified exceptions, including market conditions, the Company will be required, upon the holder's request, to register their then held registrable shares.

"At-the-market" program

On March 23, 2020, the Company filed a shelf registration statement on Form S-3 (the "Shelf Registration Statement"), which was declared effective by the SEC on August 5, 2020. Under the Shelf Registration Statement, the Company is permitted to sell from time to time up to $200 million of common stock, preferred stock, debt securities, warrants, or units comprised of any combination of these securities, for its own account in one or more offerings. On August 5, 2020, the Company filed with the SEC a prospectus supplement, for the sale and issuance of up to $25 million of its common stock and entered into a sales agreement (the "Sales Agreement") with Cowen and Company, LLC ("Cowen") pursuant to which the Company may offer and sell shares of the Company's common stock to or through Cowen, acting as agent and/or principal, from time to time, in an "at-the-market" offering as defined in Rule 415 promulgated under the Securities Act, including without limitation sales made by means of ordinary brokers' transactions on the NASDAQ Capital Market or otherwise at market prices prevailing at the time of sale, in block transactions, or as otherwise directed by the Company. Under the Sales Agreement, Cowen will use commercially reasonable efforts to sell the Common Stock from time to time, based upon instructions from the Company (including any price, time or size limits or other customary parameters or conditions the Company may impose). The Company will pay Cowen a commission of up to 3.0% of the gross sales proceeds of any Common Stock sold through Cowen under the Sales Agreement, and we have provided Cowen with customary indemnification rights. Any shares of Common Stock offered pursuant to the Sales Agreement will be offered and sold pursuant to the Shelf Registration Statement. The Company is not obligated to make any sales of Common Stock under the Sales Agreement. The offering of shares of Common Stock pursuant to the Sales Agreement will terminate upon the earlier of (i) the sale of all Common Stock subject to the Sales Agreement or (ii) termination of the Sales Agreement in accordance with its terms. As of the date hereof, the Company has not sold any shares under the Sales Agreement.

2021 common stock offering

On February 17, 2021, the Company closed an offering of its common stock under the Shelf Registration Statement and issued and sold 3,238,095 shares of its common stock at a public offering price of $26.25 per share (adjusted for the 1-for-25 reverse stock split), for aggregate net proceeds of approximately $79.6 million. The Company intends to use the net proceeds of the offering of the shares for general corporate purposes.

Registered direct offering

On September 23, 2020, the Company and a healthcare-focused institutional investor entered into a subscription agreement, pursuant to which the Company sold (i) 340,483 shares of its common stock and accompanying warrants to purchase up to 340,483 shares of common stock and (ii) pre-funded warrants to purchase up to 379,718 shares of common stock and accompanying warrants to purchase up to 379,718 shares of common stock in a registered direct offering (in each case, adjusted for the 1-for-25 reverse stock split) for gross proceeds of approximately $17.3 million. The common stock (or pre-funded warrants in lieu thereof) and accompanying warrants were sold as units, each consisting of one share (or one pre-funded warrant to purchase

one share of common stock in lieu thereof) and one warrant to purchase one share of common stock, at an offering price of $23.95 per unit.

The pre-funded warrants became exercisable immediately upon issuance, have an exercise price of $0.0025 per share and were exercisable until all of the pre-funded warrants were exercised in full. As of March 31, 2021, all pre-funded warrants were exercised. The warrants became exercisable immediately upon issuance, have an exercise price of $21.87 per share (adjusted for the 1-for-25 reverse stock split), and will expire five years from the date of issuance. The pre-funded warrants and the warrants each prohibit the holder from exercising any portion thereof to the extent that the holder would own more than 9.99% of the number of shares of common stock outstanding immediately after exercise. The number of shares issuable upon exercise of the warrants and pre-funded warrants and the exercise price of the warrants and pre-funded warrants is adjustable in the event of stock splits, stock dividends, combinations of shares and similar recapitalization transactions. The net proceeds to the Company from the offering, after deducting the placement agent's fees and other estimated offering expenses payable by the Company, was approximately $15.9 million.

Warrants

The Company has issued warrants to certain investors and consultants to purchase shares of the Company's common stock. Based on the Company's assessment of the warrants granted in 2013 and 2014 relative to ASC 480, *Distinguishing Liabilities from Equity*, such warrants are classified as equity. According to ASC 480, an entity shall classify as a liability any financial instrument, other than an outstanding share, that, at inception, both a) embodies an obligation to repurchase the issuer's equity shares, or is indexed to such obligation and b) requires or may require the issuer to settle the obligation by transferring assets. The warrants do not contain any provision that requires the Company to repurchase the shares and are not indexed to such an obligation. The warrants also do not require the Company to settle by transferring assets. All of these warrants were exercisable immediately upon issuance.

In connection with the September 23, 2020 registered direct offering, the Company issued 379,718 pre-funded common stock warrants with an exercise price of $0.0025 per share and an additional 720,201 common stock warrants with an exercise price of $21.87 per share (in each case, adjusted for the 1-for-25 reverse stock split). All of these warrants are exercisable for one share of common stock and were exercisable immediately. As of March 31, 2023, approximately 240,000 of the common stock warrants have been exercised. The pre-funded warrants were exercisable indefinitely, while the additional warrants are exercisable for 5 years from the date of issuance. All pre-funded warrants were exercised. Based on the Company's assessment of the warrants granted relative to ASC 480, *Distinguishing Liabilities from Equity* and ASC 815-40, *Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock,* these warrants are classified as equity instruments. The fair value of the common stock warrants of approximately $10.2 million at the date of issuance was estimated using the Black-Scholes model which used the following inputs: term of 5 years, risk free rate of 0.28%, 0% dividend yield, volatility of 90.15%, an exercise price of $21.87 and share price of $20.83 per share based on the trading price of the Company's common stock (adjusted for the 1-for-25 reverse stock split).

Warrants to purchase 480,837 shares of common stock were outstanding as of March 31, 2023 and December 31, 2022. Outstanding common stock warrants are currently exercisable with varying exercise expiration dates from 2024 through 2025. At March 31, 2023 and December 31, 2022, the weighted average warrant exercise price per share for common stock and the weighted average contractual life was as follows:

	Number of Common Stock Warrants*	Weighted Average Exercise Price Per Share*	Weighted Average Remaining Contractual Life	Number of Warrants Exercisable*	Weighted Average Price Per Share*
Outstanding December 31, 2022	480,837	$ 22.22	2.73	480,837	$ 22.22
Granted	—	$ —	—	—	$ —
Exercised	—	—	—	—	—
Cancelled/expired	—	—	—	—	—
Outstanding March 31, 2023	480,837	$ 22.22	2.48	480,837	$ 22.22

*Adjusted for the 1-for-25 reverse stock split

Stock option plans

The 2015 Stock Incentive Plan ("2015 Plan") provides for an annual increase, to be added on the first day of each fiscal year, beginning with the fiscal year ending December 31, 2016 and continuing until, and including, the fiscal year ending December 31, 2025, equal to the lesser of (a) 3,000,000 shares of the Company's common stock, (b) 3% of the number of share of its common stock outstanding on the first day of such fiscal year and (c) an amount determined by the Company's board of directors. Effective January 1, 2023, an additional 120,000 shares of the Company's common stock were added to the 2015 Plan under the terms of this provision (adjusted for the 1-for-25 reverse stock split), and at the 2021 Annual Meeting of Stockholders on May 24, 2021, the Company' Stockholders approved a First Amendment to the 2015 Plan to increase by 240,000 (adjusted for the 1-for-25 reverse stock split), the maximum number of shares of common stock available for issuance under the 2015 Plan ("Plan Amendment"). As of March 31, 2023, 315,063 shares of common stock were available for future issuance under the 2015 Plan (adjusted for the 1-for-25 reverse stock split).

On April 29, 2019, the stockholders approved the Conformis, Inc. 2019 Sales Team Performance-Based Equity Incentive Plan ("2019 Sales Team Plan") for up to 3,000,000 shares of common stock available to grant to certain sales representatives or independent sales agents. The 2019 Sales Team Plan provides for the grant of performance-based equity, including incentive stock options, nonstatutory stock options, stock appreciation rights, restricted stock awards, restricted stock units and other stock-based awards. Shares covered by awards under the 2019 Sales Team Plan that expire or are terminated, surrendered, or cancelled without having been fully exercised or are forfeited in whole or in part (including as the result of shares subject to such award being repurchased by us at the original issuance price pursuant to a contractual repurchase right) or that result in any shares not being issued, will again be available for the grant of awards under the 2019 Sales Team Plan. Equity granted under the 2019 Sales Team Plan will expire ten years from the date of grant.

As of March 31, 2023, there were 94,481 shares of common stock available for future issuance under the 2019 Sales Team Plan (adjusted for the 1-for-25 reverse stock split).

