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**SECURITIES AND EXCHANGE COMMISSION**

WASHINGTON, D.C. 20549

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**FORM 8-K**

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**CURRENT REPORT**

**Pursuant to Section 13 or 15(d) of the  
Securities Exchange Act of 1934**

**Date of earliest event reported: February 4, 2004**

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**Nuvelo, Inc.**

(Exact Name of Registrant as Specified in Charter)

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**Nevada**  
(State or Other Jurisdiction  
of Incorporation)

**000-22873**  
(Commission File Number)

**36-3855489**  
(I.R.S. Employer  
Identification No.)

**675 Almanor Avenue, Sunnyvale, California 94085**  
(Address of Principal Executive Offices) (Zip Code)

**(408) 215-4000**  
(Registrant's telephone number, including area code)

**N/A**  
(Former Name or Former Address, if Changed Since Last Report)

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EXHIBIT 99.1

EXHIBIT 99.2

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**ITEM 5. Other Events.**

The text of a press release dated February 4, 2004 is attached to this report as Exhibit 99.1.

**ITEM 7. Financial Statements, Pro Forma Financial Information and Exhibits.**

(c) Exhibits.

The following exhibits are filed with this Form 8-K:

99.1 Press Release dated February 4, 2004.

99.2 Press Release dated February 5, 2004.

**ITEM 12. Results of Operations and Financial Condition.**

On February 5, 2004, we issued a press release, which sets forth our results of operations for the year ended December 31, 2003. A copy of the press release is attached hereto as Exhibit 99.2 and is incorporated herein by reference.

The information in this Current Report on Form 8-K, including Exhibit 99.1 and Exhibit 99.2, is furnished pursuant to Item 5 and Item 12 and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liability of that section, and is not incorporated by reference into any filing of the company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

**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/ Peter S. Garcia

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Peter S. Garcia  
Senior Vice President and Chief Financial Officer

Dated: February 5, 2004

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**Exhibit Index**

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release dated February 4, 2004.
99.2	Press Release dated February 5, 2004.

**Nuvelo Contacts:**

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**NUVELO LICENSES rNAPc2, A NOVEL ANTICOAGULANT, FROM DENDREON**

*—Nuvelo adds Phase 2 product candidate to its cardiovascular pipeline—*

SUNNYVALE, Calif. and SEATTLE, Wash., February 4, 2004 /PRNewswire/— Nuvelo, Inc. (Nasdaq: NUVO) today announced a worldwide licensing agreement with Dendreon Corporation (Nasdaq: DNDN) for Dendreon's novel anticoagulant, recombinant nematode anticoagulant protein c2 (rNAPc2) and all other rNAPc proteins.

Under the terms of the agreement, Nuvelo will pay to Dendreon in cash and common stock an upfront payment of \$4 million. In addition to the upfront payment, the agreement provides for milestone payments for development and royalties upon the commercialization of rNAPc product candidates. Nuvelo will own worldwide rights to all indications for rNAPc products. No additional financial terms were disclosed.

“Given Dendreon's focus on oncology product development, we are pleased to license the rNAPc2 program to Nuvelo while maintaining the downstream potential for this product candidate through a potential royalty stream,” said Mitchell H. Gold, M.D., president and chief executive officer of Dendreon. “We believe Nuvelo has the capabilities to effectively advance rNAPc2.”

“rNAPc2 is a natural fit for Nuvelo,” said Dr. Ted W. Love, president and chief executive officer of Nuvelo. “The addition of this molecule strengthens our cardiovascular portfolio of product candidates and our promising research pipeline.”

The novel anticoagulant rNAPc2 is a naturally occurring protein that was originally isolated from hookworms and is currently manufactured as a recombinant protein for clinical use. The anticoagulant effect of rNAPc2 results from its apparent ability to block the Factor VIIa/Tissue Factor protease complex, which is responsible for the initiation of the process leading to blood clot formation. Unlike aspirin, heparin and antiplatelet agents, which exert their effects at later stages of the blood coagulation cascade, rNAPc2 blocks the first step in the clotting cascade, inhibiting coagulation before it starts.

