

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK**

---

BARRY LOGAN, Individually and On Behalf of All Others Similarly Situated,	)	
	)	<b>CIVIL ACTION NO.</b>
	)	
Plaintiff,	)	
	)	<b>CLASS ACTION COMPLAINT</b>
vs.	)	
	)	
NUVELO, INC., TED W. LOVE, GARY S. TITUS, and SHELLY D. GUYER	)	<b><u>JURY TRIAL DEMANDED</u></b>
	)	
Defendants.	)	

---

Plaintiff, Barry Logan (“Plaintiff”), alleges the following based upon the investigation by Plaintiff’s counsel, which included, among other things, a review of the Defendants’ public documents, conference calls and announcements made by Defendants, United States Securities and Exchange Commission (“SEC”) filings, wire and press releases published by and regarding Nuvelo, Inc. (“Nuvelo” or the “Company”), securities analysts’ reports and advisories about the Company, and information readily available on the Internet, and Plaintiff believes that substantial additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

**NATURE OF THE ACTION AND OVERVIEW**

1. This is a federal class action on behalf of purchasers of the publicly traded securities of Nuvelo between January 5, 2006 and December 8, 2006, inclusive (the “Class Period”), including purchasers in Nuvelo’s January 30, 2006 \$119 million follow-on offering (“Follow-On Offering”), seeking to pursue remedies under the Securities Exchange Act of 1934 (the “Exchange Act”).

2. Nuvelo is a biopharmaceutical company that engages in the discovery, development, and commercialization of various treatment drugs, including alfineprase, a thrombolytic agent with a novel mechanism of action. Prior to and during the Class Period, the Company pursued alfineprase for its use in catheter occlusion, acute peripheral arterial occlusion (“PAO”) and other medical conditions.

3. The complaint alleges that, throughout the Class Period, Defendants failed to disclose or indicate: (1) that the clinical trial information regarding multiple alfineprase studies was inaccurate; (2) specifically, clinical data from testing failed to show that alfineprase, when administered through a catheter, could dissolve blood clots; (3) that no reliable data existed to show that alfineprase would meet the high standards for efficacy for FDA approval; (4) that such information, as described above, was known to Defendants as early as December 2004, when Amgen discontinued its investment in alfineprase; and (5) that, as a result of the above, the Company’s statements concerning alfineprase and its clinical trials were lacking in any reasonable basis when made.

4. On December 11, 2006, Nuvelo shocked investors when it revealed that, contrary to earlier positive reports provided by the Defendants, Nuvelo’s clinical trials of alfineprase did not meet any of the primary or key secondary endpoints established for success. In addition, the Company announced that it had temporarily suspended enrollment in all other ongoing trials, pending discussions with outside experts and regulatory agencies due to safety concerns and the usefulness of alfineprase.

5. On this shocking and unexpected news, shares of Nuvelo plummeted \$15.50, or 79 percent, to close, on December 11, 2006, at \$4.05 per share, on unusually high trading volume.

## **JURISDICTION AND VENUE**

6. The claims asserted herein arise under and pursuant to Sections 10(b) and 20(a) of the Exchange Act, (15 U.S.C. §§ 78j(b) and 78t(a)), and Rule 10b-5 promulgated thereunder (17 C.F.R. § 240.10b-5).

7. This Court has jurisdiction over the subject matter of this action pursuant to Section 27 of the Exchange Act (15 U.S.C. § 78aa) and 28 U.S.C. § 1331.

8. Venue is proper in this Judicial District pursuant to Section 27 of the Exchange Act, 15 U.S.C. § 78aa and 28 U.S.C. § 1391(b). JP Morgan, Deutsche Bank Securities, Inc. and Lehman Bros. are all headquartered in New York City, and the investment banking and post-offering market-making activities in connection with the Follow-On Offering all took place in this District.

9. In connection with the acts, conduct and other wrongs alleged in this complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including but not limited to, the United States mails, interstate telephone communications and the facilities of the national securities exchange.

