

Conformis Inc
Form 10-Q
May 03, 2019

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2019

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 (I.R.S. Employer
incorporation or organization) Identification Number)
600 Technology Park Drive 01821
Billerica, MA
(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,"

Edgar Filing: Conformis Inc - Form 10-Q

“accelerated filer” and “smaller reporting company” and "emerging growth company," in Rule 12b-2 of the Exchange Act.

Large accelerated filer Accelerated filer x

Non-accelerated filer Smaller reporting company x

Emerging growth company x

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. x

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No x

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	CFMS	NASDAQ

As of April 30, 2019, there were 67,863,789 shares of Common Stock, \$0.00001 par value per share, outstanding.

Conformis, Inc.

INDEX

	Page
<u>Part I - FINANCIAL INFORMATION</u>	
<u>Item 1. Financial Statements (interim periods unaudited)</u>	<u>1</u>
<u>Consolidated Balance Sheets as of March 31, 2019 and December 31, 2018</u>	<u>1</u>
<u>Consolidated Statements of Operations for the three months ended March 31, 2019 and 2018</u>	<u>2</u>
<u>Consolidated Statements of Comprehensive Loss for the three months ended March 31, 2019 and 2018</u>	<u>3</u>
<u>Consolidated Statements of Changes in Stockholders' Equity for the three months ended March 31, 2019 and 2018</u>	<u>4</u>
<u>Consolidated Statements of Cash Flows for the three months ended March 31, 2019 and 2018</u>	<u>5</u>
<u>Notes to Consolidated Financial Statements</u>	<u>6</u>
<u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	<u>26</u>
<u>Item 4. Controls and Procedures</u>	<u>38</u>
<u>Part II- OTHER INFORMATION</u>	
<u>Item 1. Legal Proceedings</u>	<u>39</u>
<u>Item 1A. Risk Factors</u>	<u>39</u>
<u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u>	<u>39</u>
<u>Item 6. Exhibits</u>	<u>39</u>
<u>Signatures</u>	<u>41</u>

PART I - FINANCIAL INFORMATION

Item 1. FINANCIAL STATEMENTS
CONFORMIS, INC. AND SUBSIDIARIESConsolidated Balance Sheets
(in thousands, except share and per share data)

	March 31, 2019 (unaudited)	December 31, 2018
Assets		
Current Assets		
Cash and cash equivalents	\$ 18,616	\$ 16,380
Investments	—	7,245
Accounts receivable, net	12,992	13,244
Royalty receivable	148	145
Inventories	9,561	9,534
Prepaid expenses and other current assets	1,477	1,408
Total current assets	42,794	47,956
Property and equipment, net	14,156	14,439
Operating lease right-of-use assets	6,678	—
Other Assets		
Restricted cash	462	462
Intangible assets, net	83	109
Other long-term assets	17	17
Total assets	\$ 64,190	\$ 62,983
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	\$ 4,443	\$ 3,445
Accrued expenses	7,122	7,930
Operating lease liabilities	1,427	—
Current portion of long-term debt	1,250	—
Total current liabilities	14,242	11,375
Other long-term liabilities	—	616
Long-term debt, less debt issuance costs	13,567	14,792
Operating lease liabilities	5,994	—
Total liabilities	33,803	26,783
Commitments and contingencies	—	—
Stockholders' equity		
Preferred stock, \$0.00001 par value:		
Authorized: 5,000,000 shares authorized at March 31, 2019 and December 31, 2018; no shares issued and outstanding as of March 31, 2019 and December 31, 2018	—	—
Common stock, \$0.00001 par value:		
Authorized: 200,000,000 shares authorized at March 31, 2019 and December 31, 2018; 67,880,664 and 65,290,879 shares issued and outstanding at March 31, 2019 and December 31, 2018, respectively	1	1
Additional paid-in capital	514,484	513,336
Accumulated deficit	(483,248)	(475,667)
Accumulated other comprehensive loss	(850)	(1,470)

Edgar Filing: Conformis Inc - Form 10-Q

Total stockholders' equity	30,387	36,200
Total liabilities and stockholders' equity	\$ 64,190	\$ 62,983

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

1

CONFORMIS, INC. AND SUBSIDIARIES

Consolidated Statements of Operations

(unaudited)

(in thousands, except share and per share data)

	Three Months Ended	
	March 31,	
	2019	2018
Revenue		
Product	\$20,469	\$19,483
Royalty	175	173
Total revenue	20,644	19,656
Cost of revenue	10,813	10,869
Gross profit	9,831	8,787
Operating expenses		
Sales and marketing	8,181	10,411
Research and development	2,912	4,694
General and administrative	5,329	6,140
Total operating expenses	16,422	21,245
Loss from operations	(6,591)	(12,458)
Other income and expenses		
Interest income	107	140
Interest expense	(453)	(735)
Foreign currency exchange transaction (loss) income	(653)	1,085
Total other (expenses) income, net	(999)	490
Loss before income taxes	(7,590)	(11,968)
Income tax provision	(9)	33
Net loss	\$(7,581)	\$(12,001)
Net loss per share		
Basic and diluted	\$(0.12)	\$(0.22)
Weighted average common shares outstanding		
Basic and diluted	62,849,335	54,741,828

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

CONFORMIS, INC. AND SUBSIDIARIES

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

	Three Months Ended March 31,	
	2019	2018
Net loss	\$(7,581)	\$(12,001)
Other comprehensive income (loss)		
Foreign currency translation adjustments	620	(939)
Change in unrealized gain (loss) on available-for-sale securities, net of tax	—	7
Comprehensive loss	\$(6,961)	\$(12,933)

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)

	Common Stock		Additional	Accumulated	Accumulated	
	Shares	Par Value	Paid-In Capital	Deficit	Other Comprehensive Income (Loss)	Total
Balance, December 31, 2017	45,528,519	\$ —	\$ 486,570	\$ (436,821)	\$ (3,236)	\$ 46,513
Issuance of common stock—restricted stock	(23,326)	—	—			—
Issuance of common stock—2018 offering	15,333,333	1	21,324			21,325
Compensation expense related to issued stock options and restricted stock awards			873			873
Cumulative-effect adjustment from adoption of ASC 606				4,519		4,519
Net loss				(12,001)		(12,001)
Other comprehensive loss					(932)	(932)
Balance, March 31, 2018	60,838,526	\$ 1	\$ 508,767	\$ (444,303)	\$ (4,168)	\$ 60,297

	Common Stock		Additional	Accumulated	Accumulated	
	Shares	Par Value	Paid-In Capital	Deficit	Other Comprehensive Income (Loss)	Total
Balance, December 31, 2018	65,290,879	\$ 1	\$ 513,336	\$ (475,667)	\$ (1,470)	\$ 36,200
Issuance of common stock—restricted stock	2,589,785	—	—			—
Compensation expense related to issued stock options and restricted stock awards			1,148			1,148
Net loss				(7,581)		(7,581)
Other comprehensive income					620	620
Balance, March 31, 2019	67,880,664	\$ 1	\$ 514,484	\$ (483,248)	\$ (850)	\$ 30,387

