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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): April 19, 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 8.01 Other Events.**

On April 19, 2021, Conformis, Inc. (the "Company") received 510(k) clearance by the U.S. Food and Drug Administration for patient-specific instrumentation ("PSI") that the Company developed under its License Agreement and Development Agreement with Howmedica Osteonics Corp, a wholly owned subsidiary of Stryker Corporation ("Stryker"). With the clearance of this PSI system, which is designed for use with Stryker's Triathlon® Total Knee System, the Company has achieved the third of three milestones under the agreements and will receive \$11.0 million from Stryker. On April 22, 2021, the Company issued a press release announcing the 510(k) clearance. A copy of the press release is furnished herewith as Exhibit 99.2 and is incorporated into this Item 8.01 by reference.

On April 8, 2021, the Company entered into a license agreement with Paragon 28, Inc. ("Paragon 28"), granting Paragon 28 a non-exclusive license under a subset of the Company's U.S. patents for the use of patient-specific instruments with off-the-shelf implants in Paragon 28's APEX 3D™ Total Ankle Replacement System. With the signing of the license agreement, the Company will receive \$1 million and up to an additional \$0.5 million from Paragon 28. On April 19, 2021, the Company issued a press release announcing the license agreement. A copy of the press release is furnished herewith as Exhibit 99.1 and is incorporated into this Item 8.01 by reference.

The information furnished under this Item 8.01, including the press releases 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 April 19, 2021</a>
<a href="#">99.2*</a>	<a href="#">Press Release of Conformis, Inc. dated April 22, 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

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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: April 22, 2021

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

## **Conformis Announces License Agreement with Paragon 28**

*Commercial Interest in Accurate, Disposable,  
Patient-Specific Instrumentation Continues to Expand*

BILLERICA, Mass., April 19, 2021 (GLOBE NEWSWIRE) – Conformis, Inc.(NASDAQ:CFMS) announced today that it has entered into a license agreement with Paragon 28, Inc., granting Paragon 28 a non-exclusive license under a subset of Conformis’ U.S. patents for the use of patient-specific instruments with off-the-shelf implants in Paragon 28’s APEX 3D™ Total Ankle Replacement System.

“We are pleased to reach this agreement with Paragon 28, enabling it to incorporate our patient-specific instrument technology in its anticipated total ankle replacement offering,” said Mark Augusti, President and Chief Executive Officer. “We believe that this latest license agreement further demonstrates the broad applicability and clinical appeal of Conformis’ technology.”

### **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. 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 settlement of patent disputes and the collection of payments, 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. You should not place undue reliance on our forward-looking statements. Actual results could differ materially from the expectations disclosed in the forward-looking statements we make as a result of a variety of risks and uncertainties, including 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.

**CONTACT:**

Investor Contact

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+1 (781) 374-5598

## **Conformis Announces Achievement of Third Milestone Under Development and License Agreements**

BILLERICA, Mass., April 22, 2021 (GLOBE NEWSWIRE) -- Conformis, Inc. (NASDAQ:CFMS) announced today that it received 510(k) clearance by the U.S. Food and Drug Administration for patient-specific instrumentation (“PSI”) developed by the Company under its License Agreement and Development Agreement with Howmedica Osteonics Corp., a wholly owned subsidiary of Stryker Corporation also known as Stryker Orthopaedics. With the clearance of this PSI system, which is designed for use with Stryker’s Triathlon® Total Knee System, the Company has achieved the third of three milestones under the agreements and will receive \$11.0 million from Stryker.

“With the recent FDA clearance, we are pleased to have attained the last milestone of our project and to report the successful conclusion of our joint development agreement with Stryker,” said Mark Augusti, President and Chief Executive Officer. “Despite the global challenges of the last 12 months, the dedication of our project and support teams has enabled us to achieve this major milestone on schedule. We now will turn our efforts to focusing on our long-term distribution agreement, under which Conformis will manufacture and supply PSI to Stryker. We continue to believe this initiative will create shareholder value as we satisfy the increasing demand for efficient outpatient ambulatory surgery center joint replacement.”

### **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](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 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 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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