

Conformis Inc
Form 10-Q
November 05, 2018

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2018

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

As of October 31, 2018, there were 63,272,653 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 September 30, 2018 and December 31, 2017</u>	<u>1</u>
<u>Consolidated Statements of Operations for the three and nine months ended September 30, 2018 and 2017</u>	<u>2</u>
<u>Consolidated Statements of Comprehensive Loss for the three and nine months ended September 30, 2018 and 2017</u>	<u>3</u>
<u>Consolidated Statements of Cash Flows for the nine months ended September 30, 2018 and 2017</u>	<u>4</u>
<u>Notes to Consolidated Financial Statements</u>	<u>5</u>
<u>Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>	<u>29</u>
<u>Item 4. Controls and Procedures</u>	<u>47</u>
<u>Part II- OTHER INFORMATION</u>	
<u>Item 1. Legal Proceedings</u>	<u>48</u>
<u>Item 1A. Risk Factors</u>	<u>49</u>
<u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u>	<u>51</u>
<u>Item 6. Exhibits</u>	<u>51</u>
<u>Signatures</u>	<u>53</u>

PART I - FINANCIAL INFORMATION

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

	September 30, December 31, 2018 2017 (unaudited)	
Assets		
Current Assets		
Cash and cash equivalents	\$ 21,685	\$ 18,348
Investments	15,248	26,880
Accounts receivable, net	11,664	13,200
Royalty receivable	10,634	—
Inventories	10,059	9,184
Prepaid expenses and other current assets	1,830	2,246
Total current assets	71,120	69,858
Property and equipment, net	14,582	16,514
Other Assets		
Restricted cash	462	462
Intangible assets, net	134	210
Goodwill	—	6,731
Other long-term assets	23	23
Total assets	\$ 86,321	\$ 93,798
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	\$ 4,457	\$ 4,891
Accrued expenses	7,997	7,720
Deferred revenue	—	305
Total current liabilities	12,454	12,916
Other long-term liabilities	627	651
Deferred tax liabilities	36	37
Deferred revenue	—	4,014
Long-term debt, less debt issuance costs	29,749	29,667
Total liabilities	42,866	47,285
Commitments and contingencies	—	—
Stockholders' equity		
Preferred stock, \$0.00001 par value:		
Authorized: 5,000,000 shares authorized at September 30, 2018 and December 31, 2017; no shares issued and outstanding as of September 30, 2018 and December 31, 2017	—	—
Common stock, \$0.00001 par value:		
Authorized: 200,000,000 shares authorized at September 30, 2018 and December 31, 2017; 63,638,018 and 45,528,519 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively	1	—
Additional paid-in capital	511,249	486,570
Accumulated deficit	(465,797) (436,821)
Accumulated other comprehensive loss	(1,998) (3,236)

Edgar Filing: Conformis Inc - Form 10-Q

Total stockholders' equity	43,455	46,513
Total liabilities and stockholders' equity	\$ 86,321	\$ 93,798

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		Nine Months Ended	
	September 30, 2018	2017	September 30, 2018	2017
Revenue				
Product	\$18,332	\$18,176	\$56,723	\$56,601
Royalty	10,652	249	11,017	763
Total revenue	28,984	18,425	67,740	57,364
Cost of revenue	9,265	11,111	30,123	37,307
Gross profit	19,719	7,314	37,617	20,057
Operating expenses				
Sales and marketing	9,053	8,741	29,273	28,932
Research and development	3,867	4,081	13,411	12,976
General and administrative	6,582	7,402	18,524	22,304
Goodwill impairment	6,731	—	6,731	—
Total operating expenses	26,233	20,224	67,939	64,212
Loss from operations	(6,514)	(12,910)	(30,322)	(44,155)
Other income and expenses				
Interest income	164	137	475	367
Interest expense	(788)	(718)	(2,289)	(1,397)
Foreign currency exchange transaction (loss) income	(272)	1,099	(1,285)	3,606
Total other income (expenses), net	(896)	518	(3,099)	2,576
Loss before income taxes	(7,410)	(12,392)	(33,421)	(41,579)
Income tax provision	27	80	74	143
Net loss	\$(7,437)	\$(12,472)	\$(33,495)	\$(41,722)
Net loss per share				
Basic and diluted	\$(0.12)	\$(0.29)	\$(0.58)	\$(0.97)
Weighted average common shares outstanding				
Basic and diluted	60,225,504	43,468,559	58,224,963	43,182,090

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 September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Net loss	\$(7,437)	\$(12,472)	\$(33,495)	\$(41,722)
Other comprehensive income (loss)				
Foreign currency translation adjustments	261	(1,006)	1,206	(3,286)
Change in unrealized gain (loss) on available-for-sale securities, net of tax	3	9	32	(9)
Comprehensive loss	\$(7,173)	\$(13,469)	\$(32,257)	\$(45,017)

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

CONFORMIS, INC. AND SUBSIDIARIES

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

	Nine Months Ended September 30,	
	2018	2017
Cash flows from operating activities:		
Net loss	\$(33,495)	\$(41,722)
Adjustments to reconcile net loss to net cash used by operating activities:		
Depreciation and amortization expense	3,015	2,698
Stock-based compensation expense	2,744	4,149
Provision for bad debts on trade receivables	(16) 5
Impairment of goodwill	6,731	—
Impairment of long-term assets	1,940	805
Disposal of long term-assets	(2) —
Non-cash interest expense	82	73
Amortization/accretion on investments	17	159
Deferred taxes	(1) 42
Changes in operating assets and liabilities:		
Accounts receivable	1,552	2,071
Royalty receivable	(10,434) —
Inventories	(875) 1,143
Prepaid expenses and other assets	416	1,504
Accounts payable and accrued liabilities	(156) (1,368
Deferred royalty revenue	—	(229
Other long-term liabilities	(23) 488
Net cash used in operating activities	(28,505) (30,182
Cash flows from investing activities:		
Acquisition of property and equipment	(2,946) (4,114
Business acquisition, net of cash acquired	—	(5,780
Decrease in restricted cash	—	(162
Purchase of investments	(19,449) (23,002
Maturity of investments	31,095	23,125
Net cash provided/(used) in investing activities	8,700	(9,933
Cash flows from financing activities:		
Proceeds from exercise of common stock options	112	2,102
Debt issuance costs	—	(434
Proceeds from issuance of debt	—	30,000
Net proceeds from issuance of common stock	21,824	1,023
Net cash provided by financing activities	21,936	32,691
Foreign exchange effect on cash and cash equivalents	1,206	(3,286
Increase in cash and cash equivalents	3,337	(10,710
Cash and cash equivalents, beginning of period	18,348	37,257

Edgar Filing: Conformis Inc - Form 10-Q

Cash and cash equivalents, end of period	\$21,685	\$26,547
Supplemental information:		
Cash paid for interest	1,887	860
Non cash investing activities:		
Issuance of common stock for business acquisition	—	594

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

4

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 has its corporate offices in Billerica, Massachusetts.

These consolidated financial statements as of September 30, 2018 and for the three and nine months ended September 30, 2018 and 2017, 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 September 30, 2018, the Company had an accumulated deficit of \$465.8 million and cash and cash equivalents, and investments of \$36.9 million, and \$0.5 million in restricted cash allocated to lease deposits.

