
**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): July 28, 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 7.01 Regulation FD.

Warning Letter Resolution

On July 28, 2021, Conformis, Inc. (“the Company”) received a letter from the U.S. Food and Drug Administration (the “FDA”) stating that the FDA has completed its evaluation of the Company’s corrective actions in response to the December 2019 Warning Letter (defined below). Based on such evaluation, the FDA has determined that it appears that the Company has addressed the violations contained in the December 2019 Warning Letter, and that future FDA inspections and regulatory activities will further assess the adequacy and sustainability of these corrections.

Background

As previously disclosed in its Current Reports on Form 8-K filed on [December 18, 2019](#) and [March 17, 2020](#), respectively, the Company received, on December 18, 2019, a warning letter from the FDA concerning issues relating to Vaporized Hydrogen Peroxide (“VHP”) sterilizers that the Company used as a limited, alternative sterilization method for a small quantity of products (the “December 2019 Warning Letter”). The warning letter did not question product sterility. In response to the warning letter, the Company noted that it had been planning to decommission and replace the VHP sterilizers, that it had previously procured and validated a new onsite Steris VHP LTS-V sterilization unit, and that it had submitted a premarket notification to the FDA for 510(k) clearance of the new unit. On March 13, 2020, the FDA notified the Company that the FDA cleared the 510(k), allowing the Company to use the new onsite sterilizer. The Company subsequently brought the new unit into service and began processing different product groups over a period of time, decommissioning the existing VHP sterilizers as appropriate.

The information furnished under this Item 7.01 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.

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: July 30, 2021

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