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

CONFORMIS, INC. AND SUBSIDIARIES

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

	Three Months Ended March 31,	
	2019	2018
Cash flows from operating activities:		
Net loss	\$(7,581)	\$(12,001)
Adjustments to reconcile net loss to net cash used by operating activities:		
Depreciation and amortization expense	1,065	948
Stock-based compensation expense	1,148	873
Unrealized foreign exchange (gain)/loss, net	639	(994)
Non-cash lease expense	310	—
Provision for bad debts on trade receivables	—	(20)
Non-cash interest expense	26	27
Amortization/accretion on investments	(4)	33
Deferred tax	—	(17)
Changes in operating assets and liabilities:		
Accounts receivable	252	1,331
Royalty receivable	(3)	—
Inventories	(27)	1,005
Prepaid expenses and other assets	(69)	15
Accounts payable and accrued liabilities	322	802
Other current liabilities	8	—
Other long-term liabilities	(324)	(2)
Net cash used in operating activities	(4,238)	(8,000)
Cash flows from investing activities:		
Acquisition of property and equipment	(757)	(1,300)
Purchase of investments	—	(3,244)
Maturity of investments	7,250	10,895
Net cash provided in investing activities	6,493	6,351
Cash flows from financing activities:		
Net proceeds from issuance of common stock	—	21,324
Net cash provided by financing activities	—	21,324
Foreign exchange effect on cash and cash equivalents	(19)	55
Increase in cash and cash equivalents	2,236	19,730
Cash and cash equivalents, beginning of period	16,380	18,348
Cash and cash equivalents, end of period	\$18,616	\$38,078
Supplemental information:		
Cash paid for interest	331	598
Non cash investing and financing activities:		
Operating leases right-of-use assets obtained in exchange for lease obligations	6,988	—

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

5

CONFORMIS, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements (unaudited)

Note A—Organization and Basis of Presentation

Conformis, Inc. and its subsidiaries (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 customized, to fit each patient’s unique anatomy. The Company’s proprietary iFit® technology platform is potentially applicable to all major joints. The Company offers a broad line of customized knee implants designed to restore the natural shape of a patient’s knee.

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 through a limited commercial launch. The Company has its corporate offices in Billerica, Massachusetts.

These consolidated financial statements as of March 31, 2019 and for the three months ended March 31, 2019 and 2018, 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, bank debt and convertible debt financings, equity financings, equipment purchase loans, and product revenue beginning in 2007. The Company has not yet attained profitability and continues to incur operating losses and negative operating cash flows, which adversely impacts the Company’s ability to continue as a going concern. At March 31, 2019, the Company had an accumulated deficit of \$483.2 million and cash and cash equivalents of \$18.6 million, and \$0.5 million in restricted cash allocated to lease deposits.

On January 6, 2017, the Company entered into a senior secured loan and security agreement (the “2017 Secured Loan Agreement”) with Oxford Finance LLC (“Oxford”) and accessed \$15 million of borrowings at closing (the “Term A Loan”), and an additional \$15 million of borrowings under Term Loan B on June 30, 2017 (the “Term B Loan”). Pursuant to a fifth amendment to the 2017 Secured Loan Agreement (the “Fifth Amendment”), on December 13, 2018, the Company pre-paid \$15 million aggregate principal amount of the \$30 million outstanding principal amount, as a pro rata portion of the Term A Loan and Term B Loan, together with accrued and unpaid interest thereon and a pro rata prepayment fee.

The Fifth Amendment also reduced revenue milestones required by the 2017 Secured Loan Agreement through December 31, 2019. New minimum revenue milestones, based on product revenue projections, are to be established prior to the start of 2020 and prior to the start of each fiscal year thereafter by the mutual agreement of Oxford and the Company. If the Company is not able to agree with Oxford on new minimum revenue milestones for 2020 or a fiscal year thereafter, the Company must refinance the 2017 Secured Loan Agreement by March 31, 2020 or that next fiscal year, and if the Company fails to refinance the 2017 Secured Loan Agreement, the Company must notify Oxford of such default and Oxford would be permitted to exercise remedies against the Company and its assets in respect of such event of default, including taking control of our cash and commencing foreclosure proceedings on our other assets.

The initial principal payment on the 2017 Secured Loan Agreement is due on February 1, 2020. The Company intends to refinance the 2017 Secured Loan Agreement before the interest only period ends and the principal repayments begin in January 2020. The Company may not be able to refinance or obtain additional financing on terms favorable to us, or at all. To the extent that the Company raises additional capital through the future sale of equity or debt, the ownership interest of our stockholders will be diluted. The terms of these future equity or debt securities may include liquidation or other preferences that adversely affect the rights of our existing common stockholders or involve negative covenants that restrict our ability to take specific actions, such as incurring additional debt or making capital expenditures. If the Company is unable to refinance the 2017 Secured Loan Agreement before the interest only period ends or shortly thereafter, then the Company will be required to make principal repayments beginning in January 2020 which will require the Company to raise additional capital through the sale of equity and the ownership interest of our stockholders will be diluted.

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 allows 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 a Distribution Agreement ("Distribution Agreement") with Canaccord Genuity Inc. ("Canaccord") pursuant to which Canaccord agreed to sell shares of the Company's common stock from time to time, as our agent, in an "at-the-market" offering ("ATM") as defined in Rule 415 promulgated under the U.S. Securities Act of 1933, as amended. The Company is not obligated to sell any shares under the Distribution Agreement. As of March 31, 2019, the Company has sold 785,280 shares under the Distribution Agreement resulting in net proceeds of \$1.5 million.

The Company anticipates that its principal sources of funds in the future will be revenue generated from the sale of its products, including the successful full commercial launch of the Conformis Hip System, potential future capital raises through the issuance of equity or other securities, potential debt financings, and revenue that may be generated in connection with licensing its intellectual property. Additionally, in order for the Company to meet our operating plan, gross margin improvements and operating expense reductions will be necessary to reduce cash used in operations. When the Company needs additional equity or debt financing proceeds to fund its operations, whether within the next 12 months or later, the Company may not be able to obtain additional financing on terms favorable to the Company, or at all.

Basis of presentation and use of estimates

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States 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, intangible valuation, purchase accounting, impairment assessments, equity instruments, stock compensation, income tax reserves and related allowances, and the lives of property and equipment, and valuation of right-of-use lease assets and lease liabilities. 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, 2018.

Unaudited Interim Financial Information

The accompanying Interim Consolidated Financial Statements as of March 31, 2019 and for the three months ended March 31, 2019 and 2018, 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 generally accepted accounting principles in the United States, or U.S. GAAP. In management's opinion, the unaudited interim consolidated financial statements have been prepared on the same basis as the audited financial statements and include all adjustments (including normal recurring adjustments) necessary for the fair presentation of the Company's financial position as of March 31, 2019, results of operations for the three months ended March 31, 2019 and 2018, and comprehensive loss, stockholders' equity, and cash flows for the three months ended March 31, 2019 and 2018. The results for the three months ended March 31, 2019 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. Except for the adoption of ASU 2016-02 "Leases" ("Topic 842" or "ASC 842") described below in "Leases", there were no material changes in the three months ended March 31, 2019 to the application of significant accounting policies and estimates as described in our audited consolidated financial statements for the year ended December 31, 2018.

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.

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 on-going basis, the Company validates alternate suppliers relative to certain key components as needed.

For the three months ended March 31, 2019 and 2018, no customer represented greater than 10% of revenue. There were no customers that represented greater than 10% of the total gross receivable balance as of March 31, 2019 or December 31, 2018.

Principles of consolidation

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

Cash and cash equivalents

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, money market accounts, and repurchase agreements on deposit with certain financial institutions, in addition to cash deposits in excess of federally insured limits. Demand deposits are carried at cost which approximates their fair value. Money market accounts are carried at fair value based upon level 1 inputs. Repurchase agreements are valued using level 2 inputs. See "Note C-Fair Value Measurements" below. The associated risk of concentration is mitigated by banking with credit worthy financial institutions. The Company had \$1.5 million as of March 31, 2019 and \$1.1 million as of December 31, 2018 held in foreign bank accounts that are not federally insured. In addition, the Company has recorded restricted cash of \$0.5 million as of March 31, 2019 and December 31, 2018. Restricted cash consisted of security provided for lease obligations. Oxford has a security interest in the Company's cash accounts held at multiple institutions.

Investment securities

The Company classifies its investment securities as available-for-sale. Those investments with maturities less than 12 months at the date of purchase are considered short-term investments. Those investments with maturities greater than 12 months at the date of purchase are considered long-term investments. The Company's investment securities classified as available-for-sale are recorded at fair value based upon quoted market prices at period end. Unrealized gains and losses, deemed temporary in nature, are reported as a separate component of accumulated other comprehensive income (loss).

