NUVELO INC
Form 8-K
December 12, 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: December 11, 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)

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 8.01 OTHER EVENTS.

On December 11, 2006, Nuvelo, Inc. and Bayer HealthCare issued a press release regarding top-line data demonstrating 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. The companies also announced 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. These trials did not meet key secondary endpoints. In addition, the companies announced that they have temporarily suspended enrollment in the ongoing Phase 3 trials, NAPA-3 and SONOMA-3, until further analyses and discussions with outside experts and regulatory agencies are completed.

A copy of Nuvelo s press release, titled Nuvelo and Bayer Healthcare Announce Phase 3 Trials of Alfimeprase in Patients with Acute Peripheral Arterial Occlusion and Catheter Occlusion Did Not Meet Primary Endpoints, is attached hereto as Exhibit 99.1 and incorporated herein by reference.

Forward-looking statements

This Current Report on Form 8-K contains forward-looking statements regarding the timing and progress of Nuvelo s clinical programs, including the timing of the availability of data from Nuvelo s Phase 3 alfimeprase trials and the potential improvement or benefit that current and future clinical trial programs may demonstrate, 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 our 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; and uncertainties relating to our ability to obtain funding. These and other factors are identified and described in more detail in Nuvelo filings with the SEC, including without limitation Nuvelo s Quarterly Report on Form 10-Q for the quarter ended September 30, 2006 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.

(d) Exhibits

Exhibit Number	Description
99.1	Press Release titled Nuvelo and Bayer Healthcare Announce Phase 3 Trials of Alfimeprase in Patients with Acute Peripheral Arterial Occlusion and Catheter Occlusion Did Not Meet Primary Endpoints, dated December 11, 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: December 12, 2006

EXHIBIT INDEX

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