
**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 30, 2019

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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common Stock, \$0.00001 par value per share	CFMS	The Nasdaq Global Select Market

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

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 30, 2019, Conformis, Inc. issued a press release announcing its financial results for the quarter ended September 30, 2019. 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 30, 2019</u>

*Furnished herewith

SIGNATURES

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

CONFORMIS, INC.

Date: October 30, 2019

By: /s/ J. Brent Alldredge
J. Brent Alldredge
Chief Legal Officer & Corporate Secretary

Conformis Reports Third Quarter 2019 Financial Results

BILLERICA, Mass., October 30, 2019 (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, 2019.

Third Quarter 2019 Summary

- Total revenue of \$17.3 million, a decrease of 40% year-over-year on a reported and constant currency basis, including a royalty settlement of \$10.5 million in the third quarter of 2018.
- Product revenue of \$17.1 million, a decrease of 7% year-over-year on a reported basis and 6% on a constant currency basis.
 - U.S. product revenue of \$15.1 million, a decrease of 7% year-over-year.
 - Rest of World product revenue of \$2.0 million, a decrease of 5% year-over-year on a reported basis and 1% on a constant currency basis.
- Royalty revenue of \$0.2 million.
- Gross margin of 44%, a decrease of 2,400 basis points year-over-year, including 18.1% gross margin or 1,810 basis points related to a \$10.5 million royalty settlement in the third quarter of 2018.

"The third quarter, as expected, was challenging for us given the Aetna insurance coverage denials. I am pleased with our OUS performance improvement," said Mark Augusti, President and Chief Executive Officer of Conformis, Inc. "Also, in the third quarter we had two very significant positive events occur. The first being the execution of the Stryker transaction for patient specific instrumentation as announced earlier this month. The second being the successful limited launch of our new Identity total knee system which has received excellent physician feedback."

(\$, in thousands)	Three months ended September 30,		Increase/(decrease)		
	2019	2018	\$ Change	% Change	% Change
				<i>(as reported)</i>	<i>(constant currency)</i>
United States	\$ 15,144	\$ 16,271	\$ (1,127)	(7)%	(7)%
Rest of world	1,968	2,061	(93)	(5)%	(1)%
Product revenue	17,112	18,332	(1,220)	(7)%	(6)%
Royalty revenue	191	10,652	(10,461)	(98)%	(98)%
Total revenue	\$ 17,303	\$ 28,984	\$ (11,681)	(40)%	(40)%

Third Quarter 2019 Financial Results

Total revenue for the three-month period ended September 30, 2019 decreased \$11.7 million to \$17.3 million, or 40% year-over-year on a reported and constant currency basis. Total revenue in the third quarter of 2019 and 2018 includes royalty revenue of \$0.2 million and \$10.7 million, respectively, related to patent license agreements. The decrease in royalty revenue in the third quarter of 2019 compared to the

same quarter in the prior year is due to the royalty settlement of \$10.5 million in third quarter of 2018 from Smith & Nephew.

Product revenue decreased \$1.2 million to \$17.1 million, or 7% year-over-year on a reported basis and 6% on a constant currency basis. U.S. product revenue decreased \$1.1 million to \$15.1 million, or 7% year-over-year, and Rest of World product revenue decreased \$0.1 million to \$2.0 million, or 5% year-over-year on a reported basis and 1% on a constant currency basis. Product revenue from sales of iTotal PS increased \$0.3 million to \$6.4 million, or 5% year-over-year on a reported and constant currency basis. Product revenue from sales of iTotal CR, iDuo and iUni decreased \$1.7 million to \$10.3 million, or 14% year-over-year on a reported and constant currency basis. Conformis Hip System sales in the third quarter of 2019 were \$0.4 million, which were all in the United States.

Total gross profit decreased \$12.1 million to \$7.6 million, or 44% of revenue, in the third quarter of 2019, compared to \$19.7 million, or 68% of revenue, in the third quarter of 2018. This 2,400 basis point decrease in gross margin year-over-year was driven primarily by the \$10.5 million royalty settlement in the third quarter of 2018, which contributed 1,810 basis points of the decrease, and 600 basis points due to lower volumes and other miscellaneous charges to cost of goods sold in the third quarter of 2019.

Total operating expenses decreased \$11.8 million to \$14.5 million, or 45% year-over-year. Of this decrease in expenses, \$3.2 million was driven by reductions in personnel costs, marketing programs and patent litigation expense as part of a plan announced at the end of 2018 to reduce cash burn in 2019. The remaining \$8.6 million reduction in expense was due to the third quarter of 2018 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.