On January 6, 2017, the Company entered into a senior secured \$50 million loan and security agreement (the "2017 Secured Loan Agreement") with Oxford Finance LLC ("Oxford"). Through the 2017 Secured Loan Agreement, the Company accessed the initial \$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"), causing the outstanding principal balance owing to Oxford to be an aggregate \$30 million as of September 30, 2018. In connection with incurring the Oxford debt, the Company granted Oxford a security interest in substantially all of its assets, including its cash and its intellectual property. On July 31, 2018, the Company and Oxford entered into an amendment (the “Amendment”) to the 2017 Secured Loan Agreement. See "Note J-Debt and Notes Payable" for additional information on the 2017 Secured Loan Agreement and the Amendment (collectively, the “Amended 2017 Secured Loan Agreement”). Under the Amended 2017 Secured Loan Agreement, the Company is subject to the satisfaction of certain revenue milestones which were increased under the Amendment beginning January 2019 and that the Company does not expect to satisfy as of the end of January 2019. It will constitute an event of default under the Amended 2017 Secured Loan Agreement if the Company fails to meet such financial covenants as of January 31, 2019. 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 the Company's cash and commencing foreclosure proceedings on the Company's other assets. The Company would need to refinance this debt prior to Oxford exercising remedies against the Company in order to prevent such exercise of remedies. The Company has engaged an advisor and is actively seeking to refinance the Amended 2017 Secured Loan Agreement prior to any exercise of remedies by Oxford.

Management is in the initial stages of the refinancing process and it is too early to determine whether the Company will be successful in refinancing the Oxford debt. Accordingly, this factor, among others, raises substantial doubt about the Company's ability to continue as a going concern. The Company's consolidated financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. The financial statements for the three and nine months ended September 30, 2018 do not include any adjustments to

reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from uncertainty related to the Company's ability to continue as a going concern.

The Company anticipates that its principal sources of funds in the future will be revenue generated from the sale of its products, potential future capital raises through the issuance of equity or other securities, debt financings and revenue that may be generated in connection with licensing its intellectual property. Management has based this expectation on assumptions that may prove to be wrong, such as the revenue that it expects to generate from the sale of its products, the gross profit the Company expects to generate from that revenue, the Company's ability to successfully refinance its Oxford debt, and the Company could use its capital resources sooner than expected. 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.

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 September 30, 2018, the Company has sold 785,280 shares under the Distribution Agreement resulting in net proceeds of \$1.5 million.

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.

On September 14, 2018, the Company entered into a Settlement and License Agreement (the "Settlement and License Agreement") with Smith & Nephew, Inc. ("Smith & Nephew"), pursuant to which the parties agreed to resolve all of their existing patent disputes. Pursuant to the Settlement and License Agreement, the Company granted to Smith & Nephew (i) a fully paid-up, non-exclusive, worldwide license to certain patents for the exploitation of patient-specific instrumentation for use with off-the-shelf knee implants, (ii) a royalty-bearing, non-exclusive, worldwide license to certain patents in the event Smith & Nephew commercializes patient-specific instrumentation for use with off-the-shelf implants other than knee implants, and (iii) a fully paid-up, non-exclusive, worldwide license to certain other patents for exploitation of off-the-shelf implants. Also pursuant to the Settlement and License Agreement, Smith & Nephew granted to the Company a fully paid-up, non-exclusive, worldwide license to certain patents for the exploitation of patient-specific implants and paid the Company \$10.5 million. See "Item 1. Legal Proceedings" for additional information on the Settlement and License Agreement.

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, goodwill valuation, intangible valuation, purchase accounting, impairment assessments, equity instruments, stock compensation, income tax reserves and related allowances, and the lives of property and equipment. Actual results may differ from those estimates. The interim financial statements should be read in conjunction with the audited financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2017.

Unaudited Interim Financial Information

The accompanying Interim Consolidated Financial Statements as of September 30, 2018 and for the three and nine months ended September 30, 2018 and 2017, 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 September 30, 2018, results of operations for the three and nine months ended September 30, 2018 and 2017, and cash flows for the nine months ended September 30, 2018 and 2017. The results for the three and nine months ended September 30, 2018 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 2014-9 "Revenue from Contracts with Customers" ("Topic 606" or "ASC 606") described below in "Revenue Recognition", there were no material changes in the nine months ended September 30, 2018 to the application of significant accounting policies and estimates as described in our audited consolidated financial statements for the year ended December 31, 2017.

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 and nine months ended September 30, 2018 and 2017, 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 September 30, 2018 or December 31, 2017.

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 \$2.2 million as of September 30, 2018 and December 31, 2017

held in foreign bank accounts that are not federally insured. In addition, the Company has recorded restricted cash of \$0.5 million as of September 30, 2018 and December 31, 2017. 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

7

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 and nine months ended September 30, 2018, the Company recognized provisions in cost of revenue of \$0.5 million and \$1.4 million, respectively, 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. During the three and nine months ended September 30, 2017, \$0.4 million and \$2.1 million, respectively, was recognized in cost of revenue for estimated unused product.

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

8

assets and liabilities is recorded as goodwill. Acquisition-related expenses are recognized separately from the business combination and are expensed as incurred.

On August 9, 2017, the Company completed the purchase of certain assets and assumed certain liabilities of Broad Peak Manufacturing, LLC ("BPM"). The Company completed the BPM purchase price allocation. Of the total purchase price, approximately \$2.2 million related to earn out provisions tied to certain employee retention by the Company and achieving certain cost targets that was paid into an escrow account. An additional \$0.7 million was paid into the escrow account and could be earned by BPM if the actual cost targets were exceeded. Alternatively, the earn out provisions could be paid back to the Company if the employee retention and cost targets were not achieved. On August 16, 2018, \$910,000 related to employee retention was released from the escrow account, and on September 21, 2018, \$1.3 million related to the earn out was released from the escrow account which satisfied the earn out provisions.

Intangibles and other long-lived assets

Intangible assets consist of developed technology and a favorable lease asset from the Company's acquisition of BPM 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 September 30, 2018, in connection with the Company's goodwill impairment analysis, the Company evaluated the estimated undiscounted cash flows, including estimated residual value, generated from the asset group were sufficient to support the carrying value of the assets. If the cash flow estimates or the significant operating assumptions upon which they are based change in the future, the Company may be required to record impairment charges. During the three and nine months ended September 30, 2018, the Company recognized \$1.9 million in impairment charges related to unused manufacturing equipment that was abandoned in July. During the three and nine months ended September 30, 2017, the Company recognized a \$0.8 million impairment charge related to the discontinuance of a software capital project. Impairment charges are included in General and administrative expense.

Goodwill

Goodwill relates to amounts that arose in connection with the acquisition of ImaTx, Inc. in 2009 and the acquisition of BPM in August 2017. The Company tests goodwill at least annually for impairment, or more frequently when events or changes in circumstances indicate that the assets may be impaired. This impairment test is performed annually during the fourth quarter at the reporting unit level. Goodwill may be considered impaired if the carrying value of the reporting unit, including goodwill, exceeds the reporting unit's fair value. The Company is comprised of one reporting unit. When testing goodwill for impairment, the Company first assesses the qualitative factors to determine whether it is more likely than not that the fair value of its reporting unit is less than its carrying amount. This qualitative analysis is used as a basis for determining whether it is necessary to perform the one-step goodwill impairment analysis. If the Company determines that it is more likely than not that its fair value is less than its carrying amount, then the one-step goodwill impairment test will be performed. During the three months ended September 30, 2018, the Company's qualitative analysis indicated a triggering event which required a step one analysis to determine the fair value of the reporting unit for the period ended September 30, 2018. The Company's drop in market capitalization and decrease in cash flow position were indicators of impairment. The Company determined the fair value of the reporting unit using the combination of its market capitalization, income approach, and the merger and acquisition method concluding that the fair value of the reporting unit is less than the carrying amount in excess of Goodwill, therefore fully impairing Goodwill. Goodwill impairment is presented within continuing operations.

The changes in the carrying amount of goodwill are as follows:

9

	September 30, December 31,	
	2018	2017
Beginning Balance	\$ 6,731	\$ 753
Acquired	—	5,978
Impairment	(6,731)	—
Ending Balance	\$ —	\$ 6,731

Revenue recognition

Adoption of ASC Topic 606, Revenue from Contracts with Customers

The Company adopted ASU No. 2014-9, "Revenue from Contracts with Customers (ASC 606)" as of January 1, 2018. ASU 2014-9 outlines a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers and supersedes most current revenue recognition guidance, including industry-specific guidance. The core principle of the revenue model is that an entity recognizes revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. In applying the revenue model to contracts within its scope, an entity identifies the contract(s) with a customer, identifies the performance obligations in the contract, determines the transaction price, allocates the transaction price to the performance obligations in the contract, and recognizes revenue when (or as) the entity satisfies a performance obligation.

