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 September 30, 2021

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 October 31, 2021, there were 186,096,188 shares of Common Stock, $0.00001 par value per share, outstanding.

Conformis, Inc.

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PART I - FINANCIAL INFORMATION

Item 1. FINANCIAL STATEMENTS

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

	September 30, 2021 (unaudited)	December 31, 2020
Assets		
Current Assets		
Cash and cash equivalents	$ 97,111	$ 28,673
Accounts receivable, net	8,943	8,515
Royalty and licensing receivable	15,634	1,256
Inventories, net	14,478	12,585
Prepaid expenses and other current assets	1,787	2,315
Total current assets	137,953	53,344
Property and equipment, net	10,914	12,240
Operating lease right-of-use assets	7,906	5,215
Other Assets		
Restricted cash	562	462
Other long-term assets	211	239
Total assets	$ 157,546	$ 71,500
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 5,110	$ 4,918
Accrued expenses	8,309	7,213
Operating lease liabilities	1,809	1,620
Advance on research and development	—	3,168
Contract liability	—	14,000
Total current liabilities	15,228	30,919
Long-term debt, less debt issuance costs	20,799	25,003
Operating lease liabilities	6,817	4,206
Total liabilities	42,844	60,128
Commitments and contingencies		
Stockholders’ equity		
Preferred stock, $0.00001 par value:		
Authorized: 5,000,000 shares authorized at September 30, 2021 and December 31, 2020; no shares issued and outstanding as of September 30, 2021 and December 31, 2020	—	—
Common stock, $0.00001 par value:		
Authorized: 300,000,000 shares authorized at September 30, 2021 and December 31, 2020; 185,879,973 and 95,546,577 shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively	2	1
Additional paid-in capital	631,475	543,809
Accumulated deficit	(514,875)	(528,438)
Accumulated other comprehensive loss	(1,900)	(4,000)
Total stockholders’ equity	114,702	11,372
Total liabilities and stockholders’ equity	$ 157,546	$ 71,500

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 September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Revenue				
Product	$ 14,130	$ 15,975	$ 43,040	$ 42,008
Royalty and licensing	123	146	41,396	10,056
Total revenue	14,253	16,121	84,436	52,064
Cost of revenue	8,231	8,437	24,703	26,148
Gross profit	6,022	7,684	59,733	25,916
Operating expenses				
Sales and marketing	6,434	5,755	17,851	16,420
Research and development	3,548	2,866	10,738	8,594
General and administrative	7,407	6,134	20,762	18,344
Total operating expenses	17,389	14,755	49,351	43,358
(Loss) income from operations	(11,367)	(7,071)	10,382	(17,442)
Other income and expenses				
Interest income	20	8	77	66
Interest expense	(601)	(611)	(1,802)	(1,769)
Other income	—	—	7,252	—
Foreign currency exchange transaction (loss) income	(996)	1,511	(2,302)	1,491
Total other (expenses) income	(1,577)	908	3,225	(212)
(Loss) income before income taxes	(12,944)	(6,163)	13,607	(17,654)
Income tax provision	29	20	44	17
Net (loss) income	$ (12,973)	$ (6,183)	$ 13,563	$ (17,671)
Net (loss) income per share				
Basic	$ (0.07)	$ (0.09)	$ 0.08	$ (0.25)
Diluted	$ (0.07)	$ (0.09)	$ 0.08	$ (0.25)
Weighted average common shares outstanding				
Basic	178,452,296	71,224,786	162,646,412	69,799,495
Diluted	178,452,296	71,224,786	167,369,631	69,799,495

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 September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Net (loss) income	$ (12,973)	$ (6,183)	$ 13,563	$ (17,671)
Other comprehensive income (loss)				
Foreign currency translation adjustments	906	(1,450)	2,100	(1,501)
Comprehensive (loss) income	$ (12,067)	$ (7,633)	$ 15,663	$ (19,172)

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 September 30, 2021					
	Common Stock					
	Shares	Par Value	Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total
Balance, June 30, 2021	186,053,533	$ 2	$ 630,435	$ (501,902)	$ (2,806)	$ 125,729
Issuance of common stock—restricted stock	(173,560)	—	—	—	—	—
Issuance of common stock at public offering, less issuance costs of $5.4 million	—	—	14	—	—	14
Compensation expense related to issued stock options and restricted stock awards	—	—	1,026	—	—	1,026
Net loss	—	—	—	(12,973)	—	(12,973)
Other comprehensive income	—	—	—	—	906	906
Balance, September 30, 2021	185,879,973	$ 2	$ 631,475	$ (514,875)	$ (1,900)	$ 114,702

	Nine Months Ended September 30, 2021					
	Common Stock					
	Shares	Par Value	Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total
Balance, December 31, 2020	95,546,577	$ 1	$ 543,809	$ (528,438)	$ (4,000)	$ 11,372
Issuance of common stock—restricted stock	3,375,974	—	—	—	—	—
Issuance of common stock at public offering, less issuance costs of $5.4 million	80,952,381	1	79,636	—	—	79,637
Issuance of common stock upon exercise of common stock warrants	6,005,041	—	5,253	—	—	5,253
Compensation expense related to issued stock options and restricted stock awards	—	—	2,777	—	—	2,777
Net income	—	—	—	13,563	—	13,563
Other comprehensive income	—	—	—	—	2,100	2,100
Balance, September 30, 2021	185,879,973	$ 2	$ 631,475	$ (514,875)	$ (1,900)	$ 114,702

	Three Months Ended September 30, 2020					
	Common Stock					
	Shares	Par Value	Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total
Balance, June 30, 2020	76,103,605	$ 1	$ 524,991	$ (515,633)	$ (916)	$ 8,443
Issuance of common stock—restricted stock	104,489	—	—	—	—	—
Issuance of common stock—LPC offering	1,400,000	—	1,086	—	—	1,086
Issuance of common stock— ATM offering	52,888	—	41	—	—	41
Issuance of common stock and pre-funded warrants under registered direct offering, less issuance costs	8,512,088	—	15,896	—	—	15,896
Compensation expense related to issued stock options and restricted stock awards	—	—	972	—	—	972
Net loss	—	—	—	(6,183)	—	(6,183)
Other comprehensive loss	—	—	—	—	(1,450)	(1,450)
Balance, September 30, 2020	86,173,070	$ 1	$ 542,986	$ (521,816)	$ (2,366)	$ 18,805

	Nine Months Ended September 30, 2020					
	Common Stock					
	Shares	Par Value	Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total
Balance, December 31, 2019	70,427,400	$ 1	$ 521,356	$ (504,145)	$ (865)	$ 16,347
Issuance of common stock—restricted stock	3,840,651	—	2	—	—	2
Issuance of common stock—LPC offering	2,600,000	—	2,403	—	—	2,403
Issuance of common stock— ATM offering	792,931	—	746	—	—	746
Issuance of common stock and pre-funded warrants under registered direct offering, less issuance costs	8,512,088	—	15,896	—	—	15,896
Compensation expense related to issued stock options and restricted stock awards	—	—	2,583	—	—	2,583
Net loss	—	—	—	(17,671)	—	(17,671)
Other comprehensive loss	—	—	—	—	(1,501)	(1,501)
Balance, September 30, 2020	86,173,070	$ 1	$ 542,986	$ (521,816)	$ (2,366)	$ 18,805

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

CONFORMIS, INC. AND SUBSIDIARIES

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

	Nine Months Ended September 30,	
	2021	2020
Cash flows from operating activities:		
Net income (loss)	$ 13,563	$ (17,671)
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Depreciation and amortization expense	3,158	3,292
Stock-based compensation expense	2,777	2,583
Unrealized foreign exchange loss	2,238	(1,513)
Non-cash lease expense	1,073	875
Provision for bad debts on trade receivables	55	72
Gain on forgiveness of PPP loan	(4,772)	—
Non-cash interest expense	547	531
Changes in operating assets and liabilities:		
Accounts receivable	(483)	2,015
Royalty and licensing receivable	(14,378)	(3,586)
Inventories	(1,894)	(836)
Prepaid expenses and other assets	524	16
Accounts payable, accrued expenses and other liabilities	378	(3,358)
Contract liability	(14,000)	2,000
Advance on research and development	(3,168)	1,305
Net cash used in operating activities	(14,382)	(14,275)
Cash flows from investing activities:		
Acquisition of property and equipment	(1,832)	(3,001)
Net cash used in investing activities	(1,832)	(3,001)
Cash flows from financing activities:		
Proceeds from exercise of common stock warrant	5,253	—
Debt issuance costs	—	(10)
Proceeds from issuance of debt	—	4,720
Net proceeds from issuance of common stock	79,637	3,151
Issuance of common stock and pre-funded warrants under registered direct offering, net	—	15,896
Net cash provided by financing activities	84,890	23,757
Foreign exchange effect on cash and cash equivalents	(138)	13
Increase in cash, cash equivalents and restricted cash	68,538	6,494
Cash, cash equivalents and restricted cash beginning of period	29,135	26,856
Cash, cash equivalents and restricted cash end of period	$ 97,673	$ 33,350
Supplemental information:		
Cash paid for interest	1,064	691
Non cash investing and financing activities:		
Operating leases right-of-use assets obtained in exchange for lease obligations	3,763	—

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, and its Conformis hip system in 2018. The Company has its corporate offices in Billerica, Massachusetts.

These consolidated financial statements as of September 30, 2021 and for the three and nine months ended September 30, 2021 and 2020, 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.

Liquidity and operations

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. At September 30, 2021, the Company had an accumulated deficit of $514.9 million and cash and cash equivalents of $97.1 million, and $0.6 million in restricted cash allocated to lease deposits.

The Company expects that its existing cash and cash equivalents as of September 30, 2021, funds from potential exercises of its common stock warrants, and anticipated revenue from operations, will enable the Company to fund its operations, capital expenditure requirements and debt service for at least the next 12 months from the date of filing. In order 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. It cannot be assured that the Company will be successful.

On June 25, 2019, the Company entered into a Loan and Security Agreement (the "2019 Secured Loan Agreement") with Innovatus Life Sciences Lending Fund I, LP ("Innovatus"), as collateral agent and lender, East West Bank and the other lenders party thereto from time to time (collectively, the "Lenders"), pursuant to which the Lenders agreed to make term loans and revolving credit facility to the Company to repay existing indebtedness, for working capital and general business purposes, in a principal amount of up to $30 million. For further information regarding the 2019 Secured Loan Agreement and the Amendments, 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 February 17, 2021, the Company closed an offering of its common stock under the Company's shelf registration statement on Form S-3, pursuant to which the Company issued and sold 80,952,381 shares of its common stock at a public offering price of $1.05 per share, for aggregate net proceeds of approximately $79.6 million. For further information regarding this public offering, see "Note J—Stockholders' Equity" in the financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q.

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. The future progression of the pandemic, including the scope, severity and duration of the pandemic, potential resurgences, the speed and effectiveness of vaccine and treatment developments, and the direct and indirect economic effects of the pandemic and containment measures, and its effects on the Company's business and operations remain uncertain. The Company has experienced significantly decreased demand for its products during the pandemic as healthcare providers and individuals have de-prioritized and deferred medical procedures deemed to be elective, such as joint replacement procedures, which has had, and is expected to continue to have a significant negative effect on the Company's revenue. Such negative effects were most pronounced during the second quarter of 2020, when a significant number of hospitals were either closed for elective procedures or otherwise operating at significantly reduced volumes. Generally, the Company saw an increase in procedure volumes from these levels during the summer of 2020, as many regions were able to reopen for elective procedures, with an existing patient backlog.

