
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

FORM 8-K

**CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): October 31, 2018

Conformis, Inc.

(Exact Name of Company as Specified in Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-37474
(Commission
File Number)

56-2463152
(IRS Employer
Identification No.)

**600 Technology Park Drive
Billerica, MA 01821**
(Address of Principal Executive Offices) (Zip Code)

Company's telephone number, including area code: **(781) 345-9001**

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

- * Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- * Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- * Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- * Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
- Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

Emerging growth company If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02 Results of Operations and Financial Condition

On October 31, 2018, Conformis, Inc. issued a press release announcing its financial results for the quarter ended September 30, 2018. A copy of such press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference in its entirety.

The information furnished under this Item 2.02, including the press release attached hereto, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that Section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as otherwise expressly stated in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
<u>99.1*</u>	<u>Press Release of Conformis, Inc., dated October 31, 2018</u>

*Furnished herewith

Conformis Reports Third Quarter 2018 Financial Results and Updates Fiscal Year 2018 Guidance

BILLERICA, Mass., October 31, 2018 (GLOBE NEWSWIRE) - Conformis, Inc. (NASDAQ:CFMS), a medical technology company that uses its proprietary iFit Image-to-Implant technology platform to develop, manufacture and sell patient specific joint replacement implants designed to fit each patient's unique anatomy, announced today financial results for the third quarter ended September 30, 2018.

Q3 Summary

- Total revenue of \$29.0 million, up 57% year-over-year on a reported and constant currency basis, including a royalty settlement of \$10.5 million
- Product revenue of \$18.3 million, up 1% year-over-year on a reported and constant currency basis
 - U.S. product revenue of \$16.3 million, up 5% year-over-year
 - Rest of World product revenue of \$2.1 million, down 22% year-over-year on a reported basis and 23% year-over-year on a constant currency basis
- Royalty revenue of \$10.7 million, including the royalty settlement of \$10.5 million
- Gross margin of 68%, an increase of 2,800 basis points year-over-year, or 50%, an increase of 1,000 basis points year-over-year, excluding the \$10.5 million royalty settlement

"Our US growth of 5% represents a meaningful step-up in performance year-over-year. However, US sales in the fourth quarter are anticipated to be lower than previously expected, and we are taking steps to improve performance in 2019. We continue to face headwinds in our OUS business due to reimbursement challenges," said Mark Augusti, President and Chief Executive Officer of Conformis, Inc. "Our continued gross margin expansion gives us increasing confidence that the margin improvements we have shown in previous quarters should be sustainable and we are continuing to focus on achieving operational efficiency."

(\$, in thousands)	Three months ended September 30,		Increase/(decrease)		
	2018	2017	\$ Change	% Change (as reported)	% Change (constant currency)
United States	\$ 16,271	\$ 15,519	\$ 752	5 %	5 %
Rest of world	2,061	2,657	(596)	(22)%	(23)%
Product revenue	18,332	18,176	156	1 %	1 %
Royalty revenue	10,652	249	10,403	4,178 %	4,178 %
Total revenue	\$ 28,984	\$ 18,425	\$ 10,559	57 %	57 %

Third Quarter 2018 Financial Results

Total revenue for the three-month period ended September 30, 2018 increased \$10.6 million to \$29.0 million, or 57% year-over-year on a reported and constant currency basis. Total revenue in the third quarter of 2018 and 2017 includes royalty revenue of \$10.7 million and \$0.2 million, respectively, related to patent license agreements. The increase in royalty revenue in the third quarter of 2018 compared to the same quarter in the prior year is primarily due to the royalty settlement of \$10.5 million due from Smith & Nephew.

Product revenue increased \$0.2 million to \$18.3 million, or 1% year-over-year on a reported and constant currency basis. U.S. product revenue increased \$0.8 million to \$16.3 million, or 5% year-over-year, and Rest of World product revenue decreased \$0.6 million to \$2.1 million, or 22% year-over-year on a reported basis and 23% on a constant currency basis. Product revenue from sales of iTotal PS increased \$0.8 million to \$6.1 million or 15% year-over-year on a reported and constant currency basis. Product revenue from sales of iTotal CR, iDuo and iUni decreased \$0.9 million to \$12.0 million, or 7% year-over-year on a reported and constant currency basis. The decrease in product revenue was primarily attributable to reimbursement challenges in Germany. Conformis hip system sales in the third quarter of 2018 was \$0.2 million in the U.S.

Total gross profit increased \$12.4 million to \$19.7 million, or 68% of revenue, in the third quarter of 2018, compared to \$7.3 million, or 40% of revenue, in the third quarter of 2017. This 2,800 basis point increase in gross margin year-over-year was driven primarily by the \$10.5 million royalty settlement, which contributed 1,800 basis points of the increase, and by cost reductions as a result of vertical integration and manufacturing efficiencies.

Total operating expenses increased \$6.0 million to \$26.2 million, or 30% year-over-year. This increase in expenses was driven primarily by an increase in general and administrative expense due to the non-cash write-off of \$1.9 million of unused manufacturing equipment and a non-cash write-off of \$6.7 million related to impairment of goodwill due to the Company's market capitalization and cash flow position. These expenses were partially offset by \$2.8 million of reductions in patent litigation expense, business insurance expense, personnel costs and other administrative expenses.

Net loss was \$7.4 million, or \$0.12 per basic share, in the third quarter of 2018, compared to a net loss of \$12.5 million, or \$0.29 per basic share, for the same period last year. Net loss in the third quarter of 2018 included foreign currency exchange expense of \$272,000 compared to foreign currency exchange income of \$1.1 million in the same period last year. Net loss per basic share calculations assume weighted

average basic shares outstanding of 60.2 million for the third quarter of 2018, compared to 43.5 million for the same period last year.