A decline in the fair value of any security below cost that is deemed other than temporary results in a charge to earnings and the corresponding establishment of a new cost basis for the security. Premiums (discounts) are amortized (accrued) over the life of the related security using the constant yield method. Dividend and interest income are recognized when earned and reported in other income. Realized gains and losses are included in earnings and are derived using the specific identification method for determining the cost of securities sold.

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. Based on borrowing rates currently available to the Company for loans with similar terms, the carrying value of the Company's long-term debt approximates its fair value.

Accounts receivable and allowance for doubtful accounts

Accounts receivable consist of billed and unbilled amounts due from medical facilities. Upon completion of a procedure, revenue is recognized and an unbilled receivable is recorded. Upon receipt of a purchase order number from a medical facility, a 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 order numbers 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 months ended March 31, 2019 and 2018, the Company recognized provisions in cost of revenue of \$0.5 million, to adjust its inventory value to the lower of cost or market 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.

Business combinations and purchase accounting

The Company includes the results of operations of the businesses that it acquires as of the applicable acquisition date. The purchase price of the acquisition is allocated to the assets acquired and liabilities assumed based on their estimated fair values. The excess of the purchase price over the fair values of these identifiable assets and liabilities is recorded as goodwill. Acquisition-related expenses are recognized separately from the business combination and are expensed as incurred.

Intangibles and other long-lived assets

Intangible assets consist of developed technology and a favorable lease asset from the Company's acquisition of Broad Peak Manufacturing LLC in August 2017. Intangible assets are carried at cost less accumulated amortization. The Company tests impairment of long-lived assets when events or changes in circumstances indicate that the assets might be impaired. For assets with determinable useful lives, amortization is computed using the straight-line method over the estimated economic lives of the respective intangible assets. Furthermore, periodically the Company assesses whether long-lived assets, including intangible assets, should be tested for recoverability whenever events or circumstances indicate that their carrying value may not be recoverable. The amount of impairment, if any, is measured based on fair value, which is determined using estimated undiscounted cash flows to be generated from such assets or group of assets. During the three months ended March 31, 2019 and 2018, no such impairment charges were recognized.

Leases

The Company adopted ASU No. 2016-02-Leases ("Topic 842" or "ASC 842"), as of January 1, 2019, in accordance with ASU 2018-11-Leases (Topic 842) ("ASU 2018-11"), issued by the FASB in July 2018. ASU 2018-11 allows an entity to elect not to recast its comparative periods in the period of adoption when transitioning to ASC 842 (the "Comparatives Under 840 Option"). Effectively, an entity would be permitted to change its date of initial application to the beginning of the period of adoption of ASC 842. In doing so, the entity would apply ASC 840 in the comparative periods and provide the disclosures required by ASC 840 for all periods that continue to be presented in accordance with ASC 840. Further, the entity would recognize the effects of applying ASC 842 as a cumulative-effect adjustment to retained earnings as of the effective date. Under the Comparatives Under 840 Option, this date would represent the date of initial application. The Company is not required to restate comparative periods for the effects of applying ASC 842, provide the disclosures required by ASC 842 for the comparative periods, nor change how the transition requirements apply, only when the transition requirements apply. The Company elected to report results for periods after January 1, 2019 under ASC 842 and prior period amounts are reported in accordance with ASC 840.

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 initial term 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.

Adoption of the new standard resulted in the recording of additional right-of-use assets and lease liabilities of \$7.0 million and \$7.7 million, respectively, as of January 1, 2019. The difference between the additional lease assets and lease liabilities is related to deferred rent, which was previously recorded as deferred rent within Accrued expenses and Other long-term liabilities under ASC 840. The adoption of the standard did not impact the Company's consolidated net earnings and had no impact on cash flows.

Revenue Recognition

Revenue is recognized when, or as, obligations under the terms of a contract are satisfied, which occurs when control of the promised products or services is transferred to customers. Revenue is measured as the amount of consideration the Company expects to receive in exchange for transferring products or services to a customer ("transaction price"). When determining the transaction price of a contract, an adjustment is made if payment from a customer occurs either significantly before or significantly after performance, resulting in a significant financing component. Applying the

practical expedient in paragraph 606-10-32-18, the Company does not assess whether a significant financing component exists if the period between when the Company performs its obligations under the contract and when the customer pays is one year or less. None of the Company's contracts contained a significant financing component as of March 31, 2019. Payment is typically due between 30 - 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.

The Company does not have any contract assets or liabilities with customers. Unconditional rights to consideration are reported as receivables. Incidental items that are immaterial in the context of the contract are recognized as expense.

Disaggregation of Revenue

See "Note M—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 for the three months ended March 31, 2019 (in thousands):

	March
	31,
	2019
Beginning Balance	\$97
Provision related to current period sales	41
Adjustment related to prior period sales	5
Payments or credits issued to customer	(9)
Ending Balance	\$134

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 three months ended March 31, 2019 and 2018, 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 and \$0.2 million for the three months ended March 31, 2019 and 2018, 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 customized joint replacement products and that the Company operates as one segment. See "Note M—Segment and Geographic Data".

Comprehensive loss

At March 31, 2019 and December 31, 2018, accumulated other comprehensive loss consists of foreign currency translation adjustments and changes in unrealized gain and loss of available-for-sale securities, net of tax. The following table summarizes accumulated beginning and ending balances for each item in Accumulated other comprehensive income (loss) (in thousands):

	Foreign currency translation adjustments	Change in unrealized gain (loss) on available-for-sale securities, net of tax	Accumulated other comprehensive income (loss)
Balance December 31, 2018	\$ (1,470)	\$ —	\$ (1,470)
Change in period	620	—	620
Balance March 31, 2019	\$ (850)	\$ —	\$ (850)

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) income. 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 operating results of German operations will be permanently reinvested in that jurisdiction. As a result, the Company has only provided for income taxes at local rates when required.

The Company is subject to U.S. federal, state, and foreign income taxes. The Company recorded a provision for income taxes of \$(9,000) and \$33,000 for the three months ended March 31, 2019 and 2018, respectively. The Company recognizes interest and penalties related to income taxes as a component of income tax expense. As of

March 31, 2019 and 2018, a cumulative balance of \$47,000 and \$41,000 of interest and penalties had been accrued, respectively.

At March 31, 2019, the Company's foreign earnings, which have not been significant, have been retained indefinitely by foreign subsidiary companies for reinvestment. Upon repatriation of those earnings, in the form of dividends or otherwise, the Company could be subject to withholding taxes payable to the various foreign countries.

Medical device excise tax

The Company has been subject to the Health Care and Education Reconciliation Act of 2010 (the “Act”), which imposes a tax equal to 2.3% on the sales price of any taxable medical device by a medical device manufacturer, producer or importer of such device. Under the Act, a taxable medical device is any device defined in Section 201(h) of the Federal Food, Drug, and Cosmetic Act, intended for humans, which includes an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which meets certain requirements. The Consolidated Appropriations Act of 2016 includes a two-year moratorium on the medical device excise tax, which moratorium suspended taxes on the sale of a taxable medical device by the manufacturer, producer, or importer of the device during the period beginning on January 1, 2016 and ending on December 31, 2017. On January 22, 2018, legislation was passed that suspends the medical device excise tax for sales in 2018 and 2019. The tax is not scheduled to take effect again until sales on or after January 1, 2020. It is unclear at this time if the suspension will be further extended, and we are currently subject to the tax after December 31, 2019. As such, the Company did not incur medical device excise tax expense during the three months ended March 31, 2019 and 2018.