Activity under all stock option plans was as follows:

	Number of Options*	Weighted Average Exercise Price per Share*	Aggregate Intrinsic Value (in Thousands)*
Outstanding December 31, 2022	175,783	$ 44.76	$ —
Granted	—	—	—
Expired	(2,046)	158.55	—
Cancelled/Forfeited	—	—	—
Outstanding March 31, 2023	173,737	$ 43.42	$ —
Total vested and exercisable	43,947	$ 136.49	$ —

*Adjusted for the 1-for-25 reverse stock split

The total fair value of stock options that vested during the three months ended March 31, 2023 was $0.0 million. The weighted average remaining contractual term for the total stock options outstanding was 7.91 years as of March 31, 2023. The weighted average remaining contractual term for the total stock options vested and exercisable was 4.43 years as of March 31, 2023.

Restricted common stock award activity under the plan was as follows:

	Number of Shares*	Weighted Average Fair Value*
Unvested December 31, 2022	237,966	$ 18.77
Granted	—	—
Vested	(4,136)	27.19
Forfeited	(8,014)	18.39
Unvested March 31, 2023	225,816	$ 18.63

*Adjusted for the 1-for-25 reverse stock split

The total fair value of restricted common stock awards that vested during the three months ended March 31, 2023 was $0.1 million.

Inducement Awards

In February 2020, the Company granted inducement awards outside of the 2015 Plan and 2019 Sales Team Plan (i) to the Company's Chief Financial Officer in the form of an option to purchase 5,000 shares of the Company's common stock with an exercise price per share equal to $24.50 and 5,000 restricted stock units (in each case, adjusted for the 1-for-25 reverse stock split). The option and restricted stock unit awards were granted as inducements material to their commencement of employment with the Company in accordance with Nasdaq Listing Rule 5635(c)(4).

In November 2021, the Company granted inducement awards outside of the 2015 Plan and 2019 Sales Team Plan to the Company's Vice President, Marketing in the form of 6,000 restricted stock units (adjusted for the 1-for-25 reverse stock split). The restricted stock unit award was granted as an inducement material to his commencement of employment with the Company in accordance with NASDAQ Listing Rule 5635(c)(4).

In March 2022, the Company granted inducement awards outside of the 2015 Plan and 2019 Sales Team Plan to the Company's Chief Legal Officer and Corporate Secretary in the form of an option to purchase 18,000 shares of the Company's common stock with an exercise price per share equal to $15.25 and 18,000 restricted stock units (in each case, adjusted for the 1-for-25 reverse stock split). The option and restricted stock unit awards were granted as inducements material to her commencement of employment with the Company in accordance with NASDAQ Listing Rule 5635(c)(4).

In April 2022, the Company granted inducement awards outside of the 2015 Plan and 2019 Sales Team Plan to the Company's Chief Operating Officer in the form of an option to purchase 17,000 shares of the Company's common stock with an exercise price per share equal to $16.00 and 17,000 restricted stock units (in each case, adjusted for the 1-for-25 reverse stock split). The option and restricted stock unit awards were granted as inducements material to his commencement of employment with the Company in accordance with NASDAQ Listing Rule 5635(c)(4).

Stock-based compensation

The Company uses the Black-Scholes option pricing model to determine the fair value of stock options. The determination of the fair value of stock-based payment awards on the date of grant using a pricing model is affected by the value of the Company's common stock as well as assumptions regarding a number of complex and subjective variables. The valuation of the Company's common stock prior to its initial public offering was performed with the assistance of an independent third-party valuation firm using a methodology that includes various inputs including the Company's historical and projected financial results, peer company public data and market metrics, such as risk-free interest and discount rates. As the valuations included unobservable inputs that were primarily based on the Company's own assumptions, the inputs were considered level 3 inputs within the fair value hierarchy.

The fair value of options at date of grant was estimated using the Black-Scholes option pricing model, based on the following assumptions:

	Three Months Ended March 31,	
	2023	2022
Risk-free interest rate	—%	2.54%
Expected term (in years)	0.00	8.00
Dividend yield	—%	—%
Expected volatility	—%	87.49%

Risk-free interest rate. The risk-free interest rate is based on U.S. Treasury zero-coupon issues with remaining terms similar to the expected term on the options.

Expected term. The expected term of stock options represents the period the stock options are expected to remain outstanding and is based on the "SEC Shortcut Approach" as defined in "Share-Based Payment" (SAB 107) ASC 718-10-S99, "Compensation-Stock Compensation-Overall-SEC Materials," which is the midpoint between the vesting date and the end of the contractual term. With certain stock option grants, the exercise price may exceed the fair value of the common stock. In these instances, the Company adjusts the expected term accordingly.

Dividend yield. The Company has never declared or paid any cash dividends and does not plan to pay cash dividends in the foreseeable future, and, therefore, used an expected dividend yield of zero in the valuation model.

Expected volatility. Expected volatility measures the amount that a stock price has fluctuated or is expected to fluctuate during a period. The Company estimates volatility based on the historical volatility of the Company's stock.

Forfeitures. The Company recognizes forfeitures as they occur.

Stock-based compensation expense was $0.6 million and $0.7 million for the three months ended March 31, 2023 and 2022, respectively. Stock-based compensation expense was calculated based on awards ultimately expected to vest. To date, the amount of stock-based compensation capitalized as part of inventory was not material.

The following is a summary of stock-based compensation expense (in thousands):

	Three Months Ended March 31,	
	2023	2022
Cost of revenues	$ 14	$ (35)
Sales and marketing	136	176
Research and development	71	138
General and administrative	400	457
	$ 621	$ 736

As of March 31, 2023, the Company had $1.0 million of total unrecognized compensation expense for options that will be recognized over a weighted average period of 4.12 years. As of March 31, 2023, the Company had $3.2 million of total unrecognized compensation expense for restricted awards that will be recognized over a weighted average period of 1.91 years.

Note K—Segment and Geographic Data

The Company operates as one reportable segment as described in Note B to the Consolidated Financial Statements. The countries in which the Company has local revenue generating operations have been combined into the following geographic areas: the United States (including Puerto Rico), Germany and the rest of world, which consists of Europe predominately (including the United Kingdom) and other foreign countries. Sales are attributable to a geographic area based upon the customer's country of domicile and distributors managed by that respective country. Product revenue is also presented by knee and hip which are the Company's major product lines. Net property, plant and equipment are based upon physical location of the assets.

Geographic and product category information consisted of the following (in thousands):

	Three Months Ended March 31,					
	2023			2022		
Product revenue	Knee	Hip	Total	Knee	Hip	Total
United States	$9,766	$801	$10,567	$11,939	$776	$12,715
Germany	826	—	826	1,177	—	1,177
Rest of world	1,298	—	1,298	992	—	992
	$11,890	$801	$12,691	$14,108	$776	$14,884

Geographic information consisted of the following (in thousands):

	March 31, 2023	December 31, 2022
Property and equipment, net		
United States	$ 7,971	$ 8,065
Germany	38	29
Rest of World	51	60
	$ 8,060	$ 8,154

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following Management's Discussion and Analysis of Financial Condition and Results of Operations ("MD&A") is intended to promote an understanding of the financial condition and results of operations and should be read in conjunction with our consolidated financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q and our Annual Report on Form 10-K for the year ended December 31, 2022. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report on Form 10-Q, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of our Annual Report on Form 10-K for the fiscal year ended December 31, 2022, our actual results could differ materially from the results described, in or implied, by these forward-looking statements.

Forward-Looking Statements

This Quarterly Report on Form 10-Q contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this Quarterly Report on Form 10-Q, including statements regarding our strategy, future operations, future financial position, future revenue, projected costs, prospects, our ability to raise additional funds, plans and objectives of management, effects of pandemics or other widespread health problems, and expected market growth are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

The words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "might," "plan," "potential," "predict," "project," "should," "target," "will," or "would" or the negative of these terms or other similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

These forward-looking statements include, among other things, statements about:

- whether our capital resources will be adequate to meet the needs of our business and our ability to raise any additional capital;
- our ability to continue as a going concern;
- our estimates regarding the potential market opportunity and timing of estimated commercialization for our current and future products, including our iUni, iDuo, iTotal CR, iTotal PS, iTotal Identity, Identity Imprint, Cordera hip system, Actera Hip System and the planned launch of our new product extensions, including the cementless option of the Identity Imprint knee platform and our Platinum Services℠ Program;
- our expectations regarding the transition of our U.S. knee implant business to Identity Imprint™ and our new Image-to-Implant® Platinum Services℠ Program offering, and related operational and regulatory risks we may be exposed to as a result of such transition;
- our expectations regarding our sales, expenses, gross margin and other results of operations;
- our strategies for growth and sources of new sales;
- maintaining and expanding our customer base and our relationships with our independent sales representatives and distributors;
- our current and future products and plans to promote them;
- the anticipated trends and challenges in our business and in the markets in which we operate;
- the implementation of our business model, strategic plans for our business, products, product candidates and technology;
- our ability to successfully develop and commercialize planned products and services;
- the future availability of raw materials used to manufacture, and finished components for, our products from third-party suppliers, including single source suppliers;
- product liability claims;
- litigation claims against Aetna;