Based on the Company's assessment, generally revenue recognition from the sale of its products to customers effectively remains unaffected by the adoption of ASC 606. The assessment of the royalty revenue associated with the Company's 2015 license agreements previously entered into with Wright Medical Group Inc. and MicroPort Orthopedics, Inc. was affected by the adoption of ASC 606. Previously, under ASC 605, the Company recognized an initial \$5.1 million, in aggregate, as deferred royalty revenue under these agreements, to be recognized ratably through 2031. The Company's analysis of these contracts indicated that under ASC 606 the licenses are functional and thus revenue would have been recognized in full on the execution date. Further the on-going royalty from MicroPort was previously recognized as royalty revenue upon receipt of payment. Under ASC 606, royalty is recognized in the period the sale occurred. The Company elected to apply the adoption of ASU 2014-09 using the modified retrospective method for contracts that were not complete as of December 31, 2017, resulting in an adjustment to the 2018 opening balance of accumulated deficit to recognize the deferred royalty revenue immediately. Comparative information has not been restated and continues to be reported under the accounting policy in effect for those periods, including ASC 605, Revenue Recognition. For more information about revenue recognition prior to January 1, 2018, refer to "Note B - Summary of Significant Accounting Policies-Revenue recognition" in the Company's Annual Report on Form 10-K for the year ended December 31, 2017.

Edgar Filing: Conformis Inc - Form 10-Q

The following table summarizes the balance sheet adjustments upon adoption of ASC 606 (in thousands):

	As Reported December 31, 2017	Balance at January 1, 2018	ASC 606 Adjustment	
Current Assets				
Royalty receivable	\$ 13,200	\$13,400	\$ 200	(1)
Current liabilities				
Deferred revenue	305	—	(305)	(2)
Long-term liabilities				
Deferred revenue	4,014	—	(4,014)	(2)
Stockholders' equity				
Accumulated deficit	(436,821)	(432,302)	4,519	(1),(2)

(1) MicroPort sales-based royalty recognized in period earned under Topic 606, previously recognized when cash received and amortization of deferred royalty revenue.

(2) Wright Medical and MicroPort royalty deferred and recognized ratably through 2031 under Topic 605, recognized in full at contract inception date under Topic 606.

The following table summarizes the effect of ASC 606 on the Company's consolidated financial statements as of September 30, 2018 (in thousands, except per share amounts):

Balance Sheet as of September 30, 2018	As Reported	Pro-forma (1)	Effect
Current Assets			
Royalty receivable	\$ 10,634	\$ 10,500	\$ 134 (2)
Current liabilities			
Deferred revenue	—	305	(305) (3)
Long-term Liabilities			
Deferred revenue	—	3,786	(3,786) (3)
Stockholders' equity			
Accumulated deficit	(465,797)	(461,572)	4,225 (2),(3)
Statement of Operations for the three months ended September 30, 2018	As Reported	Pro-forma (1)	Effect
Revenue			
Royalty	\$ 10,652	\$ 10,772	\$(120) (2),(3)
Net loss	(7,437)	(7,317)	(120) (2),(3)
Net loss per share - basic and diluted	\$(0.12)	\$(0.12)	\$—
Statement of Operations for the nine months ended September 30, 2018	As Reported	Pro-forma (1)	Effect
Royalty	\$ 11,017	\$ 11,311	\$(294) (2),(3)
Net loss	(33,495)	(33,201)	(294) (2),(3)
Net loss per share - basic and diluted	\$(0.58)	\$(0.57)	\$(0.01)
Cash Flows for the nine months ended September 30, 2018	As Reported	Pro-forma (1)	Effect
Cash flows from operating activities:			
Net loss	\$(33,495)	\$(33,201)	\$(294) (2),(3)
Changes in operating assets and liabilities	(28,505)	(28,799)	294 (2),(3)

(1) Pro-forma balances without adoption of ASC 606.

(2) Effect relates to MicroPort sales-based royalty recognized in period earned under Topic 606, previously recognized when cash received and amortization of deferred royalty revenue.

(3) Effect relates to Wright Medical and MicroPort royalty deferred and recognized ratably through 2031 under Topic 605, recognized in full at contract inception date under Topic 606.

Revenue Recognition

Revenue is recognized when, or as, obligations under the terms of a contract are satisfied, which occurs when control of the promised products or services is transferred to customers. Revenue is measured as the amount of consideration the Company expects to receive in exchange for transferring products or services to a customer (“transaction price”). When determining the transaction price of a contract, an adjustment is made if

payment from a customer occurs either significantly before or significantly after performance, resulting in a significant financing component. Applying the practical expedient in paragraph 606-10-32-18, the Company does not assess whether a significant financing component exists if the period between when the Company performs its obligations under the contract and when the customer pays is one year or less. None of the Company's contracts contained a significant financing component as of September 30, 2018. 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 nine months ended September 30, 2018 (in thousands):

	September 30, 2018
Beginning Balance	\$ 119
Provision related to current period sales	124

Edgar Filing: Conformis Inc - Form 10-Q

Adjustment related to prior period sales	40
Payments or credits issued to customer	(188)
Ending Balance	\$ 95

12

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 \$0.4 million and \$0.3 million three months ended September 30, 2018 and 2017, respectively, and \$1.1 million and \$1.0 million for the nine months ended September 30, 2018 and 2017, 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, 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 \$146,000 and \$8,000 for the three months ended September 30, 2018 and 2017, respectively, and \$428,000 and \$273,000 for the nine months ended September 30, 2018 and 2017, 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 September 30, 2018 and 2017, 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):

13

	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, 2017	\$ (3,203)	\$ (33)	\$ (3,236)
Change in period	1,206	32	1,238
Balance September 30, 2018	\$ (1,997)	\$ (1)	\$ (1,998)

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 realized from 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 \$27,000 and \$80,000 for the three months ended September 30, 2018 and 2017, respectively, and \$74,000 and \$143,000 for the nine months ended September 30, 2018 and 2017, respectively. The Company recognizes interest and penalties related to income taxes as a component of income tax expense. As of September 30, 2018 and 2017, a cumulative balance of \$34,000 and \$20,000 of interest and penalties have been accrued, respectively.

In December 2017, the SEC staff issued SAB 118 to address the application of GAAP in situations when a registrant does not have the necessary information available, prepared, or analyzed (including computations) in reasonable detail to complete the accounting for certain income tax effects of H.R.1. The Company has recognized the provisional tax impacts related to deemed repatriated earnings and the revaluation of deferred tax assets and liabilities and included these amounts in its consolidated financial statements for the year ended December 31, 2017. The Company has an accumulated deficit from its foreign operations and does not have an associated liability from the repatriation tax on accumulated earnings in H.R.1. The ultimate impact to the Company may differ from these provisional amounts, possibly materially, due to, among other things, additional analysis, changes in

interpretations and assumptions the Company has made, additional regulatory guidance that may be issued, and actions the Company may take as a result of H.R.1. The Company's accounting treatment is expected to be complete in the fourth quarter of 2018, which is one year from the enactment of H.R.1.

At September 30, 2018, 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. At September 30, 2018, the Company has an accumulated E&P Deficit.

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 nine months ended September 30, 2018 and 2017.