Stock-based compensation

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

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

Net loss per share

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

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

(in thousands, except share and per share data)	Three Months Ended	
	2019	2018
Numerator:		
Basic and diluted loss per share		
Net loss	\$(7,581)	\$(12,001)
Denominator:		
Basic and diluted weighted average shares	62,849,335	62,741,828
Loss per share attributable to Conformis, Inc. stockholders:		

Basic and diluted

\$(0.12) \$(0.22)

14

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

	Three Months Ended March 31,	
	2019	2018
Stock options and restricted stock awards	2,538,495	44,564

Recent accounting pronouncements

In August 2018, the FASB issued ASU No. 2018-15, "Intangibles - Goodwill and Other - Internal-Use Software (Subtopic 350-40): Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract". Under the new guidance, implementation costs should be evaluated for capitalization using the same approach as implementation costs associated with internal-use software and should be expensed over the term of the hosting arrangement, including any reasonably certain renewal periods. This ASU is effective for fiscal years beginning after December 15, 2019. Early adoption is permitted, including adoption in any interim period. Prospective adoption for eligible costs incurred on or after the date of adoption or retrospective adoption are permitted. The Company does not expect the adoption of ASU 2018-15 will have a material impact on its consolidated financial statements.

In August 2018, the FASB issued ASU No. 2018-13, "Fair Value Measurement (Topic 820): Disclosure Framework - Changes to the Disclosure Requirements for Fair Value Measurement". This ASU modifies disclosure requirements relative to the three levels of inputs used to measure fair value in accordance with Topic 820. This ASU is effective for fiscal years beginning after December 15, 2019, including interim periods. Early adoption is permitted for any eliminated or modified disclosures. The Company does not expect the adoption of ASU 2018-13 will have a material impact on its consolidated financial statements.

In June 2016, the FASB issued ASU 2016-13, "Credit Losses (Topic 326)." ASU 2016-13 requires that financial assets measured at amortized cost, such as trade receivables, be represented net of expected credit losses, which may be estimated based on relevant information such as historical experience, current conditions, and future expectation for each pool of similar financial asset. The new guidance requires enhanced disclosures related to trade receivables and associated credit losses. The guidance is effective beginning January 1, 2020. The Company is currently evaluating the impact of this pronouncement on its consolidated financial statements.

Reclassification

Certain amounts in prior periods have been reclassified to conform to the current period presentation. The Company reclassified the cash flow presentation of unrealized foreign currency transaction gains or losses resulting from changes in exchange rates between the functional currency and the currency in which a foreign currency transaction is denominated to reflect such cash flows as non-cash adjustment to cash flows from operating activities.

Note C—Fair Value Measurements

The Fair Value Measurements topic of the FASB Codification establishes a framework for measuring fair value in accordance with US GAAP, clarifies the definition of fair value within that framework and expands disclosures about fair value measurements. This guidance requires disclosure regarding the manner in which fair value is determined for assets and liabilities and establishes a three-tiered value hierarchy into which these assets and liabilities must be grouped, based upon significant levels of inputs as follows:

Level 1—Quoted prices in active markets for identical assets or liabilities.

Level 2—Observable inputs, other than Level 1 prices, such as quoted prices in active markets for similar assets and liabilities, quoted prices for identical or similar assets and liabilities in markets that are not active, or other inputs that

are observable or can be corroborated by observable market data.

Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities. This includes certain pricing models, discounted cash flow methodologies and similar techniques that use significant unobservable inputs.

15

The Company's investment policy is consistent with the definition of available-for-sale securities. All investments have been classified within Level 1 or Level 2 of the fair value hierarchy because of the sufficient observable inputs for revaluation. The Company's Level 1 cash and equivalents and investments are valued using quoted prices that are readily and regularly available in the active market. The Company's Level 2 investments are valued using third-party pricing sources based on observable inputs, such as quoted prices for similar assets at the measurement date; or other inputs that are observable, either directly or indirectly.

The following table summarizes, by major security type, the Company's assets that are measured at fair value on a recurring basis and are categorized using the fair value hierarchy and where they are classified on the Consolidated Balance Sheets (in thousands):

	March 31, 2019					
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value	Cash and equivalents	Short-term (1) investments
Cash	\$6,575	\$ —	—\$	—\$6,575	\$ 6,575	\$ —
Level 1 securities:						
Money market funds	12,041	—	—	12,041	12,041	—
Total	\$18,616	\$ —	—\$	—\$18,616	\$ 18,616	\$ —
	December 31, 2018					
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value	Cash and equivalents	Short-term (1) investments
Cash	\$9,837	\$ —	—\$	—\$9,837	\$ 9,837	\$ —
Level 1 securities:						
Money market funds	1,046	—	—	1,046	1,046	—
U.S. treasury bonds	10,494	—	—	10,494	5,497	4,997
Level 2 securities:						
Corporate bonds	1,249	—	—	1,249	—	1,249
Commercial Paper	999	—	—	999	—	999
Total	\$23,625	\$ —	—\$	—\$23,625	\$ 16,380	\$ 7,245

(1) Contractual maturity due within one year.

Note D—Accounts Receivable

Accounts receivable consisted of the following (in thousands):

	March 31, December 31,	
	2019	2018
Total receivables	\$13,402	\$13,634
Allowance for doubtful accounts and returns	(410)	(390)
Accounts receivable, net	\$12,992	\$13,244

Accounts receivable included unbilled receivable of \$2.1 million and \$2.2 million at March 31, 2019 and December 31, 2018, respectively. Write-offs related to accounts receivable were approximately \$0 and \$25,000 for the three months ended March 31, 2019 and 2018, respectively.

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

	March 31, December 31,	
	2019	2018
Beginning balance	(390)	(635)
Provision for bad debts on trade receivables	—	72
Other allowances	(20)	58
Accounts receivable write offs	—	115
Ending balance	\$ (410)	\$ (390)

Note E—Inventories

Inventories consisted of the following (in thousands):

	March 31, December 31,	
	2019	2018
Raw Material	\$ 4,247	\$ 4,498
Work in process	1,569	1,518
Finished goods	3,745	3,518
Total Inventories	\$ 9,561	\$ 9,534

Note F—Property and Equipment

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

	Estimated Useful Life (Years)	March 31, December 31,	
		2019	2018
Equipment	5-7	\$ 18,752	\$ 18,602
Furniture and fixtures	5-7	954	954
Computer and software	3	8,842	8,783
Leasehold improvements	3-7	1,977	1,978
Reusable instruments	5	2,062	1,573
Total property and equipment		32,587	31,890
Accumulated depreciation		(18,431)	(17,451)
Property and equipment, net		\$ 14,156	\$ 14,439

Depreciation expense related to property and equipment was \$1.0 million and \$0.9 million for the three months ended March 31, 2019 and 2018, respectively.

Note G—Intangible Assets

The components of intangible assets consisted of the following (in thousands):

	Estimated Useful Life (Years)	March 31, 2019	December 31, 2018
Developed technology	10	\$979	\$ 979
Accumulated amortization		(906)	(881)
Developed technology, net		73	98
Acquired favorable lease	5	15	15
Accumulated amortization		(5)	(4)
Acquired favorable lease, net		10	11
Intangible assets, net		\$83	\$ 109

The Company recognized amortization expense of \$25,000 for the three months ended March 31, 2019, and 2018. The weighted-average remaining life of total amortizable intangible assets is 1.06 years for the developed technology and license agreements and favorable lease asset.

The estimated future aggregated amortization expense for intangible assets owned as of March 31, 2019 consisted of the following (in thousands):

	Amortization expense
2019 (remainder of the year)	\$ 75
2020	3
2021	3
2022	2
	\$ 83

Note H—Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	March 31, 2019	December 31, 2018
Accrued employee compensation	\$ 2,749	\$ 3,138
Deferred rent	—	132
Accrued legal expense	507	215
Accrued consulting expense	21	84
Accrued vendor charges	1,580	1,441
Accrued revenue share expense	641	1,134
Accrued clinical trial expense	432	549
Accrued other	1,192	1,237
	\$ 7,122	\$ 7,930

Note I—Leases

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

The Company's leases have remaining lease terms of approximately one to seven 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.