- patent infringement claims;
- our ability to retain and hire necessary employees and to staff our operations appropriately;
- our ability to compete in our industry and with innovations by our competitors;
- potential reductions in reimbursement levels by third-party payors and cost containment efforts of accountable care organizations;
- our ability to obtain reimbursement or direct payment for our products and services;
- our ability to protect proprietary technology and other intellectual property and potential claims against us for infringement of the intellectual property rights of third parties;
- potential challenges relating to changes in and compliance with governmental laws and regulations affecting our United States and international businesses, including regulations of the U.S. Food and Drug Administration (the "FDA") and foreign government regulators, such as more stringent requirements for regulatory clearance of our products;
- potential further negative impacts related to the COVID-19 pandemic, including with respect to the magnitude of further resurgent case waves, the effectiveness of vaccines against current and future variant strains and public adoption rates of vaccines (including booster shots), and the actions that we have taken and are planning in response, including our ability to continue production and manufacturing activities at desired levels, the reliability of our supply chain, the pandemic's effect on labor conditions, our ability to meet obligations and covenants under our loan agreements, the duration of decreased demand for our products, and whether or when the demand for elective surgery procedures will increase; and
- our ability to satisfy all applicable NASDAQ continued listing requirements;

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in this Quarterly Report on Form 10-Q, particularly in the "Risk Factors" section, that could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, collaborations, joint ventures or investments that we may make or enter into.

You should read this Quarterly Report on Form 10-Q and the documents that we have filed as exhibits to this Quarterly Report on Form 10-Q and our other filings with the SEC completely and with the understanding that our actual future results may be materially different from what we expect. We do not assume any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

Trademarks

Solely for convenience, our trademarks and trade names in this report are referred to without the ® and ™ symbols, but such references should not be construed as any indicator that we will not assert, to the fullest extent under applicable law, our rights thereto.

Overview

We are a medical technology company and innovator in the orthopedic industry since our founding in 2004. In particular, we believe that we are a leader in the development, manufacturing, and sales of patient-specific products and instrumentation that are individually sized and shaped to fit each patient's unique knee and hip anatomy. The worldwide market for total knee and hip replacement products is approximately $17 billion annually. In the U.S. elective total joint procedures are shifting from the hospital to outpatient facilities and ambulatory surgery centers ("ASCs"). We believe that approximately 50% of all primary hip and knee procedures will be performed in ASCs within the next five years.

A key driver in the outpatient shift of orthopedic procedures is the ongoing changes by the Centers for Medicare & Medicaid Services ("CMS"). In recent years, CMS removed key musculoskeletal services from the inpatient-only list, including total knee arthroplasty in 2018 and total hip arthroplasty in 2020. CMS also continues to expand the ASCs covered procedure list, including total knee arthroplasty in 2020 and total hip arthroplasty in 2021.
As healthcare costs rise, governments and government agencies, including CMS, are looking to reduce their healthcare expenditures markedly through reimbursement reductions and cost-shifting to patients.

On January 6, 2022, we announced the launch of our new Image-to-Implant® Platinum Services℠ Program, a premium service offering for the U.S. market. New to orthopedics, this program addresses the rapidly evolving demands of the healthcare marketplace where generic products are being commoditized and patients are increasingly willing to pay a premium for deluxe services. As of September 1, 2022, U.S. medical facility customers are only able to obtain our fully personalized iTotal Identity knee system through participation in our Image-to-Implant Platinum Services℠ Program.

Both Medicare and most commercial payors permit patients to pay out-of-pocket for non-covered, deluxe services. Through the Image-to-Implant® Platinum Services℠ Program, Conformis is bringing this approach to orthopedics by enabling participating medical facilities to establish and offer patients an out-of-pocket services upgrade to obtain the Company's fully personalized iTotal Identity™ knee system. Combined with our new Made-to-Measure Identity Imprint™ knee system, we believe that we now address multiple market segments within knee arthroplasty:

- the Identity Imprint™ knee system provides a data-informed high-quality knee implant system that provides a level of personalization through its patient-specific instruments ("PSI") and proprietary algorithms for pre-surgical planning, but is only available in pre-designed standard sizes, all at a price comparable to standard off-the-shelf options; and

- the Image-to-Implant® Platinum Services℠ Program gives patients in the United States the opportunity to upgrade to a fully-personalized iTotal Identity™ knee implant system by paying an incremental deluxe services fee.

As of December 31, 2022, we had sold a total of more than 149,000 knee implants, including more than 123,000 total knee implants and 26,000 partial knee implants. In multiple clinical studies, iTotal CR, our cruciate-retaining total knee replacement implant, demonstrated superior clinical outcomes, including with respect to function, kinematics and objective functional measures, and greater patient satisfaction compared to those of standard, or off-the-shelf, implants that it was tested against. On August 16, 2021, the first procedure was performed using the Imprint knee replacement system. Imprint, available in both cruciate retaining ("CR") and posterior stabilized ("PS") implants, utilizes a proprietary algorithm to select the appropriate implant size from 12 standard sizes that most closely meet the geometric and anatomic requirements of the patient's knee based on the individual's CT scan. As with our personalized iTotal knee product line, Imprint uses our sterile Surgery-in-a-Box delivery system, which we believe provides ASCs and hospitals with greater procedural efficiency and improved sterilization cost savings over comparable systems. With the interest in our Imprint system from ASC customers, we have prioritized applying our porous-coated technology to the Imprint system which will be our first cementless TKA product offering. We are targeting a limited commercial launch of the porous-coated technology in the second half of 2023, however the launch may be delayed to the first half of 2024 due to regulatory or technical challenges.

On November 11, 2019, we entered full commercial launch of the Conformis personalized hip system, now branded as Cordera Rx. Since the launch of the personalized hip system, we have introduced multiple product line extensions including Cordera Standard, Cordera Pro and Cordera Match. In November 2022, we completed the first procedure using our Actera™ Hip System, a second hip stem within our hip portfolio. The system, designed for hip reconstruction, uses the cutting-edge tri-taper stem design, and features a range of sizes and angles derived from our data analytics. This cementless hip stem component features a proximally coated titanium spray with a

hydroxyapatite layer to encourage initial and long-term fixation. We believe that the system's tri-taper stem design will enable surgeons to treat a broader range of patient anatomies and the shorter length options offer easier access to the femur while maintaining the fixation and integrity required for long term success of the implant. For the initial limited launch, the Actera™ Hip System will feature a range of standard sizes in both stem and cup components. We plan to launch future Actera™ line extensions that will offer additional personalization options for surgeons to choose what best fits their patients, even for complex anatomies. The new system is currently rolling out to select sites across the U.S., and we currently anticipate the commercial launch to occur in mid-2023.

All of our currently marketed knee and hip replacement products and related design software have been cleared by the U.S. Food and Drug Administration (the "FDA") under the premarket notification process of Section 510(k) of the federal Food, Drug, and Cosmetic Act (the "FDCA"). We have received CE Certificates of Conformity allowing us to affix the CE Mark.

We market our products and services to orthopedic surgeons, hospitals, and other medical facilities, and patients. We use direct sales representatives, independent sales representatives and distributors to market and sell our products in the United States, Germany, the United Kingdom, Austria, Ireland, Switzerland, Spain, Portugal, the Netherlands, Belgium, the Dutch Antilles, Brazil, Suriname, Australia, the United Arab Emirates, the Sultanate of Oman, Italy, Poland and other markets.

We were incorporated in Delaware and commenced operations in 2004.

COVID-19 Pandemic Update

In December 2019, a human infection originating in China was traced to a novel strain of coronavirus. The virus subsequently spread to other parts of the world, including the United States and Europe, and caused unprecedented disruptions in the global economy as efforts to contain the spread of the virus intensified. In March 2020, the World Health Organization declared this coronavirus outbreak (COVID-19) to be a pandemic. We experienced significantly decreased demand for our products during the pandemic as healthcare providers and individuals de-prioritized and deferred medical procedures deemed to be elective, such as joint replacement procedures, which had a significant negative effect on our revenue. In the third and fourth quarters of 2021, the Company experienced higher levels of deferred and rescheduled knee and hip procedures as a result of the surge in COVID-19 cases associated with the Delta and Omicron variants. During the first quarter of 2022, United States case counts peaked in January and then trended downward for the remainder of the year. The future progression of the pandemic remains uncertain.

Components of our results of operations

The following is a description of factors that may influence our results of operations, including significant trends and challenges that we believe are important to an understanding of our business and results of operations.

