Wright Medical Group N.V.
Form 8-K
April 07, 2016

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): April 4, 2016

WRIGHT MEDICAL GROUP N.V.

(Exact name of registrant as specified in its charter)

The Netherlands	**1-35065**	**98-0509600**
(State or other jurisdiction	**(Commission**	**(I.R.S. Employer**

of incorporation)	File Number)	Identification No.)

Prins Bernhardplein 200

1097 JB Amsterdam

The Netherlands	None
(Address of principal executive offices)	(Zip Code)

(+ 31) 20 521 4777

(Registrant s telephone number, including area code)

Not Applicable

(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:

¨ 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 1.01. Entry into a Material Definitive Agreement.

On April 4, 2016, BioMimetic Therapeutics, LLC (Company), a Delaware limited liability company and wholly-owned subsidiary of Wright Medical Group N.V. (Wright), entered into a commercial supply agreement (Supply Agreement) with FUJIFILM Diosynth Biotechnologies U.S.A., Inc., a Delaware corporation (Fujifilm), pursuant to which Fujifilm has agreed to manufacture and sell to the Company and the Company has agreed to purchase recombinant human platelet-derived growth factor (rhPDGF-BB) for use in AUGMENT® Bone Graft. The Supply Agreement reflects the culmination of a technology transfer from the Company s former supplier to Fujifilm which began in December 2013 when the Company was notified that its former supplier was exiting the rhPDGF-BB business.

Pursuant to the Supply Agreement, commercial production of rhPDGF-BB is expected to begin in 2019. The Company believes that its current supply of rhPDGF-BB from its former supplier should be sufficient to last until after rhPDGF-BB becomes available under the Supply Agreement.

Under the Supply Agreement, the Company has agreed to pay certain specified fees to Fujifilm in 2017 and 2018, and beginning in 2019, has agreed to pay fees based on the actual amount of rhPDGF-BB ordered, with annual orders subject to a minimum and maximum quantity.

The Supply Agreement has a five-year term with automatic three-year renewal terms unless either party provides 24-months notice of non-renewal. The Supply Agreement may be terminated earlier by a party if the other party is in default of its material obligations under the agreement and has not cured them after a 45-day notice and cure period. In addition, either party may immediately terminate upon written notice to the other party if the other party is declared insolvent or bankrupt, files a voluntary petition in bankruptcy or the agreement is assigned by the other party for the benefit of creditors.

Upon expiration or termination of the Supply Agreement under certain specified circumstances, Fujifilm is required to provide and sell to the Company and the Company is required to purchase from Fujifilm a minimum quantity of rhPDGF-BB and Fujifilm is required, upon the Company s written request and at its expense, to initiate a technical transfer of the manufacturing process to a third-party manufacturer specified by the Company.

The foregoing description of the Supply Agreement is qualified in its entirety by reference to the Supply Agreement, which is filed as Exhibit 10.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
10.1*	Commercial Supply Agreement dated March 29, 2016 between BioMimetic Therapeutics, LLC and FUJIFILM Diosynth Biotechnologies U.S.A., Inc. (filed herewith)

* Certain portions of this exhibit have been omitted pursuant to a request for confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934, as amended, and have been filed separately with the Securities and Exchange Commission.

Cautionary Note Regarding Forward-Looking Statements

This Current Report on Form 8-K includes forward-looking statements under the Private Securities Litigation Reform Act of 1995. These forward-looking statements generally can be identified by the use of words such as expect, anticipate, could, should, may, will, believe, estimate, continue, future, other words of similar meani future dates. Forward-looking statements in this report include, but are not limited to, statements about the anticipated timing of commercial production of rhPDGF-BB and the Company s current supply of and future requirements for rhPDGF-BB. Forward-looking statements by their nature address matters that are, to different degrees, uncertain. Each forward-looking statement contained in this report is subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statement. Applicable risks and uncertainties include, among others, the ability of Fujifilm to manufacture and supply rhPDGF-BB in sufficient quantities required by the Company and the anticipated timing thereof; the adequacy of the Company s current supply of rhPDGF-BB and how long it is expected to last; required regulatory approvals and the timing thereof; physician acceptance, endorsement, and use of AUGMENT® Bone Graft; failure to achieve the anticipated benefits from approval of and anticipated future sales of AUGMENT® Bone Graft; the effect of regulatory actions, changes in and adoption of reimbursement rates; product liability claims and product recalls; pending and threatened litigation; competitor activities; and the other risks identified under the heading Risk Factors in Wright s Annual Report on Form 10-K for the year ended December 27, 2015 filed by Wright with the SEC on February 23, 2016. Investors should not place considerable reliance on the forward-looking statements contained in this report. You are encouraged to read Wright s filings with the SEC, available at www.sec.gov, for a discussion of these and other risks and uncertainties. The forward-looking statements in this report speak only as of the filing date of this report, and Wright undertakes no obligation to update or revise any of these statements. Wright s business is subject to substantial risks and uncertainties, including those referenced above. Investors, potential investors, and others should give careful consideration to these risks and uncertainties.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: April 7, 2016

WRIGHT MEDICAL GROUP N.V.

By: /s/ James A. Lightman
Name: James A. Lightman
Title: Senior Vice President, General Counsel and Secretary

WRIGHT MEDICAL GROUP N.V.

CURRENT REPORT ON FORM 8-K

EXHIBIT INDEX

Exhibit No.	Description	Method of Filing
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