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

As of March 31, 2019 the Company has not entered into any leases which have not yet commenced which would entitle the Company to significant rights or create additional obligations.

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

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

	Three months ended March	
	March 31, 2019	March 31, 2018
Rent expense	\$381	\$379
Variable lease cost (1)	101	—
	\$482	\$379

(1) Variable operating lease expenses consist primarily common area maintenance and real estate taxes of for the three months ended March 31, 2019.

Deferred rent was \$0.7 million as of December 31, 2018. Deferred rent is included in accrued expenses and other long-term liabilities.

As of March 31, 2019, the remaining weighted-average lease term of the operating leases was 5.7 years and the weighted-average discount rate was 6.0%.

The future minimum rental payments under these agreements as of March 31, 2019 were as follows (in thousands):

Year	Minimum lease Payments
2019 remainder of year	\$ 1,190
2020	1,614
2021	1,633

Edgar Filing: Conformis Inc - Form 10-Q

2022	1,399
2023	1,053
After 2023	1,886
Total lease payments	\$ 8,775
Present value adjustment	(1,355)
Present value of lease liabilities	\$ 7,420

19

Note J—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 customized 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 \$0.7 million during the three months ended March 31, 2019, representing 3.5% of product revenue and \$0.9 million during the three months ended March 31, 2018, representing 4.7% of product revenue. Revenue share expense is included in research and development.

Other obligations

In the ordinary course of business, the Company is a party to certain non-cancellable contractual obligations typically related to product royalty and research and development. The Company accrues a liability for such matters when it is probable that future expenditures will be made and such expenditures can be reasonably estimated. There have been no contingent liabilities requiring accrual at March 31, 2019 or December 31, 2018.

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. An estimate of the possible loss or range of loss as a result of any of these matters cannot be made; however, management does not believe that these matters, individually or in the aggregate, are material to its financial condition, results of operations or cash flows.

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 enables it to recover a portion of any amounts paid for future claims.

Note K—Debt and Notes Payable

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

	March 31, December 31,	
	2019	2018
Oxford Finance, LLC, Term A Loan	\$7,500	\$ 7,500
Oxford Finance, LLC, Term B Loan	7,500	7,500
	15,000	15,000
Less unamortized debt issuance costs	(183)	(208)
Total Debt, less debt issuance costs	\$14,817	\$ 14,792
Less current installments	1,250	—
Long-term debt, excluding current installments	\$13,567	\$ 14,792

Principal payments due as of March 31, 2019 consisted of the following (in thousands):

	Principal Payment
2019 (remainder of the year)	\$—
2020	6,875
2021	7,500
2022	625
Total	\$15,000

2017 Secured Loan Agreement

On January 6, 2017, the Company entered into the 2017 Secured Loan Agreement with Oxford. Through the 2017 Secured Loan Agreement, the Company accessed \$15 million under Term Loan A at closing and an additional \$15 million of borrowings under Term Loan B on June 30, 2017. On December 13, 2018, the Company entered into a fifth amendment (the "Fifth Amendment") to the 2017 Secured Loan Agreement, with Oxford, and pursuant to the Fifth Amendment, the Company pre-paid \$15 million aggregate principal amount of the \$30 million outstanding principal amount, as a pro rata portion of the Term A Loan and Term B Loan, together with accrued and unpaid interest thereon and a pro rata prepayment fee. Under the Fifth Amendment, the Company's cash collateral requirements was reduced to \$5 million.

The Fifth Amendment also reduced the revenue milestones through December 31, 2019. New minimum revenue milestones, based on product revenue projections, are to be established prior to the start of 2020 and prior to the start of each fiscal year thereafter by the mutual agreement of Oxford and the Company. If the Company is not able to agree with Oxford on new minimum revenue milestones for 2020 or a fiscal year thereafter, the Company will have to refinance the 2017 Secured Loan Agreement by March 31, 2020 or that next fiscal year, and if the Company fails to refinance the 2017 Secured Loan Agreement, the Company must notify Oxford of such default and Oxford would be permitted to exercise remedies against the Company and our assets in respect of such event of default, including taking control of our cash and commencing foreclosure proceedings on our other assets.

The 2017 Secured Loan Agreement is secured by substantially all of the Company's personal property other than the Company's intellectual property. Under the terms of the 2017 Secured Loan Agreement, the Company cannot grant a security interest in its intellectual property to any other party.

The term loans under the 2017 Secured Loan Agreement bear interest at a floating annual rate calculated at the greater of 30 day LIBOR or 0.53%, plus 6.47%. The Company is required to make monthly interest-only payments in arrears commencing on the second payment date following the funding date of each term loan, and continuing on the payment date of each successive month thereafter through and including the payment date immediately preceding the amortization date of February 1, 2020. Commencing on the amortization date, and continuing on the payment date of each month thereafter, the Company is required to make consecutive equal monthly payments of principal of each term loan, together with accrued interest, in arrears, to Oxford. All unpaid principal, accrued and unpaid interest with respect to each term loan, and a final payment in the amount of 5.0% of the amount of loans advanced, is due and payable in full on the term loan maturity date. The 2017 Secured Loan Agreement has a term of five years and matures on January 1, 2022.

At the Company's option, the Company may prepay all, but not less than all, of the term loans advanced by Oxford under the 2017 Secured Loan Agreement, 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 payment, plus all other amounts that are due and payable, including Oxford's expenses and interest at the default rate with respect to any past due amounts.

The Company intends to refinance the 2017 Secured Loan Agreement before the interest only period ends and the principal repayments begin in January 2020. The Company may not be able to refinance or obtain additional financing on terms favorable to the Company, or at all. To the extent that we raise additional capital through the future sale of equity or debt, the ownership interest of our stockholders will be diluted. The terms of these future equity or debt securities may include liquidation or other preferences that adversely affect the rights of our existing common stockholders or involve negative covenants that restrict the Company's ability to take specific actions, such as incurring additional debt or making capital expenditures. If the Company is unable to refinance the 2017 Secured Loan Agreement before the interest only period ends or shortly thereafter, then the Company will be required to make principal repayments beginning in January 2020 which will require the Company to raise additional capital through the sale of equity and the ownership interest of our stockholders will be diluted.

The 2017 Secured Loan Agreement also 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 Oxford, as collateral agent with the right to exercise remedies against us, including taking control of the Company's cash and commencing foreclosure proceedings on the Company's other assets. These events of default include, among other things, the Company's failure to pay any amounts due under the 2017 Secured Loan Agreement, a breach of covenants under the 2017 Secured Loan Agreement, including, among other customary debt covenants, achieving certain revenue levels, maintaining a certain amount of cash collateral and limiting the amount of cash and cash equivalents held by the Company's foreign subsidiaries, the Company's insolvency, a material adverse change, the occurrence of any default under certain other indebtedness in an amount greater than \$500,000, one or more judgments against the Company in an amount greater than \$500,000, a material adverse change with respect to any governmental approval and any delisting event.

As of March 31, 2019, the Company was not in breach of covenants under the Amended 2017 Secured Loan Agreement.

Note L—Stockholders' Equity

Common stock

On January 29, 2018, the Company closed an offering of its common stock pursuant to the Shelf Registration Statement and issued and sold 15,333,333 shares of its common stock (including 2,000,000 shares of common stock issued in connection with the exercise in full by the underwriters of their over-allotment option) at a public offering

price of \$1.50 per share, for aggregate net proceeds of approximately \$21.3 million. The Company intends 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 the Company's secured term loan facility, working capital and capital expenditures.

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.

Preferred stock

The Company's Restated Certificate of Incorporation authorizes the Company to issue 5,000,000 shares of preferred stock, \$0.00001 par value, all of which is undesignated. No shares were issued and outstanding at March 31, 2019 and December 31, 2018.