Revenue

Our product revenue is generated from sales to hospitals and other medical facilities that are served through a direct sales force, independent sales representatives and distributors in the United States, Germany, the United Kingdom, Switzerland, Australia, and other markets. In order for surgeons to use our products, the medical facilities where these surgeons treat patients typically require us to enter into pricing agreements. The process of negotiating a pricing agreement can be lengthy and time-consuming, requiring extensive management time and may not be successful.

Revenue from sales of our products fluctuates principally based on the selling price of the joint replacement product, as the sales price of our products varies among hospitals and other medical facilities. In addition, our product revenue may fluctuate based on the product sales mix and mix of sales by geography. Our product revenue from international sales can be significantly impacted by fluctuations in foreign currency exchange rates, as our sales are denominated in the local currency in the countries in which we sell our products. We expect our product revenue to fluctuate from quarter-to-quarter due to a variety of factors, including seasonality, as we have historically experienced lower sales in the summer months and higher sales around year-end, the timing of the introduction of our new products, if any, and the impact of the buying patterns and implant volumes of medical facilities.

Royalty and licensing revenue for the three months ended March 31, 2022 includes revenue of $0.5 million generated from our license agreement (the "License Agreement") with Paragon 28. Ongoing royalty revenue is generated from our license agreement (the "MicroPort License Agreement") with MicroPort Orthopedics Inc., a wholly owned subsidiary of MicroPort Scientific Corporation, or collectively, MicroPort. The MicroPort License Agreement will expire upon the expiration of the last to expire of our patents and patent applications licensed to MicroPort, which currently is expected to occur in 2031.

We provide certain information regarding our financial results or projected financial results on a non-GAAP "constant currency basis." This information estimates the impact of changes in foreign currency rates on the translation of our current or projected future period financial results as compared to the applicable comparable period. This impact is derived by taking the adjusted current or projected local currency results and translating them into U.S. dollars based upon the foreign currency exchange rates for the applicable comparable period. It does not include any other effect of changes in foreign currency rates on our results or business. Non-GAAP information is not a substitute for, and is not superior to, information presented on a GAAP basis.

This non-GAAP financial measure may be different from non-GAAP financial measures used by other companies, limiting its usefulness for comparison purposes. Moreover, presentation of revenue on a constant currency basis is provided for year-over-year comparison purposes, and investors should be cautioned that the effect of changing foreign currency exchange rates has an actual effect on our operating results. We consider the use of a period over period revenue comparison on a constant currency basis to be helpful to investors, as it provides a revenue growth measure free of positive or negative volatility due to currency fluctuations.

Cost of revenue

We produce our computer aided designs, or CAD, in-house and in India and use them to direct most of our product manufacturing efforts. We manufacture all of our patient-specific instruments, or iJigs, tibial trays used in our total knee implants, and polyethylene tibia tray inserts for our iTotal CR and our iTotal PS product, in our facility in Wilmington, Massachusetts. We polish our femoral implants used in our total and partial knee products in our facility in Wallingford, Connecticut. Starting in 2019, we began to manufacture the lateral partial tibial tray components in our facility in Wilmington, Massachusetts. We outsource the production of the remainder of the partial knee tibial components, femoral castings, and other knee and hip components to third-party suppliers. Our suppliers make our personalized implant components using the CAD designs we supply. Cost of revenue consists primarily of costs of raw materials, manufacturing personnel, outsourced CAD labor, manufacturing supplies, inbound freight, manufacturing overhead, and depreciation expense.

We calculate gross margin as revenue less cost of revenue divided by revenue. Our gross margin has been and will continue to be affected by a variety of factors, including primarily volume of units produced, mix of product components manufactured by us versus sourced from third parties, our average selling price, foreign exchange rates, the geographic mix of sales, product sales mix, manufacturing efficiencies, raw material costs, the number of cancelled sales orders resulting in wasted implants, and royalty revenue.

We expect our gross margin from the sale of our products, which excludes royalty and licensing revenue, to expand over time to the extent we are successful in reducing our manufacturing costs per unit, increasing our manufacturing efficiency, and increasing sales volume through the launch of Identity Imprint™ and our Image-to-Implant® Platinum Services℠ Program. We believe that areas of opportunity to expand our gross margin in the future, if and as the volume of our product sales increases, include the following:

- absorbing overhead costs across a larger volume of product sales;
- increased sales mix of our higher margin Identity Imprint™ product and an increased selling price as a result of our Image-to-Implant® Platinum Services℠ Program;
- obtaining more favorable pricing for the materials used in the manufacture of our products;
- obtaining more favorable pricing of certain components of our products manufactured for us by third parties;
- increasing the proportion of our CAD design activities that is performed in-house at our India facility;
- developing new versions of our software used in the design of our joint replacement implants, which we believe will reduce costs associated with the design process; and
- improving the efficiency of our internal manufacturing processes.

We also continue to explore other opportunities to reduce our manufacturing costs. However, these and the above opportunities may not be realized. In addition, our gross margin may fluctuate from period to period.

Operating expenses

Our operating expenses consist of sales and marketing, research and development and general and administrative expenses. Personnel costs are the most significant component of operating expenses and consist of salaries, benefits, stock-based compensation, and sales commissions.

Sales and marketing. Sales and marketing expense consists primarily of personnel costs, including salary, employee benefits and stock-based compensation for personnel employed in sales, marketing, customer service, medical education and training, as well as investments in surgeon training programs, industry events and other promotional activities. In addition, our sales and marketing expense includes sales commissions and bonuses, generally based on a percentage of sales, to our sales managers, direct sales representatives and independent sales representatives. Recruiting, training and retaining productive sales representatives and educating surgeons about the benefits of our products are required to generate and grow revenue. We expect sales and marketing expense to decrease in 2023 as part of our cost reduction plans. Our sales and marketing expense may fluctuate from period to period due to the seasonality of our revenue and the timing and extent of our expenses.

Research and development. Research and development expense consists primarily of personnel costs, including salary, employee benefits and stock-based compensation for personnel employed in research and development, regulatory and clinical areas. Research and development expense also includes costs associated with product design, product refinement and improvement efforts before and after receipt of regulatory clearance, development of prototypes, testing, clinical study programs and regulatory activities, contractors and consultants, and equipment and software to support our development. As our revenue increases, we will also incur additional expense for revenue share payments to our past and present scientific advisory board members, including one of our past directors. We expect research and development expense to decrease in 2023 as part of our cost reduction plans.

General and administrative. General and administrative expense consists primarily of personnel costs, including salary, employee benefits and stock-based compensation for our administrative personnel that support our general operations, including executive management, general legal and intellectual property, finance and accounting, information technology and human resources personnel. General and administrative expense also includes outside legal costs associated with intellectual property and general legal matters, financial audit fees, insurance, fees for other consulting services, depreciation expense, long-lived asset impairment charges, freight, facilities expense, allocation of manufacturing training costs, and severance expense. We expect our general and administrative expense to decrease in 2023 primarily due to lower litigation and other expenses associated with our cost reduction plans. Our general and administrative expense may fluctuate from period to period due to the timing and extent of the expenses.

Total other (expenses) income, net

Total other income (expenses), net consists primarily of interest expense and amortization of debt discount associated with our term loans outstanding during the year, gain on forgiveness of PPP loan, income related to the development agreement with Stryker, and gains (losses) from foreign currency transactions. The effect of exchange rates on our foreign currency-denominated asset and liability balances are recorded as foreign currency translation adjustments in the consolidated statements of comprehensive loss.

Income tax provision

Income tax provision consists primarily of a provision for income taxes in foreign jurisdictions in which we conduct business. We maintain a full valuation allowance for deferred tax assets including net operating loss carryforwards and research and development credits and other tax credits.

Consolidated results of operations

Comparison of the three months ended March 31, 2023 and 2022

The following table sets forth our results of operations expressed as dollar amounts, percentage of total revenue and year-over-year change (in thousands):

	2023		2022		2023 vs 2022	
Three Months Ended March 31,	Amount	As a% of Total Revenue	Amount	As a% of Total Revenue	$ Change	% Change
Revenue						
Product revenue	$ 12,691	99 %	$ 14,884	96 %	$ (2,193)	(15)%
Royalty and licensing	146	1	667	4	(521)	(78)
Total revenue	12,837	100	15,551	100	(2,714)	(17)
Cost of revenue	7,734	60	9,810	63	(2,076)	(21)
Gross profit	5,103	40	5,741	37	(638)	(11)
Operating expenses:						
Sales and marketing	$ 5,051	39 %	$ 6,665	43 %	$ (1,614)	(24)%
Research and development	2,458	19	4,479	29	(2,021)	(45)
General and administrative	7,023	55	9,333	60	(2,310)	(25)
Total operating expenses	14,532	113	20,477	132	(5,945)	(29)
Loss from operations	(9,429)	(73)	(14,736)	(95)	5,307	36
Total other (expenses) income, net	(160)	(1)	(1,261)	(8)	1,101	87
Loss before income taxes	(9,589)	(75)	(15,997)	(103)	6,408	40
Income tax provision	(18)	—	34	—	(52)	(153)
Net loss	$ (9,571)	(75)%	$ (16,031)	(103)%	$ 6,460	40 %

Product revenue. Product revenue was $12.7 million for the three months ended March 31, 2023 compared to $14.9 million for the three months ended March 31, 2022, a decrease of $2.2 million or 15%. The decrease in product revenue was primarily due to declines in U.S. knee orders following our business model transition and manufacturing/supply chain challenges.