Net loss was \$8.7 million, or \$0.13 per basic and diluted share, in the third quarter of 2019, compared to a net loss of \$7.4 million, or \$0.12 per basic and diluted share, in the same period last year. Net loss in the third quarter of 2019 included foreign currency exchange expense of \$1.3 million compared to foreign currency exchange expense of \$0.3 million in the same period last year. Net loss per basic and diluted share calculations assume weighted average basic and diluted shares outstanding of 64.8 million for the third quarter of 2019, compared to 60.2 million for the same period last year.

Cash and cash equivalents and investments totaled \$29.4 million as of September 30, 2019, compared to \$23.6 million as of December 31, 2018. The cash balance as of September 30, 2019 includes the \$14 million we received from Stryker related to the Development, License and Distribution Agreements.

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.

Webcast

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/mmc/p/w788nkk7> 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 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 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 and growth, 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 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 U.S. 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.

CONTACT:

Investor contact
ir@conformis.com
(781) 374-5598

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

	Three Months Ended September 30,	
	2019	2018
	<u> </u>	<u> </u>
Revenue		
Product	\$ 17,112	\$ 18,332
Royalty	191	10,652
Total revenue	<u>17,303</u>	<u>28,984</u>
Cost of revenue	<u>9,675</u>	<u>9,265</u>
Gross profit	7,628	19,719
Operating expenses		
Sales and marketing	6,153	9,053
Research and development	3,162	3,867
General and administrative	5,165	6,582
Goodwill impairment	—	6,731
Total operating expenses	<u>14,480</u>	<u>26,233</u>
Loss from operations	(6,852)	(6,514)
Other income and expenses		
Interest income	58	164
Interest expense	(573)	(788)
Foreign currency exchange transaction (loss) income	<u>(1,313)</u>	<u>(272)</u>
Total other (expenses) income, net	<u>(1,828)</u>	<u>(896)</u>
Loss before income taxes	(8,680)	(7,410)
Income tax provision	<u>21</u>	<u>27</u>
Net loss	<u>\$ (8,701)</u>	<u>\$ (7,437)</u>
Net loss per share		
Basic and diluted	\$ (0.13)	\$ (0.12)
Weighted average common shares outstanding		
Basic and diluted	64,750,275	60,225,504

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

	September 30, 2019	December 31, 2018
	(unaudited)	
Assets		
Current Assets		
Cash and cash equivalents	\$ 29,433	\$ 16,380
Investments	—	7,245
Accounts receivable, net	10,477	13,244
Royalty receivable	170	145
Inventories, net	11,558	9,534
Prepaid expenses and other current assets	1,435	1,408
Total current assets	<u>53,073</u>	<u>47,956</u>
Property and equipment, net	13,362	14,439
Operating lease right-of-use assets	6,136	—
Other Assets		
Restricted cash	462	462
Intangible assets, net	24	109
Other long-term assets	232	17
Total assets	<u>\$ 73,289</u>	<u>\$ 62,983</u>
Liabilities and stockholder's equity		
Current liabilities		
Accounts payable	\$ 4,601	\$ 3,445
Accrued expenses	8,515	7,930
Operating lease liabilities	1,454	—
Advance on research and development	2,500	—
Total current liabilities	<u>17,070</u>	<u>11,375</u>
Other long-term liabilities	—	616
Contract liability	11,500	—
Long-term debt, less debt issuance costs	19,435	14,792
Operating lease liabilities	5,384	—
Total liabilities	<u>53,389</u>	<u>26,783</u>
Commitments and contingencies	—	—
Stockholders' equity		
Preferred stock, \$0.00001 par value:		
Authorized: 5,000,000 shares authorized at September 30, 2019 and December 31, 2018; no shares issued and outstanding as of September 30, 2019 and December 31, 2018	—	—
Common stock, \$0.00001 par value:		
Authorized: 200,000,000 shares authorized at September 30, 2019 and December 31, 2018; 68,379,064 and 65,290,879 shares issued and outstanding at September 30, 2019 and December 31, 2018, respectively	1	1
Additional paid-in capital	518,636	513,336
Accumulated deficit	(498,712)	(475,667)
Accumulated other comprehensive loss	(25)	(1,470)
Total stockholders' equity	<u>19,900</u>	<u>36,200</u>
Total liabilities and stockholders' equity	<u>\$ 73,289</u>	<u>\$ 62,983</u>