Demand registration rights

In conjunction with the IPO, the Company entered into an Amended and Restated Information and Registration Rights Agreement effective June 29, 2015 (the "Registration Rights Agreement"), which provided, among other things, registration rights to certain investors that had held the Company's preferred stock prior to the IPO. Subject to specified limitations set forth in a registration rights agreement, at any time, the holders of at least 25% of the then outstanding registrable shares may at any time demand in writing that the Company register all or a portion of the registrable shares under the Securities Act on a Form other than Form S-3 for an offering of at least 20% of the then outstanding registrable shares or a lesser percentage of the then outstanding registrable shares provided that it is reasonably anticipated that the aggregate offering price would exceed \$20 million. The Company is not obligated to file a registration statement pursuant to these rights on more than two occasions. Additionally, after such time as the Company became eligible to use Form S-3, subject to specified limitations set forth in the registration rights agreement, the holders of at least 25% of the then outstanding registrable shares became able to at any time demand in writing that the Company register all or a portion of the registrable shares under the Securities Act on Form S-3 for an offering of at least 25% of the then outstanding registrable shares having an anticipated aggregate offering price to the public, net of selling expenses, of at least \$5 million (a "Resale Registration Statement"). The Company is not obligated to effect a registration pursuant to a Resale Registration Statement on more than one occasion.

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.

Warrants

The Company also issued warrants to certain investors and consultants to purchase shares of the Company's preferred stock and common stock. Based on the Company's assessment of the warrants granted in 2013 and 2014 relative to ASC 480, Distinguishing Liabilities from Equity, the warrants are classified as equity. No warrants were issued in the three months ended March 31, 2019. 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.

Common stock warrants

The Company also issued warrants to certain investors and consultants to purchase shares of common stock. Warrants to purchase 28,926 shares of common stock were outstanding as of March 31, 2019 and December 31, 2018.

Outstanding warrants are currently exercisable with varying exercise expiration dates from 2020 through 2024. At March 31, 2019 and December 31, 2018, the weighted average warrant exercise price per share for common stock underlying warrants and the weighted average contractual life was as follows:

	Number of Warrants	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Life	Number of Warrants Exercisable	Weighted Average Price Per Share
Outstanding December 31, 2018	28,926	\$ 9.80	4.66	28,926	\$ 9.80
Outstanding March 31, 2019	28,926	\$ 9.80	4.41	28,926	\$ 9.80

Stock option plans

As of March 31, 2019, 1,387,185 shares of common stock were available for future issuance under the 2015 Stock Incentive Plan ("2015 Plan"). The 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 our common stock, (b) 3% of the number of share of our common stock outstanding on the first day of such fiscal year and (c) an amount determined by the Board. Effective January 1, 2019, an additional 1,958,726 shares of our common stock were added to the 2015 Plan under the terms of this provision.

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, 2018	2,876,199	\$ 6.57	
Expired	(445,102)	6.93	
Cancelled/Forfeited	(314)	18.83	
Outstanding March 31, 2019	2,430,783	\$ 6.50	\$ —
Total vested and exercisable	1,959,379	\$ 6.94	\$ —

The total fair value of stock options that vested during the three months ended March 31, 2019 was \$0.6 million. The weighted average remaining contractual term for the total stock options outstanding was 4.76 years as of March 31, 2019. The weighted average remaining contractual term for the total stock options vested and exercisable was 3.91 years as of March 31, 2019.

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

	Number of Shares	Weighted Average Fair Value
Unvested December 31, 2018	2,473,372	\$ 2.45
Granted	2,696,003	0.39
Vested	(63,321)	5.49

Edgar Filing: Conformis Inc - Form 10-Q

Forfeited	(106,218)	2.45
Unvested March 31, 2019	4,999,836	\$ 1.30

The total fair value of restricted common stock awards that vested during the three months ended March 31, 2019 was \$0.3 million.

24

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 the IPO was performed with the assistance of an independent third-party valuation firm using a methodology that includes various inputs including the Company's historical and projected financial results, peer company public data and market metrics, such as risk-free interest and discount rates. As the valuations included unobservable inputs that were primarily based on the Company's own assumptions, the inputs were considered level 3 inputs within the fair value hierarchy.

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

	Three Months Ended March 31, 2019 2018	
Risk-free interest rate	N/A	2.75%
Expected term (in years)	N/A	6.25
Dividend yield	N/A	—%
Expected volatility	N/A	52.81%

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 does not have sufficient history of market prices of its common stock as it is a newly public company. Therefore, the Company estimates volatility using historical volatilities of similar public entities.

Forfeitures. The Company recognizes forfeitures as they occur.

Stock-based compensation expense was \$1.1 million and \$0.9 million for the three months ended March 31, 2019 and 2018, respectively. Stock-based compensation expense was calculated based on awards ultimately expected to vest. To date, the amount of stock-based compensation capitalized as part of inventory was not material.

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

	Three Months Ended March 31, 2019 2018	
Cost of revenues	\$ 166	\$ 39
Sales and marketing	644	125

Research and development	257	290
General and administrative	81	419
	\$1,148	\$873

As of March 31, 2019, the Company had \$1.1 million of total unrecognized compensation expense for options that will be recognized over a weighted average period of 2.25 years. As of March 31, 2019, the Company had \$4.1 million of total unrecognized compensation expense for restricted awards that will be recognized over a weighted average period of 2.29 years.

Note M—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. Net property, plant and equipment are based upon physical location of the assets.

Geographic information consisted of the following (in thousands):

	Three Months Ended March 31,	
	2019	2018
Product revenue		
United States	\$17,554	\$16,027
Germany	2,469	3,087
Rest of world	446	369
	\$20,469	\$19,483
	March 31, December 31,	
	2019	2018
Property and equipment, net		
United States	\$ 14,089	\$ 14,367
Germany	67	72
	\$ 14,156	\$ 14,439

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, 2018. 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, 2018, 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 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," "p," "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 and Conformis Hip System
- 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;
- the anticipated timing of our product launches;
- 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 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 U.S. 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;

our ability to continue as a going concern; and

our expectations regarding the time during which we will be an emerging growth company under the JOBS Act.

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.

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 that are individually sized and shaped, which we refer to as customized, to fit each patient's unique anatomy. The worldwide market for joint replacement products is approximately \$18.1 billion annually and growing, and we believe our iFit technology platform is applicable to all major joints in this market. We offer a broad line of customized knee implants designed to restore the natural shape of a patient's knee. We have sold a total of more than 90,000 knee implants, including more than 70,000 total knee implants and 20,000 partial knee implants. In clinical studies, iTotal CR, our cruciate-retaining total knee replacement implant and best-selling product, demonstrated superior clinical outcomes, including better function and greater patient satisfaction compared to off-the-shelf implants. In March 2016, we initiated the broad commercial launch of the iTotal PS, our posterior-stabilized total knee replacement implant which addresses the largest segment of the knee replacement market. On July 31, 2018, our first Conformis Hip Systems were implanted. We are in limited commercial launch with the Conformis Hip System and intend to enter full commercial launch in the second half of 2019.

Our iFit technology platform comprises three key elements:

iFit Design, our proprietary algorithms and computer software that we use to design customized implants and associated single-use patient-specific instrumentation, which we refer to as iJigs, based on computed tomography, or CT scans of the patient and to prepare a surgical plan customized 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 customized hip and 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 off-the-shelf implants.

All of our joint replacement products have been cleared by the FDA under the premarket notification process of Section 510(k) of the Federal Food, Drug, and Cosmetic Act, or the FDCA, and all of our knee replacement products have received certification to CE Mark. We market our products 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 and other markets.

We were incorporated in Delaware and commenced operations in 2004.

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, Singapore, Hong Kong, Malaysia, Monaco, Hungary, Spain, and Australia. 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, require 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 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.

On-going royalty revenue is generated from our agreement with MicroPort Orthopedics Inc., a wholly owned subsidiary of MicroPort Scientific Corporation, and was generated through December 31, 2017 with Wright Medical Group, Inc. and its wholly owned subsidiary Wright Medical Technology, Inc., both agreements entered into in April 2015.