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		Nine Months Ended	
	September 30, 2018	September 30, 2017	September 30, 2018	September 30, 2017
Numerator:				
Numerator for basic and diluted loss per share:				
Net loss	\$ (7,437)	\$ (12,472)	\$ (33,495)	\$ (41,722)
Denominator:				
Basic and diluted weighted average shares	60,225,504	43,468,559	58,224,963	43,182,090
Loss per share attributable to Conformis, Inc. stockholders:				
Basic and diluted	\$ (0.12)	\$ (0.29)	\$ (0.58)	\$ (0.97)

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		Nine Months Ended	
	September 30, 2018	September 30, 2017	September 30, 2018	September 30, 2017
Stock options and restricted stock awards	27,919	322,450	92,378	466,646

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 is currently evaluating the impact of this pronouncement 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 is currently evaluating the impact of this pronouncement on its consolidated financial statements.

In July 2018, the FASB issued ASU No. 2018-09, "Codification Improvements". This ASU makes amendments to multiple codification Topics and the transition and effective date is based on the facts and circumstances of each amendment. Many of the amendments in this ASU have transition guidance with effective dates for annual periods beginning after December 15, 2018. The Company is currently evaluating the impact of the pronouncement on its consolidated financial statements.

In June 2018, the FASB issued ASU No. 2018-07, "Improvements to Nonemployee Share-Based Payment Accounting." This ASU supersedes Subtopic 505-50, "Equity - Equity-Based Payments to Non-Employees" and expands on the scope of Topic 718, "Compensation - Stock Compensation", to include share-based payments issued to nonemployees for goods or services. This ASU is effective for fiscal years beginning after December 15, 2018, including interim periods within that fiscal year. Early adoption is permitted. The Company is currently evaluating the

impact of this pronouncement on its consolidated financial statements.

In February 2016, the FASB issued ASU No. 2016-02, "Leases (Topic 842)." This ASU amends various aspects of existing guidance for leases and requires additional disclosures about leasing arrangements. It will require companies to recognize lease assets and lease liabilities by lessees for those leases classified as operating leases under GAAP. Topic 842 retains a distinction between finance leases and operating leases. The classification criteria for distinguishing between finance leases and operating leases are substantially similar to the classification

criteria for distinguishing between capital leases and operating leases in the previous leases guidance. This ASU is effective for annual periods beginning after December 15, 2018, including interim periods within those fiscal years; earlier adoption is permitted. In the financial statements in which the ASU is first applied, leases shall be measured and recognized at the beginning of the earliest comparative period presented with an adjustment to equity. Practical expedients are available for election as a package and if applied consistently to all leases. In July 2018, the FASB issued ASU No. 2018-11, "Leases (Topic 842): Targeted Improvements" which allows entities the option not to recast the comparative periods presented when transitioning to Topic 842. The Company has begun its assessment process to evaluate the impact on its consolidated financial statements. The Company expects to elect the 'package of practical expedients' and carry over our prior conclusions about lease identification, lease classification and initial direct costs. The Company will continue to assess the effects of adoption and currently believes the most significant effect will relate to the recognition of new right of use assets and lease liabilities related to our real estate operating leases on the Balance Sheet. The Company expects to adopt this pronouncement commencing in the first quarter of 2019.

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.

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):

	September 30, 2018					
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value	Cash and equivalents	Short-term (1) investments
Cash	\$13,613	\$—	\$—	\$13,613	\$13,613	\$—
Level 1 securities:						
Money market funds	7,077	—	—	7,077	7,077	—
U.S. treasury bonds	11,989	—	—	11,989	—	11,988
Level 2 securities:						
Corporate bonds	2,268	—	(1)	2,267	—	2,267
Commercial paper	1,988	—	—	1,988	995	993
Total	\$36,935	\$—	(1)	\$36,934	\$21,685	\$15,248

Edgar Filing: Conformis Inc - Form 10-Q

December 31, 2017						
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value	Cash and equivalents	Short-term (1) investments
Cash	\$9,849	\$ —	—\$ —	\$ 9,849	\$ 9,849	\$ —
Level 1 securities:						
Money market funds	3,499	—	—	3,499	3,499	—
U.S. treasury bonds	9,243	—	(4)	9,239	—	9,239
Level 2 securities:						
Corporate bonds	4,935	—	(6)	4,929	—	4,929
Agency bonds	12,734	—	(22)	12,712	—	12,712
Repurchase agreement	5,000	—	—	5,000	5,000	—
Total	\$45,260	\$ —	—\$ (32)	\$ 45,228	\$ 18,348	\$ 26,880

(1) Contractual maturity due within one year.

The following table summarizes the Company's assets that are measured at fair value on a non-recurring basis at September 30, 2018 and are categorized using the fair value hierarchy and where they are classified on the Consolidated Balance Sheets (in thousands):

	Level 1	Level 2	Level 3	Total Losses	Estimated Fair Value
Goodwill		6,731	(6,731)	—	—

Note D—Accounts Receivable

Accounts receivable consisted of the following (in thousands):

	September 30, 2018	December 31, 2017
Total receivables	\$ 12,157	\$ 13,835
Allowance for doubtful accounts and returns	(493)	(635)
Accounts receivable, net	\$ 11,664	\$ 13,200

Accounts receivable included unbilled receivable of \$2.0 million and \$1.4 million at September 30, 2018 and December 31, 2017, respectively. Write-offs related to accounts receivable were approximately \$2,000 and \$18,000 for the three months ended September 30, 2018 and 2017, respectively, and \$67,000 and \$29,000 for the nine months ended September 30, 2018 and 2017, respectively.

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

	September 30, 2018	December 31, 2017
Beginning balance	(635)	(681)
Provision for bad debts on trade receivables	15	15
Other allowances	60	(61)
Accounts receivable write offs	67	92
Ending balance	\$ (493)	\$ (635)

Note E—Inventories

Inventories consisted of the following (in thousands):

18

	September 30, 2018	December 31, 2017
Raw Material	\$ 4,572	\$ 2,905
Work in process	1,599	1,718
Finished goods	3,888	4,561
Total Inventories	\$ 10,059	\$ 9,184

Note F—Property and Equipment

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

	Estimated Useful Life (Years)	September 30, 2018	December 31, 2017
Equipment	5-7	\$ 18,552	\$ 19,331
Furniture and fixtures	5-7	954	955
Computer and software	3	8,619	7,877
Leasehold improvements	2-8	1,922	1,830
Total property and equipment		30,967	29,993
Accumulated depreciation		(16,385)	(13,479)
Property and equipment, net		\$ 14,582	\$ 16,514

During the period ended March 31, 2018, the Company substantially completed the reusable instrumentation tray design and commenced capitalization under ASC 360 "Property, Plant, and Equipment".

Depreciation expense related to property and equipment was \$1.0 million and \$0.9 million for the three months ended September 30, 2018 and 2017, respectively. Depreciation expense related to property and equipment was \$2.9 million and \$2.5 million for the nine months ended September 30, 2018 and 2017, respectively.

During the three and nine months ended September 30, 2018, the Company recognized \$1.9 million in impairment charges related to unused manufacturing equipment. During the three and nine months ended September 30, 2017, the Company recognized \$0.8 million in impairment charges related to discontinuance of a software capital project.

Note G—Intangible Assets

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

	Estimated Useful Life (Years)	September 30, 2018	December 31, 2017
Developed technology	10	\$ 979	\$ 979
Accumulated amortization		(856)	(783)
Developed technology, net		123	196
Acquired favorable lease	5	15	15
Accumulated amortization		(4)	(1)
Acquired favorable lease, net		11	14

Intangible assets, net	\$ 134	\$ 210
------------------------	--------	--------

The Company recognized amortization expense of \$24,000 and \$63,000 for the three months ended September 30, 2018, and 2017, respectively, and \$73,000 and \$187,000 for the nine months ended September 30,

19

2018 and 2017, respectively. The weighted-average remaining life of total amortizable intangible assets is 1.48 years for the developed technology and license agreements and favorable lease asset.

