NUVELO INC
Form 8-K
January 06, 2006

# 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: January 4, 2006**

# 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)**

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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 January 4, 2006, Nuvelo, Inc. entered into a license and collaboration agreement with Bayer Healthcare AG, or Bayer, regarding the development and commercialization of alfimeprase, Nuvelo s lead Phase 3 product candidate. Under the terms of this agreement, Nuvelo has granted an exclusive, fee-bearing license for alfimeprase to Bayer in all countries of the world except the United States, and Nuvelo has retained the right to exclusively develop and commercialize alfimeprase in the United States. Bayer has the right, subject to certain conditions, to sublicense its rights to develop and commercialize alfimeprase, and also has a right of first refusal should Nuvelo offer a third party an exclusive or co-exclusive license to commercialize alfimeprase in the United States.

Subject to certain limitations, all expenses in the global development of alfimeprase incurred after January 1, 2006 will be funded 60% by Nuvelo and 40% by Bayer. Nuvelo is not obligated to expend more than $60 million in any calendar year on its share of global development expenses for alfimeprase. Each party will solely bear the expense of any country-specific alfimeprase clinical trials conducted by it, where the country-specific clinical trials are not part of the agreed global development program. The license and collaboration agreement establishes joint committees with equal representation of both Nuvelo and Bayer to manage the global development and commercialization of alfimeprase. The committees will operate by consensus, but if consensus cannot be reached, Nuvelo will have the deciding vote with respect to the alfimeprase global development program and any issues related to global branding of alfimeprase.

Nuvelo will supply alfimeprase to Bayer for use in global development of alfimeprase without charging Bayer separately for those supplies, but will be entitled to include the costs of manufacturing these supplies in the development expenses shared by the two parties. In addition, the parties have agreed to use diligent efforts to negotiate and complete a manufacturing agreement within 6 months, pursuant to which Nuvelo will sell alfimeprase to Bayer for use in any country-specific trials conducted by Bayer and for commercial sale by Bayer in any countries outside the United States in which alfimeprase is approved for sale.

Under the license and collaboration agreement, Bayer will pay to Nuvelo an up-front payment of $50 million. In addition, Bayer has agreed to make milestone payments upon the occurrence of negotiated development milestone events and sales milestone events. If all development milestone events are achieved, total development milestone payments due to Nuvelo under the agreement will total $165 million. If all sales milestone events are achieved, total sales milestone payments due to Nuvelo under the agreement will total $170 million.

Bayer has agreed to pay Nuvelo a royalty based on annual net sales of alfimeprase made by Bayer or its affiliates in any country outside the United States. The royalty rate varies based on the level of annual net sales of alfimeprase made by Bayer and its affiliates, ranging from a minimum of 15% up to a maximum of 37.5%. Nuvelo s right to receive royalties from Bayer for the sale of alfimeprase expires on a country by country basis upon the later of (a) ten years after the date of first commercial sale of alfimeprase in that country and (b) the earlier of (i) the expiration of regulatory exclusivity in that country or (ii) the expiration of the last-to-expire of certain patent rights related to alfimeprase in that country, subject to certain exceptions. Nuvelo retains the obligation to pay any amounts due to Amgen Inc. under the license agreement between Nuvelo and Amgen dated November 4, 2004.

On January 5, 2006, Nuvelo issued a press release titled Nuvelo And Bayer Healthcare Enter Comprehensive Collaboration Agreement to Maximize Global Development and Commercialization of Alfimeprase, a copy of which is attached hereto as Exhibit 99.1 and is incorporated by reference herein.

This Current Report on Form 8-K contains forward-looking statements regarding the timing and amount of payments that Nuvelo may receive from Bayer under the license and collaboration agreement between Nuvelo and Bayer, the timing and progress of Nuvelo s alfimeprase clinical programs, and the potential improvement or benefit that Nuvelo s alfimeprase clinical programs may demonstrate and alfimeprase s market potential, which statements are hereby identified as forward-looking statements for purposes of the safe harbor provided by the Private Securities Litigation Reform Act of 1995. Such statements are based on Nuvelo s management s current expectations and involve risks and uncertainties. Actual results and performance could differ materially from those projected in the forward looking statements as a result of many factors, including, without limitation, uncertainties relating to drug discovery; clinical development processes; enrollment rates for patients in clinical trials; changes in relationships with strategic partners and dependence upon strategic partners for the performance of critical activities under collaborative agreements; the impact of competitive products and technological changes; uncertainties relating to patent protection and uncertainties relating to Nuvelo s ability to obtain funding. These and other factors are identified and described in more detail in Nuvelo s filings with the Securities and Exchange Commission, including without limitation Nuvelo s recent annual report on Form 10-K for the year ended December 31, 2004 and subsequent filings. Nuvelo disclaims any intent or obligation to update these forward-looking statements.

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.**

**(c) Exhibits**

| **Exhibit Number** | **Description** |
|---|---|
| 99.1 | Press Release titled Nuvelo And Bayer Healthcare Enter Comprehensive Collaboration Agreement to Maximize Global Development and Commercialization of Alfimeprase, dated January 5, 2006. |

**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: January 6, 2006

**EXHIBIT INDEX**

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