However, in the United States and Germany, which are the Company's major sales markets, estimated case counts increased in the fourth quarter of 2020 and peaked in January 2021. While worldwide case counts have declined since January, the Company saw a decline in elective procedures during the first quarter of 2021. In Germany, case counts declined after January 2021 but then increased again in the second quarter. Germany case counts began to decline mid-way through the second quarter but the Company saw a decline in Germany elective procedures during the second quarter of 2021. In the United States, elective procedures have improved sequentially second quarter of 2021 over first quarter of 2021 consistent with the market. However, in the third quarter 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 variant. The Company expects that these negative effects will continue in the near term until infection rates decline further from their current level, and more of the population is vaccinated. The future progression of the pandemic remains uncertain, including with respect to new or potential variants. 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, 2020.

Unaudited Interim Financial Information

The accompanying Interim Consolidated Financial Statements as of September 30, 2021 and for the three and nine months ended September 30, 2021 and 2020, 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 September 30, 2021, results of operations for and stockholders' equity for the three and nine months ended September 30, 2021 and 2020, and comprehensive (loss) income, and cash flows for the nine months ended September 30, 2021 and 2020. The results for the three and nine months ended September 30, 2021 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 nine months ended September 30, 2021 to the application of significant accounting policies and estimates as described in its audited consolidated financial statements for the year ended December 31, 2020.

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 $1.5 million as of September 30, 2021 and $1.0 million as of December 31, 2020 held in foreign bank accounts that are not federally insured.

The Company and its contract manufacturers rely on sole source suppliers and service providers for certain components. There can be no assurance that a shortage or stoppage of shipments of the materials or components that the Company purchases will not result in a delay in production or adversely affect the Company's business. On an ongoing basis, the Company validates alternate suppliers relative to certain key components as needed.

For the three months ended September 30, 2021, no customer represented greater than 10% of total revenue. For the nine months ended September 30, 2021, Stryker Corporation ("Stryker"), Wright Medical Technology, Inc. ("Wright Medical"), and Tornier, Inc. ("Tornier," and collectively with Stryker and Wright Medical, the "Stryker Parties") represented 47% of total revenue. For the three months ended September 30, 2020, no customer represented greater than 10% of total revenue. For the nine months ended September 30, 2020, Zimmer Biomet Holdings, Inc. ("Zimmer Biomet"), represented 18% of total revenue. As of September 30, 2021, payments due from Stryker represented 61% of the total net receivable balance. As of December 31, 2020, payments due from Zimmer Biomet represented 13% of our 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 $0.6 million as of September 30, 2021, and $0.5 million as of December 31, 2020. 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.

	September 30, 2021	December 31, 2020
Cash and cash equivalents	$ 97,111	$ 28,673
Restricted cash	562	462
Total cash, cash equivalents, and restricted cash shown in the statement of cash flows	$ 97,673	$ 29,135

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 doubtful accounts

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 doubtful accounts based on the aging of the underlying invoices, collections experience to date and any specific collection issues that have been identified. The allowance for doubtful accounts 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 and nine months ended September 30, 2021, the Company recognized provisions of $0.5 million and $1.6 million, respectively, to adjust its inventory value to the lower of cost or net realizable value for estimated unused product related to known and potential cancelled cases, which is included in cost of revenue. During the three and nine months ended September 30, 2020, the Company recognized provisions of $0.4 million and $2.1 million, respectively, to adjust its inventory value to the lower of cost or net realizable value for 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. If the cash flow estimates or the significant operating assumptions upon which they are based change in the future, the Company may be required to record impairment charges. During the three months ended September 30, 2021, there were no changes in circumstances that led the Company to believe that its long-lived assets may be impaired.

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 September 30, 2021. 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.

Unconditional rights to consideration are reported as receivables. Incidental items that are immaterial in the context of the contract are recognized as expense.

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 September 30, 2019 the Company entered into an Asset Purchase Agreement with Howmedica Osteonics Corp., a wholly-owned subsidiary of Stryker. In connection with entering into the Asset Purchase Agreement, the Company also entered into a Development Agreement, a License Agreement, and other ancillary agreements contemplated by the Asset Purchase Agreement with Stryker (the "Stryker Agreements"). The Company determined that the Asset Purchase Agreement and the License Agreement are within the scope of ASC 606. Under the Asset Purchase Agreement and License Agreement, the Company is required to provide certain assets and the right to use the license for a specific purpose. The assets and the right to use the license are highly interdependent and considered one performance obligation. The Company bifurcated the total transaction price of $30.0 million into two components; $5.0 million related to cost reimbursement for other services (development) and $25.0 million allocated to royalty revenue determined using the residual approach of deducting the cost

reimbursement component from the total transaction price. The arrangement does not contain a significant financing component.

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. The Company has concluded that Stryker meets the definition of a customer for a portion of the obligations under the Stryker Agreements. The contract liability balances as of January 1, 2021 and 2020, were $14.0 million and $12.0 million, respectively, which were related to consideration received from the customer under the Asset Purchase Agreement and Development Agreement. The Company concluded the license rights under the License Agreement were functional and would be recognized at the point in time when 510(k) clearance was received from the FDA as required under Milestone 3 in the License Agreement, or upon termination by Stryker and Stryker's election to purchase the license rights. On April 19, 2021, the Company achieved the third of three milestones under the License Agreement when it received 510(k) clearance from the FDA and received $11.0 million from Stryker. In connection with the 510(k) clearance, the Company recognized as royalty and license revenue the $14.0 million that was previously deferred as contract liability, plus the $11.0 million payment received, for a total aggregate of $25.0 million during the quarter ended June 30, 2021. There are no amounts recorded as contract liability as of September 30, 2021. In addition, during the quarter ended June 30, 2021, the Company recorded $2.5 million in other income for the remaining portion of the advance on research and development, that was not used to offset against research and development expenses.

On May 22, 2020 the Company entered into a settlement and license agreement (the “Zimmer Settlement and License Agreement”) with Zimmer Biomet, pursuant to which both parties 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 Zimmer Biomet, Zimmer Biomet was required to pay the Company $3.5 million promptly after execution of the Zimmer Settlement and License Agreement, which it has, and additional payments on specified dates through January 15, 2021, for a total amount payable of $9.6 million. The agreement provides for the grant of the licenses, covenants not to sue, releases, and other significant deliverables upon execution of the contract. 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 Zimmer Biomet 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. Zimmer Biomet legally obtained control of the license and other rights upon execution of the contract. As such, the earnings process is complete and revenue was recognized upon the execution of the contract, when collectability became probable and all other revenue recognition criteria had been met within the scope of ASC 606. In connection with the Zimmer Settlement and License Agreement, the Company recognized revenue of $9.6 million during the nine months ended September 30, 2020. See “Note H—Commitments and Contingencies, Legal proceedings” for further discussion of the Zimmer Biomet settlement.

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 may receive an additional $0.5 million from Paragon 28 before April 8, 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 excluded from the transaction price given it is contingent on a future event that was not probable as of September 30, 2021.

On June 30, 2021 the Company entered into a settlement and license agreement (the “Settlement and License Agreement”) with the Stryker Parties, 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 Stryker Parties, the Stryker Parties are required to make a one-time payment to the Company of $15.0 million no later than October 15, 2021. The agreement provides for the grant of the licenses, covenants-not-to-sue, releases, and other deliverables upon execution of the contract. 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 Stryker Parties is not separately identifiable from other promises in the agreement. As a result, the Company accounts for the promises in the Settlement and License Agreement as a single performance obligation. The Stryker Parties legally obtained control of the license and other rights upon execution of the contract. As such, the earnings process is complete and revenue was recognized upon the execution of the contract, when collectability became probable 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 revenue of $15.0 million during the quarter ended June 30, 2021 and payment in the same amount was received from the Stryker Parties on October 15, 2021. See “Note H—Commitments and Contingencies, Legal proceedings” for further discussion of the Stryker Parties settlement.

Disaggregation of Revenue

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

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):

	September 30, 2021	December 31, 2020
Beginning Balance	$ 81	$ 127
Provision related to current period sales	83	146
Adjustment related to prior period sales	—	(55)
Payments or credits issued to customer	(84)	(137)
Ending Balance	$ 80	$ 81

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 $0.6 million and $0.4 million for the three months ended September 30, 2021 and 2020, respectively, and $1.5 million and $1.1 million for the nine months ended September 30, 2021 and 2020, 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 $0.1 million for each of the three months ended September 30, 2021 and 2020, and $0.2 million and $0.3 million for the nine months ended September 30, 2021 and 2020, 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 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. In April 2020, new interpretations of a German law related to intellectual property and withholding tax were released. The Company is currently evaluating whether the interpretations will have an impact on its consolidated financial statements.

The Company is subject to U.S. federal, state, and foreign income taxes. The Company recorded a provision for income taxes of $29,000 and $20,000 for the three months ended September 30, 2021 and 2020, respectively, and $44,000 and $17,000 for the nine months ended September 30, 2021 and 2020, respectively. The Company recognizes interest and penalties related to income taxes as a component of income tax expense. As of September 30, 2021 and 2020, a cumulative balance of $54,000 and $42,000 of interest and penalties had been accrued, respectively.

On March 27, 2020, the U.S. government enacted the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act") which included modifications to the limitation on business interest expense, net operating loss provisions, and other various U.S. tax law updates. The Company does not expect that these aspects of the CARES Act will have a material impact on its consolidated financial statements.

On December 27, 2020, the U.S government enacted the Consolidated Appropriations Act, 2021 (the "Appropriations Act"), which included various tax extenders, an update to meals and entertainment expensing, and the deductibility of expenses related to the Paycheck Protection Program (“PPP”) loan proceeds. The Company applied the Appropriations Act in regards to expenses related to the PPP loan proceeds, which previously would have been non-deductible.

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) income per share

The Company calculates net (loss) income 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 September 30, 2021	Three Months Ended September 30, 2020	Nine Months Ended September 30, 2021	Nine Months Ended September 30, 2020
Numerator:				
Basic and diluted (loss) income per share				
Net (loss) income	$ (12,973)	$ (6,183)	$ 13,563	$ (17,671)
Denominator:				
Basic weighted average shares	178,452,296	71,224,786	162,646,412	69,799,495
Diluted weighted average shares	178,452,296	71,224,786	167,369,631	69,799,495
(Loss) income per share attributable to Conformis, Inc. stockholders:				
Basic	$ (0.07)	$ (0.09)	$ 0.08	$ (0.25)
Diluted	$ (0.07)	$ (0.09)	$ 0.08	$ (0.25)

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 September 30, 2021	Three Months Ended September 30, 2020	Nine Months Ended September 30, 2021	Nine Months Ended September 30, 2020
Common stock warrants	4,554,069	—	—	—
Stock options and restricted stock awards	3,117,957	694,817	—	993,012

Note C—Accounts Receivable

Accounts receivable consisted of the following (in thousands):

	September 30, 2021	December 31, 2020
Total receivables	$ 9,200	$ 8,805
Allowance for doubtful accounts and returns	(257)	(290)
Accounts receivable, net	$ 8,943	$ 8,515

The beginning accounts receivable balance as of January 1, 2021 and 2020, was $8.5 million and $11.1 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 $1.0 million at September 30, 2021 and December 31, 2020, respectively. Write-offs related to accounts receivable were approximately $5,000 and $0 for the three months ended September 30, 2021 and 2020, respectively, and $76,000 and $71,000 for the nine months ended September 30, 2021 and 2020, respectively.