The estimated future aggregated amortization expense for intangible assets owned as of September 30, 2018 consisted of the following (in thousands):

	Amortization expense
2018 (remainder of the year)	\$ 25
2019	101
2020	3
2021	3
2022	2
	\$ 134

Note H—Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	September 30, 2018	December 31, 2017
Accrued employee compensation	\$ 4,039	\$ 2,989
Deferred rent	128	115
Accrued legal expense	310	1,231
Accrued consulting expense	21	115
Accrued vendor charges	1,190	912
Accrued revenue share expense	919	968
Accrued clinical trial expense	398	196
Accrued other	992	1,194
	\$ 7,997	\$ 7,720

Note I—Commitments and Contingencies

Operating Leases - Real Estate

The Company maintains its corporate headquarters in a leased building located in Billerica, Massachusetts. The Company moved its corporate headquarters from Bedford, Massachusetts in April 2017. The Company maintains its manufacturing facilities in leased buildings located in Wilmington, Massachusetts and Wallingford, Connecticut.

The Billerica facility is leased under a long-term, non-cancellable lease that is scheduled to expire in October 2025.

The Company leases its Wilmington, Massachusetts facility under a long-term, non-cancellable lease that commenced in April 2015 and will expire in March 2022 (the "Wilmington Lease"). The Company also rents a satellite facility under short-term non-cancellable operating lease. The Company has a right to extend the term for one additional five-year period following termination of the lease in March 2022. The initial base rental rate for the additional space is \$0.2 million annually, subject to 2% annual increases until the expiration of the initial term.

On August 9, 2017, the Company entered into a lease for 4,099 square feet of space in Wallingford, Connecticut which houses the Company's polishing and passivation processes. The lease term is five years with the option to extend for two additional years beyond the original term and an additional three years past the first extension term.

The future minimum rental payments under the Company's non-cancellable operating leases for real estate as of September 30, 2018 were as follows (in thousands):

20

Year	Minimum lease Payments
2018 remainder of year	\$ 382
2019	1,558
2020	1,595
2021	1,633
2022	1,397
2023-2025	2,939
	\$ 9,504

Rent expense of \$0.4 million for the three months ended September 30, 2018 and 2017, and \$1.1 million and \$1.3 million for the nine months ended September 30, 2018 and 2017, respectively, was charged to operations. The Company's real estate operating lease agreements contain scheduled rent increases, which are being amortized over the terms of the agreements using the straight-line method. Deferred rent was \$0.8 million as of September 30, 2018 and December 31, 2017. Deferred rent is included in accrued expenses and other long-term liabilities.

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.

Philipp Lang, M.D., the Company's former Chief Executive Officer and former director, joined the Company's scientific advisory board in 2004 prior to becoming an employee. The Company first entered into a revenue share agreement with Dr. Lang in 2008 when he became the Company's Chief Executive Officer. In 2011, the Company entered into an amended and restated revenue share agreement with Dr. Lang. This agreement provides that the specified percentage of the Company's net revenue payable to Dr. Lang ranges from 0.875% to 1.33% and applies to all of the Company's current products, including the Company's iUni, iDuo, iTot CR, iTot PS, and Hip System products, as well as certain other knee, hip and shoulder replacement products and related instrumentation the Company may develop in the future. This agreement provides that the Company's payment obligations expire on a product-by-product basis on the last to expire of the Company's patents on which Dr. Lang is named an inventor that claim the applicable product and that these payment obligations survived the termination of Dr. Lang's employment with the Company. Pursuant to the terms of this revenue share agreement with Dr. Lang, the Company incurred revenue share expense of \$88,000 and \$233,000 for the three months ended September 30, 2018, and 2017, respectively, and \$581,000 and \$722,000 for the nine months ended September 30, 2018 and 2017, respectively.

The Company incurred aggregate revenue share expense including all amounts payable under the Company's scientific advisory board and Dr. Lang's revenue share agreements of \$0.7 million during the three months ended September 30,

2018, representing 3.6% of product revenue and \$2.5 million during the nine months ended September 30, 2018, representing 4.3% of product revenue, \$0.9 million during the three months ended September 30, 2017, representing 4.7% of product revenue, and \$2.7 million during the nine months ended September 30, 2017, representing 4.8% of product revenue. Revenue share expense is included in research and development. See “Note K—Related Party Transactions” for further information regarding the Company’s arrangement with Dr. Lang.

Other obligations

In the ordinary course of business, the Company is a party to certain non-cancellable contractual obligations typically related to product royalty and research and development. The Company accrues a liability for such matters when it is probable that future expenditures will be made and such expenditures can be reasonably estimated. There have been no contingent liabilities requiring accrual at September 30, 2018 or December 31, 2017.

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.

On February 29, 2016, the Company filed a lawsuit against Smith & Nephew, Inc. ("Smith & Nephew") in the United States District Court for the District of Massachusetts Eastern Division, and the Company amended its complaint on June 13, 2016 (the "Smith & Nephew Lawsuit"). The Smith & Nephew Lawsuit alleged that Smith & Nephew's Visionaire® patient-specific instrumentation as well as the implant systems used in conjunction with the Visionaire instrumentation infringe nine of the Company's patents, and it requested, among other relief, monetary damages for willful infringement, enhanced damages and a permanent injunction.

On May 27, 2016, Smith & Nephew filed its answer and counterclaims in response to the Company's lawsuit, which it subsequently amended on July 22, 2016. Smith & Nephew denied that its Visionaire® patient-specific instrumentation as well as the implant systems used in conjunction with the Visionaire instrumentation infringe the patents asserted by the Company in the lawsuit. It also alleged two affirmative defenses: that the Company's asserted patents are invalid and that the Company is barred from relief under the doctrine of laches. In addition, Smith & Nephew asserted a series of counterclaims, including counterclaims seeking declaratory judgments that Smith & Nephew's accused products do not infringe the Company's patents and that the Company's patents are invalid. Smith & Nephew also alleged that Conformis infringed ten patents owned or exclusively licensed by Smith & Nephew: two of those patents Smith & Nephew alleged are infringed by the Company's iUni and iDuo products; three of those patents Smith & Nephew alleged are infringed by the Company's iTot products; and five of those patents Smith & Nephew licenses from Kinamed, Inc. of Camarillo, California and alleged are infringed by the Company's iUni, iDuo and iTot products. Due to Smith & Nephew's licensing arrangement with Kinamed, Kinamed was named as a party to the lawsuit. Smith & Nephew and Kinamed requested, among other relief, monetary damages for willful infringement, enhanced damages and a permanent injunction. On March 9, 2017, the Court entered a stipulation of dismissal by the parties that dismissed from the lawsuit eight patents asserted by Smith & Nephew, including the patents involving Kinamed, and two patents asserted by Conformis. With the dismissal of all claims involving Kinamed's patents, Kinamed was no longer a party to the lawsuit.

On January 27, 2017, Smith & Nephew filed a motion seeking a stay of the Smith & Nephew Lawsuit until all requested IPRs (defined and described below) were resolved. On April 27, 2017, the Court stayed certain aspects of the proceedings and indicated that it would make a final decision on the motion to stay after the USPTO has decided more of the petitions for IPR.

Between September 21, 2016 and March 1, 2017, Smith & Nephew filed sixteen petitions with the United States Patent & Trademark Office ("USPTO") requesting Inter Partes Review ("IPR") of the nine patents that the Company asserted against Smith & Nephew in the lawsuit. In its petitions, Smith & Nephew alleged that the Company's patents are obvious in light of certain prior art. As of October 31, 2017, the USPTO decided to institute IPR proceedings with

respect to seven of the petitions; decided to deny the requests for IPR with respect to seven of the petitions; and, with respect to the remaining two petitions, decided to institute IPR proceedings for some of the subject patent claims and to deny the requests for the remaining subject patent claims (“Subject Patent Claims”). On April 24, 2018, the Supreme Court of the United States issued its ruling in SAS Institute, Inc. v. Iancu (the “SAS Decision”) which held that the IPR proceedings cannot be instituted in part and denied in part. In response to the SAS Decision and guidance from the USPTO, the Patent Trial and Appeal Board (“PTAB”) issued an order on April 27, 2018 including the Subject Patent Claims within the prior instituted IPR proceedings. In total, the USPTO instituted IPR proceedings for claims in six of the patents in the Smith & Nephew lawsuit (five patents

that were currently asserted, and one of the patents that was voluntarily dismissed from the lawsuit), and denied the petitions for claims in three of the patents (two patents that were currently asserted and one of the patents that was voluntarily dismissed from the lawsuit). Smith & Nephew filed requests for rehearing of three of the petitions that were denied and the PTAB denied those requests. Smith & Nephew filed requests with the USPTO for reexamination of two of the patents for which IPR proceedings were not instituted and the USPTO granted those requests for reexamination. On August 7, 2018 and October 2, 2018, the USPTO ruled in the Company's favor on both reexamination proceedings finding the claims patentable in both patents.

