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**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): November 3, 2021

**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 Capital 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.

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**Item 2.02 Results of Operations and Financial Condition.**

On November 3, 2021, Conformis, Inc. issued a press release announcing its financial results for the quarter ended September 30, 2021. 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.

Exhibit No.	Description
<a href="#">99.1*</a>	<a href="#">Press Release of Conformis, Inc. dated November 3, 2021</a>

\*Furnished herewith

***Cautionary Statement Regarding Forward-Looking Statements***

Statements in this Current Report on Form 8-K about the Company’s future expectations, plans and prospects, including statements about the impact of the COVID-19 pandemic and the Company’s 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” or the negative of these terms or other and similar expressions are intended to identify forward-looking statements within the meaning of the safe harbor provisions of The Private Securities Litigation Reform Act of 1995, although not all forward-looking statements contain these identifying words. The Company may not actually achieve the expectations disclosed in these forward-looking statements, and you should not place undue reliance on these forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements the Company makes as a result of a variety of risks and uncertainties, including risks related to the COVID-19 pandemic and the response to the pandemic; risks related to the Company’s estimates and expectations regarding the Company’s revenue, gross margin, expenses, revenue growth and other results of operations, and the other risks and uncertainties described in the “Risk Factors” sections of the Company’s public filings with the U.S. Securities and Exchange Commission. In addition, the forward-looking statements included in this Current Report on Form 8-K represent the Company’s views as of the date hereof. The Company anticipates that subsequent events and developments may cause the Company’s views to change. However, while the Company may elect to update these forward-looking statements at some point in the future, the Company specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing the Company’s views as of any date subsequent to the date hereof.

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## 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: November 3, 2021

By: /s/ Robert S. Howe  
Robert S. Howe  
Chief Financial Officer

## Conformis Reports Third Quarter 2021 Financial Results

BILLERICA, Mass., November 3, 2021 (GLOBE NEWSWIRE) - Conformis, Inc. (NASDAQ:CFMS), an orthopedic medical device company that features personalized knee and hip replacement products, announced today financial results for the third quarter ended September 30, 2021.

### Third Quarter 2021 Summary

- Total revenue of \$14.3 million, a decrease of 12% year-over-year on a reported and constant currency basis.
- Product revenue of \$14.1 million, a decrease of 12% year-over-year on a reported and constant currency basis.
- Conformis hip system revenue down 16% year-over-year to \$0.7 million.
- First procedures successfully completed using Identity Imprint™ knee replacement system.
- First procedures successfully completed under the Stryker<sup>1</sup> partnership program for the Triathlon knee utilizing patient-specific instrumentation.
- Cash and cash equivalents of \$97.1 million as of September 30, 2021.

### Executive Commentary – Mark Augusti, President and CEO

“I am pleased with the progress we made on our growth strategy over the last three months. As COVID-19’s Delta variant became more pronounced during the quarter, the impact on elective procedures and our business was greater than expected. This resulted in a number of deferred procedures, many of which have already been rescheduled. The disruption caused by the Delta variant has had minimal affect on the limited market releases of our new Identity Imprint knee offering and our manufacturing partnership with Stryker. Both are progressing and we are positioned to capitalize on the shift in procedures to the ASC in 2022 and beyond.”

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<sup>1</sup> Stryker and Triathlon are registered trademarks of Stryker Corporation or affiliated entities in the United States and other countries.

(\$, in thousands)	Three months ended September 30,		Increase/(decrease)		
	2021	2020	\$ Change	% Change (as reported)	% Change (constant currency)
United States	\$ 12,405	\$ 14,139	\$ (1,734)	(12)%	(12)%
Rest of world	1,725	1,836	(111)	(6)%	(10)%
<b>Product revenue</b>	<b>14,130</b>	<b>15,975</b>	<b>(1,845)</b>	<b>(12)%</b>	<b>(12)%</b>
<b>Royalty revenue</b>	<b>123</b>	<b>146</b>	<b>(23)</b>	<b>(16)%</b>	<b>(16)%</b>
<b>Total revenue</b>	<b>\$ 14,253</b>	<b>\$ 16,121</b>	<b>\$ (1,868)</b>	<b>(12)%</b>	<b>(12)%</b>

### Third Quarter 2021 Highlights

#### Revenue

- Decrease in revenue year-over-year was primarily due to deferred and rescheduled elective surgeries as a result of the increase in COVID-19 cases associated with the Delta variant.
- Product revenue compared to the third quarter of 2020 was down 12%.