Summary of allowance for doubtful accounts and returns activity was as follows (in thousands):

	September 30, 2021	December 31, 2020
Beginning balance	$ (290)	$ (335)
Provision for bad debts on trade receivables	(55)	(50)
Other allowances	12	20
Accounts receivable write offs	76	75
Ending balance	$ (257)	$ (290)

Note D—Inventories

Inventories consisted of the following (in thousands):

	September 30, 2021	December 31, 2020
Raw Material	$ 6,384	$ 5,513
Work in process	2,107	1,833
Finished goods	5,987	5,239
Total Inventories	$ 14,478	$ 12,585

Note E—Property and Equipment

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

	Estimated Useful Life (Years)	September 30, 2021	December 31, 2020
Equipment	5-7	$ 19,949	$ 19,461
Furniture and fixtures	5-7	990	864
Computer and software	3	10,293	9,873
Leasehold improvements	3-7	2,243	2,068
Reusable instruments	5	6,077	5,739
Molding and Tooling	5	376	91
Total property and equipment		39,928	38,096
Accumulated depreciation		(29,014)	(25,856)
Property and equipment, net		$ 10,914	$ 12,240

Depreciation expense related to property and equipment was $1.1 million for each of the three months ended September 30, 2021 and 2020, and $3.2 million and $3.3 million for the nine months ended September 30, 2021 and 2020, respectively.

Note F—Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	September 30, 2021	December 31, 2020
Accrued employee compensation	$ 3,758	$ 3,365
Accrued legal expense	2,052	952
Accrued consulting expense	21	21
Accrued vendor charges	475	766
Accrued revenue share expense	696	697
Accrued clinical trial expense	304	306
Accrued other	1,003	1,106
	$ 8,309	$ 7,213

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-six 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 September 30, 2021, 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 September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Rent expense	$ 491	$ 381	$ 1,372	$ 1,144
Variable lease cost [1]	110	88	315	265
	$ 601	$ 469	$ 1,687	$ 1,409

(1) Variable operating lease expenses consist primarily of common area maintenance and real estate taxes for the three and nine months ended September 30, 2021 and 2020, respectively.

As of September 30, 2021, the remaining weighted-average lease term of the operating leases was 5.0 years and the weighted-average discount rate was 6.0%.

The future minimum rental payments under these agreements as of September 30, 2021 were as follows (in thousands):

Year	Minimum Lease Payments
2021 remainder of year	548
2022	1,815
2023	2,067
2024	2,126
2025	1,885
2026	970
2027	741
Total lease payments	$ 10,152
Present value adjustment	(1,526)
Present value of lease liabilities	$ 8,626

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 $0.6 million during the three months ended September 30, 2021, representing 4.3% of product revenue and $1.6 million during the nine months ended September 30, 2021, representing 3.6% of product revenue and $0.4 million during the three months ended September 30, 2020, representing 2.7% of product revenue and $1.1 million during the nine months ended September 30, 2020 representing, 2.6% 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 September 30, 2021 or December 31, 2020.

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.

On August 15, 2019, the Company filed a lawsuit against Zimmer Biomet Holdings, Inc. and Zimmer, Inc. ("Zimmer Biomet"), in the United States District Court for the District of Delaware seeking damages for Zimmer Biomet's infringement of certain of the Company's patents related to patient-specific instrument and implant systems. The complaint alleged that Zimmer Biomet's multiple lines of patient-specific instruments, as well as the implant components used in conjunction with them, infringed four of the Company's patents. The accused product lines included Zimmer Biomet's patient-specific instrument and implant systems for knee, shoulder, and hip replacement procedures.

On November 5, 2019, Zimmer Biomet filed a lawsuit against the Company in the United States District Court for the District of Delaware, alleging that the Company infringed five patents owned by Zimmer Biomet. Zimmer Biomet alleged that the Company's iTotal CR and iTotal PS products infringed all five asserted patents, that the Company's iDuo product infringed three of the asserted patents, and that the Company's iUni product infringed two of the asserted patents. On January 13, 2020, Zimmer Biomet filed a motion to dismiss the Company's complaint, and the Company filed its answer to Zimmer Biomet's complaint, denying that the Company's products infringed Zimmer Biomet's asserted patents. The Company's answer also alleged that Zimmer Biomet's asserted patents were invalid.

On May 22, 2020, the Company entered into a settlement and license Agreement (the “Zimmer Settlement and License Agreement”) with Zimmer Biomet, Zimmer US, Inc. and Biomet Manufacturing, LLC, pursuant to which the parties agreed to terms for resolving the patent disputes described in the preceding two paragraphs. Under the Zimmer Settlement and License Agreement, the Company and Zimmer Biomet agreed to dismiss both outstanding patent infringement lawsuits between the parties, the Company granted to Zimmer Biomet a royalty-free, non-exclusive, worldwide license to certain of the Company's patents for Zimmer Biomet’s patient-specific instrumentation used with off-the-shelf knee, hip, and shoulder implants, and Zimmer Biomet granted to the Company a fully paid-up, royalty-free, non-exclusive, worldwide license to certain Zimmer Biomet patents for the Company's implants and patient-specific instruments for the knee. Under the agreement, Zimmer Biomet was required to pay the Company a total of $9.6 million, in installments through January 15, 2021, and all such payments were made and received by such date. No payment was due from the Company to Zimmer Biomet under the agreement.

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. Discovery in the lawsuit is ongoing.

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. Discovery in the lawsuit is ongoing.

On April 24, 2020, the Company 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 the Company's 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 the Company’s 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 the Company. Wright Medical’s answer also alleged the affirmative defense that the Company’s asserted patents are invalid.

On June 30, 2021, the Company reached a settlement and license agreement (the "Settlement and License Agreement") with Stryker Corporation ("Stryker") and Wright Medical (collectively, the "Stryker Parties"), pursuant to which the parties agreed to terms for resolving the outstanding patent infringement lawsuit described in the preceding paragraph. Wright Medical was acquired by Stryker in November 2020, subsequent to the Company's commencement of the lawsuit. In consideration of the non-exclusive license to certain of the Company's patents, releases, covenants and other immunities granted by the Company to the Stryker Parties, the Stryker Parties were required to make a one-time payment to the Company of $15.0 million no later than October 15, 2021. The Company recognized revenue of $15.0 million during the quarter ended June 30, 2021 and payment in the same amount was received from the Stryker Parties on October 15, 2021.

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 patient-specific instruments, 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 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.

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 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 has 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 Company filed an amended complaint based on discovery relating to the individual plaintiff's claims and proposed a settlement in three parts, including (1) a financial component, (2) full coverage when surgery involves a standardized knee implant, and (3) coverage for the costs of the procedure (but not the implant) when surgery involves a personalized knee implant. Aetna has yet to negotiate a settlement of the Company's appellate claims.

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.

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):

	September 30, 2021	December 31, 2020
PPP "Term Loan"	—	4,720
Innovatus, Term Loan	20,000	20,000
Innovatus, Term Loan accrued payment-in-kind interest	1,167	775
Less unamortized debt issuance costs	(368)	(492)
Long-term debt, less debt issuance costs	$ 20,799	$ 25,003

Principal payments, including the Term Loan Basic Interest Rate in-kind (described below), due as of September 30, 2021 consisted of the following (in thousands):

	Principal Payment
2021 (remainder of the year)	—
2022	—
2023	8,986
2024	12,580
Total	$ 21,566

2019 Secured Loan Agreement

On June 25, 2019, the Company entered into the 2019 Secured Loan Agreement with Innovatus, as collateral agent and lender, East West Bank and the Lenders, pursuant to which the Lenders agreed to make term loans and revolving credit facility to the Company to repay existing indebtedness, for working capital and general business purposes, in a principal amount of up to $30 million.

The term loan facility established under the 2019 Secured Loan Agreement is secured by substantially all of the Company's and its U.S. subsidiaries' properties, rights and assets.

The 2019 Secured Loan Agreement includes a trailing six months' revenue test, a liquidity covenant and an additional liquidity covenant that is applicable if there are borrowings under the revolving credit facility. The 2019 Secured Loan Agreement also includes customary representations, affirmative and negative covenants. Additionally, the 2019 Secured Loan Agreement includes events of default, the occurrence and continuation of which could cause interest to be charged at the rate that is otherwise applicable plus 5.0% and would provide Innovatus, as collateral agent, with the right to accelerate all obligations under the 2019 Secured Loan Agreement and to exercise remedies against the Company and the collateral securing the credit facility, including foreclosure against assets securing the credit facilities, including the Company's cash. These events of default include, among other things, the Company's failure to pay any amounts due under the credit facility, a breach of covenants under the credit facility, the Company's insolvency, a material adverse change, the occurrence of any default under certain other indebtedness in an amount greater than $250,000, one or more judgments against the Company in an amount greater than $500,000, changes with respect to governmental approvals and FDA actions.

On July 1, 2020, the Company entered into a third amendment to its 2019 Secured Loan Agreement, which, among other things, waived the trailing six-month revenue covenant milestones that applied to the quarters ended June 30, September 30 and December 31, 2020 under the agreement, reduced the revenue covenant milestones that apply thereafter, and delays until June 25, 2021 the Company's option to prepay all, but not less than all, of the term loans advanced under the 2019 Secured Loan Agreement. On August 20, 2020, the Company entered into a fourth amendment to the 2019 Secured Loan Agreement, which, among other things, waived certain provisions of the 2019 Secured Loan Agreement that apply to Conformis India LLP.

On March 1, 2021, the Company entered into a fifth amendment to the 2019 Secured Loan Agreement, which, among other things, waives the trailing six-month revenue covenant milestones that apply to the quarters ending March 31, June 30, September 30 and December 31, 2021 and reduces the revenue covenant milestones that will apply in 2022. The revenue covenant milestones remain unchanged for 2023 and 2024. The amendment also increases the Company's minimum cash covenant to $5 million until December 31, 2021.

As of September 30, 2021, the Company was not in breach of covenants under the 2019 Secured Loan Agreement.

Term Loan - Innovatus

The term loan under the 2019 Secured Loan Agreement bears interest at a floating annual rate calculated at the greater of the variable rate of interest as most recently announced by East West Bank as prime or 5.50%, plus 3.75% ("Term Loan Basic Interest Rate"), bearing an effective interest rate of 9.25% at September 30, 2021. The Company is required to make interest only payments in arrears on the term loan for four years; provided that the Company has elected to pay 2.50% per annum as such Term Loan Basic Interest Rate in-kind by adding an amount equal to 2.50% per annum of the outstanding principal amount to the then outstanding principal balance on a monthly basis until the third anniversary of the 2019 Secured Loan Agreement. Commencing July 1, 2023, and continuing on the payment date of each month thereafter, the Company is required to make consecutive equal monthly payments of principal of the term loan, together with accrued interest, in arrears, to the Lenders. All unpaid principal, accrued and unpaid interest with respect to the term loan, and a final fee in the amount of 5.0% of the term loan commitment, is due and payable in full on the term loan maturity date on June 1, 2024.

