
**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): August 4, 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.

Item 2.02 Results of Operations and Financial Condition.

On August 4, 2021, Conformis, Inc. issued a press release announcing its financial results for the quarter ended June 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
99.1*	Press Release of Conformis, Inc. dated August 4, 2021

*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.

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: August 4, 2021

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

Conformis Reports Second Quarter 2021 Financial Results

BILLERICA, Mass., August 4, 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 second quarter ended June 30, 2021.

Second Quarter 2021 Summary

- Total revenue of \$56.3 million, an increase of 189% year-over-year on a reported and constant currency basis.
- Product revenue of \$15.2 million, an increase of 56% year-over-year on a reported basis and 54% on a constant currency basis.
- Royalty and licensing revenue of \$41.1 million, including \$25.0 million in connection with the third and final milestone under the Stryker development and license agreements and the settlement and license agreement with Stryker, Wright Medical, and Tornier.
- Conformis Hip System revenue up 62% year-over-year to \$0.9 million.
- Received 510(k) clearance for Identity Imprint™ Knee Replacement System.
- Received 510(k) clearance for patient-specific instrumentation developed in connection with the Stryker license and development agreements. First procedure successfully completed on July 14, 2021.
- Full forgiveness of Paycheck Protection Program (“PPP”) loan of \$4.7 million principal loan amount, plus accrued interest.

Executive Commentary – Mark Augusti, President and CEO

“We had another steady quarter of progress as we executed our growth strategy. The environment for orthopedic surgical procedures has improved and we believe procedure levels will continue to normalize. We remain cautiously optimistic about the second half of the year as we aim to get back to our 2019 revenue run rate.

We continue to make progress with our new product development plans. As part of a limited market release, the first surgery using our patient-specific instrumentation with a Stryker knee implant recently occurred and was successful. We also obtained 510(k) clearance from the FDA for our new Imprint knee offering, and we expect our first surgeries to occur soon. We believe that these two new products position us well as medical facilities, particularly ambulatory surgical centers, continue returning to normal operations and look for efficient, cost-effective knee implant solutions.

We are also pleased that we have been able to continue protecting and monetizing our intellectual property. This quarter, we generated \$41 million in royalties and license revenue. This adds to an increasingly strong balance sheet that gives us the runway to execute our plan.”

(\$, in thousands)	Three months ended June 30,		Increase/(decrease)		
	2021	2020	\$ Change	% Change (as reported)	% Change (constant currency)
United States	\$ 13,424	\$ 8,331	\$ 5,093	61 %	61 %
Rest of world	1,775	1,412	363	26 %	14 %
Product revenue	15,199	9,743	5,456	56 %	54 %
Royalty revenue	41,149	9,725	31,424	323 %	323 %
Total revenue	\$ 56,348	\$ 19,468	\$ 36,880	189 %	189 %

Second Quarter 2021 Highlights

Revenue

- Increase in revenue year-over-year was driven primarily by increased elective procedure volumes, and an increase in royalty and licensing revenue related to patent license settlement and development agreements.
- Conformis Hip System revenue of \$0.9 million for the second quarter of 2021 was up 62% year-over-year and increased 38% from the first quarter of 2021.
- Product Revenue compared to the second quarter of 2019 was down 21%, a sequential improvement from the 33% decline in the first quarter.

Gross Margin

- Total gross profit increased \$36.5 million to \$47.5 million, or 84% of revenue, in the second quarter of 2021, compared to \$11.0 million, or 57% of revenue, in the second quarter of 2020.
- The 2,780 basis-point increase in gross margin year-over-year was driven primarily by the increase in royalty and licensing revenue associated with the Stryker development and license agreements and the settlement and license agreement with Stryker, Wright Medical, and Tornier.
- Product gross margin of 42% increased by 1,180 basis points as compared to the second quarter of 2020 driven primarily by lower cancelled case inventory expense and lower manufacturing variances as a result of increased production volumes.

Operating Expenses

- Total operating expenses of \$16.6 million, an increase of 25% year-over-year.
- Sales and marketing expenses increased \$2.2 million primarily due to higher sales commissions, travel expenses, marketing programs, and training events.
- Research and development expenses increased \$0.9 million primarily driven by personnel and project related costs to support our new product pipeline.
- General and administrative expenses increased \$0.2 million primarily driven by higher professional fees related to the protection of our intellectual property.

Net Income

- Net income was \$38.0 million, or \$0.21 per basic and diluted share, in the second quarter of 2021, compared to a net loss of \$2.1 million, or \$0.03 per basic and diluted share, in the same period last year.

