

ANGIODYNAMICS INC  
Form 8-K  
January 26, 2011

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

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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): January 24, 2011

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

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

603 Queensbury Avenue, Queensbury, New York 12804  
(Address of Principal Executive Offices) (Zip Code)

(518) 798-1215  
(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.

On January 24, 2011, AngioDynamics, Inc. received a warning letter, dated January 21, 2011, from the U.S. Food and Drug Administration (the “FDA”) in connection with our marketing of the NanoKnife System. In the warning letter, the FDA states that certain statements made by AngioDynamics, including those on our company website, promote the use of the NanoKnife System beyond its currently cleared indications.

The warning letter does not restrict or prohibit the sale or marketing of our products. The warning letter does not require us to recall any products. The Company takes these matters seriously and is committed to complying with all applicable laws, rules and regulations in connection with the marketing and sale of its products. We are currently addressing the matters raised by the FDA in the warning letter and intend to work closely with the FDA to resolve any outstanding issues. Until the matters raised in the warning letter are corrected, we may be subject to additional regulatory action by the FDA, and any such actions could significantly disrupt our business and operations and have a material adverse impact on our financial position and results of operations. There can be no assurance that the FDA will be satisfied with our response. The warning letter will be posted on the FDA’s website at [www.fda.gov](http://www.fda.gov) and, once posted, will be available for viewing.

On January 25, 2011, AngioDynamics issued a press release announcing receipt of the warning letter. A copy of the press release is attached hereto as Exhibit 99.1.

Forward-Looking Statements

This document and its attachments include “forward-looking statements” intended to qualify for the safe harbor from liability established by the Private Securities Litigation Reform Act of 1995. Investors can identify these statements by the fact that they do not relate strictly to historical or current facts. These statements contain words such as “expect,” “reaffirm,” “anticipate,” “plan,” “believe,” “estimate,” “may,” “will,” “predict,” “project,” “might,” “intend,” “potential,” “could,” “would,” “should,” “optimistic,” “seek,” “continue,” “pursue,” or “our future success depends,” or the negative or other variations thereof or comparable terminology, are intended to identify such forward-looking statements. In particular, they include statements relating to, among other things, future actions, strategies, future performance and future financial results of the Company. These forward-looking statements are based on current expectations and projections about future events.

Investors are cautioned that forward-looking statements are not guarantees of future performance or results and involve risks and uncertainties that cannot be predicted or quantified and, consequently, the actual performance or results of the Company may differ materially from those expressed or implied by such forward-looking statements. Such risks and uncertainties include, but are not limited to, the factors described from time to time in the Company's reports filed with the SEC, including the Company's Form 10-K for the fiscal year ended May 31, 2010, financial community and

rating agency perceptions of the Company; the effects of economic, credit and capital market conditions on the economy in general, and on medical device companies in particular; domestic and foreign health care reforms and governmental laws and regulations; third-party relations and approvals, technological advances and patents attained by competitors; and challenges inherent in new product development, including obtaining regulatory approvals. In addition to the matters described above, the ability of the Company to develop its products, future actions by the FDA or other regulatory agencies, results of pending or future clinical trials, the outcome of pending litigation, overall economic conditions, general market conditions, market acceptance, foreign currency exchange rate fluctuations, and the effects on pricing from group purchasing organizations and competition and the ability of the Company to integrate purchased businesses, may affect the actual results achieved by the Company.

Any forward-looking statements are made pursuant to the Private Securities Litigation Reform Act of 1995 and, as such, speak only as of the date made. The Company disclaims any obligation to update the forward-looking statements. Investors are cautioned not to place undue reliance on these forward-looking statements which speak only as of the date stated, or if no date is stated, as of the date of this document.

Item 9.01 – Financial Statements and Exhibits.

(d) Exhibits.

Exhibit	Description
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No.	
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99.1	Press Release dated January 25, 2011.
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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.  
(Registrant)

Date: January 25, 2011

By: D. Joseph Gersuk  
D. Joseph Gersuk  
Chief Financial Officer

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EXHIBIT INDEX

Exhibit No.	Description
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