

OSI SYSTEMS INC
Form 8-K
August 11, 2014

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 6, 2014**

OSI SYSTEMS, INC.

(EXACT NAME OF REGISTRANT SPECIFIED IN CHARTER)

DELAWARE
(STATE OR OTHER JURISDICTION
OF INCORPORATION)

000-23125
(COMMISSION
FILE NUMBER)

330238801
(IRS EMPLOYER
IDENTIFICATION NO.)

12525 CHADRON AVENUE

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HAWTHORNE, CA 90250

(ADDRESS OF PRINCIPAL EXECUTIVE OFFICES) (ZIP CODE)

(310) 978-0516

(REGISTRANT'S TELEPHONE NUMBER, INCLUDING AREA CODE)

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:

- ☐ 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))

Item 8.01. Other Events

Spacelabs Healthcare, Inc. ("Spacelabs"), a subsidiary of OSI Systems, Inc. (the "Company"), received a warning letter, dated August 5, 2014, from the U.S. Food and Drug Administration ("FDA"). The letter relates primarily to the maintenance of certain procedures and internal processes at the Spacelabs Snoqualmie, Washington facility.

The Company believes the warning letter does not restrict the manufacture, production or shipment of the Company's products from this facility. The Company is in the process of evaluating what corrective actions and associated costs may be required to address the matters raised in the warning letter.

The Company takes this matter seriously and intends to respond fully and in a timely manner to the FDA's warning letter. The Company cannot give any assurances that the FDA will be satisfied with the Company's response to the warning letter or its proposed resolution of the outstanding issues or that the Company will not be subject to additional regulatory action by the FDA.

Forward-Looking Statements:

This Form 8-K contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These forward-looking statements are based on the Company's current assumptions, expectations and estimates of future events and trends. Forward-looking statements are only predictions and are subject to many risks, uncertainties and other factors that may affect the Company's businesses and operations and could cause actual results to differ materially from those predicted. These risks and uncertainties include, but are not limited to, additional actions by or requests from the FDA and unanticipated costs or delays associated with resolution of these matters. Forward-looking statements contained in this Form 8-K should be considered in light of these factors and those factors discussed from time to time in the Company's public reports filed with the Securities and Exchange Commission, such as those discussed under the heading, "Risk Factors," in the Company's most recent annual report on Form 10-K and those discussed in other documents the Company files with the Securities and Exchange Commission. Given these risks and uncertainties, readers are cautioned not to place undue reliance on any forward-looking statements. Forward-looking statements contained in this Form 8-K speak only as of the date of this Form 8-K. The Company undertakes no obligation to update any forward-looking statements as a result of new information, events or circumstances or other factors arising or coming to the Company's attention after 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.

OSI SYSTEMS, INC.

Date: August 11, 2014

By:

/s/ Alan Edrick
Alan Edrick
Chief Financial Officer