- Several non-recurring items drove net income this quarter including royalty and licensing revenue, forgiveness of the PPP loan plus accrued interest of \$4.8 million, and \$2.5 million for the unused portion of the advance on research and development under the development agreement with Stryker. The last two items are included in other income.
- Foreign currency exchange income was \$0.5 million in the second quarter of 2021, compared to \$0.7 million in the same period last year.
- Weighted average basic and diluted shares outstanding of 177.7 million and 180.0 million respectively, for the second quarter of 2021, compared to 68.2 million for both weighted average basic and diluted shares outstanding for the same period last year.

Capital Structure and Liquidity

- Cash and cash equivalents totaled \$108.3 million as of June 30, 2021, compared to \$28.7 million as of December 31, 2020.
- \$4.7 million PPP loan forgiven in full. Loan proceeds were used to maintain our staffing through the pandemic.

Outlook

- We expect our third quarter product revenue to improve sequentially from the second quarter and to be in the range of \$15.5 million to \$16.5 million.
- We believe elective procedure volumes will continue to improve and approach 2019 levels in the fourth quarter as vaccines become more widely available and medical facilities recover from pandemic-related staffing impacts.

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/djinyqx6>.

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 each patient's unique anatomy. Conformis offers a broad line of sterile, personalized knee and hip implants and single-use instruments delivered to hospitals and ambulatory surgical centers. In clinical studies, the 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 personalized implants and 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](mailto: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, 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 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)

	Three Months Ended June 30,	
	2021	2020
Revenue		
Product	\$ 15,199	\$ 9,743
Royalty and licensing	41,149	9,725
Total revenue	<u>56,348</u>	<u>19,468</u>
Cost of revenue	<u>8,810</u>	<u>8,450</u>
Gross profit	47,538	11,018
Operating expenses		
Sales and marketing	6,304	4,102
Research and development	3,650	2,738
General and administrative	6,689	6,474
Total operating expenses	<u>16,643</u>	<u>13,314</u>
Income (loss) from operations	30,895	(2,296)
Other income and expenses		
Interest income	39	23
Interest expense	(607)	(584)
Other income	7,252	—
Foreign currency exchange transaction income	455	694
Total other income	<u>7,139</u>	<u>133</u>
Income (loss) before income taxes	38,034	(2,163)
Income tax provision	<u>(8)</u>	<u>(28)</u>
Net income (loss)	<u>\$ 38,042</u>	<u>\$ (2,135)</u>
Net income (loss) per share:		
Basic	\$ 0.21	\$ (0.03)
Diluted	\$ 0.21	\$ (0.03)
Weighted average common shares outstanding:		
Basic	177,668,627	68,187,128
Diluted	180,015,105	68,187,128

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

	June 30, 2021	December 31, 2020
	(unaudited)	
Assets		
Current Assets		
Cash and cash equivalents	\$ 108,320	\$ 28,673
Accounts receivable, net	8,903	8,515
Royalty and licensing receivable	15,643	1,256
Inventories, net	13,421	12,585
Prepaid expenses and other current assets	2,314	2,315
Total current assets	148,601	53,344
Property and equipment, net	11,108	12,240
Operating lease right-of-use assets	8,268	5,215
Other Assets		
Restricted cash	562	462
Other long-term assets	218	239
Total assets	\$ 168,757	\$ 71,500
Liabilities and stockholder's equity		
Current liabilities		
Accounts payable	\$ 4,957	\$ 4,918
Accrued expenses	8,550	7,213
Operating lease liabilities	1,782	1,620
Advance on research and development	—	3,168
Contract liability	—	14,000
Total current liabilities	15,289	30,919
Long-term debt, less debt issuance costs	20,627	25,003
Operating lease liabilities	7,112	4,206
Total liabilities	43,028	60,128
Commitments and contingencies		
Stockholders' equity		
Preferred stock, \$0.00001 par value:		
Authorized: 5,000,000 shares authorized at June 30, 2021 and December 31, 2020; no shares issued and outstanding as of June 30, 2021 and December 31, 2020	—	—
Common stock, \$0.00001 par value:		
Authorized: 300,000,000 shares authorized at June 30, 2021 and December 31, 2020; 186,053,533 and 95,546,577 shares issued and outstanding at June 30, 2021 and December 31, 2020, respectively	2	1
Additional paid-in capital	630,435	543,809
Accumulated deficit	(501,902)	(528,438)
Accumulated other comprehensive loss	(2,806)	(4,000)
Total stockholders' equity	125,729	11,372
Total liabilities and stockholders' equity	\$ 168,757	\$ 71,500