Currently, a multi-center, Phase 2a study to investigate the safety and efficacy of rNAPc2 in patients with acute coronary syndromes (ACS) is being conducted with the TIMI Study Group led by Dr. Eugene Braunwald of Brigham and Women's Hospital and Harvard Medical School. Nuvelo plans to complete the Phase 2a study and based on the data, further evaluate how to move clinical development forward.

ACS is a potentially life threatening heart condition that usually occurs when an atherosclerotic plaque ruptures in one or more arteries of the heart. This rupture triggers a series of biochemical events known as the blood coagulation cascade, which results in the formation of a blood clot. Blocking the flow of blood through the heart, the clot deprives heart tissues of oxygen, causing chest pain. The use of rNAPc2 may significantly reduce the risk of heart attack or death in patients suffering from ACS.

In both the United States and Europe, ACS accounts for more than 1 million hospitalizations annually. Despite current treatments, a significant proportion of patients still experience recurrent angina, myocardial infarction or death.

“Given the significant number of patients with acute coronary syndromes who continue to experience poor outcomes, there is a clear need for better anticoagulant therapy,” said Dr. Love. “rNAPc2 has the potential to offer safer, more effective anticoagulation, reducing bleeding side-effects and the formation of unwanted blood clots.”

To date, rNAPc2 has been shown to be well tolerated in over 500 patients and healthy volunteers in several Phase 1 and 2 studies. A Phase 2 study for the prevention of deep vein thrombosis (DVT) demonstrated that rNAPc2 appears to reduce the risk of developing DVT and related complications by over 50% compared to the current standard therapy for patients undergoing total knee replacement surgery without compromising safety. A second Phase 2a study demonstrated that rNAPc2 was well-tolerated when added to standard therapy with unfractionated heparin, aspirin and clopidogrel in patients undergoing elective percutaneous coronary intervention (PCI). This study also demonstrated that rNAPc2 suppresses the formation of thrombin for at least 36 hours following a single administration, compared to standard therapy alone, in which thrombin generation continued unabated.

Other potential indications under evaluation include orthopedic and vascular surgery, Ebola and cancer. A recent study published in *The Lancet* suggests rNAPc2 may be effective in the treatment of the Ebola virus infection. In addition, preclinical studies published in *Cancer Research* showed that blocking the protease complex Factor VIIa/Tissue Factor prevented the growth of primary and metastatic tumors in animal models.

#### About Nuvelo

Nuvelo, Inc. is engaged in the discovery, development and commercialization of life improving therapeutics for the treatment of human disease. Nuvelo's lead product candidate, alfimeprase, is partnered with Amgen and is currently in two Phase 2 trials in two indications, peripheral arterial occlusion and catheter occlusion. Additional programs include cardiovascular candidate ARC183, and drug discovery focused on antibody targets and secreted proteins.

Further information about Nuvelo is available at [www.nuvelo.com](http://www.nuvelo.com) or by phoning 408-215-4000.

#### About Dendreon

Dendreon Corporation is a biotechnology company developing targeted therapies for cancer. The company's lead investigational product candidate, Provenge<sup>®</sup>, is a cancer immunotherapy undergoing a pivotal Phase 3 clinical trial for the treatment of androgen independent prostate cancer. In addition to its immunotherapies in clinical and preclinical development for a variety of cancers, Dendreon's product pipeline also includes monoclonal antibody, small molecule and pro-drug product candidates.

#### Nuvelo Safe Harbor

Statements contained in this press release which are not historical in nature, are intended to be, and are hereby identified as “forward-looking statements” for purposes of the safe harbor provided by the Private Securities Litigation Reform Act of 1995. Forward-looking statements may be identified by words such as “believe,” “expect,” “anticipate,” “should,” “may,” “estimate,” “goals,” and “potential,” among others. Such statements are based on our 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 and the development and commercialization of our molecular diagnostics technology;

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 regulatory approval; and uncertainties relating to our ability to obtain substantial additional funds required for progress in drug discovery and development. These and other factors are identified and described in more detail in Nuvelo and Hyseq filings with the SEC, including without limitation Nuvelo's annual report on Form 10-K and the related Form 10-K/A for the year ended December 31, 2002 and Nuvelo's quarterly report on Form 10-Q for the quarter ended September 30, 2003. We disclaim any intent or obligation to update these forward-looking statements.

