NUVELO INC
Form 8-K
June 26, 2007

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 earliest event reported: June 26, 2007

Nuvelo, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware	**000-22873**	**36-3855489**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

201 Industrial Road, Suite 310, San Carlos, CA 94070-6211

(Address of Principal Executive Offices) (Zip Code)

(650) 517-8000

(Registrant s telephone number, including area code)

N/A

(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 1.01. Entry into a Material Definitive Agreement.

On June 26, 2007, Nuvelo, Inc. and Bayer Healthcare AG, or Bayer, entered into a letter agreement pursuant to which, among other things, (i) the license and collaboration agreement with Bayer Healthcare AG, or Bayer, entered into by the companies on January 4, 2006 regarding the development and commercialization of alfimeprase (the Bayer Agreement), was terminated and (ii) Nuvelo granted to Bayer a one-time, non-transferable option to re-acquire rights to develop and commercialize alfimeprase outside of the United States. Item 1.02 of this Current Report on Form 8-K is incorporated by reference into this Item 1.01.

Item 1.02. Termination of a Material Definitive Agreement.

On June 26, 2007, Nuvelo announced Bayer had terminated the Bayer Agreement. Under the terminated Bayer Agreement, and subject to certain limitations, all expenses in the global development of alfimeprase incurred after January 1, 2006 were to be funded 60% by Nuvelo and 40% by Bayer. Each party solely bore the expense of any country-specific alfimeprase clinical trials conducted by it, where the country-specific clinical trials were not part of the agreed global development program. Upon entry into the Bayer Agreement, Bayer paid to Nuvelo an up-front payment of $50 million.

On December 11, 2006, Nuvelo and Bayer announced that the Phase 3 clinical trial of alfimeprase in acute peripheral arterial occlusion (PAO) known as NAPA-2 (Novel Arterial Perfusion with Alfimeprase-2), did not meet its primary endpoint of avoidance of open vascular surgery within 30 days of treatment, and that the Phase 3 trial in catheter occlusion (CO), known as SONOMA-2 (Speedy Opening of Non-functional and Occluded catheters with Mini-dose Alfimeprase-2), did not meet the endpoint of restoration of function at 15 minutes. In addition, on December 11, 2006, the companies announced that they had suspended enrollment in the ongoing Phase 3 trials, NAPA-3 and SONOMA-3. As a result of these announcements, and based on further analyses and discussions with outside experts and regulatory agencies, the companies determined that further prosecution of the Bayer Agreement was not in the best interests of the companies and the agreement was terminated.

The termination of the Bayer Agreement was memorialized in a letter agreement entered into June 26, 2007. Pursuant to this letter agreement, Bayer is to pay Nuvelo the non-refundable sum of $15 million within 30 days. Separately, any development expenses incurred during the calendar quarter ending June 30, 2007 will be reconciled between the companies in accordance with the terms of the Bayer Agreement. Nuvelo agreed to waive its rights under the Bayer Agreement to require Bayer to (i) provide twelve months written notice of termination, (ii) to continue to reimburse Nuvelo for Bayer s share of approved development expenses, and (iii) to pay Nuvelo the milestone payment, if any, upon Nuvelo s initiation of a phase 2 clinical trial in a stroke indication. The termination of the Bayer Agreement will otherwise be in accordance with its terms.

Further, pursuant to the letter agreement, Nuvelo granted to Bayer a one-time, non-transferable option to re-acquire, upon payment of an additional $15 million, the right to develop and commercialize alfimeprase outside of the United States. The option is exercisable by Bayer in its sole discretion for 30 days following notice of either Nuvelo s initiation of a pivotal trial of alfimeprase in a stroke indication or Nuvelo s public announcement that it is discontinuing further development of alfimeprase in a stroke indication.

Nuvelo incurred no early termination penalties as a result of the termination of the Bayer Agreement.

On June 26, 2007, Nuvelo issued a press release titled Nuvelo Resumes Development of

Alfimeprase in Multiple Blood-Clot Related Indications, a copy of which is attached hereto as Exhibit 99.1 and is incorporated by reference herein. Neither the filing of any press release as an exhibit to this Current Report on Form 8-K nor the inclusion in that press release of a reference to Nuvelo s Internet address shall, under any circumstances, be deemed to incorporate the information available at such Internet address into this Current Report on Form 8-K. The information available at such Internet address is not part of this Current Report on Form 8-K or any other report filed by Nuvelo with the Securities and Exchange Commission.

ITEM 9.01 FINANCIAL STATEMENTS AND EXHIBITS.

(d) Exhibits

Exhibit Number	**Description**
10.61	Letter Agreement dated June 26, 2007 between Bayer Healthcare AG and Nuvelo, Inc
99.1	Press Release titled Nuvelo Resumes Development of Alfimeprase in Multiple Blood-Clot Related Indications dated June 26, 2007

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.

Nuvelo, Inc.

(Registrant)

By: /s/ Lee Bendekgey
Lee Bendekgey
Senior Vice President and General Counsel

Dated: June 26, 2007

EXHIBIT INDEX

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