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 July 2018, we manufacture our patient specific Conformis Hip System implants in our facility in Wilmington, Massachusetts. We outsource the production of the remainder of the partial knee tibial components, the manufacture of femoral castings and other knee and hip implant components to third-party suppliers. Our suppliers make our customized implant components using the CAD designs we supply. Cost of revenue consists primarily of costs of raw materials, manufacturing personnel, manufacturing supplies, outside supplier processes, inbound freight and manufacturing overhead and depreciation expense.

We calculate gross margin as revenue less cost of revenue divided by revenue. Our gross margin has been and will continue to be affected by a variety of factors, including primarily volume of units produced, mix of product components manufactured by us versus sourced from third parties, our average selling price, 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 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 component 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;
- developing new versions of our software used in the design of our customized joint replacement implants, which we believe will reduce costs associated with the design process; and
- continue to transition our in-house CAD labor force to India, which we believe will reduce labor costs required to design our products.

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.

30

Sales and marketing. Sales and marketing expense consists primarily of personnel costs, including salary, employee benefits and stock-based compensation for personnel employed in sales, marketing, customer service, medical education and training, as well as investments in surgeon training programs, industry events and other promotional activities. In addition, our sales and marketing expense includes sales commissions and bonuses, generally based on a percentage of sales, to our sales managers, direct sales representatives and independent sales representatives. Recruiting, training and retaining productive sales representatives and educating surgeons about the benefits of our products are required to generate and grow revenue. We expect sales and marketing expense to 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 prototypes, testing, clinical study programs and regulatory activities, contractors and consultants, and equipment and software to support our development. As our revenue increases, we will also incur additional 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, general legal and intellectual property, finance and accounting, information technology and human resources personnel. General and administrative expense also includes outside legal costs associated with intellectual property and general legal matters, financial audit fees, insurance, fees for other consulting services, depreciation expense, 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 income (expenses), 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 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 transaction adjustments in the consolidated statements of comprehensive loss.

Income tax provision

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

Consolidated results of operations

Comparison of the three months ended March 31, 2019 and 2018

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 March 31,	2019		2018		2019 vs 2018	
	Amount	As a % of Total Revenue	Amount	As a % of Total Revenue	\$ Change	% Change
Revenue						
Product revenue	\$20,469	99 %	\$19,483	99 %	\$986	5 %
Royalty	175	1	173	1	2	1
Total revenue	20,644	100	19,656	100	988	5
Cost of revenue	10,813	52	10,869	55	(56)	(1)
Gross profit	9,831	48	8,787	45	1,044	12
Operating expenses:						
Sales and marketing	8,181	40	10,411	53	(2,230)	(21)
Research and development	2,912	14	4,694	24	(1,782)	(38)
General and administrative	5,329	26	6,140	31	(811)	(13)
Total operating expenses	16,422	80	21,245	108	(4,823)	(23)
Loss from operations	(6,591)	(32)	(12,458)	(63)	5,867	47
Total other income (expenses), net	(999)	(5)	490	2	(1,489)	(304)
Loss before income taxes	(7,590)	(37)	(11,968)	(61)	4,378	37
Income tax provision	(9)	—	33	—	(42)	(127)
Net loss	\$(7,581)	(37)%	\$(12,001)	(61)%	\$4,420	37 %

Product revenue. Product revenue was \$20.5 million for the three months ended March 31, 2019 compared to \$19.5 million for the three months ended March 31, 2018, an increase of \$1.0 million or 5%, due principally to increased sales of our iTotal PS and Hip System, partially offset by decreased sales of our partial knee products and iTotal CR.

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 March 31,	2019		2018		2019 vs 2018	
	Amount	As a % of Product Revenue	Amount	As a % of Product Revenue	\$ Change	% Change
United States	\$17,554	86 %	\$16,027	82 %	\$1,527	10 %
Germany	2,469	12	3,087	16	(618)	(20)
Rest of world	446	2	369	2	77	21
Product revenue	\$20,469	100 %	\$19,483	100 %	\$986	5 %

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 86% for the three months ended March 31, 2019 compared to 82% for the three months ended March 31, 2018. We believe the higher level of revenue as a percentage of product revenue inside the United States in the three months ended March 31, 2019 was due to the introduction of the iTotal PS and Hip System in the United States, and the negative impact in Germany is due to (i) the decrease in reimbursement of our iUni and iDuo partial implants and (ii) continued reimbursement challenges of our

iTotal CR and iTotals PS business.

Royalty revenue. Royalty revenue was \$0.2 million for the three months ended March 31, 2019 compared to \$0.2 million for the three months ended March 31, 2018 comprised of royalty revenue from MicroPort Orthopedics Inc.

32

Cost of revenue, gross profit and gross margin. Cost of revenue was \$10.8 million for the three months ended March 31, 2019 compared to \$10.9 million for the three months ended March 31, 2018, a decrease of \$0.1 million or 1%. The decrease was due primarily to vertical integration and other cost saving initiatives. Gross profit was \$9.8 million for the three months ended March 31, 2019 compared to \$8.8 million for the three months ended March 31, 2018, an increase of \$1.0 million or 12%. Gross margin increased 300 basis points to 48% for the three months ended March 31, 2019 from 45% for the three months ended March 31, 2018. This increase in gross margin was driven primarily by savings from vertical integration efforts and other cost saving initiatives.

Sales and marketing. Sales and marketing expense was \$8.2 million for the three months ended March 31, 2019 compared to \$10.4 million for the three months ended March 31, 2018, a decrease of \$2.2 million or 21%. The decrease was due primarily to a \$1.3 million decrease in sales and marketing salaries and benefits, a \$1.2 million decrease in program and PR spending, and a decrease of \$0.2 million in travel. This was offset by an increase of \$0.2 million in instrumentation and bioskill lab expenses related to the hip launch, an increase of \$0.2 million in sales commissions and an increase of \$0.1 million in outside labor and other expenses. Sales and marketing expense decreased as a percentage of total revenue to 40% for the three months ended March 31, 2019 compared to 53% for the three months ended March 31, 2018.

Research and development. Research and development expense was \$2.9 million for the three months ended March 31, 2019 compared to \$4.7 million for the three months ended March 31, 2018, a decrease of \$1.8 million or 38%. The decrease was due primarily to a decrease in revenue share expense of \$1.0 million related to selling fee adjustments, a decrease in personnel costs of \$0.8 million decrease in prototype supplies of \$0.3 million related to timing, partially offset by an increase in consulting of \$0.3 million. Research and development expense decreased as a percentage of total revenue to 14% for the three months ended March 31, 2019 from 24% for the three months ended March 31, 2018.

General and administrative. General and administrative expense was \$5.3 million for the three months ended March 31, 2019 compared to \$6.1 million for the three months ended March 31, 2018, a decrease of \$0.8 million or 13%. The decrease was due to a \$0.8 million reduction in litigation fees. General and administrative expense decreased as a percentage of total revenue to 26% for the three months ended March 31, 2019 from 31% for the three months ended March 31, 2018.

Total other income (expenses), net. Other income (expenses), net was \$(1.0) million for the three months ended March 31, 2019 compared to \$0.5 million for the three months ended March 31, 2018, a change of \$(1.5) million. The change was primarily due to a \$1.7 million increase in foreign currency exchange transaction expense partially offset by a \$0.3 million decrease in interest expense.

Income taxes. Income tax provision was \$(9,000) and \$33,000 for the three months ended March 31, 2019 and 2018, respectively. We continue to generate losses for U.S. federal and state tax purposes and have net operating loss carryforwards creating a deferred tax asset. We maintain a full valuation allowance for deferred tax assets.

Liquidity, capital resources and plan of operations

Sources of liquidity and funding requirements

From our inception in June 2004 through the three months ended March 31, 2019, we have financed our operations primarily through private placements of preferred stock, our initial public offering, or IPO, equity offerings, bank and other debt and product revenue. We have not yet attained profitability and continue to incur operating losses. As of March 31, 2019, we have an accumulated deficit of \$483.2 million.