## **PARTIES**

10. Plaintiff, Barry Logan, as set forth in the accompanying certification, incorporated by reference herein, purchased Nuvelo securities at artificially inflated prices during the Class Period and has been damaged thereby.

11. Defendant Nuvelo is a Delaware corporation with its principal place of business located at 201 Industrial Road, Suite 310, San Carlos, California.

12. Defendant Ted W. Love (“Love”) was, at all relevant times, the Company’s President and Chief Executive Officer (“CEO”) and Chairman of the Board.

13. Defendant Gary S. Titus (“Titus”) was, at relevant times, the Company’s Chief Accounting Officer (“CAO”) and Vice President of Finance.

14. Defendant Shelly D. Guyer (“Guyer”) was, at relevant times, the Company’s Vice President of Business Development and Investor Relations.

15. Defendants Love, Titus, and Guyer are collectively referred to hereinafter as the “Individual Defendants.” The Individual Defendants, because of their positions with the Company, possessed the power and authority to control the contents of Nuvelo’s quarterly reports, press releases and presentations to securities analysts, money and portfolio managers and institutional investors, i.e., the market. Each Defendant was provided with copies of the Company’s reports and press releases alleged herein to be misleading prior to or shortly after their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Because of their positions and access to material non public information available to them, each of these Defendants knew that the adverse facts specified herein had not been disclosed to and were being concealed from the public and that the positive representations which were being made were then materially false and misleading. The Individual Defendants are liable for the false and misleading statements pleaded herein, as those statements were each “group-published” information, the result of the collective actions of the Individual Defendants.

## **SUBSTANTIVE ALLEGATIONS**

### **Background**

16. Nuvelo is a biopharmaceutical company that engages in the discovery, development, and commercialization of various treatment drugs, including alfimeprase, a thrombolytic agent with a novel mechanism of action.

17. Prior to and during the Class Period, the Company was pursuing alfimeprase for its use in catheter occlusion, acute PAO and other medical conditions. The Company described

alfimeprase as:

[A]n enzyme produced by recombinant DNA technology that rapidly dissolves blood clots through a unique mechanism of action; it directly degrades fibrin, a protein that provides the scaffolding for blood clots. **In clinical studies to date, alfimeprase has been shown to have the ability to degrade peripheral arterial (e.g. leg) clots within four hours of initiation of dosing and to clear occluded catheters in 15 minutes or less.** In addition, its lytic activity is localized to the site of delivery due to its rapid inhibition by alpha-2 macroglobulin, a naturally occurring protein in the blood, as soon as it moves away from the clot and into the general circulation. This clearance mechanism helps focus the thrombolytic activity to the site of delivery and, in clinical testing, appears to minimize bleeding side effects. [Emphasis added.]

18. Alfimeprase was originally researched and developed by Amgen, although they abandoned commercialization of the drug after they were unable to identify any positive results following testing. Following Amgen's disappointing results with alfimeprase, Nuvelo sought to assume the future development of alfimeprase, with the possibility of commercialization upon achieving marketable clinical results. In order to capitalize on this opportunity, Nuvelo needed to achieve two prerequisites – it needed to achieve marketable results from clinical testing of the drug, and it needed to obtain sufficient funding to back its pitiable business operations.

19. To achieve the first objective, prior to and during the Class Period, Nuvelo continually stressed that identifiable benefits of alfimeprase were realized during early clinical trials of the drug. Statements by the Company touted alfimeprase as a highly beneficial future treatment option for patients suffering from catheter occlusion, peripheral arterial occlusion (PAO), and other medical conditions. For example, on December 14, 2005, Nuvelo issued a statement entitled “Nuvelo Receives Special Protocol Assessment for Phase 3 Trial of Alfimeprase in Acute Peripheral Arterial Occlusion.” Therein, the Company, in relevant part, stated:

**Previously announced results from the NAPA-1 trial, a Phase 2 multi-center, multi-national, open-label, dose-escalation study, demonstrated that alfimeprase can restore arterial blood flow within four hours of initiation of dosing, has a favorable safety profile with minimal bleeding complications and resulted in a minority of patients requiring open vascular surgery within 30 days of treatment.**

"We believe that patients with acute PAO would benefit from a new and improved therapy as current treatments such as open vascular surgery and off-label use of plasminogen activators can be time-consuming and can cause significant side effects, particularly bleeding," said Steven R. Deitcher, M.D., vice president of medical affairs for Nuvelo. **"In clinical trials conducted to date, alfimeprase has shown promise as an easily administered, rapid-acting clot dissolver with a favorable safety profile."** [Emphasis added.]

20. Based on such representation by the Company, it seemed that Nuvelo was somehow able to achieve the beneficial results that had escaped Amgen. Despite this apparent success with the drug, the Company continued to suffer from the lack of capital funding necessary to support a wide scale testing of alfimeprase. Not to be deterred, Nuvelo solicited several potential investors to enter into a partnership to develop and eventually commercialize alfimeprase. Eventually Nuvelo found a partner in Bayer Healthcare AG ("Bayer"), and negotiated an immediate capital infusion, as well as significant additional cash payments from Bayer upon the achievement of identifiable milestones in the testing of alfimeprase. Bayer provided these payments and incentives to Nuvelo in exchange for the exclusive right to market the drug outside of the United States.

21. On the surface, such a contingent structured deal seemed optimal for all parties involved in the transaction. However, Bayer neglected to require Nuvelo to demonstrate efficacy initially, merely trusting Nuvelo to simply report such achievements. In conformity with the enticement laden understanding with Bayer, Nuvelo reported positive results from multiple rounds of clinical trials of alfimeprase. What Nuvelo failed to tell its partner and the public was

they were not accurately reporting the data that was gleaned from these clinical trials. Adding insult to injury, and contrary to statements made prior to and throughout the Class Period, it was eventually revealed that alfineprase was not able to achieve any of the primary or secondary endpoints that it sought to achieve through the clinical trials.

**Materially False and Misleading  
Statements Issued During the Class Period**

22. The Class Period commences on January 5, 2006. On this day, Nuvelo issued a press release entitled “Nuvelo and Bayer Healthcare Enter Comprehensive Collaboration Agreement to Maximize Global Development and Commercialization of Alfineprase.” Therein, the Company, in relevant part, stated:

- **Bayer HealthCare to Commercialize in All Territories Outside of the U.S., Nuvelo Retains Full U.S. Commercialization Rights and Will Receive Rest of World Royalties, Milestone Payments Totaling \$385M and Development Funding**
- Partners to Expand Beyond Current Phase 3 Programs to Develop Alfineprase for Stroke and Deep Vein Thrombosis

\* \* \*

Nuvelo Inc. (Nasdaq: NUVO) today announced that it has entered into a collaboration agreement with Bayer HealthCare AG (BHC) **to maximize the global development and commercialization of alfineprase, Nuvelo’s lead Phase 3 product candidate. Alfineprase, a novel, first-in-class thrombolytic or blood clot dissolver that directly degrades fibrin, has been shown in clinical studies to provide rapid clot dissolution with a well tolerated safety profile.**

**Under the terms of the agreement, Nuvelo will retain all commercialization rights and profits from alfineprase sales in the United States. BHC will commercialize alfineprase in all territories outside the U.S. and will pay Nuvelo tiered royalties ranging up to 37.5% that reflect the late-stage development status and significant market potential of alfineprase.**