#### Dendreon Safe Harbor

Except for historical information contained herein, this news release contains forward looking statements that are subject to risks and uncertainties that may cause actual results to differ materially from the results discussed in the forward-looking statements, particularly those risks and uncertainties relating to our dependence on the efforts of third parties, including Nuvelo, Inc., and risks and uncertainties inherent in the process of discovering, developing and commercializing drugs that are safe and effective for use as human therapeutics. Factors that may cause such a difference include risks related to Dendreon's limited operating history, risks associated with development of product candidates through clinical research and development, risks associated with completing clinical trials, the risk that the safety and/or efficacy results of clinical trials will not support further development, the risks that the safety and/or efficacy results of a clinical trial will not support an application for a biologics license, the risk that the FDA will not approve a product for which a biologics license application has been applied, the failure by Dendreon to secure and maintain relationships with collaborators, and dependence on intellectual property. Further information on the factors and risks that could affect Dendreon's business, financial condition and results of operations, are contained in Dendreon's public disclosure filings with the U.S. Securities and Exchange Commission, which are available at [www.sec.gov](http://www.sec.gov).

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NUVELO REPORTS FOURTH QUARTER AND YEAR END 2003 RESULTS,  
ACCOMPLISHMENTS AND 2004 FORWARD OUTLOOK

SUNNYVALE, Calif., February 5, 2004 /PRNewswire/ – Nuvelo, Inc. (Nasdaq: NUVO) today announced fourth quarter and year end 2003 financial results, accomplishments and 2004 forward outlook.

For the three months ended December 31, 2003, Nuvelo reported a net loss of \$9.4 million or \$0.12 per share compared to a net loss of \$16.5 million or \$0.72 per share for the same period in 2002. The net loss decrease of \$7.1 million was primarily attributed to decreased research and administrative costs in the fourth quarter as Nuvelo continued to streamline operations, focusing spending on the development of its lead drug candidate, alfimeprase. This was partially offset by a decrease in revenue from Nuvelo's collaboration with BASF Plant Science LLC which was completed in January 2003. Revenues for the fourth quarter of 2003 were approximately \$0.4 million, compared to revenues of \$3.5 million for the same period in 2002. For the twelve months ended December 31, 2003 Nuvelo reported a net loss of \$50.2 million or \$0.79 per share, compared to a net loss of \$45.0 million or \$2.08 per share for the same period in 2002. The loss per share for the three months and year ended December 31, 2003 was impacted and reduced from the same period in 2002 as a result of additional shares issued through the acquisition of VARIAGENICS, Inc., which was completed on January 31, 2003.

As of December 31, 2003, Nuvelo had approximately \$34.7 million in cash, cash equivalents, short-term investments and restricted cash compared to approximately \$3.3 million at December 31, 2002.

“This time last year we committed to a singular strategic focus on therapeutic products and a promise to build a formidable biopharmaceutical business,” stated Dr. Ted W. Love, president and chief executive officer of Nuvelo. “Throughout the past year, Nuvelo has continued to deliver on this promise. Through its recent partnerships, Nuvelo has created a robust cardiovascular franchise including alfimeprase, a novel thrombolytic currently in two Phase 2 trials, ARC183, an anticoagulant poised to begin a Phase 1 trial in the second half of 2004 and most recently, rNAPc2, a novel anticoagulant currently in Phase 2 trials.”

## Recent Highlights

- Licensed novel anticoagulant, rNAPc2, from Dendreon, acquiring worldwide rights to all indications including acute coronary syndromes (ACS), orthopedic and vascular surgery, Ebola and cancer
- Appointed former Goldman Sachs executive, Barry L. Zubrow, to Nuvelo's board of directors
- Filed a universal shelf registration statement with the SEC to offer up to \$75 million worth of common or preferred stock, or debt securities, to be used for general corporate purposes, including capital expenditures and to meet working capital needs
- Entered into a 50/50 partnership with Archemix to develop and commercialize ARC183, Archemix's thrombin inhibitor for potential use in coronary artery bypass graft (CABG) surgery, percutaneous coronary intervention (PCI) and other acute anticoagulant applications
- Appointed current Gilead Sciences executive, Mark L. Perry, to Nuvelo's board of directors
- Completed a financing with net proceeds of approximately \$26 million
- Successfully completed the Phase 1 alfimeprase trial in peripheral arterial occlusion (PAO) and rapidly initiated two Phase 2 trials in both PAO and catheter occlusion. Subsequently reported successful completion of an interim analysis of our Phase 2 clinical trial for the potential treatment of patients with PAO
- Entered into a patent assignment and license agreement with SEQUENOM assigning to them the entire chemical cleavage patent estate acquired through our merger with VARIAGENICS, as well as an exclusive worldwide license to nine restriction enzyme patents
- Completed the merger with VARIAGENICS and changed our name to Nuvelo