Between December 18, 2017 and April 18, 2018, IPR hearings were held for the six patents for which IPR proceedings were instituted. On March 26, 2018, the USPTO issued its first ruling holding that our U.S. Patent No. 9,055,953 (the “953 Patent”) is invalid over prior art. On April 19, 2018, the USPTO issued its second ruling holding that our U.S. Patent No. 9,216,025 (the “025 Patent”) is invalid over prior art. Following the USPTO's grant of the Company's request for consolidation, the Company filed an opening brief on October 1, 2018 appealing the PTAB's rulings on the '953 Patent and the '025 patent. On June 11, 2018, the USPTO issued its third ruling holding that our U.S. Patent No. 7,981,158 (the “158 Patent”) is invalid over prior art. On June 12, 2018, the USPTO issued its fourth ruling holding that our U.S. Patent No. 8,551,169 (the “169 Patent”) is invalid over prior art. The '953 Patent is not part of the lawsuit having been voluntarily dismissed on March 9, 2017. The '025, '169 and '158 Patents were part of the lawsuit. On September 26, 2018, the PTAB terminated the remaining IPR proceedings in response to a joint motion to terminate filed by the Company and Smith & Nephew pursuant to the Settlement and License Agreement (defined and described below).

On September 14, 2018, the Company and Smith & Nephew entered into a Settlement and License Agreement (the “Settlement and License Agreement”) including terms for resolving all of the parties' existing patent disputes. The Settlement and License Agreement includes terms for dismissal of all outstanding litigation, prohibitions against commencement of litigation with respect to existing product lines, and Smith & Nephew agreed to cease their opposition to certain Company patents currently in IPR proceedings.

Pursuant to the Settlement and License Agreement, the Company granted to Smith & Nephew (i) a fully paid-up, non-exclusive, worldwide license to certain patents for the exploitation of patient-specific instrumentation for use with off-the-shelf knee implants, (ii) a royalty-bearing, non-exclusive, worldwide license to certain patents in the event Smith & Nephew commercializes patient-specific instrumentation for use with off-the-shelf implants other than knee implants, and (iii) a fully paid-up, non-exclusive, worldwide license to certain other patents for exploitation of off-the-shelf implants. Also pursuant to the Settlement and License Agreement, Smith & Nephew granted to the Company a fully paid-up, non-exclusive, worldwide license to certain patents for the exploitation of patient-specific implants and paid the Company \$10.5 million. The Company is not required to make a payment to Smith & Nephew.

The foregoing description is qualified in its entirety by reference to the text of the Settlement and License Agreement filed as exhibit 10.1 hereto.

Legal costs associated with legal proceedings are accrued as incurred.

Indemnifications

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 J—Debt and Notes Payable

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

23

	September 30, December 31,	
	2018	2017
Oxford Finance, LLC, Term A Loan	\$ 15,000	\$ 15,000
Oxford Finance, LLC, Term B Loan	15,000	15,000
	30,000	30,000
Less unamortized debt issuance costs	(251)	(333)
Long-term debt, less debt issuance costs	\$ 29,749	\$ 29,667

Principal payments due as of September 30, 2018 consisted of the following (in thousands):

	Principal Payment
2018 (remainder of the year)	\$—
2019	—
2020	13,750
2021	15,000
2022	1,250
Total	\$ 30,000

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 the initial \$15 million under Term Loan A at closing and an additional \$15 million of borrowings under Term Loan B on June 30, 2017. On July 31, 2018, the Company and Oxford entered into the Amendment. The Amendment added a requirement that the Company maintain at least \$10 million in cash collateral and requires liens on the Company's copyrights, trademarks and patents. Pursuant to the Amendment, the Company also agreed to pay Oxford a fee of \$1 million within 30 days of consummation of a sale of the Company. In addition, the Amendment amended the Company's financial covenants, including an increase of the revenue covenant beginning in January 2019. The Company does not expect to satisfy the increased revenue covenant at the end of January 2019. Pursuant to the Amended 2017 Secured Loan Agreement, it would constitute an event of default under the Amended 2017 Secured Loan Agreement if the Company fails to meet such financial covenants at the end of January 2019, and the Company would have until February 2019 to refinance this debt. The Company has engaged an advisor and is actively seeking to refinance the Amended 2017 Secured Loan Agreement. The proceeds of the Term A and Term B Loans are used to fund the Company's ongoing working capital needs.

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

The Term A Loan and Term B Loan 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 Amended 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 Amended 2017 Secured Loan Agreement also specifies 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 Amended 2017 Secured Loan Agreement, a breach of covenants under the Amended 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 September 30, 2018, the Company was not in breach of covenants under the Amended 2017 Secured Loan Agreement. However, the Company does not expect to satisfy the increased revenue covenant at the end of January 2019, which would constitute an event of default under the Amended 2017 Secured Loan Agreement, and the Company would have until February 2019 to refinance this debt. The Company has engaged an advisor and is actively seeking to refinance the Amended 2017 Secured Loan Agreement.

Note K—Related Party Transactions

Vertegen

In April 2007, the Company entered into a license agreement with Vertegen, Inc., or Vertegen, which was amended in May 2015 (the "Vertegen Agreement"). Vertegen is an entity that is wholly owned by Dr. Lang, the Company's former Chief Executive Officer. Under the Vertegen Agreement, Vertegen granted the Company an exclusive, worldwide license under specified Vertegen patent rights and related technology to make, use and sell products and services in the fields of diagnosis and treatment of articular disorders and disorders of the human spine. The Company may sublicense the rights licensed to it by Vertegen. The Company is required to use commercially reasonable efforts, at its sole expense, to prosecute the patent applications licensed to the Company by Vertegen. Pursuant to the Vertegen Agreement, the Company is required to pay Vertegen a 6% royalty on net sales of products covered by the patents licensed to the Company by Vertegen, the subject matter of which is directed primarily to spinal implants, and any proceeds from the Company enforcing the patent rights licensed to the Company by Vertegen. Such 6% royalty rate will be reduced to 3% in the United States during the five-year period following the expiration of the last-to-expire applicable patent in the United States and in the rest of the world during the five-year period following the expiration of the last-to-expire patent anywhere in the world. The Company has not sold any products subject to this agreement and has paid no royalties under this agreement. The Company has cumulatively paid approximately \$150,000 in expenses as of September 30, 2018 in connection with the filing and prosecution of the patent applications licensed to the Company by Vertegen.

The Vertegen Agreement may be terminated by the Company at any time by providing notice to Vertegen. In addition, Vertegen may terminate the Vertegen Agreement in its entirety if the Company is in material breach of the agreement, and the Company fails to cure such breach during a specified period.