At the Company's option, the Company may prepay all, but not less than all, of the term loans advanced by the Lenders under the term loan facility after the second year, subject to a prepayment fee and an amount equal to the sum of all outstanding principal of the term loans plus accrued and unpaid interest thereon through the prepayment date, a final fee, plus all other amounts that are due and payable, including the Lenders' expenses and interest at the default rate with respect to any past due amounts.

Revolving Credit Facility - East West Bank

Under the 2019 Secured Loan Agreement, East West Bank will make loans of up to $10 million from time to time outstanding, subject to availability based on a borrowing base equal to (i) 85.00% of eligible customer accounts, subject to a maximum of 2.50% dilution based upon collections, minus (ii) the Company's foreign accounts receivable credit insurance's outstanding co-payment and minimum annual deductible (that has not been used at the applicable time). Advances under the revolving credit facility bear interest at a rate of 0.50% above the greater of East West Bank's prime rate or 5.50%. Interest on the revolving advances is payable monthly in arrears. The revolving credit facility terminates and the principal and all amounts are due in full on June 25, 2024, provided that if an optional or mandatory prepayment (other than regularly scheduled payments) is made under the term loan, the Company must satisfy in full the obligations under the revolving credit line. The revolving credit facility requires a lockbox arrangement, which provides for all receipts to be swept daily to reduce the borrowings outstanding under the revolving credit facility.

There were no amounts outstanding under the revolving credit facility at September 30, 2021.

PPP Loan- East West Bank

On April 17, 2020, the Company entered into an approximately $4.7 million promissory note (the "PPP Note") with East West Bank under the Paycheck Protection Program ("PPP") offered by the U.S. Small Business Administration (the "SBA") to mitigate the negative financial and operational impacts of the COVID-19 pandemic. The interest rate on the PPP Note is a fixed rate of 1%per annum. The Company is required to make one payment of all outstanding principal plus all accrued unpaid interest on April 9, 2022 (the "Maturity Date"). The Company was required to pay regular monthly payments in an amount equal to one month's accrued interest commencing on August 2, 2021, with all subsequent interest payments to be due on the same day of each month after that. All interest which accrues during the deferral period will be payable on the Maturity Date. According to the terms of the PPP, all or a portion of the loan as well as any accrued interest may be fully forgiven if the funds are used for payroll costs (and at least 60% of the forgiven amount must have been used for payroll), interest on certain other outstanding debt, rent, and utilities. In accordance with the CARES Act, the Company used the proceeds of the loan primarily for payroll costs. The Company accounted for the PPP Note as a debt instrument in accordance with ASC 470-50-40-2, with the proceeds from the loan recognized as a long-term liability, less any debt issuance costs, within the consolidated balance sheet. Interest is accrued at the stated rate on a monthly basis by applying the interest method under ASC 835.

The Company submitted the loan forgiveness application to the lender on December 11, 2020. On June 30, 2021, the Company received notification through its lender that the SBA had rendered a final decision regarding its review of the PPP loan forgiveness application, fully approving the loan forgiveness application as of June 28, 2021. The Company accounted for the forgiveness of the PPP Note in accordance with ASC 405-20-40-1 and ASC 470-50-40-2, where the liability was derecognized from the balance sheet upon formal forgiveness of the loan. The resulting gain on forgiveness was measured based on the net carrying value of the PPP Note, which includes accrued interest and deferred financing costs. The Company recorded a gain on forgiveness of PPP loan of $4.8 million within Other income and expenses on the consolidated statement of operations during the nine months ended September 30, 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. On May 25, 2021, the Certificate of Amendment was filed with the Secretary of State for the State of Delaware, a copy of which was filed as Exhibit 3.1 to the Current Report on Form 8-K filed on May 27, 2021.

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 September 30, 2021 and December 31, 2020.

Demand registration rights

In conjunction with the 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

In January 2017, the Company filed a shelf registration statement on Form S-3, which was declared effective by the SEC on May 9, 2017 (the "Shelf Registration Statement"). The Shelf Registration Statement allowed the Company 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 May 10, 2017, the Company filed with the SEC a prospectus supplement (the "Prospectus Supplement") for the sale and issuance of up to $50 million of its common stock and entered into an Equity Distribution Agreement ("Distribution Agreement") with Canaccord Genuity LLC (formerly, Canaccord Genuity Inc.) ("Canaccord") pursuant to which Canaccord agreed to sell shares of the Company's common stock from time to time, as its agent, in an "at-the-market" ("ATM") offering as defined in Rule 415 promulgated under the U.S. Securities Act of 1933, as amended (the "Securities Act"). The Company was not obligated to sell any shares under the Distribution Agreement. On August 4, 2020, the Company and Canaccord mutually agreed to terminate the Distribution Agreement and, as of that date, the Company had sold 2,663,000 shares under the Distribution Agreement resulting in net proceeds of $4.4 million.

On March 23, 2020, the Company filed a new shelf registration statement on Form S-3 (the "New Shelf Registration Statement"), which was declared effective by the SEC on August 5, 2020. Under the New 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. 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 also provided Cowen with customary indemnification rights. The shares of Common Stock being offered pursuant to the Sales Agreement will be offered and sold pursuant to the New 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 September 30, 2021, the Company had not sold any shares under the Sales Agreement.

Stock purchase agreement

On December 17, 2018, the Company entered into a stock purchase agreement (the "Stock Purchase Agreement") with Lincoln Park Capital ("LPC"). Upon entering into the Stock Purchase Agreement, the Company sold 1,921,968 shares of common stock for $1.0 million to LPC, representing a premium of 110% to the previous day's closing price. As consideration for LPC's commitment to purchase shares of common stock under the Stock Purchase Agreement, the Company issued 354,430 shares to LPC. The Company has the right at its sole discretion to sell to LPC up to $20.0 million worth of shares over a 36-month period subject to the terms of the Stock Purchase Agreement. The Company controls the timing of any sales to LPC and LPC will be obligated to make purchases of the Company's common stock upon receipt of requests from the Company in accordance with the terms of the Stock Purchase Agreement. There are no upper limits to the price per share LPC may pay to purchase up to $20.0 million worth of common stock subject to the Stock Purchase Agreement, and the purchase price of the shares will be based on the then prevailing market prices of the Company's shares at the time of each sale to LPC as described in the Stock Purchase Agreement, provided that LPC will not be obligated to make purchases of the Company's common stock pursuant to receipt of a request from the Company on any business day on which the last closing trade price of the Company's common stock on the NASDAQ Capital Market (or alternative national exchange in accordance with the Stock Purchase Agreement) is below a floor price of $0.25 per share. No warrants, derivatives, financial or business covenants are associated with the Stock Purchase Agreement and LPC has agreed not to cause or engage in any manner whatsoever, any direct or indirect short selling or hedging of shares of the Company's common stock. The Stock Purchase Agreement may be terminated by the Company at any time, at the Company's sole discretion, without any cost or penalty. On August 5, 2020, the Company filed with the SEC a

prospectus supplement, for the sale and issuance of up to $17.6 million of its common stock pursuant to the Stock Purchase Agreement dated December 17, 2018. As of September 30, 2021, the Company had sold 4,521,968 shares under the Stock Purchase Agreement resulting in proceeds of $3.4 million.

2021 common stock offering

On February 17, 2021, the Company closed an offering of its common stock under the New Shelf Registration Statement and issued and sold 80,952,381 shares of its common stock at a public offering price of $1.05 per share, 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) 8,512,088 shares of its common stock and accompanying warrants to purchase up to 8,512,088 shares of common stock and (ii) pre-funded warrants to purchase up to 9,492,953 shares of common stock and accompanying warrants to purchase up to 9,492,953 shares of common stock in a registered direct offering 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 $0.9581 per unit.

The pre-funded warrants became exercisable immediately upon issuance, have an exercise price of $0.0001 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 $0.8748 per share, 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 warrants were exercisable immediately upon issuance.

In connection with the September 23, 2020 registered direct offering, the Company issued 9,492,953 pre-funded common stock warrants with an exercise price of $0.0001 per share and an additional 18,005,041 common stock warrants with an exercise price of $0.8748 per share. All of the warrants are exercisable for one share of common stock and are exercisable immediately. As of September 30, 2021, approximately 6.0 million of the common stock warrants have been exercised. The pre-funded warrants are exercisable indefinitely, while the additional warrants are exercisable for 5 years from the date of issuance. As of September 30, 2021, 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 $0.875 and share price of $0.833 per share based on the trading price of the Company's common stock.

Warrants to purchase 12,020,926 shares of common stock were outstanding as of September 30, 2021 and warrants to purchase 18,025,967 shares were outstanding as of December 31, 2020. Outstanding common stock warrants are currently exercisable with varying exercise expiration dates from 2024 through 2025. At September 30, 2021 and December 31, 2020, the weighted average warrant exercise price per share for common stock and the weighted average contractual life was as follows:

	Number of Common Warrants	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Life	Number of Warrants Exercisable	Weighted Average Price Per Share
Outstanding December 31, 2020	18,025,967	$ 0.89	4.73	18,025,967	$ 0.89
Granted	—	$ —	—	—	$ —
Exercised	(6,005,041)	—	—	(6,005,041)	—
Cancelled/expired	—	—	—	—	—
Outstanding September 30, 2021	12,020,926	$ 0.89	3.98	12,020,926	$ 0.89

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, 2021, an additional 2,866,390 shares of the Company's common stock were added to the 2015 Plan under the terms of this provision, 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 6,000,000, the maximum number of shares of common stock available for issuance under the 2015 Plan ("Plan Amendment"), the Plan, as amended by the Plan Amendment, was filed as Exhibit 10.1 to the Current Report on Form 8-K filed on May 27, 2021. As of September 30, 2021, 4,927,167 shares of common stock were available for future issuance under the 2015 Plan.

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 September 30, 2021, there were 2,383,748 shares of common stock available for future issuance under the 2019 Sales Team Plan.

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, 2020	1,767,579	$ 5.16	$ —
Granted	—	—	—
Expired	(166,573)	5.29	—
Cancelled/Forfeited	—	—	—
Outstanding September 30, 2021	1,601,006	$ 5.15	$ 231
Total vested and exercisable	1,252,280	$ 6.33	$ 52

The total fair value of stock options that vested during the three and nine months ended September 30, 2021 was $0.0 million and $0.2 million respectively. The weighted average remaining contractual term for the total stock options outstanding was 5.12 years as of September 30, 2021. The weighted average remaining contractual term for the total stock options vested and exercisable was 4.10 years as of September 30, 2021.

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

	Number of Shares	Weighted Average Fair Value
Unvested December 31, 2020	6,275,789	$ 1.18
Granted	3,875,572	0.91
Vested	(2,170,527)	1.08
Forfeited	(589,685)	0.98
Unvested September 30, 2021	7,391,149	$ 1.08

The total fair value of restricted common stock awards that vested during the three and nine months ended September 30, 2021 was $0.2 million and $2.3 million respectively.