On January 6, 2017, we entered into a senior secured loan and security agreement, or the 2017 Secured Loan Agreement with Oxford Finance LLC, or Oxford. Through the Secured Loan Agreement with Oxford, the Company accessed \$15 million of borrowings on January 6, 2017 and a second \$15 million of borrowings on June 30, 2017. On December 13, 2018, we pre-paid \$15 million principal amount of the \$30 million outstanding principal amount using short-term investment maturities and cash and cash equivalents. New minimum revenue milestones, based on product revenue projections, are to be established prior to the start of 2020 and prior to the start of each fiscal year thereafter by the mutual agreement of Oxford and us. If we are not able to agree with Oxford on new minimum revenue milestones for 2020 or a fiscal year thereafter, we will be required to refinance the 2017 Secured Loan Agreement by March 31, 2020 or that next fiscal year, and if we fail to do so, we may default under the 2017 Secured Loan Agreement. In such an event, we would be required to notify Oxford of such default and Oxford would be permitted to exercise remedies against us and our assets in respect of such event of default, including taking control of our cash and commencing foreclosure proceedings on our other assets.

The initial principal payment on the 2017 Secured Loan Agreement is due on February 1, 2020. We intend to refinance the 2017 Secured Loan Agreement before the interest only period ends and the principal repayments begin in January 2020. We may not be able to refinance or obtain additional financing on terms favorable to us, or at all. To the extent that we raise additional capital through the future sale of equity or debt, the ownership interest of our stockholders will be diluted. The terms of these future equity or debt securities may include liquidation or other preferences that adversely affect the rights of our existing common stockholders or involve negative covenants that restrict our ability to take specific actions, such as incurring additional debt or making capital expenditures. If we are unable to refinance the 2017 Secured Loan Agreement before the interest only period ends or shortly thereafter, then we will be required to make principal repayments beginning in January 2020 which will require us to raise additional capital through the sale of equity and the ownership interest of our stockholders will be diluted. For further information regarding this facility, see Note K—Debt and Notes Payable in the financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q.

In January 2017, we filed a shelf registration statement on Form S-3, which was declared effective by the SEC on May 9, 2017, or the "Shelf Registration Statement". The Shelf Registration Statement allows 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 may issue and sell up to \$50 million of our common stock and entered into the Distribution Agreement with Canaccord Genuity, pursuant to which Canaccord has agreed to sell shares of our common stock from time to time, as our agent in an "at-the-market" offering ("ATM") as defined in Rule 415 promulgated under the U.S. Securities Act of 1933, as amended. We are not obligated to sell any number of shares under the Distribution Agreement. As of March 31, 2019, we have sold 785,280 shares under the Distribution Agreement resulting in net proceeds of \$1.5 million.

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.

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, including the successful full commercial launch of the Conformis Hip System, potential future capital raises through the issuance of equity or other securities, debt financings, and revenues that we may generate in connection with licensing our intellectual property. Additionally, in order for us to meet our operating plan, gross margin improvements and operating expense reductions 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 anticipate needing 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 March 31, 2019, we had cash and cash equivalents of \$18.6 million and \$0.5 million in restricted cash allocated to lease deposits. Based on our current operating plan, we expect that our existing cash and cash equivalents as of March 31, 2019, anticipated revenue from operations, and the ability to issue equity to LPC will enable us to fund our operating expenses and capital expenditure requirements and pay our debt service as it becomes due for at least the next 12 months from the date of filing. 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 revenue, the reduction in operating expenses in 2019, and we could use our capital resources sooner than we expect.

Cash flows

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

	Three Months Ended March 31,			
	2019	2018	\$ Change	% Change
Net cash (used in) provided by:				
Operating activities	\$(4,238)	\$(8,000)	\$3,762	47 %
Investing activities	6,493	6,351	142	2
Financing activities	—	21,324	(21,324)	(100)
Effect of exchange rate on cash	(19)	55	(74)	(135)
Total	\$2,236	\$19,730	\$(17,494)	(89)%

Net cash (used in) provided by operating activities. Net cash used in operating activities was \$4.2 million for the three months ended March 31, 2019 and \$8.0 million for the three months ended March 31, 2018, a decrease of \$3.8 million. These amounts primarily reflect net loss of \$7.6 million for the three months ended March 31, 2019 and \$12.0 million for the three months ended March 31, 2018. The net cash used in operating activities for the three months ended March 31, 2019 was affected by charges, including an increase from inventory of \$1.0 million, an increase from accounts payable and accrued liabilities of \$0.5 million, and an increase from other long term liabilities of \$0.3 million, an increase from prepaid expenses of \$0.1 million, an increase from accounts receivable of \$1.1 million, partially offset by a decrease from stock compensation expense of \$0.3 million, a decrease in unrealized foreign exchange gain/loss of \$1.6 million and a decrease of \$0.3 million due to non-cash lease expense.

Net cash provided by investing activities. Net cash provided by investing activities was \$6.5 million for the three months ended March 31, 2019, and for the three months ended March 31, 2018 net cash used by investing activities was \$6.4 million, a change of \$0.1 million. These amounts primarily reflect a decrease in cash used to purchase investments of \$3.2 million, a decrease in cash provided from matured investments of \$3.6 million, and a decrease in costs related to the acquisition of property, plant, and equipment of \$0.5 million.

Net cash provided by financing activities. There was no net cash provided by financing activities for the three months ended March 31, 2019 and \$21.3 million for the three months ended March 31, 2018, a decrease of \$21.3 million. The decrease was due to proceeds from issuance of common stock of \$21.3 million in 2018.

Contractual obligations and commitments

There have not been any material changes to our contractual obligations and commitments as described in 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, 2018.

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 customized 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 our 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 3.4% to 5.8%. We incurred aggregate revenue share expense including all amounts payable under our scientific advisory board revenue share agreements of \$0.7 million during the three months ended March 31, 2019, representing 3.5% of product revenue, and \$0.9 million during the three months ended March 31, 2018, representing 4.7% of product revenue. Revenue share expense is included in research and development. For further information, see “Note J—Commitments and Contingencies” to the consolidated financial statements appearing in this Quarterly Report on Form 10-Q.

Segment information

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

Off-balance sheet arrangements

Through March 31, 2019, 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 significant judgments and use of 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. The accounting estimates that require our most significant estimates include revenue recognition, accounts receivable valuation, inventory valuations, intangible valuation, purchase accounting, impairment assessments, equity instruments, stock compensation, income tax reserves and related allowances, the lives of property and equipment, and valuation of right-of-use lease assets and liabilities. 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 are more fully described under the heading “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Critical accounting policies and significant judgments and use of estimates” in our Annual Report on Form 10-K for the year ended December 31, 2018, with the exception of the critical accounting policy related to valuation methodology for goodwill impairment assessment. We updated our critical accounting policy to determine of the reporting unit using the combination of the market and income approaches which is more fully described in Note B to the consolidated financial statements appearing in this Quarterly Report on Form 10-Q.

Recent accounting pronouncements

Information with respect to recent accounting developments is provided in Note B to the consolidated financial statements appearing in this Quarterly Report on Form 10-Q.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer (our principal executive officer and principal financial officer, respectively), evaluated the effectiveness of our disclosure controls and procedures as of March 31, 2019. 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 March 31, 2019, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the three months ended March 31, 2019 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.

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, 2018 (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. 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 26 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.

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

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
<u>31.1*</u>	<u>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</u>
<u>31.2*</u>	<u>Certification of Principal 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</u>
<u>32.1*#</u>	<u>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</u>
<u>32.2*#</u>	<u>Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</u>
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: 5/3/2019

CONFORMIS, INC.

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

Date: 5/3/2019

CONFORMIS, INC.

By: /s/ Paul Weiner
Paul Weiner
Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)