#### Gross Margin

- Total gross profit decreased \$1.7 million to \$6.0 million, or 42% of revenue, in the third quarter of 2021, compared to \$7.7 million, or 48% of revenue, in the third quarter of 2020.
- The 540 basis-point decrease in gross margin year-over-year was driven primarily by lower volume, increased material, labor, and other manufacturing costs, higher cancelled case inventory expense, and a reduction in product selling price.

#### Operating Expenses

- Total operating expenses of \$17.4 million, an increase of 18% year-over-year.
- Sales and marketing expenses increased \$0.7 million primarily due to higher tradeshow, surgeon training, and travel expenses, which were partially offset by lower commission expenses.
- Research and development expenses increased \$0.7 million primarily driven by personnel and project-related costs to support our new product pipeline.
- General and administrative expenses increased \$1.3 million primarily driven by higher planned professional fees related to the ongoing protection of our intellectual property.

#### Net Loss

- Net loss was \$13.0 million, or \$0.07 per basic and diluted share, in the third quarter of 2021, compared to a net loss of \$6.2 million, or \$0.09 per basic and diluted share, in the same period last year.
- Foreign currency exchange transaction loss was \$1.0 million in the third quarter of 2021, compared to foreign currency exchange transaction income of \$1.5 million in the same period last year.
- Weighted average basic and diluted shares outstanding of 178.5 million for the third quarter of 2021, compared to 71.2 million for the same period last year.

#### Capital Structure and Liquidity

- Cash and cash equivalents totaled \$97.1 million as of September 30, 2021, compared to \$28.7 million as of December 31, 2020.

### **Outlook**

- We expect our fourth quarter product revenue to improve sequentially from the third quarter and to be in the range of \$15.0 million to \$17.0 million.
- The wider-than-usual range we are providing is due to the unpredictable recovery from the Delta variant and its potential impact on our existing scheduled fourth quarter surgeries.

### **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. Company management uses these non-GAAP measures internally to measure operational performance.

### **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/wvne4ujy>.

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 and instruments that are individually sized and shaped, which we refer to as personalized, individualized, or sometimes as customized, to fit and conform to each patient's unique anatomy. Conformis also offers Identity Imprint™, a new line of total knee replacement products that utilizes a proprietary algorithm to select the implant size that most closely meets the geometric and anatomic requirements of the patient's knee. Conformis' sterile, just-in-time, Surgery-in-a-Box™ delivery system is available with all of its implants and personalized, single-use instruments. Conformis owns or exclusively in-licenses issued patents and pending patent applications that cover personalized implants and patient-specific instrumentation for all major joints.

For more information, visit [www.conformis.com](http://www.conformis.com). To receive future releases in e-mail alerts, sign up at [ir.conformis.com](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 impact of the novel coronavirus (COVID-19) pandemic and the Delta variant, the anticipated timing of our product launches, whether or when restrictions on elective surgeries will be relaxed and demand for procedures will increase, 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" or the negative of these terms or other and similar expressions are intended to identify forward-looking statements within the meaning of the safe harbor provisions of The Private Securities Litigation Reform Act of 1995, although not all forward-looking statements contain these identifying words. 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 as a result of a variety of risks and uncertainties, including risks related to the novel coronavirus pandemic and the response to the pandemic; 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 Annual Report on Form 10-K for the fiscal year ended December 31, 2020, Quarterly Reports on Form 10-Q for each of the fiscal quarters ended March 31, 2021, June 30, 2021 and September 30, 2021, respectively, and other 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 Relations  
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(781) 374-5598

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

	<b>Three Months Ended September 30,</b>	
	<b>2021</b>	<b>2020</b>
Revenue		
Product	\$ 14,130	\$ 15,975
Royalty and licensing	123	146
Total revenue	14,253	16,121
Cost of revenue	8,231	8,437
Gross profit	6,022	7,684
Operating expenses		
Sales and marketing	6,434	5,755
Research and development	3,548	2,866
General and administrative	7,407	6,134
Total operating expenses	17,389	14,755
Loss from operations	(11,367)	(7,071)
Other income and expenses		
Interest income	20	8
Interest expense	(601)	(611)
Foreign currency exchange transaction (loss) income	(996)	1,511
Total other (expenses) income	(1,577)	908
Loss before income taxes	(12,944)	(6,163)
Income tax provision	29	20
Net loss	\$ (12,973)	\$ (6,183)
Net loss per share:		
Basic and diluted	\$ (0.07)	\$ (0.09)
Weighted average common shares outstanding:		
Basic and diluted	178,452,296	71,224,786

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

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