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 125,000 shares of the Company's common stock with an exercise price per share equal to $0.98 and 125,000 restricted stock units and (ii) to the Company's Senior Vice President, Operations in the form of an option to purchase 66,667 shares of the Company's common stock with an exercise price per share equal to $0.98 and 61,350 restricted stock units. 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 August 2020, the Company granted inducement awards outside of the 2015 Plan and 2019 Sales Team Plan to the Company's Vice President, US Marketing in the form of an option to purchase 100,000 shares of the Company's common stock with an exercise price per share equal to $0.7427 and 100,000 restricted stock units. 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).

In November 2020, the Company granted inducement awards outside of the 2015 Plan and 2019 Sales Team Plan to the Company's Vice President, International Sales and Marketing in the form of 75,000 restricted stock units. The 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 September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Risk-free interest rate	—%	0.38%	—%	1.14%
Expected term (in years)	0	6	0	6.16
Dividend yield	—%	—%	—%	—%
Expected volatility	—%	52.92%	—%	54.89%

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 has limited history of market prices of its common stock over the historical period equal in length to the expected term, and may sometimes estimate volatility using historical volatilities of similar public entities.

Forfeitures. The Company recognizes forfeitures as they occur.

Stock-based compensation expense was $1.0 million for each of the three months ended September 30, 2021 and 2020, and $2.8 million and $2.6 million for the nine months ended September 30, 2021 and 2020, 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 September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Cost of revenues	$ 26	$ 29	$ 49	$ 43
Sales and marketing	181	136	516	364
Research and development	127	166	436	480
General and administrative	692	641	1,776	1,696
	$ 1,026	$ 972	$ 2,777	$ 2,583

As of September 30, 2021, the Company had $0.1 million of total unrecognized compensation expense for options that will be recognized over a weighted average period of 1.14 years. As of September 30, 2021, the Company had $8.4 million of total unrecognized compensation expense for restricted awards that will be recognized over a weighted average period of 2.48 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. Net property, plant and equipment are based upon physical location of the assets.

Geographic information consisted of the following (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Product revenue				
United States	$ 12,405	$ 14,139	$ 37,434	$ 36,298
Germany	1,226	1,536	4,242	4,852
Rest of world	499	300	1,364	858
	$ 14,130	$ 15,975	$ 43,040	$ 42,008

	September 30, 2021	December 31, 2020
Property and equipment, net		
United States	$ 10,758	$ 12,195
Germany	42	45
Rest of World	114	—
	$ 10,914	$ 12,240

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our consolidated financial statements and 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, 2020. 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, 2020, 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 such as the ongoing COVID-19 pandemic on our business, 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:

- 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, Conformis Cordera hip system, and the planned launch of a new knee replacement offering to be targeted at hospital outpatient and ambulatory surgery centers;
- 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;
- 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;
- 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 and foreign government regulators, such as more stringent requirements for regulatory clearance of our products;
- the anticipated adequacy of our capital resources to meet the needs of our business or our ability to raise any additional capital;
- anticipated continuing negative impacts related to the COVID-19 pandemic, including with respect to the potential rise of variant stains and the speed and effectiveness of vaccine distribution, and the actions that we have taken and are planning in response, including our ability to continue production, the reliability of our supply chain, 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;
- our ability to satisfy all applicable NASDAQ continued listing requirements; and
- our ability to continue as a going concern.

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 that uses our proprietary iFit Image-to-Implant technology platform to develop, manufacture and sell joint replacement implants and instruments that are individually sized and shaped, which we refer to as personalized, individualized, or sometimes as customized, to fit each patient's unique anatomy. The worldwide market for joint replacement products is approximately $19.5 billion annually and growing. We believe our iFit technology platform is applicable to all major joints in this market.

We offer a broad line of personalized knee implants and instruments designed to restore the natural shape of a patient’s knee. As of December 31, 2020, we had sold a total of more than 125,000 knee implants worldwide, including more than 100,000 total knee implants and 25,000 partial knee implants. In multiple clinical studies, iTotal CR, our cruciate-retaining total knee replacement implant, demonstrated superior clinical outcomes, including better function, including 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 Identity Imprint knee replacement system. Identity Imprint, available in both cruciate retaining (CR) and posterior stabilized (PS) implants, utilizes a proprietary algorithm to select the implant size that most closely meets the geometric and anatomic requirements of the patient’s knee based on the individual’s CT scan. As with Conformis’ personalized iTotal knee product line, Identity Imprint uses Conformis’ sterile Surgery-in-a-Box delivery system, which provides ambulatory surgical centers (ASCs) and hospitals greater procedural efficiency and improved sterilization cost savings over comparable systems. With the growing interest in our Identity Imprint system from ASC customers, we have prioritized applying the cementless technology to Identity Imprint. With this change, we now anticipate a limited commercial launch of the cementless option on the Imprint Identity knee platform late in 2022.

On November 11, 2019, we entered full commercial launch of the Conformis hip system. We are planning for a limited commercial launch of a second stem within our hip portfolio in the first half of 2022. In September 2020, we announced the new Cordera hip system, and in December 2020, we commenced the U.S. commercial launch of the new Cordera Match hip system, one of multiple planned product extensions featuring the Cordera hip system.

Our iFit technology platform comprises three key elements:

- *iFit Design*, our proprietary algorithms and computer software that we use to design personalized implants and associated single-use, patient-specific instrumentation, which we refer to as iJigs, based on a computed tomography, or CT scan of the patient and to prepare a surgical plan personalized for the patient that we call iView.
- *iFit Printing*, a three-dimensional, or 3D, printing technology that we use to manufacture iJigs and that we may extend to manufacture certain components of our personalized knee replacement implants.
- *iFit Just-in-Time Delivery*, our just-in-time manufacturing and delivery capabilities.

We believe our iFit technology platform enables a scalable business model that greatly lowers our inventory requirements, reduces the amount of working capital required to support our operations and allows us to launch new products and product improvements more rapidly, as compared to manufacturers of traditional off-the-shelf implants.

All of our knee 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, or the FDCA, and 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, Suriname, Australia, Argentina, the United Arab Emirates, the Sultanate of Oman, Italy, San Marino, 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. The future progression of the pandemic, including the scope, severity and duration of the pandemic, potential resurgences, the speed and effectiveness of vaccine and treatment developments, and the direct and indirect economic effects of the pandemic and containment measures, and its effects on our business and operations remain uncertain. We have experienced significantly decreased demand for our products during the pandemic as healthcare providers and individuals have de-prioritized and deferred medical procedures deemed to be elective, such as joint replacement procedures, which has had and is expected to continue to have, a significant negative effect on our revenue.

Such negative effects were most pronounced during the second quarter of 2020, when a significant number of hospitals were either closed for elective procedures or otherwise operating at significantly reduced volumes. Generally, we saw an increase in procedure volumes during the summer of 2020, as many regions were able to reopen for elective procedures, with an existing patient backlog.

However, in the United States and Germany, which are our major sales markets, estimated case counts increased in the fourth quarter of 2020 and peaked in January 2021. While worldwide case counts have declined since January, we saw a decline in elective procedures during the first quarter of 2021. In Germany, case counts declined after January 2021 but then increased again in the second quarter. Germany case counts began to decline mid-way through the second quarter but the Company saw a decline in Germany elective procedures during the second quarter of 2021. In the United States, elective procedures improved sequentially in second quarter of 2021 over first quarter of 2021 consistent with the market. However, in the third quarter of 2021, we 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 variant. We expect that these negative effects will continue in the near-term until infection rates decline further from their current level, and more of the population is vaccinated. However, 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.

On March 20, 2020, we provided notice to our employees of a furlough of approximately 80 employees effective as of March 23, 2020 to help address decreased demand for our products. The furlough resulted in reduced production capacity at our manufacturing facilities, but sufficient to meet demand. While we have not experienced and do not currently anticipate significant interruptions in our supply chain, extended or additional quarantines, travel restrictions and other measures may significantly impact the ability of employees of our third-party suppliers to get to their places of work to manufacture the key components and materials necessary for our products. We have experienced and may experience further shortages of mask and gown consumables used in our clean room processes, which may further limit our production capacity and further delay the joint replacement procedures in which our products are used. Any delay or shortage of such components or materials or delays in delivering our products may result in our inability to satisfy consumer demand for our products in a timely manner or at all, which could harm our reputation, future sales, profitability and financial condition. On April 17, 2020, we entered into an approximately $4.7 million promissory note, or the PPP Note, with East West Bank under the Paycheck Protection Program, or the PPP offered by the U.S. Small Business Administration, or the SBA, to mitigate the negative financial and operational impacts of the pandemic. On April 23, 2020, we accelerated a plan to return to full-time employment the vast majority of those employees who were furloughed on March 23, 2020. This plan was completed at the end of April 2020.

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, Austria, Ireland, Switzerland, Spain, Portugal, the Netherlands, Belgium, the Dutch Antilles, Suriname, Australia, the United Arab Emirates, the Sultanate of Oman, Italy, Poland 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 nine months ended September 30, 2021 includes revenue of $15.0 million generated from our settlement with Stryker Corporation (“Stryker”), Wright Medical Technology, Inc. (“Wright Medical”), and Tornier, Inc. (“Tornier” and, collectively with Stryker and Wright Medical, the "Stryker Parties"), $25.0 million recognized under the Development and License Agreements with Stryker, and $1.0 million generated from our license agreement (the "License Agreement") with Paragon 28. Royalty and licensing revenue for the nine months ended September 30, 2020 includes revenue of $9.6 million generated from our settlement and license agreement (the "Zimmer Settlement and License Agreement") with Zimmer Biomet. 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. Also included in cost of revenue for the nine months ended September 30, 2020, are legal fees payable to external counsel in connection with our patent licensing and enforcement activities related to the Zimmer Settlement and License Agreement with Zimmer Biomet.

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, 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 continuing to reduce our manufacturing costs per unit and increasing our manufacturing efficiency as sales volume increases. 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;
- 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 certain components of our products that we manufacture in-house, which we believe we can manufacture at a lower unit cost than vendors we currently use; and
- developing new versions of our software used in the design of our personalized joint replacement implants, which we believe will reduce costs associated with the design process.

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, market access, 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 as well as educating surgeons about the benefits of our products are required to generate and grow revenue. We expect sales and marketing expense to increase as we build up our sales and support personnel and expand our marketing efforts. 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, regulatory activities, contractors, consultants, equipment, and software development. As our revenue increases, we will also incur additional expenses for revenue share payments to our past and present scientific advisory board members. We expect research and development expense to increase in absolute dollars as we develop new products to expand our product pipeline, add research and development personnel and conduct clinical activities.

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, legal, 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, freight, and facilities expense. We expect our general and administrative expense will increase in absolute dollars as we increase our headcount and expand our infrastructure to support growth in our business and our operations. As our revenue increases, we also incur additional expenses for freight. 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.

