

ANGIODYNAMICS INC
Form 8-K
November 14, 2014

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 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 5, 2014

AngioDynamics, Inc.
(Exact Name of Registrant as Specified in its Charter)

| | | |
|---|---------------------------------------|---|
| Delaware (State or Other Jurisdiction of Incorporation) | 000-50761 (Commission File Number) | 11-3146460 (IRS Employer Identification No.) |
|---|---------------------------------------|---|

| | |
|---|---------------------|
| 14 Plaza Drive Latham, New York (Address of Principal Executive Offices) | 12110 (Zip Code) |
|---|---------------------|

Registrant's telephone number, including area code: (518) 795-1400

(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))

Item 7.01 – Regulation FD Disclosure.

Immaterial Error Corrections

As previously disclosed, during the financial closing process for the first quarter of fiscal year 2015, AngioDynamics, Inc. (the “Company”) determined that financial management had incorrectly accounted for certain asset, liability and income statement balances, beginning in 2011. The Company has identified the amounts and concluded that they were not material, individually or in the aggregate, to any of the Company’s previously issued annual and interim financial statements. Although management has determined the amounts individually and in the aggregate are not material to prior periods, in accordance with authoritative accounting literature on considering the effects of misstatements in prior years when quantifying misstatements in the current year, the financial information included in Exhibit 99.1 hereto (the “Financial Information”) has been adjusted to correct for the impact of these items. Exhibit 99.1 is incorporated by reference into this Item 7.01.

The Company has corrected the relevant financial information from previous reporting periods contained in the Financial Information. The immaterial error corrections identified were primarily related to our failure to recognize the expense associated with prepaid and other assets in accordance with the underlying contractual terms (cumulative impact of approximately \$1.2 million) and depreciation expense (cumulative impact of approximately \$0.4 million), and other individually immaterial items.

The information being furnished pursuant to this Item 7.01 shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities under that Section. Furthermore, the information in Exhibit 99.1 shall not be deemed to be incorporated by reference into the filings of the Company under the Securities Act of 1933, as amended.

Item 8.01 – Other Events.

On November 5, 2014, the Company received a Warning Letter from the FDA relating to observations noted during FDA’s inspection of the Company’s Navilyst Medical facilities located in Marlborough, Massachusetts and Glens Falls, New York in 2014. The matters raised in the Warning Letter and observations focused on design control processes related to packaging validations and accelerated and real time aging testing in connection with the Company’s fluid management and PICC families of products, inconsistency of a manufacturing product test process used among similar valved PICC products, a particular verification test of valved PICC products and non-conforming product control procedures. The Company takes these matters seriously and is committed to complying with all applicable laws, regulations and rules in connection with the manufacturing, sale and marketing of its products. The Company intends to make a comprehensive response to the issues raised in the letter and is committed to working with FDA to resolve all outstanding issues.

Item 9.01 – Financial Statements and Exhibits.

(d) Exhibits.

99.1 Revised historical financial information.

Signature

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.

ANGIODYNAMICS, INC.

Date: November 14, 2014

/s/ Stephen A. Trowbridge
Stephen A. Trowbridge
Senior Vice President and General
Counsel

EXHIBIT INDEX

| Exhibit No. | Description |
|-------------|---|
| 99.1 | Revised historical financial information. |