The following table sets forth, for the periods indicated, our product revenue by geography expressed as U.S. dollar amounts, percentage of product revenue and year-over-year change (in thousands):

	2023		2022		2023 vs 2022	
Three Months Ended March 31,	Amount	As a % of Product Revenue	Amount	As a % of Product Revenue	$ Change	% Change
United States	$ 10,567	83 %	$ 12,715	85 %	$ (2,148)	(17)%
Germany	826	7	1,177	8	(351)	(30)
Rest of world	1,298	10	992	7	306	31
Product revenue	$ 12,691	100 %	$ 14,884	100 %	$ (2,193)	(15)%

Product revenue in the United States was generated through our direct sales force and independent sales representatives. The percentage of product revenue generated in the United States was 83% for the three months ended March 31, 2023 compared to 85% for the three months ended March 31, 2022.

The United States product revenue decreased $2.1 million to $10.6 million or 17% year over year. The decrease in product revenue was primarily due to declines in U.S. knee orders following our business model transition and manufacturing/supply chain challenges. Following the September 1, 2022 transition to the new business model, we have seen a reduction in our orders as existing customers migrate to the new product and service offering. Additionally, some of our existing customers have chosen not to offer our fully personalized iTotal Identity product given it will require an out-of-pocket patient pay upgrade and some have chosen not to order Identity Imprint given it is not a fully personalized knee system. Germany product revenue decreased $0.4 million to $0.8 million, or 30% year over year on a reported basis and 26% on a constant currency basis. We believe the decline was primarily due to continued reimbursement headwinds from Medizinischer Dienst der Krankenversicherung ("MDK"), operational disruptions, and foreign currency exchange rates. Rest of World product

revenue increased $0.3 million to $1.3 million, or 31% year-over-year on a reported basis and 39% on a constant currency basis. The increase is primarily due to an increase in elective surgeries in the UK which were lower in the prior period as a result of the COVID-19 pandemic, and growth in Australia.

Royalty and licensing revenue. Royalty and licensing revenue was $0.1 million for the three months ended March 31, 2023 compared to $0.7 million for the three months ended March 31, 2022, a decrease of $0.5 million or 78%. The decrease in royalty and licensing revenue was driven by $0.5 million in revenue recognized under the License Agreement with Paragon 28 in the prior period.

Cost of revenue, gross profit and gross margin. Cost of revenue was $7.7 million for the three months ended March 31, 2023 compared to $9.8 million for the three months ended March 31, 2022, a decrease of $2.1 million, or 21%. Gross profit was $5.1 million for the three months ended March 31, 2023 compared to $5.7 million for the three months ended March 31, 2022, a decrease of $0.6 million or 11%. Gross margin increased 290 basis points to 40% for the three months ended March 31, 2023 from 37% for the three months ended March 31, 2022. The increase in gross margin was driven primarily by higher selling prices on our fully personalized knees due to our Platinum Services℠ Program, volume transition to our lower cost Imprint™ knee system, and decreased cancelled case inventory expense partially offset by increased labor and material costs and lower manufacturing volumes.

Sales and marketing. Sales and marketing expense was $5.1 million for the three months ended March 31, 2023 compared to $6.7 million for the three months ended March 31, 2022, a decrease of $1.6 million or 24%. The decrease was due primarily to lower tradeshow expenses of $0.5 million, commission expense of $0.6 million, personnel costs of $0.4 million, and other expense of $0.1 million. Sales and marketing expense decreased as a percentage of total revenue to 39% for the three months ended March 31, 2023 compared to 43% for the three months ended March 31, 2022.

Research and development. Research and development expense was $2.5 million for the three months ended March 31, 2023 compared to $4.5 million for the three months ended March 31, 2022, a decrease of $2.0 million, or 45%. The decrease was due primarily to a reduction in project related expenses of $0.7 million, personnel costs of $1.0 million, and revenue share expense of $0.3 million. Research and development expense decreased as a percentage of total revenue to 19% for the three months ended March 31, 2023 compared to 29% for the three months ended March 31, 2022.

General and administrative. General and administrative expense was $7.0 million for the three months ended March 31, 2023 compared to $9.3 million for the three months ended March 31, 2022, a decrease of $2.3 million, or 25%. The decrease was primarily due to a decrease in litigation expense of $1.1 million, professional and outside services of $0.5 million, shipping costs of $0.3 million, personnel costs of $0.2 million, and other costs of $0.2 million. General and administrative expense decreased as a percentage of total revenue to 55% for the three months ended March 31, 2023 from 60% for the three months ended March 31, 2022.

Total other (expenses) income, net. Other (expenses) income, net was $0.2 million of other expenses for the three months ended March 31, 2023 compared to $1.3 million of other expenses for the three months ended March 31, 2022, a change of $1.1 million, or 87%. The change was primarily due to an increase in foreign currency exchange transaction income of $1.3 million, partially offset by higher interest expense of $0.2 million.

Income taxes. Income tax provision was $(18,000) and $34,000 for the three months ended March 31, 2023 and 2022, respectively. We continue to generate losses for U.S. federal and state tax purposes and have net operating loss carryforwards creating a deferred tax asset. We maintain a full valuation allowance for deferred tax assets.

Liquidity, capital resources and plan of operations

Reverse Stock Split

On October 26, 2022, our Board of Directors approved a 1-for-25 reverse stock split of our Common Stock ("Reverse Stock Split"), which was implemented in November 2022. As a result of the Reverse Stock Split, each of the holders of our Common Stock received one (1) new share of Common Stock for every twenty-five (25) shares such shareholder held immediately prior. Fractional shares as a result of the Reverse Stock Split were paid in cash. The Reverse Stock Split also affected the Company's outstanding stock options and warrants and resulted in the shares underlying such instruments being reduced and the exercise price being increased proportionately to the Reverse Stock Split ratio.

All share and per share information has been retroactively adjusted to give effect to the Reverse Stock Split for all periods presented, unless otherwise indicated. The total number of our authorized shares of preferred stock was not affected by the foregoing. However, the total number of our authorized common stock was decreased to 20,000,000 after giving effect to the Reverse Stock Split. In connection with the Reverse Stock Split, there was no change in the par value per share of $0.00001.

Sources of liquidity and funding requirements

From our inception in June 2004 through the three months ended March 31, 2023, we have financed our operations primarily through private placements of preferred stock, our initial public offering in 2015, other equity financings, debt and convertible debt financings, equipment purchase loans, patent licensing, and product revenue beginning in 2007. We have not yet attained profitability and continue to incur operating losses and negative operating cash flows. As of March 31, 2023, we had an accumulated deficit of $590.9 million.

We expect to incur substantial expenditures in the foreseeable future in connection with the following:

- expansion of our sales and marketing efforts, including the expanded advertising of our Platinum Services℠ Program;
- expansion of our manufacturing capacity;
- funding research and development activities related to new and existing products, including our porous-coated technology for the Imprint system and Actera™ line extensions;
- pursuing and maintaining appropriate regulatory clearances and approvals for our existing products and any new products that we may develop; and
- enforcing our intellectual property rights and pursuing our claims against Aetna.

We anticipate that our principal sources of funds in the future will be revenue generated from the sales of our products, potential future capital raises through the issuance of equity or other securities, available sales of shares under the Sales Agreement, or potential debt financings, and revenues that we may generate in connection with licensing our intellectual property. Additionally, in order for us to meet our long-term operating plan, revenue growth, gross margin improvements and leveraging operating expenses will be necessary to reduce cash used in operations. We will need to generate significant additional revenue to achieve and maintain profitability, and even if we achieve profitability, we cannot be sure that we will remain profitable for any substantial period of time. It is also possible that we may allocate significant amounts of capital toward products or technologies for which market demand is lower than anticipated and, as a result, abandon such efforts. If we are unable to obtain adequate financing or financing on terms satisfactory to us when we require it, or if we expend capital on projects that are not successful, our ability to continue to support our business growth and to respond to business challenges could be significantly limited, and we may even have to scale back our operations. Our failure to become and remain profitable could impair our ability to raise capital, expand our business, maintain our research and development efforts or continue to fund our operations.