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 September 30, 2021 and 2020

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

Three Months Ended September 30,	2021 Amount	2021 As a% of Total Revenue	2020 Amount	2020 As a% of Total Revenue	2021 vs 2020 $ Change	2021 vs 2020 % Change
Revenue						
Product revenue	$ 14,130	99 %	$ 15,975	99 %	$ (1,845)	(12) %
Royalty and licensing	123	1	146	1	(23)	(16)
Total revenue	14,253	100	16,121	100	(1,868)	(12)
Cost of revenue	8,231	58	8,437	52	(206)	(2)
Gross profit	6,022	42	7,684	48	(1,662)	(22)
Operating expenses:						
Sales and marketing	$ 6,434	45 %	$ 5,755	36 %	$ 679	12 %
Research and development	3,548	25	2,866	18	682	24
General and administrative	7,407	52	6,134	38	1,273	21
Total operating expenses	17,389	122	14,755	92	2,634	18
Loss from operations	(11,367)	(80)	(7,071)	(44)	(4,296)	(61)
Total other (expenses) income, net	(1,577)	(11)	908	6	(2,485)	(274)
Income (loss) before income taxes	(12,944)	(91)	(6,163)	(38)	(6,781)	(110)
Income tax provision	29	—	20	—	9	45
Net loss	$ (12,973)	(91) %	$ (6,183)	(38) %	$ (6,790)	(110) %

Product revenue. Product revenue was $14.1 million for the three months ended September 30, 2021 compared to $16.0 million for the three months ended September 30, 2020, a decrease of $1.8 million or 12%. We believe the decline is primarily due to deferred and rescheduled elective surgeries as a result of the surge in COVID-19 cases associated with the Delta variant.

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):

Three Months Ended September 30,	2021 Amount	2021 As a % of Product Revenue	2020 Amount	2020 As a % of Product Revenue	2021 vs 2020 $ Change	2021 vs 2020 % Change
United States	$ 12,405	88 %	$ 14,139	89 %	$ (1,734)	(12) %
Germany	1,226	9	1,536	10	(310)	(20)
Rest of world	499	3	300	1	199	66
Product revenue	$ 14,130	100 %	$ 15,975	100 %	$ (1,845)	(12) %

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 88% for the three months ended September 30, 2021 and 89% for the three months ended September 30, 2020.

The United States product revenue decreased $1.7 million to $12.4 million or 12% year over year. We believe the decline in revenue inside the United States was primarily due to deferred and rescheduled elective surgeries as a result of the surge in COVID-19 cases associated with the Delta variant. Germany product revenue decreased

$0.3 million to $1.2 million, or 20% year over year on a reported basis and 22% on a constant currency basis. We believe the decline was primarily due to the recent increase in COVID-19 cases in Germany which has negatively impacted elective procedures. Rest of World product revenue increased $0.2 million to $0.5 million, or 66% year-over-year on a reported basis and 55% on a constant currency basis, we believe 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.

Royalty and licensing revenue. Royalty and licensing revenue was $0.1 million for each of the three months ended September 30, 2021 and September 30, 2020.

Cost of revenue, gross profit and gross margin. Cost of revenue was $8.2 million for the three months ended September 30, 2021 compared to $8.4 million for the three months ended September 30, 2020, a decrease of $0.2 million, or 2%. Gross profit was $6.0 million for the three months ended September 30, 2021 compared to $7.7 million for the three months ended September 30, 2020, a decrease of $1.7 million or 22%. Gross margin decreased 540 basis points to 42% for the three months ended September 30, 2021 from 48% for the three months ended September 30, 2020. The decrease in gross margin was driven primarily by lower volume, increased material and labor costs, higher cancelled case inventory expense, and a reduction in product selling price.

Sales and marketing. Sales and marketing expense was $6.4 million for the three months ended September 30, 2021 compared to $5.8 million for the three months ended September 30, 2020, an increase of $0.7 million or 12%. The increase was due primarily to an increase in tradeshow expenses of $0.7 million, surgeon training labs of $0.1 million, professional services of $0.1 million and travel and entertainment of $0.1 million, which was partially offset by $0.3 million in commission expense. Sales and marketing expense increased as a percentage of total revenue to 45% for the three months ended September 30, 2021 compared to 36% for the three months ended September 30, 2020.

Research and development. Research and development expense was $3.5 million for the three months ended September 30, 2021 compared to $2.9 million for the three months ended September 30, 2020, an increase of $0.7 million, or 24%. The increase was due primarily to an increase in professional services of $0.3 million, revenue share expense of $0.2 million, and a reduction of $0.5 million of cost allocated to the advance on research and development, which was partially offset by $0.2 million in personnel related costs. Research and development expense increased as a percentage of total revenue to 25% for the three months ended September 30, 2021 compared to 18% for the three months ended September 30, 2020.

General and administrative. General and administrative expense was $7.4 million for the three months ended September 30, 2021 compared to $6.1 million for the three months ended September 30, 2020, an increase of $1.3 million, or 21%. The increase was primarily due to higher legal fees of $1.1 million, freight costs of $0.2 million, and professional services of $0.2 million, which was partially offset by $0.2 million in personnel related costs. General and administrative expense increased as a percentage of total revenue to 52% for the three months ended September 30, 2021 from 38% for the three months ended September 30, 2020.

Total other (expenses) income, net. Other (expenses) income, net was $1.6 million of other expenses for the three months ended September 30, 2021 compared to $0.9 million of other income for the three months ended September 30, 2020, a change of $2.5 million, or 274%. The change was primarily due to an increase in foreign currency exchange transaction loss.

Income taxes. Income tax provision was $29,000 and $20,000 for the three months ended September 30, 2021 and 2020, 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.

Comparison of the nine months ended September 30, 2021 and 2020

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

	2021		2020		2021 vs 2020	
Nine Months Ended September 30,	**Amount**	**As a% of Total Revenue**	**Amount**	**As a% of Total Revenue**	**$ Change**	**% Change**
Revenue						
Product revenue	$ 43,040	51 %	$ 42,008	81 %	$ 1,032	2 %
Royalty and licensing	41,396	49	10,056	19	31,340	312 %
Total revenue	84,436	100	52,064	100	32,372	62 %
Cost of revenue	24,703	29	26,148	50	(1,445)	(6)%
Gross profit	59,733	71	25,916	50	33,817	130 %
Operating expenses:						
Sales and marketing	$ 17,851	21 %	$ 16,420	32 %	$ 1,431	9 %
Research and development	10,738	13	8,594	17	2,144	25 %
General and administrative	20,762	25	18,344	35	2,418	13 %
Total operating expenses	49,351	58	43,358	83	5,993	14 %
Income (loss) from operations	10,382	12	(17,442)	(34)	27,824	160
Total other income (expenses), net	3,225	4	(212)	—	3,437	1,621 %
Income (loss) before income taxes	13,607	16	(17,654)	(34)	31,261	177
Income tax provision	44	—	17	—	27	159
Net income (loss)	$ 13,563	16 %	$ (17,671)	(34)%	$ 31,234	177 %

Product revenue. Product revenue was $43.0 million for the nine months ended September 30, 2021, compared to $42.0 million for the nine months ended September 30, 2020, an increase of $1.0 million or 2%. We believe the increase is primarily due to an increase in elective surgeries, which were lower in the prior period as a result of the COVID-19 pandemic.

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):

	2021		2020		2021 vs 2020	
Nine Months Ended September 30,	**Amount**	**As a % of Product Revenue**	**Amount**	**As a % of Product Revenue**	**$ Change**	**% Change**
United States	$ 37,434	87 %	$ 36,298	86 %	$ 1,136	3 %
Germany	4,242	10	4,852	12	(610)	(13)
Rest of world	1,364	3	858	2	506	59
Product revenue	$ 43,040	100 %	$ 42,008	100 %	$ 1,032	2 %

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 87% for the nine months ended September 30, 2021 compared to 86% for the nine months ended September 30, 2020

The United States product revenue increased $1.1 million to $37.4 million or 3% year over year. We believe the increase in revenue inside the United States was primarily due to an increase in elective surgeries, which were lower in the prior period as a result of the COVID-19 pandemic. Germany product revenue decreased $0.6 million to $4.2 million, or 13% year over year on a reported basis and 19% on a constant currency basis. We believe the decline was primarily due to the recent increase in COVID-19 cases in Germany which has negatively impacted elective procedures. Rest of World product revenue increased $0.5 million to $1.4 million, or 59% year-over-year on

a reported basis and 45% on a constant currency basis, we believe 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.

Royalty and licensing revenue. Royalty and licensing revenue was $41.4 million for the nine months ended September 30, 2021 and $10.1 million or the nine months ended September 30, 2020, an increase of $31.3 million, or 312%. The increase in royalty and licensing revenue was driven by $25.0 million in revenue recognized in connection with receiving 510(k) clearance from the FDA, which was for the third of three milestones under the License Agreement with Stryker, $15.0 million in revenue recognized under the Settlement and License Agreement with the Stryker Parties, and $1.0 million in revenue recognized under the License Agreement with Paragon 28. Royalty and licensing revenue for the nine months ended September 30, 2020 includes $9.6 million in revenue recognized under the Zimmer Settlement and Licensing Agreement with Zimmer Biomet.

Cost of revenue, gross profit and gross margin. Cost of revenue was $24.7 million for the nine months ended September 30, 2021 compared to $26.1 million for the nine months ended September 30, 2020, a decrease of $1.4 million, or 6%. Gross profit was $59.7 million for the nine months ended September 30, 2021 compared to $25.9 million for the nine months ended September 30, 2020, an increase of $33.8 million or 130%. Gross margin increased 2,100 basis points to 71% for the nine months ended September 30, 2021 from 50% for the nine months ended September 30, 2020. The increase in gross margin was driven primarily by the Stryker licensing revenue under the Development and License Agreements and the Stryker Parties licensing revenue under the Settlement and License Agreement.

Sales and marketing. Sales and marketing expense was $17.9 million for the nine months ended September 30, 2021 compared to $16.4 million for the nine months ended September 30, 2020, an increase of $1.4 million, or 9%. The increase was due primarily to higher commission expense of $1.0 million, tradeshow expense of $0.3 million, and surgeon training labs of $0.1 million. Sales and marketing expense decreased as a percentage of total revenue to 21% for the nine months ended September 30, 2021 compared to 32% for the nine months ended September 30, 2020.

Research and development. Research and development expense was $10.7 million for the nine months ended September 30, 2021 compared to $8.6 million for the nine months ended September 30, 2020, an increase of $2.1 million, or 25%. The increase was due primarily to an increase in professional services of $0.5 million, revenue share expense of $0.5 million, project prototype costs of $0.4 million, personnel related costs of $0.3 million, and a reduction of $0.5 million of cost allocated to the advance on research and development. Research and development expense decreased as a percentage of total revenue to 13% for the nine months ended September 30, 2021 from 17% for the nine months ended September 30, 2020.

General and administrative. General and administrative expense was $20.8 million for the nine months ended September 30, 2021 compared to $18.3 million for the nine months ended September 30, 2020, an increase of $2.4 million, or 13%. The increase was primarily due to an increase in legal fees of $2.0 million, an increase in freight costs of $0.5 million, an increase in insurance of $0.2 million, partially offset by a decrease in professional services of $0.2 million. General and administrative expense decreased as a percentage of total revenue to 25% for the nine months ended September 30, 2021 from 35% for the nine months ended September 30, 2020.