## 2004 Outlook

- Reinitiate enrollment of the Phase 2a rNAPc2 trial
- Based on our current rate of enrollment, we anticipate completing enrollment of the Phase 2 alfimeprase trial in PAO in March or April of 2004
- Based on our current rate of enrollment, we anticipate completing the interim analysis of the Phase 2 alfimeprase trial in catheter occlusion in March or April of 2004
- Expect to initiate the Phase 3 alfimeprase trial in PAO in the second half of 2004
- Expect to initiate the Phase 1 ARC183 trial in the second half of 2004
- Expect to complete the analysis of the 50 secreted protein genes in our Kirin collaboration in the first half of 2004
- Expect to advance at least one internal product candidate into IND-enabling studies in 2004
- Actively seeking to secure strategic partners for our antibody target and/or secreted proteins programs
- Continue to monetize assets outside of our therapeutic focus

## Conference Call Information

Nuvelo will hold a conference call today at 4:30 p.m. Eastern Time (1:30 p.m. Pacific Time) to discuss this announcement. To participate in the conference call, please dial 800/915-4836 for domestic callers and 973/317-5300 for international callers. A telephone replay of the conference call will be available through Thursday, February 19, 2004. To access the replay, please dial 800/428-6051 for domestic callers and 973/709-2089 for international callers, and reference pass code 333575.

This call is also being webcast by CCBN and can be accessed at Nuvelo's Web site at [www.nuvelo.com](http://www.nuvelo.com), CCBN's individual investor center at [www.companyboardroom.com](http://www.companyboardroom.com) or by visiting any of the investor sites in CCBN's Individual Investor Network. Institutional investors can access the call via CCBN's password-protected event management site, StreetEvents ([www.streetevents.com](http://www.streetevents.com)).

#### About Nuvelo

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**NUVELO, INC.**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**  
(in thousands, except per share amounts)  
(unaudited)

	Three months ended		Twelve months ended	
	December 31, 2003	December 31, 2002	December 31, 2003	December 31, 2002
Contract Revenue:	\$ 350	\$ 3,518	\$ 2,290	\$ 26,433
Operating expense:				
Research and development	6,664	9,268	33,084	50,157
General and administrative	2,837	9,005	17,223	18,108
Restructuring	—	1,462	—	2,067
Loss on sale of fixed assets	14	2	1,225	36
Total operating expenses	9,515	19,737	51,532	70,368
Loss from operations	(9,165)	(16,219)	(49,242)	(43,935)
Realized gain on investment	—	—	40	—
Interest expense, net	(224)	(291)	(985)	(1,155)
Loss before minority interest	(9,389)	(16,510)	(50,187)	(45,090)
Loss attributable to minority interest	—	—	—	112
Net loss	\$ (9,389)	\$ (16,510)	\$ (50,187)	\$ (44,978)
Basic and diluted net loss per share	\$ (0.12)	\$ (0.72)	\$ (0.79)	\$ (2.08)
Weighted average shares used in computing basic and diluted net loss per share	75,610	23,039	63,163	21,661

**CONDENSED CONSOLIDATED BALANCE SHEET  
AND OTHER DATA**  
(in thousands)  
(unaudited)

	December 31, 2003	12/31/2002 *
Cash, cash equivalents and short term investments	\$ 34,189	\$ 2,225
Restricted cash	501	1,106
Total assets	57,809	27,072
Deferred revenue	—	525
Line of credit	10,542	10,000
Noncurrent portion of capital leases	1,079	1,026
Notes payable - long term	6,600	4,000
Accumulated deficit	(203,559)	(153,372)
Total stockholders' equity (deficit)	\$ 22,701	\$ (4,564)

\* The condensed consolidated balance sheet data at December 31, 2002 has been derived from the audited financial statements as of that date.

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