On March 23, 2020, we filed a shelf registration statement on Form S-3 (the "Shelf Registration Statement"), which was declared effective by the SEC on August 5, 2020. Under the Shelf Registration Statement, we are permitted to sell from time to time up to $200 million of common stock, preferred stock, debt securities, warrants, or units comprised of any combination of these securities, for our own account in one or more offerings. The Shelf Registration Statement is intended to provide us flexibility to conduct sales of our registered securities, subject to market conditions and our future capital needs.

On August 5, 2020, we filed with the SEC a prospectus supplement, for the sale and issuance of up to $25 million of our common stock and entered into an ATM issuance sales agreement (the "Sales Agreement"), with Cowen and Company, LLC ("Cowen"), pursuant to which we may offer and sell shares of the our common stock to or through Cowen, acting as agent and/or principal, from time to time in an “at-the-market” offering as defined in Rule 415 promulgated under the Securities Act of 1933, as amended, including without limitation sales made by means of ordinary brokers’ transactions on the Nasdaq Capital Market or otherwise at market prices prevailing at the time of sale, in block transactions, or as otherwise directed by us. Under the Sales Agreement, Cowen will use commercially reasonable efforts to sell the Common Stock from time to time, based upon instructions from us (including any price, time or size limits or other customary parameters or conditions we may impose). We will pay Cowen a commission of up to 3.0% of the gross sales proceeds of any Common Stock sold through Cowen under the Sales Agreement, and we have provided Cowen with customary indemnification rights. Any shares of Common Stock offered pursuant to the Sales Agreement will be offered and sold pursuant to the Shelf Registration Statement. We are not obligated to make any sales of Common Stock under the Sales Agreement. The offering of shares of Common Stock pursuant to the Sales Agreement will terminate upon the earlier of (i) the sale of all Common Stock subject to the Sales Agreement or (ii) termination of the Sales Agreement in accordance with its terms. As of the date thereof, we have not sold any shares under the Sales Agreement.

On September 23, 2020, we and a healthcare-focused institutional investor entered into a subscription agreement the "Subscription Agreement," pursuant to which we sold (i) 340,483 shares of its common stock and accompanying warrants to purchase up to 340,483 shares of common stock and (ii) pre-funded warrants to purchase up to 379,718 shares of common stock and accompanying warrants to purchase up to 379,718 shares of common stock in a registered direct offering (adjusted for the 1-for-25 reverse stock split) for gross proceeds of approximately $17.3 million. The common stock (or one pre-funded warrants in lieu thereof) and accompanying warrants were sold as units, each consisting of one share (or one pre-funded warrant to purchase one share of common stock in lieu thereof) and one warrant to purchase one share of common stock, at an offering price of $23.95 per unit. The net proceeds to us from the offering, after deducting the placement agent's fees and other estimated offering expenses payable by us, was approximately $15.9 million.

The pre-funded warrants became exercisable immediately upon issuance, have an exercise price of $0.0025 per share and were exercisable until all of the pre-funded warrants were exercised in full. As of March 31, 2021, all pre-funded warrants were exercised. The warrants became exercisable immediately upon issuance, have an exercise price of $21.87 per share (adjusted for the 1-for-25 reverse stock split), and will expire five years from the date of issuance. As of December 31, 2022, approximately 240,000 of these warrants have been exercised. The pre-funded warrants and the warrants each prohibit the holder from exercising any portion thereof to the extent that the holder would own more than 9.99% of the number of shares of common stock outstanding immediately after exercise. The number of shares issuable upon exercise of the warrants and pre-funded warrants and the exercise price of the warrants and pre-funded warrants is adjustable in the event of stock splits, stock dividends, combinations of shares and similar recapitalization transactions.

On November 22, 2021, we entered into a Credit and Security Agreement (the “New Credit Agreement”) with MidCap Financial Services, LLC (“MidCap Financial Services”), as servicer for MidCap Financial Trust to refinance the Company's existing senior secured indebtedness. The New Credit Agreement provides for a five-year, $21 million secured term loan facility (the “Term Facility”), and replaces our existing credit facility under the 2019 Secured Loan Agreement, with Innovatus, as collateral agent and lender, East West Bank and other lenders party thereto (collectively, the "Lenders"). We used the proceeds from the debt financings to pay off our existing credit facility under the 2019 Secured Loan Agreement with the Lenders.

The New Credit Agreement contains customary affirmative and negative covenants, including limitations on our ability to incur additional debt, grant or permit additional liens, make investments and acquisitions, merge or consolidate with others, dispose of assets, pay dividends and distributions, pay subordinated indebtedness and enter into affiliate transactions. In addition, the New Credit Agreement contains a minimum liquidity covenant requiring the us to maintain unrestricted cash and cash equivalents in excess of $4.0 million. The New Credit Agreement also includes events of default customary for facilities of this type and upon the occurrence of such events of default, subject to customary cure rights, all outstanding loans under the Term Facility may be accelerated. As of March 31, 2023, we were not in breach of covenants under the New Credit Agreement. For further information regarding the New Credit Agreement see “Note I—Debt and Notes Payable” in the financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q.

On November 8, 2022 we entered into a Settlement and License Agreement with Medacta, pursuant to which the parties agreed to terms for resolving the then-existing patent disputes. In consideration of the licenses, releases, covenants and other immunities granted by us to Medacta, Medacta was required to pay us a fee promptly after execution of the Settlement and License Agreement, which was received in full on December 12, 2022. The agreement provides for the grant of the licenses, covenants-not-to-sue, releases, and other significant deliverables upon receipt of the payment from Medacta.

On February 17, 2021, we closed an offering of our common stock under the Shelf Registration Statement and issued and sold 3,238,095 shares of our common stock at a public offering price of $26.25 per share (adjusted for the 1-for-25 reverse stock split), for aggregate net proceeds of approximately $79.6 million. We intend to use the net proceeds of the offering of the shares for general corporate purposes, which may include research and development costs, sales and marketing costs, clinical studies, manufacturing development, the acquisition or licensing of other businesses or technologies, repayment and refinancing of debt, including our secured term loan facility, working capital and capital expenditures.

On April 8, 2021, we entered into a License Agreement with Paragon 28, granting Paragon 28 a non-exclusive license under a subset of our U.S. patents for the use of patient-specific instruments with off-the-shelf implants. In connection with this License Agreement, we recognized revenue of $1.0 million during the quarter ended June 30, 2021 and $0.5 million during the quarter ended March 31, 2022. see “Note B—Summary of Significant Accounting Policies” in the financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q.

We may need to engage in additional equity or debt financings to secure additional funds. We may not be able to obtain additional financing on terms favorable to us, or at all. To the extent that we raise additional capital through the future sale of equity or debt, the ownership interest of our stockholders will be diluted. The terms of these future equity or debt securities may include liquidation or other preferences that adversely affect the rights of our existing common stockholders or involve negative covenants that restrict our ability to take specific actions, such as incurring additional debt or making capital expenditures.

At March 31, 2023, we had cash and cash equivalents of $37.8 million and $0.5 million in restricted cash allocated to lease deposits. Based on our current operating plan, we expect to fund our operations, capital expenditure requirements and debt service over the next twelve months with existing cash and cash equivalents as of March 31, 2023, anticipated revenue from operations, revenue that may be generated in connection with licensing intellectual property, available sales of shares under the Sales Agreement, funds from additional equity or debt financing. We have based this expectation on assumptions that may prove to be wrong, such as the revenue that we expect to generate from the sale of our products, the gross profit we expect to generate from those revenues, and the fact that we could use our capital resources sooner than we expect.

Cash flows

The following table sets forth a summary of our cash flows for the periods indicated, as well as the year-over-year change (in thousands):

	Three Months Ended March 31,			
	2023	2022	$ Change	% Change
Net cash (used in) provided by:				
Operating activities	$ (9,847)	$ (17,102)	$ 7,255	42 %
Investing activities	(907)	(692)	(215)	(31)
Financing activities	—	—	—	100
Effect of exchange rate on cash	(127)	(45)	(82)	(182)
Total	$ (10,881)	$ (17,839)	$ 6,958	39 %

Net cash used in operating activities. Net cash used in operating activities was $9.8 million for the three months ended March 31, 2023 compared to $17.1 million used in operating activities for the three months ended March 31, 2022, a decrease in use of $7.3 million. The $7.3 million decrease in net cash used in operating activities was primarily affected by a decrease in net loss of $6.5 million, a decrease in accounts receivable of $2.3 million, a decrease in prepaid expense and other assets of $0.2 million, a decrease in royalty and licensing receivable of $0.4 million, an increase in inventory of $0.1 million, and a decrease in accounts payable, accrued expenses and other

liabilities of $0.5 million. Non-cash reconciling items include decrease in unrealized foreign exchange gain/loss of $1.3 million, a decrease in depreciation expense of $0.2 million and a decrease in stock compensation expense of $0.1 million.

Net cash used in investing activities. Net cash used in investing activities was $0.9 million for the three months ended March 31, 2023, and for the three months ended March 31, 2022 net cash used in investing activities was $0.7 million, an increase of $0.1 million. The increase is due to an increase in costs related to the acquisition of property, plant, and equipment.

