

WRIGHT MEDICAL GROUP INC

Form 8-K

September 15, 2011

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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): September 14, 2011
WRIGHT MEDICAL GROUP, INC
(Exact name of Registrant as specified in its charter)**

| | | |
|---|--|--|
| Delaware (State or other jurisdiction of incorporation or organization) | 000-32883 (Commission File Number) | 13-4088127 (I.R.S. Employer Identification No.) |
| 5677 Airline Road, Arlington, Tennessee (Address of principal executive offices) | | 38002 (Zip code) |
| | (901) 867-9971 (Registrant's telephone number including area code) | |

N/A

(Former name and 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))
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Item 1.01. Entry into a Material Definitive Agreement.

On September 14 and September 15, 2011, Wright Medical Group, Inc.'s wholly-owned subsidiary, Wright Medical Technology, Inc. (WMT), entered into agreements amending its previously-disclosed Deferred Prosecution Agreement (DPA) with the United States Attorney's Office for the District of New Jersey (USAO) and Corporate Integrity Agreement (CIA) with the Office of the Inspector General of the United States Department of Health and Human Services (OIG). The Addendum and Amendment to the Deferred Prosecution Agreement, dated September 15, 2011, and the Amendment to Corporate Integrity Agreement, dated September 14, 2011, are attached to this Current Report on Form 8-K as Exhibits 10.1 and 10.2, respectively, and incorporated by reference herein. Wright Medical Group, Inc. also issued a press release announcing the amendments to the DPA and CIA, which is set forth in Exhibit 99.1 hereto and is incorporated herein by reference.

Item 7.01. Regulation FD Disclosure.

On September 15, 2011, the Company issued a press release announcing the execution of the Addendum and Amendment to the Deferred Prosecution Agreement, dated September 15, 2011, and the Amendment to Corporate Integrity Agreement, dated September 14, 2011. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and incorporated by reference in this Item 7.01. The information contained in this Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed filed with the Securities and Exchange Commission nor incorporated by reference in any registration statement filed by the Company under the Securities Act of 1933, as amended.

Item 8.01. Other Events.

The description of the events described under Item 1.01 is incorporated by reference into this Item 8.01. As previously disclosed, at the direction of the Company's Board of Directors, WMT has continued to implement compliance measures and to take steps to enhance WMT's compliance environment. From time to time, WMT has provided, and may in the future provide, pursuant to Paragraph 20 of the DPA, written notices to the independent monitor and the USAO of credible evidence of violations of 21 U.S.C. § 331, a strict liability provision of the federal Food, Drug and Cosmetic Act (and any such notices have been and will be provided to the OIG). Paragraph 20 of the DPA requires WMT to provide written notice to the independent monitor and the USAO of credible evidence of violations of any criminal statute, regardless of whether any such violations are material. WMT has conducted a review of its clinical and regulatory affairs operations, and may conduct further reviews on an ongoing periodic basis. Although circumstances may change, the Company intends to disclose in its future filings with the Securities and Exchange Commission any additional occasions when WMT provides written notice under Paragraph 20 of the DPA or under the CIA only if such potential violation or violations, or any consequences therefrom, are required to be reported under U.S. federal securities laws.

Table of Contents**Item 9.01. Financial Statements and Exhibits.****(d) Exhibits.**

| Exhibit Number | Description |
|---------------------------|---|
| 10.1 | Addendum and Amendment to the Deferred Prosecution Agreement, dated September 15, 2011, between Wright Medical Technology, Inc. and the United States Attorney's Office for the District of New Jersey. |
| 10.2 | Amendment to Corporate Integrity Agreement, dated September 14, 2011, between Wright Medical Technology, Inc. and the Office of Inspector General of the Department of Health and Human Services. |
| 99.1 | Press Release, dated September 15, 2011. |

Cautionary Note Regarding Forward-Looking Statements:

This Current Report contains forward-looking statements as defined under U.S. federal securities laws, including statements regarding potential actions by the USAO, independent monitor, OIG and other agencies or their potential impact. These statements reflect management's current knowledge, assumptions, beliefs, estimates, and expectations and express management's current views of future performance, results, and trends and may be identified by their use of terms such as anticipate, believe, could, estimate, expect, intend, may, plan, predict, project, will, and other similar terms. Forward-looking statements are subject to a number of risks and uncertainties that could cause our actual results to materially differ from those described in the forward-looking statements. You should not place undue reliance on forward-looking statements. Such statements are made as of the date of this Current Report, and we undertake no obligation to update such statements after this date. Risks and uncertainties that could cause our actual results to materially differ from those described in forward-looking statements include those discussed in our filings with the Securities and Exchange Commission (including those described in Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2010, and our subsequently filed quarterly reports, under the heading Risk Factors and elsewhere), future actions of the FDA or any other regulatory body or government authority that could delay, limit or suspend product development, manufacturing or sale or result in seizures, injunctions, monetary sanctions or criminal or civil liabilities, the impact of any such future actions of the FDA or any other regulatory body or government authority on our settlement of the federal investigation into our consulting arrangements with orthopaedic surgeons relating to our hip and knee products in the United States, and the impact of such settlement of the federal investigation into our consulting arrangements with orthopaedic surgeons relating to our hip and knee products in the United States, including our compliance with the Deferred Prosecution Agreement through September 2012 and the Corporate Integrity Agreement through September 2015. Our failure to comply with the Deferred Prosecution Agreement or the Corporate Integrity Agreement could expose us to significant liability including, but not limited to, exclusion from federal healthcare program participation, including Medicaid and Medicare, which would have a material adverse effect on our financial condition, results of operations and cash flows, potential prosecution, including under the previously-filed criminal complaint, civil and criminal fines or penalties, and additional litigation cost and expense. In addition, a breach of the DPA or the CIA could result in an event of default under the Senior Credit Facility, which in turn could result in an event of default under the Indenture.

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Additional risks and uncertainties that could cause our actual results to materially differ from those described in forward-looking statements include the possibility of litigation brought by shareholders, including private securities litigation and shareholder derivative suits, which if initiated, could divert management's attention, harm our business and/or reputation and result in significant liabilities; demand for and market acceptance of our new and existing products; future actions of governmental authorities and other third parties; tax measures; business development and growth opportunities; product quality or patient safety issues; products liability claims; enforcement of our intellectual property rights; the geographic and product mix impact on our sales; retention of sales representatives and independent distributors; inventory reductions or fluctuations in buying patterns by wholesalers or distributors; ability to realize the anticipated benefits of restructuring initiatives; and impact of the commercial and credit environment on us and our customers and suppliers.

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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, thereunto duly authorized.

WRIGHT MEDICAL GROUP, INC.

By: /s/ David D. Stevens

David D. Stevens
Interim Chief Executive Officer

Dated: September 15, 2011

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