Revenue share agreements

As described in Note I, the Company is a party to certain agreements with advisors that participate as members of the Company's scientific advisory board. In September 2011, the Company entered into an amended and restated revenue share agreement with Philipp Lang, M.D., the Company's former Chief Executive Officer and former director, which amended and restated a similar agreement entered into in 2008 when Dr. Lang stepped down as chair of the Company's scientific advisory board and became the Company's Chief Executive Officer. This agreement provides that

the specified percentage of the Company's net revenue payable to Dr. Lang ranges from 0.875% to 1.33% and applies to all of the Company's current products, including the Company's iUni, iDuo, iTotals CR, iTotals PS, and Conformis Hip System products, as well as certain other knee, hip and shoulder replacement products and related instrumentation the Company may develop in the future. Under the agreement, 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 the Company on such product sales. The agreement provides that the Company's payment obligations expire on a product-by-product basis on the last to expire of the Company's patents on which Dr. Lang is a named inventor that claim the applicable product and that these payment obligations survived the termination of Dr. Lang's employment with the Company. Pursuant to the terms of this revenue share

agreement with Dr. Lang, the Company incurred revenue share expense of \$88,000 and \$233,000 for the three months ended September 30, 2018 and 2017, respectively, and \$581,000 and \$722,000 for the nine months ended September 30, 2018 and 2017, respectively.

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.

Summary of common stock activity was as follows:

	Shares
Outstanding December 31, 2017	45,528,519
Issuance of common stock - option exercises	80,000
Issuance of restricted common stock	2,372,832
Forfeiture of unvested restricted stock	(233,000)
Issuance of common stock - ATM offering	556,334
Issuance of common stock - Secondary offering	15,333,333
Outstanding September 30, 2018	63,638,018

Preferred stock

The Company's Restated Certificate of Incorporation authorizes the Company to issue 5,000,000 shares of preferred stock, \$0.00001 par value, all of which is undesignated. No shares were issued and outstanding at September 30, 2018 and December 31, 2017.

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

26

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 and nine months ended September 30, 2018. 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 September 30, 2018 and December 31, 2017. Outstanding warrants are currently exercisable with varying exercise expiration dates from 2020 through 2024. At September 30, 2018 and December 31, 2017, 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, 2017	28,926	\$ 9.80	5.66	28,926	\$ 9.80
Outstanding September 30, 2018	28,926	\$ 9.80	4.91	28,926	\$ 9.80

Stock option plans

As of September 30, 2018, 612,403 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, 2018, an additional 1,365,856 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)
-------------------	---	--

Edgar Filing: Conformis Inc - Form 10-Q

Outstanding December 31, 2017	3,627,995	\$ 6.48		
Granted	165,219	1.36		
Exercised	(80,000)	1.40	8	
Expired	(403,269)	6.31		
Cancelled/Forfeited	(96,858)	5.48		
Outstanding September 30, 2018	3,213,087	\$ 6.40	\$	—
Total vested and exercisable	2,451,579	\$ 6.92	\$	—

27

The total fair value of stock options that vested during the three and nine months ended September 30, 2018 was \$0.2 million and \$0.9 million, respectively. The weighted average remaining contractual term for the total stock options outstanding was 5.52 years as of September 30, 2018. The weighted average remaining contractual term for the total stock options vested and exercisable was 4.51 years as of September 30, 2018.

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

	Number of Shares	Weighted Average Fair Value
Unvested December 31, 2017	1,339,121	\$ 6.06
Granted	2,372,832	1.37
Vested	(346,699)	5.60
Forfeited	(233,000)	4.43
Unvested September 30, 2018	3,132,254	\$ 2.68

The total fair value of restricted common stock awards that vested during the three and nine months ended September 30, 2018 was \$0.3 million and \$1.9 million.

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 September 30,			
	2018		2017	
	2018	2017	2018	2017
Risk-free interest rate	N/A	2.1%	2.75% - 2.90%	2.10%-2.14%
Expected term (in years)	N/A	6.25	6.25	6.02-6.25
Dividend yield	N/A	—%	—%	—%
Expected volatility	N/A	52%	52.81% - 56.44%	50.59%-52.00%

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 \$1.0 million and \$1.4 million for the three months ended September 30, 2018 and 2017, respectively. Stock-based compensation expense was calculated based on awards ultimately expected to vest. To date, the amount of stock-based compensation capitalized as part of inventory was not material.

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

	Three Months Ended September 30, 2018		Nine Months Ended September 30, 2017	
Cost of revenues	\$55	\$133	\$141	\$348
Sales and marketing	174	130	455	611
Research and development	286	444	850	1,341
General and administrative	444	702	1,298	1,849
	\$959	\$1,409	\$2,744	\$4,149

As of September 30, 2018, the Company had \$1.8 million of total unrecognized compensation expense for options that will be recognized over a weighted average period of 2.71 years. As of September 30, 2018, the Company had \$6.7 million of total unrecognized compensation expense for restricted awards that will be recognized over a weighted average period of 3.02 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 September 30, 2018		Nine Months Ended September 30, 2017	
Product Revenue				
United States	\$16,271	\$15,519	48,654	46,702
Germany	1,684	2,335	6,957	8,727.5
Rest of World	377	322	1,112	1,171
	\$18,332	\$18,176	56,723	56,601
			September 30, 2018	December 31, 2017
Property and equipment, net				
United States			\$ 14,505	\$ 16,424
Germany			77	90
			\$ 14,582	\$ 16,514

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, 2017. 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, 2017, 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," "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 \$17.5 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. 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. A study published in May 2018 in *The Journal of Knee Surgery*, a peer-reviewed orthopedic journal, entitled "In Vivo Tibial Fit and Rotational Analysis of a Customized, Patient-Specific TKA versus Off-the-Shelf TKA," indicated that the iTOTAL CR knee replacement implant provided better rotational alignment and tibial fit compared to off-the-shelf implants (i.e., non-customized). We provided financial support for this study and the author is a paid consultant of ours on other matters. In addition, in a February 2018 report from Beyond Compliance, results were presented summarizing four year data from the England and Wales National Joint Registry ("Registry") demonstrating high survivorship in patients treated with the iTOTAL CR knee replacement implant, specifically the data showed a low cumulative percent revision of 0.5% for Conformis patients as compared with 1.9% for all total knee replacement patients.

On August 1, 2018, we announced the limited commercial launch of our Conformis Hip System for primary total hip replacement. We plan to announce the expected timing for a complete commercial launch in the first 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, Australia, Hungary, and Spain. 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. Historically, we have accounted for the agreements with Wright Medical and MicroPort under ASC 605-25, Multiple-Element Arrangements and Staff Accounting Bulletin No. 104, Revenue Recognition (ASC 605). In accordance with ASC 605, we were required to identify and account for each of the separate units of accounting. We identified the relative selling price for each and then allocated the total consideration based on their relative values. In connection with these agreements, in April 2015, we recognized in aggregate (i) back-owed royalties of \$3.4 million as royalty revenue and (ii) the value attributable to the settlements of \$0.2 million as other income. Additionally, we recognized an initial \$5.1 million in aggregate as deferred royalty revenue, to be recognized as royalty revenue ratably through the expiration of the last to expire of our patents and patent applications licensed to Wright Medical, which currently is expected to occur in 2031. On January 1, 2018, we adopted ASC 606, Revenue from Contracts with Customers. Our analysis of these contracts under ASC 606 indicated that the licenses are functional and thus revenue should have been recognized in full upon the license execution date, which resulted in a \$4.3 million adjustment to our opening balance of accumulated deficit. In addition, the on-going royalty from MicroPort, which was previously recognized as royalty revenue upon receipt of payment, is now recognized in the period the sale occurred, resulting in a \$0.2 million adjustment to our opening balance of accumulated deficit.

Royalty revenue in the three months ended September 30, 2018, includes revenue of \$10.5 million generated from our settlement with Smith & Nephew for a fully paid-up, non-exclusive, worldwide license to certain patents for the exploitation of patient-specific instruments with off-the-shelf implants. Under ASC 606, the licenses are functional and thus revenue is recognized in full upon the license execution date, resulting in a \$10.5 million adjustment to Royalty revenue.