Net cash provided by financing activities. Net cash provided by financing activities was $0.0 million for each of the three months ended March 31, 2023 and 2022.

Contractual obligations and commitments

There have not been any material changes to our contractual obligations and commitments disclosed in the Management's Discussion and Analysis of Financial Condition and Results of Operations in our Annual Report filed on Form 10-K for the year ended December 31, 2022 other than changes in our debt facilities as disclosed in "Note I—Debt and Notes Payable**"** in the financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q.

Revenue share agreements

We are party to revenue share agreements with certain past and present members of our scientific advisory board under which these advisors agreed to participate on our scientific advisory board and to assist with the development of our personalized implant products and related intellectual property. These agreements provide that we will pay the advisor a specified percentage of our net revenue, ranging from 0.1% to 1.33%, with respect to our products on which the advisor made a technical contribution or, in some cases, which we covered by a claim of one of or patents on which the advisor is a named inventor. The specific percentage is determined by reference to product classifications set forth in the agreement and is tiered based on the level of net revenue collected by us on such product sales. Our payment obligations under these agreements typically expire a fixed number of years after expiration or termination of the agreement, but in some cases expire on a product-by-product basis or expiration of the last to expire of our patents where the advisor is a named inventor that claims the applicable product.

The aggregate revenue share percentage of net revenue from our currently marketed knee replacement products, including percentages under revenue share agreements with all of our scientific advisory board members, ranges, depending on the particular product, from 0.1% to 0.6%. We incurred aggregate revenue share expense including all amounts payable under our scientific advisory board revenue share agreements of $0.3 million during the three months ended March 31, 2023, representing 2.3% of product revenue, and $0.6 million during the three months ended March 31, 2022, representing 4.0% of product revenue. Revenue share expense is included in research and development. For further information, see "Note H—Commitments and Contingencies" to the consolidated financial statements appearing in this Quarterly Report on Form 10-Q.

Segment information

We have one primary business activity and operate as one reportable segment.

Off-balance sheet arrangements

Through March 31, 2023, we did not have any relationships with unconsolidated organizations or financial partnerships, such as structured finance or special purpose entities, which would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes.

Critical accounting policies and estimates

We have prepared our consolidated financial statements in conformity with accounting principles generally accepted in the United States. Our preparation of these financial statements and related disclosures requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenue and expenses during the reporting periods. We believe the critical accounting policies and estimates that require the use

of significant estimates and judgments in the preparation of our consolidated financial statements include revenue recognition, inventory valuations, impairment assessments, and income tax reserves and related allowances. We evaluate our estimates and judgments on an ongoing basis. Actual results may differ from these estimates under different assumptions or conditions. Our critical accounting policies and estimates are more fully described under the heading “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Critical accounting policies and estimates” in our Annual Report on Form 10-K for the year ended December 31, 2022.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer (our principal executive officer and principal financial officer, respectively), evaluated the effectiveness of our disclosure controls and procedures as of March 31, 2023. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of March 31, 2023, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the three months ended March 31, 2023 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II - OTHER INFORMATION
ITEM 1. LEGAL PROCEEDINGS

In the ordinary course of our business, we are subject to routine risk of litigation, claims and administrative proceedings on a variety of matters, including patent infringement, product liability, securities-related claims, and other claims in the United States and in other countries where we sell our products. In the case of matters below in which we are a defendant, adverse outcomes of these lawsuits could have a material adverse effect on our business, financial condition or results of operations. We are presently unable to predict the outcome of these lawsuits or to reasonably estimate a range of potential losses, if any, related to the lawsuits. Legal costs associated with legal proceedings are accrued as incurred.

Settlement and License Agreement with Medacta

On August 29, 2019, we filed a lawsuit against Medacta USA, Inc. in the United States District Court for the District of Delaware. We amended our complaint on December 23, 2019, and again on October 14, 2020, adding Medacta International (Medacta USA, Inc.'s parent company) as a defendant (Medacta USA, Inc. and Medacta International SA are referred to, together, as "Medacta"). We are seeking damages for Medacta's infringement of certain of our patents related to patient-specific instrument and implant systems, alleging that Medacta's multiple lines of patient-specific instruments, as well as the implant components used in conjunction with them, infringe four of our patents. The accused product lines include Medacta patient-specific instrument and implant systems for knee and shoulder replacement procedures. On January 6, 2020, Medacta filed its answer to our original complaint, denying that its patient-specific instrument and implant systems infringe the patents asserted by us. Medacta's answer also alleges the affirmative defense that our asserted patents are invalid. On January 21, 2021, Medacta International SA filed a partial motion to dismiss; on February 16, 2021, we filed our opposition to the motion; and on March 2, 2021, Medacta International SA filed its reply. On March 4, 2021, the court issued its opinion on claim construction, ruling in our favor on the construction of all of the disputed terms. On June 3, 2022, the court denied Medacta International SA's motion to dismiss. On September 8, 2022, the parties notified the court that an agreement in principal to settle the case had been reached. The trial schedule and case deadlines have been canceled, pending the parties' preparation of and agreement to a definitive settlement agreement.

On October 20, 2021, we filed a lawsuit against Medacta Germany GmbH and Medacta International SA (together, "Medacta Europe") in the Regional Court of Düsseldorf ("German Court"). We are seeking damages for Medacta Europe's infringement of one of our German patents related to patient-specific instrument and implant systems through Medacta Europe's sales of multiple lines of PSI, as well as the implant components used in conjunction with them, in Germany. The accused product lines include Medacta Europe's patient-specific instrument and implant systems for knee, hip, and shoulder replacement procedures. Medacta Europe filed its statement of defense on January 31, 2022. On April 28, 2022, we filed our reply to Medacta's statement of defense. On September 1, 2022, an oral hearing on infringement and liability was held. On September 9, 2022, the parties notified the court that an agreement in principal to settle the case had been reached, and the issuance of further rulings by the court have been delayed, pending the parties' preparation of and agreement to a definitive settlement agreement.

On November 8, 2022, we entered into a non-exclusive, fully paid up, worldwide settlement and license agreement with Medacta, resolving the matters described in the two preceding paragraphs. Under the terms of this agreement, we granted a perpetual, irrevocable, non-exclusive license to Medacta to use patient-specific instrument technology covered by our patents and patent applications with off-the-shelf implants for the knee and shoulder. This license does not extend to patient-specific implants. This license agreement provided for a single lump-sum payment by Medacta to us upon entering into the license agreement, which was paid in the fourth quarter of 2022.

Litigation with Osteoplastics

On March 20, 2020, Osteoplastics LLC ("Osteoplastics") filed a lawsuit against us in the United States District Court for the District of Delaware, and Osteoplastics amended its complaint on April 2, 2020. Osteoplastics is seeking damages relating to allegations that our proprietary software, including our iFit software platform, and our use of our proprietary software for designing and manufacturing medical devices, including implants, infringes seven patents owned by Osteoplastics. On June 15, 2020, we filed a motion to dismiss Osteoplastics' complaint, and on October 21, 2020, the court denied the motion. On November 2, 2020, we filed our answer to the amended

complaint, denying that we infringe the patents asserted by Osteoplastics. Our answer also alleges the affirmative defense that Osteoplastics' asserted patents are invalid. Trial is currently set to begin on July 24, 2023.

Settlement and License Agreement with Wright Medical and Stryker

On April 24, 2020, we filed a lawsuit against Wright Medical Technology, Inc. and Tornier, Inc. (together, "Wright Medical"), in the United States District Court for the District of Delaware, seeking damages for Wright Medical's infringement of certain of our patents related to patient-specific instrument and implant systems. The complaint alleged that Wright Medical's multiple lines of patient-specific shoulder instruments, as well as the implant components used in conjunction with them, infringed four of our patents. The accused product lines included Wright Medical's Tornier Blueprint 3D Planning + PSI shoulder replacement systems. On December 14, 2020, Wright Medical filed its answer to the amended complaint, denying that its patient-specific instrument and implant systems infringed the patents asserted by us. Wright Medical's answer also alleged the affirmative defense that the our asserted patents are invalid.

On June 30, 2021, we reached a settlement and license agreement (the "Settlement and License Agreement") with Stryker Corporation ("Stryker") and Wright Medical (together, the "Stryker Parties"), pursuant to which the parties have agreed to terms for resolving the outstanding patent infringement lawsuit against Wright Medical. Wright Medical was acquired by Stryker in November 2020. Under the terms of the Settlement and License Agreement, the Stryker Parties will make a one-time payment of $15 million to Conformis no later than October 15, 2021, and be granted a non-exclusive license with respect to certain Conformis patents. The payment of $15 million was made and received on October 15, 2021.