Total other income (expenses), net. Other income (expenses), net was $3.2 million of other income for the nine months ended September 30, 2021 compared to $0.2 million of other expenses for the nine months ended September 30, 2020, a change of $3.4 million, or 1,621%. The change was primarily due to the recognition of a gain on forgiveness of PPP loan of $4.8 million, and the recognition of $2.5 million for the unused portion of the advance on research and development under the Development Agreement with Stryker. This was partially offset by an increase of $3.8 million in foreign currency exchange transaction loss.

Income taxes. Income tax provision was approximately $44,000 for the nine months ended September 30, 2021 and $17,000 for the nine months ended September 30, 2020. 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

Sources of liquidity and funding requirements

From our inception in June 2004 through the nine months ended September 30, 2021, 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. As of September 30, 2021, we had an accumulated deficit of $514.9 million.

In January 2017, we filed a shelf registration statement on Form S-3, which was declared effective by the SEC on May 9, 2017 (the "2017 Shelf Registration Statement"). The 2017 Shelf Registration Statement allowed us 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. On May 10, 2017, we filed with the SEC a prospectus supplement, pursuant to which we could issue and sell up to $50 million of our common stock and entered into an Equity Distribution Agreement with Canaccord Genuity LLC (formerly Canaccord Genuity Inc.) or Canaccord, pursuant to which Canaccord agreed to sell shares of our common stock from time to time, as our agent in an “at-the-market,” or ATM, offering as defined in Rule 415 promulgated under the U.S. Securities Act of 1933, as amended, or the Securities Act. We are not obligated to sell any number of shares under the Distribution Agreement. On August 4, 2020, we and Canaccord mutually agreed to terminate the Distribution Agreement, and as of that date, we had sold 2,663,000 shares under the Distribution Agreement resulting in net proceeds of $4.4 million.

On March 23, 2020, we filed a new shelf registration statement on Form S-3 or the New Shelf Registration Statement, which was declared effective by the SEC on August 5, 2020. Under the New Shelf Registration Statement, we will be 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. The New Shelf Registration Statement is intended to provide us flexibility to conduct sales of its 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 its common stock and entered into an at-the-market issuance sales agreement, or the Sales Agreement, with Cowen and Company, LLC, or 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. 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 also has provided Cowen with customary indemnification rights. The shares of Common Stock being offered pursuant to the Sales Agreement will be offered and sold pursuant to the New 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 September 30, 2021, we had not sold any shares under the Sales Agreement.

On December 17, 2018, we entered into a stock purchase agreement, or the "Stock Purchase Agreement," with Lincoln Park Capital, or "LPC." Upon entering into the Stock Purchase Agreement, we sold 1,921,968 shares of common stock for $1.0 million to LPC, representing a premium of 110% to the previous day's closing price. As consideration for LPC's commitment to purchase shares of common stock under the Stock Purchase Agreement, we issued 354,430 shares to LPC. We have the right at our sole discretion to sell to LPC up to $20.0 million worth of shares over a 36-month period subject to the terms of the Stock Purchase Agreement. We will control the timing of any sales to LPC and LPC will be obligated to make purchases of our common stock upon receipt of requests from us in accordance with the terms of the Stock Purchase Agreement. There are no upper limits to the price per share LPC may pay to purchase the up to $20.0 million worth of common stock subject to the Stock Purchase Agreement, and the purchase price of the shares will be based on the then prevailing market prices of our shares at the time of each sale to LPC as described in the Stock Purchase Agreement, provided that LPC will not be obligated to make purchases of our common stock pursuant to receipt of a request from us on any business day on which the last closing trade price of our common stock on the Nasdaq Capital Market (or alternative national exchange in accordance with the Stock Purchase Agreement) is below a floor price of $0.25 per share. No warrants, derivatives, financial or business covenants are associated with the Stock Purchase Agreement and LPC has agreed not to cause or engage in any manner whatsoever, any direct or indirect short selling or hedging of shares of our common stock. The Stock Purchase Agreement may be terminated by us at any time, at our sole discretion, without any cost or penalty. On August 5, 2020, we filed with the SEC a prospectus supplement, for the sale and issuance of up to $17.6 million of its common stock pursuant to the Stock Purchase Agreement dated December 17, 2018. As of September 30, 2021, we have sold 4,521,968 shares under the Stock Purchase Agreement resulting in proceeds of $3.4 million.

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) 8,512,088 shares of its common stock and accompanying warrants to purchase up to 8,512,088 shares of common stock and (ii) pre-funded warrants to purchase up to 9,492,953 shares of common stock and accompanying warrants to purchase up to 9,492,953 shares of common stock in a registered direct offering 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 $0.9581 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 $0.0001 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. All pre-funded warrants have been fully exercised. The warrants became exercisable immediately upon issuance, have an exercise price of $0.8748 per share, and will expire five years from the date of issuance. As of September 30, 2021, approximately 6.0 million 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 June 25, 2019, we entered into a Loan and Security Agreement or the 2019 Secured Loan Agreement with Innovatus Life Sciences Lending Fund I, LP or Innovatus, as collateral agent and lender, East West Bank and the other lenders party thereto from time to time, or Lenders, pursuant to which the Lenders agreed to make term loans and to provide a revolving credit facility to us to repay existing indebtedness, for working capital and general business purposes, in a principal amount of up to $30 million. We used the proceeds from the 2019 Secured Loan Agreement to pay off the $15 million term loan from Oxford Finance LLC. In addition, Innovatus purchased approximately $3 million of our common stock at the previous day's closing price. During the first quarter of 2020, we reported that we may not be able to meet our second quarter revenue covenant and would work with Innovatus with the goal of adjusting the revenue covenants under the 2019 Secured Loan Agreement. On July 1, 2020, we entered into a third amendment to the 2019 Secured Loan Agreement, which, among other things, waived the trailing six-month revenue covenant milestones that applied to the quarters ended June 30, September 30 and December 31, 2020 under the agreement, reduced the revenue covenant milestones that apply thereafter, and delays until June 25, 2021 our option to prepay all, but not less than all, of the term loans advanced under the 2019 Secured Loan Agreement. On August 20, 2020, we entered into a fourth amendment to the 2019 Secured Loan

Agreement, which, among other things, waived certain provisions of the agreement that apply to Conformis India LLP.

On March 1, 2021, we entered into a fifth amendment to the 2019 Secured Loan Agreement, which, among other things, waives the trailing six-month revenue covenant milestones that apply to the quarters ending March 31, June 30, September 30 and December 31, 2021 and reduces the revenue covenant milestones that apply in 2022. The revenue covenant milestones remain unchanged for 2023 and 2024. The amendment also increases our minimum cash covenant to $5 million until December 31, 2021. As of September 30, 2021, we were not in breach of covenants under the 2019 Secured Loan Agreement. For further information regarding the 2019 Secured Loan Agreement and the fifth amendment, 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 September 30, 2019, we entered into an Asset Purchase Agreement with Howmedica Osteonics Corp., a subsidiary of Stryker Corporation also known as Stryker Orthopaedics, or Stryker. In connection with entering into the Asset Purchase Agreement, we also entered into a Development Agreement, a License Agreement, and other ancillary agreements contemplated by the Asset Purchase Agreement with Stryker. Under the terms of the agreements, we agreed to sell and license to Stryker certain assets relating to our patient-specific instrumentation technology, and to develop, manufacture, and supply patient-specific instrumentation for use in connection with Stryker's "off-the-shelf" non-personalized knee implant offerings. We received $14 million upfront and became eligible to receive up to an additional $16 million in milestone payments pursuant to the License Agreement and the Development Agreement. As of September 30, 2021, we had successfully completed the third of three milestones with Stryker and received $11.0 million, for a total aggregate received of $16.0 million for achievement of these milestones. Under the long-term Distribution Agreement, we will supply patient-specific instrumentation to Stryker.

The Coronavirus Aid, Relief, and Economic Security Act, or the CARES Act, was enacted on March 27, 2020 in the United States. On April 17, 2020, we entered into an approximately $4.7 million promissory note, or the PPP Note, with East West Bank as the lender under the PPP offered by the SBA, to mitigate the negative financial and operational impacts of the COVID-19 pandemic. The interest rate on the PPP Note is a fixed rate of 1% per annum. We are required to make one payment of all outstanding principal plus all accrued unpaid interest on April 9, 2022, or the Maturity Date. We were required to pay regular monthly payments in an amount equal to one month’s accrued interest commencing on August 2, 2021, with all subsequent interest payments to be due on the same day of each month after that. All interest which accrues during the deferral period were to be payable on the Maturity Date. According to the terms of the PPP, all or a portion of the loan as well as any accrued interest may be fully forgiven if the funds are used for payroll costs (and at least 60% of the forgiven amount must have been used for payroll), interest on certain other outstanding debt, rent, and utilities. In accordance with the CARES Act, we used the proceeds of the loan primarily for payroll costs. We submitted the loan forgiveness application to the lender on December 11, 2020. We resubmitted the application on February 23, 2021 with additional supporting documentation as requested by the lender. On March 4, 2021, our lender submitted our application to the SBA for their review and on June 30, 2021, we received notification through our lender that the SBA had rendered a final decision regarding its review of the PPP loan forgiveness application, fully approving the loan forgiveness application as of June 28, 2021.

On May 22, 2020, we entered into a Zimmer Settlement and License Agreement with Zimmer Biomet, Zimmer US, Inc. and Biomet Manufacturing, LLC, or collectively, Zimmer Biomet, pursuant to which the parties agreed to terms for resolving then-existing patent disputes. Under the Settlement and License Agreement, we and Zimmer Biomet agreed to dismiss both outstanding patent infringement lawsuits between the parties; we granted to Zimmer Biomet a royalty-free, non-exclusive, worldwide license to certain of our patents for Zimmer Biomet’s patient-specific instrumentation used with off-the-shelf knee, hip, and shoulder implants; and Zimmer Biomet granted us a fully paid-up, royalty-free, non-exclusive, worldwide license to certain Zimmer Biomet patents for our implants and patient-specific instruments for the knee. Under the agreement, Zimmer Biomet was required to pay us a total of $9.6 million in installments through January 15, 2021, and all such payments were made and received by such date. No payment was due from us to Zimmer Biomet.

On February 17, 2021, we closed an offering of our common stock under the New Shelf Registration Statement and issued and sold 80,952,381 shares of our common stock at a public offering price of $1.05 per share, 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.

On June 30, 2021 we entered into a Settlement and License Agreement with the Stryker Parties, pursuant to which the parties have agreed to terms for resolving all of their existing patent disputes. Under the Settlement and License Agreement, we granted to the Stryker Parties a royalty-free, non-exclusive, worldwide license to certain of our patents for the Stryker Parties' patient-specific instrumentation used with off-the-shelf knee, hip, and shoulder implants. Under the agreement, the Stryker Parties are required to pay us a one-time payment of $15.0 million no later than October 15, 2021. The payment was received in October 2021.

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

- expansion of our sales and marketing efforts;
- expansion of our manufacturing capacity;
- funding research, development and clinical activities related to our existing products and product platform, including iFit design software and product support;
- funding research, development and clinical activities related to new products that we may develop, including other joint replacement products;
- pursuing and maintaining appropriate regulatory clearances and approvals for our existing products and any new products that we may develop; and
- preparing, filing and prosecuting patent applications, and maintaining and enforcing our intellectual property rights and position.