As of September 30, 2018, cash and cash equivalents and investments totaled \$36.9 million, which does not include the \$10.5 million royalty settlement payment received in October, compared to \$45.2 million as of December 31, 2017.

2018 Financial Guidance

For the full year 2018, the Company expects total revenue in a range of \$88.6 million to \$89.1 million. Excluding the \$10.5 million royalty settlement, the Company expects total revenue in a range of \$78.1 million to \$78.6 million. This is updated from previous guidance in a range of \$79.6 million to \$83.6 million. The Company's 2018 revenue guidance assumes the following:

- Product revenue in a range of \$77.5 million to \$78.0 million, representing year-over-year increase of 1% on a reported basis and flat on a constant currency basis. This is updated from previous guidance in a range of \$79.0 million to \$83.0 million, representing year-over-year growth of 2% to 8% on a reported basis and 2% to 7% on a constant currency basis.
- Royalty revenue of approximately \$11.1 million, including the \$10.5 million royalty settlement. This is updated from previous guidance of approximately \$0.6 million related to ongoing patent license royalty payments.
- Excluding the \$10.5 million royalty settlement, we believe we will finish the year ahead of our total gross margin guidance of 44 to 46% and well ahead of our 2017 gross margin of 37%

Note on Non-GAAP Financial Measures

In addition to disclosing financial measures prepared in accordance with U.S. generally accepted accounting principles (GAAP), the Company provides certain information regarding the Company's financial results or projected financial results on a non-GAAP "constant currency basis." This information estimates the impact of changes in foreign currency rates on the translation of the Company's current or projected future period financial results as compared to the applicable comparable period. This impact is derived by taking the adjusted current or projected local currency results and translating them into U.S. dollars based upon the foreign currency exchange rates for the applicable comparable period. It does not include any other effect of changes in foreign currency rates on the Company's results or business. Non-GAAP information is not a substitute for, and is not superior to, information presented on a GAAP basis.

Conference Call

As previously announced, Conformis will conduct a webcast today at 4:30 PM Eastern Time. Management will discuss financial results and strategic matters. The webcast will be live at <https://edge.media-server.com/m6/p/7axt74hp> and at the investor relations section of the company's website at ir.conformis.com.

The online archive of the webcast will be available on the company's website for 30 days.

About Conformis, Inc.

Conformis 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, or customized, to fit each patient's unique anatomy. Conformis offers a broad line of customized knee and hip implants and customized pre-sterilized, single-use instruments delivered in a single package to the hospital. In clinical studies, Conformis iTotal CR knee replacement system demonstrated superior clinical outcomes, including better function and greater patient satisfaction, compared to traditional, off-the-shelf implants. Conformis owns or exclusively in-licenses issued patents and pending patent applications that cover customized implants and customized patient-specific instrumentation for all major joints.

For more information, visit www.conformis.com. To receive future releases in e-mail alerts, sign up at <http://ir.conformis.com/>.

Cautionary Statement Regarding Forward-Looking Statements

Statements in this press release about our future expectations, plans and prospects, including statements about the anticipated timing of our product launches, and our financial position and results, total revenue, product revenue, gross margin, operations, as well as other statements containing the words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "might," "plan," "potential," "predict," "project," "should," "target," "will," or "would" and similar expressions, constitute forward-looking statements within the meaning of the safe harbor provisions of The Private Securities Litigation Reform Act of 1995. We may not actually achieve the forecasts disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual financial results could differ materially from the projections disclosed in the forward-looking statements we make as a result of a variety of risks and uncertainties, including whether our cash resources will be sufficient to fund our continuing operations for the periods anticipated; risks related to our estimates and expectations regarding our revenue, gross margin, expenses, revenue growth and other results of operations; and the other risks and uncertainties described in the "Risk Factors" sections of our public filings with the Securities and Exchange Commission. In addition, the forward-looking statements included in this press release represent our views as of the date hereof. We anticipate that subsequent events and developments may cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we specifically disclaim any obligation to do so. These forward-looking statements should not be relied upon as representing our views as of any date subsequent to the date hereof.

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CONFORMIS, INC. AND SUBSIDIARIES
Consolidated Statements of Operations
(unaudited)
(in thousands, except share and per share data)

	Three Months Ended September 30,	
	2018	2017
Revenue		
Product	\$ 18,332	\$ 18,176
Royalty	10,652	249
Total revenue	28,984	18,425
Cost of revenue	9,265	11,111
Gross profit	19,719	7,314
Operating expenses		
Sales and marketing	9,053	8,741
Research and development	3,867	4,081
General and administrative	6,582	7,402
Goodwill impairment	6,731	—
Total operating expenses	26,233	20,224
Loss from operations	(6,514)	(12,910)
Other income and expenses		
Interest income	164	137
Interest expense	(788)	(718)
Foreign currency exchange transaction (loss) income	(272)	1,099
Total other (expenses) income, net	(896)	518
Loss before income taxes	(7,410)	(12,392)
Income tax provision	27	80
Net loss	\$ (7,437)	\$ (12,472)
Net loss per share		
Basic and diluted	\$ (0.12)	\$ (0.29)
Weighted average common shares outstanding		
Basic and diluted	60,225,504	43,468,559

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

	September 30, 2018	December 31, 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 stockholder's 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)
Total stockholders' equity	43,455	46,513
Total liabilities and stockholders' equity	\$ 86,321	\$ 93,798