Cost of revenue

We produce our computer aided designs, or CAD, in-house and through contractors in India and use them to direct all 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 starting in December 2017, for our iTOTAL PS product, in our facility in Wilmington, Massachusetts. Starting in August 2017, we polish our femoral implants used in our total and partial knee products in our facility in Wallingford, Connecticut. Also 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
- expanding our CAD labor in India, which we believe will reduce labor costs required to design our products.

We continue to explore the application of our 3D printing technology to select metal components of our products, which we believe may be a future opportunity for reducing our manufacturing costs. 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, sales commissions, and non-cash impairment charges.

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 significantly 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 will 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 realized gains (losses) from foreign currency transactions. The effect of exchange rates on our foreign currency-denominated asset and liability balances are recorded as foreign currency translation adjustments in the consolidated statements of comprehensive loss.

Income tax provision

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

Consolidated results of operations

Comparison of the three months ended September 30, 2018 and 2017

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

Three Months Ended September 30,	2018		2017		2018 vs 2017	
	Amount	As a% of Total Revenue	Amount	As a% of Total Revenue	\$ Change	% Change
Revenue						
Product revenue	\$18,332	63 %	\$18,176	99 %	\$156	1 %
Royalty	10,652	37	249	1	10,403	4,178
Total revenue	28,984	100	18,425	100	10,559	57
Cost of revenue	9,265	32	11,111	60	(1,846)	(17)
Gross profit	19,719	68	7,314	40	12,405	170
Operating expenses:						
Sales and marketing	9,053	31	8,741	47	312	4
Research and development	3,867	13	4,081	22	(214)	(5)
General and administrative	6,582	23	7,402	40	(820)	(11)
Goodwill impairment	6,731	23	—	—	6,731	100
Total operating expenses	26,233	91	20,224	110	6,009	30
Loss from operations	(6,514)	(22)	(12,910)	(70)	6,396	50
Total other income (expenses), net	(896)	(3)	518	3	(1,414)	(273)
Loss before income taxes	(7,410)	(26)	(12,392)	(67)	4,982	40
Income tax provision	27	—	80	—	(53)	(66)
Net loss	\$(7,437)	(26)%	\$(12,472)	(68)%	\$5,035	40 %

Product revenue. Product revenue was \$18.3 million for the three months ended September 30, 2018 compared to \$18.2 million for the three months ended September 30, 2017, an increase of \$0.2 million or 1%, 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 September 30,	2018		2017		2018 vs 2017	
	Amount	As a % of Product Revenue	Amount	As a % of Product Revenue	\$ Change	% Change
United States	\$16,271	89 %	\$15,519	85 %	\$752	5 %
Germany	1,684	9	2,335	13	(651)	(28)
Rest of world	377	2	322	2	55	17
Product revenue	\$18,332	100 %	\$18,176	100 %	\$156	1 %

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 89% for the three months ended September 30, 2018 compared to 85% for the three months ended September 30, 2017. We believe the higher level of revenue as a percentage of product revenue inside the United States in the three months ended September 30, 2018

was due to the introduction of the iTTotal PS and Hip System in the United States, coupled with the negative impact in Germany from (i) the decrease in reimbursement of our iUni and iDuo partial implants and (ii) continued reimbursement challenges of our iTTotal CR and iTTotal PS business.

Royalty revenue. Royalty revenue was \$10.7 million for the three months ended September 30, 2018 compared to \$0.2 million for the three months ended September 30, 2017, an increase of \$10.4 million or 4,178%, primarily driven by the \$10.5 million royalty payment under the Settlement and License Agreement with Smith & Nephew.

Cost of revenue, gross profit and gross margin. Cost of revenue was \$9.3 million for the three months ended September 30, 2018 compared to \$11.1 million for the three months ended September 30, 2017, a decrease of \$1.8 million or 17%. The decrease was due primarily to vertical integration and other cost saving initiatives. Gross profit was \$19.7 million for the three months ended September 30, 2018 compared to \$7.3 million for the three months ended September 30, 2017, an increase of \$12.4 million or 170%. Gross margin increased 2,800 basis points to 68% for the three months ended September 30, 2018 from 40% for the three months ended September 30, 2017. This increase in gross margin was driven primarily by the \$10.5 million royalty payment under the Settlement and License Agreement with Smith & Nephew, as well as savings from vertical integration efforts and other cost saving initiatives.

Sales and marketing. Sales and marketing expense was \$9.1 million for the three months ended September 30, 2018 compared to \$8.7 million for the three months ended September 30, 2017, an increase of \$0.3 million or 4%. The increase was due primarily to selling costs of \$0.3 million related to the increase in revenue in the United States. Sales and marketing expense decreased as a percentage of total revenue to 31% for the three months ended September 30, 2018 compared to 47% for the three months ended September 30, 2017. Excluding the \$10.5 million royalty payment under the Settlement and License Agreement with Smith & Nephew, sales and marketing expense increased as a percentage of total revenue to 49% for the three months ended September 30, 2018.

Research and development. Research and development expense was \$3.9 million for the three months ended September 30, 2018 compared to \$4.1 million for the three months ended September 30, 2017, a decrease of \$0.2 million or 5%. The decrease was due primarily to a decrease in personnel costs of \$0.4 million, decrease in revenue share of \$0.2 million, decrease of \$0.1 million in other costs, partially offset by an increase in consulting of \$0.5 million. Research and development expense decreased as a percentage of total revenue to 13% for the three months ended September 30, 2018 from 22% for the three months ended September 30, 2017. Excluding the \$10.5 million royalty payment under the Settlement and License Agreement with Smith & Nephew, research and development expense decreased as a percentage of total revenue to 21% for the three months ended September 30, 2018.

General and administrative. General and administrative expense was \$6.6 million for the three months ended September 30, 2018 compared to \$7.4 million for the three months ended September 30, 2017, a decrease of \$0.8 million or 11%. The decrease was due to \$1.9 million in reductions, including decreases of \$0.7 million in personnel costs, \$0.6 million in litigation fees, \$0.4 million in severance expense, and \$0.2 million in business insurance expense, partially offset by an increase in asset impairment charges of \$1.1 million. General and administrative expense decreased as a percentage of total revenue to 23% for the three months ended September 30, 2018 from 40% for the three months ended September 30, 2017. Excluding the \$10.5 million royalty payment under the Settlement and License Agreement with Smith & Nephew, general and administrative expense decreased as a percentage of total revenue to 36% for the three months ended September 30, 2018.

Goodwill impairment. Goodwill impairment was \$6.7 million for the three months ended September 30, 2018 compared to no impairment for the three months ended September 30, 2017, an increase of \$6.7 million or 100%. Our drop in market capitalization and decrease in cash flow position were indicators of impairment and our analysis determined goodwill was fully impaired.

Total other income (expenses), net. Other income (expenses), net was \$(0.9) million for the three months ended September 30, 2018 compared to \$0.5 million for the three months ended September 30, 2017, a change of \$(1.4) million, or 273%. The change was primarily due to a \$1.4 million increase in foreign currency exchange transaction expense.

Income taxes. Income tax provision was \$27,000 and \$80,000 for the three months ended September 30, 2018 and 2017, 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.

On December 22, 2017, the Tax Cut and Jobs Act, or Tax Act, was enacted to provide for reconciliation pursuant to titles II and V of the concurrent resolution on the budget for fiscal year 2018. The Tax Act reduces the U.S. federal corporate income tax rate effective January 1, 2018 from its current 35% rate to a new 21% corporate rate and impose a one-time transition tax on unremitted foreign earnings on foreign subsidiaries. The Company has

37

not yet completed its evaluation of the impact of the changes in the tax bill but expects the net impact of these changes will be favorable to its financial results in future fiscal quarters.

Comparison of the nine months ended September 30, 2018 and 2017

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

	2018	2017	2018 vs 2017
	Amount	Amount	\$
Nine Months Ended September 30,	As a% of Total Revenue	As a% of Total Revenue	Change