We anticipate that our principal sources of funds in the future will be revenue generated from the sales of our products, available sales of shares under the Sales Agreement and the Stock Purchase Agreement, 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.

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 sales of equity or debt, the ownership interest of our stockholders will be diluted. The terms of these future 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 September 30, 2021, we had cash and cash equivalents of $97.1 million and $0.6 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 with existing cash and cash equivalents as of September 30, 2021, anticipated revenue from operations, revenue that may be generated in connection with licensing intellectual property, available sales of shares under the Sales Agreement and the Stock Purchase Agreement and funds from potential exercises of our common stock warrants. 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.

The COVID-19 pandemic has negatively impacted and will continue to impact our business, operations and financial condition. As part of our response to COVID-19, we took certain measures in preserving liquidity. In addition to the furlough implemented in March 2020, we have eliminated, reduced, or are deferring significant non-essential expense including sales, marketing, quality, clinical, regulatory and all general and administrative expense. In addition, we are working with suppliers to help match future revenue and expense.

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):

	Nine Months Ended September 30,			
	2021	2020	$ Change	% Change
Net cash (used in) provided by:				
Operating activities	$ (14,382)	$ (14,275)	$ (107)	(1)%
Investing activities	(1,832)	(3,001)	1,169	39
Financing activities	84,890	23,757	61,133	257
Effect of exchange rate on cash	(138)	13	(151)	(1,162)
Total	$ 68,538	$ 6,494	$ 62,044	955 %

Net cash used in operating activities. Net cash used in operating activities was $14.4 million for the nine months ended September 30, 2021 compared to $14.3 million used in operating activities for the nine months ended September 30, 2020, an increase in use of $0.1 million. The $0.1 million increase in net cash used in operating activities was primarily affected by an increase in net income of $31.2 million, an increase in accounts payable, accrued expenses and other liabilities of $3.7 million, and an increase in prepaid and other assets of $0.5 million, partially offset by a decrease in inventory of $1.1 million, a decrease in accounts receivable of $2.5 million, a decrease in royalty and licensing receivable of $10.8 million and a decrease in contract liability and advance on research and development under the Agreements with Stryker of $20.5 million. Non-cash reconciling items include an increase in unrealized foreign exchange gain/loss of $3.8 million and a decrease on gain on forgiveness of PPP loan of $4.8 million.

Net cash used in investing activities. Net cash used in investing activities was $1.8 million for the nine months ended September 30, 2021, and for the nine months ended September 30, 2020 net cash used in investing activities was $3.0 million, a decrease of $1.2 million. The decrease is due to a decrease in costs related to the acquisition of property, plant, and equipment.

Net cash provided by financing activities. Net cash provided by financing activities was $84.9 million for the nine months ended September 30, 2021, and for the nine months ended September 30, 2020 was $23.8 million, an increase of $61.1 million. The increase is due to $79.6 million of net proceeds from the issuance of common stock under the New Shelf Registration Statement and $5.3 million of proceeds from the exercise of common stock warrants, compared to $15.9 million of proceeds from the issuance of common stock and prefunded warrants under the registered direct offering, net proceeds of $3.1 million from issuance of common stock and $4.7 million of proceeds from the issuance of the PPP loan during the same period last year.

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, 2020 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 1.5% to 5.6%. We incurred aggregate revenue share expense including all amounts payable under our scientific advisory board revenue share agreements of $0.6 million during the three months ended September 30, 2021, representing 4.3% of product revenue, and $0.4 million during the three months ended September 30, 2020, representing 2.7% 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 September 30, 2021, 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, 2020.

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 September 30, 2021. 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, or 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 September 30, 2021, 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 September 30, 2021 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.

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. Discovery in the lawsuit is ongoing.

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 alleges 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. Discovery in the lawsuit is ongoing.

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.

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 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.

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 May 8, 2020, we and an individual plaintiff filed a lawsuit against Aetna, Inc. and Aetna Life Insurance Company or “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 complaint alleges that Aetna has 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. We filed an amended complaint based on discovery relating to the individual plaintiff's claims and proposed a settlement in three parts, including (1) a financial component, (2) full coverage when surgery involves a standardized knee implant, and (3) coverage for the costs of the procedure (but not the implant) when surgery involves a personalized knee implant. Aetna has yet to negotiate a settlement of our appellate claims.

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.

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, 2020* (the “Form 10-K”). For a detailed discussion of the other risks that affect our business, please refer to the entire section entitled “Risk Factors” in our Form 10-K. Other than as set forth below, there have been no material changes to our risk factors as previously disclosed in our 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.*

The novel coronavirus (COVID-19) pandemic and the response to it have reduced demand for our products and negatively affected manufacturing and delivery timelines, and as a result we reduced our operations and production capacity, and these circumstances have had and are expected to continue to have a significant negative affect on our revenue.

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 the COVID-19 outbreak to be a pandemic. The future progression of the pandemic, including the scope, severity and duration of the pandemic, potential resurgences, the speed and effectiveness of vaccine and treatment developments, and the direct and indirect economic effects of the pandemic and containment measures, and its effects on our business and operations remain uncertain. We have experienced significantly decreased demand for our products during the pandemic as healthcare providers and individuals have de-prioritized and deferred medical procedures deemed to be elective, such as joint replacement procedures, which has had, and is expected to continue to have, a significant negative effect on our revenue.

Such negative effects were most pronounced during the second quarter of 2020, when a significant number of hospitals were either closed for elective procedures or otherwise operating at significantly reduced volumes. Generally, we saw an increase in procedure volumes during the summer of 2020, as many regions were able to reopen for elective procedures, with an existing patient backlog.

However, in the United States and Germany, which are our major sales markets, estimated case counts increased in the fourth quarter of 2020 and peaked in January 2021. While worldwide case counts have declined since January, we saw a decline in elective procedures during the first quarter of 2021. In addition, case counts in Germany declined after January 2021 but then increased again in the second quarter. Germany case counts began to decline mid-way through the second quarter but the Company saw a decline in Germany elective procedures during the second quarter of 2021. In the United States, elective procedures have improved sequentially in the second quarter of 2021 over first quarter of 2021 consistent with the market. However, in the third quarter of 2021, we 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 variant. We expect that these negative effects will continue in the near-term until infection rates decline further from their current level, and more of the population is vaccinated. The future progression of the pandemic remains uncertain, including with respect to new or potential variants. 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.

On March 20, 2020, we provided notice to our employees of a furlough of approximately 80 employees effective as of March 23, 2020 to help address decreased demand for our products. The furlough resulted in reduced production capacity at our manufacturing facilities, but sufficient to meet demand. While we have not experienced and do not currently anticipate significant interruptions in our supply chain, extended or additional quarantines, travel restrictions and other measures may significantly impact the ability of employees of our third-party suppliers to get to their places of work to manufacture the key components and materials necessary for our products. On April 23, 2020, we accelerated a plan to return to full-time employment the vast majority of those employees who were furloughed on March 23, 2020. This plan was completed at the end of April 2020.

The pandemic has also negatively affected our manufacturing and delivery timelines, in part because of additional employee turnover at our manufacturing facility, and the difficulty of finding, hiring and training new employees on a timely basis. For example, the stringent manufacturing protocols that we follow require new manufacturing employees to receive substantial training to reach proper levels of work proficiency, and thus increased employee turnover during the pandemic has negatively affected our ability to maintain the same pace of manufacturing. In addition, employee turnover and tight labor conditions in the third-party shipping sector has contributed to an increased number of delays in the timing of products we manufacture reaching surgeon recipients. Collectively, these pandemic-related factors has made it more difficult for us to satisfy consumer demand for our products. To the extent these pandemic-related labor constraints continue, it could adversely affect our sales and profitability for the duration of time that such conditions continue.

If we fail to maintain compliance with the requirements for continued listing on the NASDAQ Capital Market, our common stock could be delisted from trading, which would adversely affect the ability to sell our stock in the public market, the liquidity of our common stock and our ability to raise additional capital.

Our common stock is currently listed on the NASDAQ Capital Market under the symbol “CFMS.” Until December 30, 2020, our common stock was listed on the NASDAQ Global Select Market which, along with the NASDAQ Capital Market, has qualitative and quantitative continued listing requirements, including corporate governance requirements, public float requirements and the $1.00 minimum closing bid price requirement. On December 30, 2020, we transferred the listing of our common stock to the NASDAQ Capital Market because we did not meet Nasdaq’s $1.00 minimum closing bid price requirement. We subsequently regained compliance with this requirement on February 17, 2021. On May 7, 2021, we received a notification letter from the Nasdaq Listing Qualifications Staff notifying the Company that the closing bid price for its common stock had been below $1.00 for the previous 30 consecutive business days and that the Company therefore was not in compliance with the minimum bid price requirement for continued inclusion on the NASDAQ Capital Market under Nasdaq Listing Rule 5550(a)(2). While we subsequently regained compliance with this requirement on July 12, 2021, there can be no assurance that our bid price will not again fall below listing requirements for 30 consecutive trading days. In such event, we may seek to cure the deficiency by effecting a reverse stock split, if necessary. We continue to actively monitor our performance with respect to the listing standards and will consider available options to resolve any deficiency and maintain compliance with the Nasdaq rules. Any potential delisting of our common stock from the NASDAQ Capital Market would make it more difficult for stockholders to sell our stock in the public market and would likely result in decreased liquidity, limited availability of market quotations for shares of our common stock, limited availability of news and analyst coverage regarding our Company, a decreased ability to issue additional securities and increased volatility in the price of our common stock.

Switzerland Medical Devices Ordinance after the EU MDR Date of Application could adversely affect our financial results and our operations in Switzerland.

Switzerland is a European country, but it is not part of the European Union (EU). It is part of the European Free Trade Association (EFTA), together with the three countries that make up the European Economic Area (EEA). The EEA follows all EU product legislation automatically, EFTA is not bound to that requirement. Trade with Switzerland is established via multiple mutual recognition agreements. There is a Mutual Recognition Agreement (MRA) covering medical devices in order to enable these devices to move freely between the EU and Swiss markets however the current MRA does not cover the EU Medical Device Regulation (2017/745) which took effect on May 26, 2021. As a result, Switzerland is considered a third country for medical devices. All foreign manufacturers from May 2021, must adhere to the revised Swiss Medical Devices Ordinance and requirements for the import of medical devices, namely the designation of an importer and a Swiss representative to ensure that foreign manufacturers continue to place medical devices in Switzerland. During a transition period, medical device manufacturers may continue to rely on EU Notified Body certificates for compliance in Switzerland and CE-marking, no unique mark of approval for Switzerland has been announced at this time.

The passage of the revised Swiss Medical Devices Ordinance, could adversely affect our sales in Switzerland, as well as our existing and future customers and future employees in Switzerland. The revised Swiss Medical Devices Ordinance could lead to legal uncertainty and potentially divergent national laws and regulations as Switzerland determines which EU laws to replace or replicate.

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 of 1933, as amended, or 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 Securities Exchange Act of 1934, as amended (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 of 1933, as amended, 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: 11/3/2021

CONFORMIS, INC.

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

Date: 11/3/2021

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: 11/3/2021

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: 11/3/2021

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 September 30, 2021 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: 11/3/2021

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 September 30, 2021 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: 11/3/2021

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