Litigation against DePuy

On April 30, 2021, we filed a lawsuit against DePuy Synthes, Inc., DePuy Synthes Products, Inc., and DePuy Synthes Sales, Inc. (together, "DePuy") in the United States District Court for the District of Delaware seeking damages for DePuy's infringement of certain of our patents related to patient-specific instrument and implant systems. The complaint alleges that DePuy's multiple lines of patient-specific instruments, as well as the implant components used in conjunction with them, infringe seven of our patents. The accused product lines include DePuy's patient-specific instrument and implant systems for knee and shoulder replacement procedures. On October 25, 2021, DePuy filed a partial motion to dismiss. On November 15, 2021, we filed an amended complaint. On December 6, 2021, DePuy filed a second partial motion to dismiss. We opposed the partial motion to dismiss on December 20, 2021, and DePuy filed a reply in support of its partial motion to dismiss on December 27, 2021. On February 14, 2022, the court denied DePuy's partial motion to dismiss. On February 28, 2022, DePuy filed its answer to our amended complaint, denying that its patient-specific instrument and implant systems infringe the patents asserted by us. A claim construction hearing was held on February 6, 2023. Discovery in the lawsuit is ongoing.

Litigation against Exactech

On June 3, 2021, we filed a lawsuit against Exactech, Inc. ("Exactech") in the United States District Court for the Middle District of Florida seeking damages for Exactech's infringement of certain of our patents related to patient-specific instrument and implant systems. The complaint alleges that Exactech's line of patient-specific instruments for use with its ankle implant systems, as well as the ankle implant components used in conjunction with them, infringe five of our patents. Discovery in the lawsuit is ongoing.

Litigation against Bodycad Laboratories

On June 3, 2021, we filed a lawsuit against Bodycad Laboratories, Inc., Bodycad USA Corp. (together, "Bodycad"), and Exactech (collectively, "Defendants"), in the United States District Court for the Middle District of Florida seeking damages for Defendants' infringement of certain of our patents related to patient-specific instrument and implant systems. The complaint alleges that Defendants' line of patient-specific surgical systems for unicondylar knee replacement surgery and Bodycad's line of patient-specific surgical systems for knee osteotomy surgery infringe six of our patents. On August 2, 2021, Exactech filed its answer to the complaint, denying that it infringed our asserted patents and also alleging that our asserted patents are invalid. On August 20, 2021, Bodycad filed a motion to dismiss and for a more definite statement. On September 10, 2021, we filed an amended complaint that continued to accuse the same products of infringing six of our patents. On September 24, 2021, Defendants filed a motion to dismiss, and we opposed the motion to dismiss on October 15, 2021. On March 30, 2022, the court denied Defendants motion to dismiss. On February 9, 2023, the parties entered into a settlement

and license agreement that resolves the patent infringement dispute filed by us in June of 2021. The parties agreed to an undisclosed amount for the dismissal of all patent litigation between the companies along with a release and license to certain Company patents related to patient-specific instrumentation and knee implants.

Litigation against Aetna

On May 8, 2020, we and an individual plaintiff filed a lawsuit against Aetna, Inc. and Aetna Life Insurance Company (together, "Aetna") in the United States District Court for the District of Massachusetts seeking damages for Aetna's improper denial of coverage for personalized knee implants under its health plans and the ones it administers. We amended our complaint on August 13, 2020, alleging that Aetna violated its duties under state and federal law, including the Employee Retirement Income Security Act. On March 31, 2021, the court dismissed our claims against Aetna, but allowed the individual plaintiff's claims to survive. The individual plaintiff settled his claims against Aetna in October 2021 and we subsequently filed a notice of appeal. We filed our appeal brief on April 15, 2022. Aetna filed its response to our appeal brief on June 15, 2022. The court is scheduled to hear oral arguments from the parties on the appeal briefs on November 8, 2022.

On January 23, 2023, the United States Court of Appeals for the First Circuit revived our trade libel claims against Aetna, finding that Aetna's policy claims that our knee implants are "experimental" and "investigational" can plausibly be considered actionable product disparagement, and that the district court had erred in dismissing these claims. The court found that we have plausibly claimed that Aetna's policy decision caused orthopedic surgeons to stop prescribing its knee replacement implants. The court also revived our related claims for unfair trade practice and interference with advantageous relations. The court issued a scheduling order on March 2, 2023 and discovery in the lawsuit has commenced. We intend to continue pursuing these claims against Aetna, and expect to incur additional legal expenses in 2023 (and potentially thereafter) in connection with doing so. We are seeking an award of monetary damages and equitable relief. We are not presently able to predict the ultimate outcome of this matter or to reasonably estimate a range of potential damages we may be awarded, if successful.

ITEM 1A. RISK FACTORS

We operate in a rapidly changing environment that involves a number of risks that may have a material adverse effect on our business, financial condition and results of operations. The following description of risk factors consists of updates to the risk factors previously disclosed in Part 1, Item 1A in our Annual Report on Form 10-K for the fiscal year ended *December 31, 2022*. For a detailed discussion of the other risks that affect our business, please refer to the entire section entitled "Risk Factors" in our Annual Report on Form 10-K. There have been no material changes to our risk factors as previously disclosed in our Annual Report on Form 10-K. *Risk factors and other information included in our Form 10-Q should be carefully considered. Additional risks and uncertainties not presently known to us or that we presently deem less significant may also impair our business operations. Please see page 31 of this Quarterly Report on Form 10-Q for a discussion of some of the forward-looking statements that are qualified by these risk factors. If any of the risks actually occur, our business, financial condition, results of operations and future growth prospects could be materially and adversely affected.*

We maintain cash deposits in excess of federally insured limits. Adverse developments affecting financial institutions, including bank failures, could adversely affect our liquidity and financial performance.

We maintain domestic cash deposits in Federal Deposit Insurance Corporation ("FDIC") insured banks that exceed FDIC insurance limits. We also maintain cash deposits in foreign banks where we operate, which are not insured by the FDIC or similar agencies. Bank failures, events involving limited liquidity, defaults, non-performance, or other adverse developments that affect financial institutions, or concerns or rumors about such events, may lead to liquidity constraints. For example, on March 10, 2023, Silicon Valley Bank failed and was taken into receivership by the FDIC. There can be no assurance that our deposits in excess of the FDIC or other comparable insurance limits will be backstopped by the U.S. or applicable foreign government, or that any bank or financial institution with which we do business will be able to obtain needed liquidity from other banks, government institutions, or by acquisition in the event of a failure or liquidity crisis. In the event of a failure of any financial institutions where we maintain our deposits or other assets, we may incur a loss to the extent such loss exceeds the FDIC insurance limitation, which could have a material adverse effect upon our liquidity, financial condition and our results of operations.

ITEM 2. UNREGISTERED SALES OF SECURITIES AND USE OF PROCEEDS

Unregistered Sales of Securities

We did not sell any shares of our common stock, shares of our preferred stock or warrants to purchase shares of our stock, or grant any stock options or restricted stock awards, during the period covered by this Quarterly Report on Form 10-Q that were not registered under the Securities Act and that have not otherwise been described in a Current Report on Form 8-K.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

The exhibits filed as part of this Quarterly Report on Form 10-Q are set forth on the Exhibit Index, which Exhibit Index is incorporated herein by reference.

EXHIBIT INDEX

Exhibit Number	Description of Exhibit
31.1*	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2*	Certification of Interim Chief Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1*#	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2*#	Certification of Interim Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Database
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document

* Filed herewith.

\# This certification will not be deemed “filed” for purposes of Section 18 of the Exchange Act, or otherwise subject to the liability of that section. Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act or the Exchange Act, except to the extent specifically incorporated by reference into such filing.

SIGNATURES

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

Date: 5/8/2023

CONFORMIS, INC.

By: /s/ Mark A. Augusti
Mark A. Augusti
President and Chief Executive Officer
(On behalf of the Registrant)

Date: 5/8/2023

CONFORMIS, INC.

By: /s/ Robert Howe
Robert Howe
Chief Financial Officer (Principal Financial Officer)

Exhibit 31.1

CERTIFICATIONS

I, Mark A. Augusti, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Conformis, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer 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.

Date: 5/8/2023

By: /s/Mark A. Augusti
Mark A. Augusti
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATIONS

I, Robert Howe, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Conformis, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer 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.

Date: 5/8/2023

By: /s/ Robert Howe
Robert Howe
Chief Financial Officer
(Principal Financial Officer)

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

In connection with the Quarterly Report on Form 10-Q of Conformis, Inc. (the "Company") for the period ended March 31, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Mark A. Augusti, President and Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of his 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.

Date: 5/8/2023

By: /s/Mark A. Augusti
Mark A. Augusti
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,

AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Conformis, Inc. (the "Company") for the period ended March 31, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Robert Howe, Chief Financial Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of his 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.

Date: 5/8/2023

By: /s/ Robert Howe
Robert Howe
Chief Financial Officer
(Principal Financial Officer)