**Nuvelo is eligible to receive up to \$385 million in milestone payments including a \$50 million up-front cash payment, up to \$165 million in development milestones and \$170 million in sales and commercialization milestones over the course of the agreement.** In addition, BHC will be responsible for 40 percent of the costs for global development programs. Nuvelo will be responsible for 60 percent of the costs and will remain the lead for the design and conduct of the global development programs. **In 2006, Nuvelo expects to receive payments totaling \$90 million, including the \$50 million up-front payment and an additional \$40 million in shared development expenses and a milestone payment for initiating a Phase 2 proof-of-concept trial in stroke.**

“In 2005 we articulated our strategy to pursue a partnership for alfineprase that would maximize its commercial potential and allow us to accelerate commercialization outside of the U.S. while establishing our own domestic sales force. As part of this strategy, we implemented a rigorous process that garnered substantial interest from multiple potential partners and ultimately enabled us to identify an ideal partner who shared our vision for alfineprase,” said Ted W. Love, M.D., chairman and chief executive officer of Nuvelo. “Bayer HealthCare proved to be the optimal partner based on its cardiovascular development and commercialization expertise, global reach and ability to provide significant resources to rapidly develop alfineprase’s full commercial potential.”

“This Phase 3 compound has the potential to be a significant addition to our cardiology/hematology business,” said Wolfgang Plischke, president of Bayer HealthCare’s Pharmaceutical Division. “Thrombosis-related diseases are highly prevalent, and alfineprase’s ability to rapidly dissolve clots in clinical trials conducted to date suggest it may be the ideal complement to our range of products that address coagulation and thrombosis. We believe alfineprase has the potential to transform the treatment of patients suffering from thrombotic-related disorders.”

Nuvelo and BHC will jointly engage in a comprehensive global development plan to maximize the clinical and commercial potential of alfineprase in the U.S. and abroad, as well as establish a worldwide franchise that addresses the unmet medical need of the large number of patients with diseases caused by blood clot formation. **Alfineprase is currently being studied in Phase 3 clinical trials for the potential treatment of acute peripheral arterial occlusion (PAO) and catheter occlusion (CO), and may have utility in a wide range of additional thrombotic-related**

**conditions such as stroke, deep venous thrombosis (DVT) and myocardial infarction.** These disorders are among the most common causes of death and morbidity in the Western world. The companies plan to expand beyond the current Phase 3 programs and initiate additional clinical programs with alfimeprase in stroke and DVT. A Phase 2 program in stroke is expected to begin in the second half of 2006 and a Phase 2 program in DVT is expected to begin in 2007. [Emphasis added.]

23. On January 5, 2006, Defendants held a conference call to discuss the recent developments with regard to alfimeprase. During the call, Defendant Love stated:

DR. TED LOVE, CHAIRMAN, CEO, NUVELO, INC.: Thank you all for joining us this morning. This is an exciting day for Nuvelo, and one we've been working diligently towards for over a year. We are very pleased to announce that we have entered into a comprehensive global collaboration agreement with Bayer HealthCare AG to maximize global development and commercialization of Alfimeprase.

**Alfimeprase is a novel first-in-class direct acting thrombolytic or blood clot dissolver that has been shown in clinical studies to provide rapid clot dissolution with a well tolerated safety profile. Bayer shares our vision now Alfimeprase has potential to change the treatment paradigm for the more than 10 million patients in the Western world who suffer from blood clot related or thrombotic conditions each year.**

As many of you know, in 2005 we articulated a strategy to pursue a partnership for Alfimeprase that would optimize its worldwide commercial potential and allow us to accelerate commercialization outside the United States while retaining rights within the United States. Specifically we plan to market Alfimeprase in the U.S. ourselves and establish a partnership with a top tier cardiovascular company to commercialize Alfimeprase outside the United States.

As part of this strategy we implemented a rigorous process that garnered substantial interest from multiple potential partners. Our collaboration with Bayer delivers exactly what we set out to accomplish. It enables Nuvelo to retain sole commercial rights for Alfimeprase in the United States while engaging a world-class partner who can best deliver Alfimeprase to patients in all territories outside the United States. Bayer proved to be the ideal partner from many perspectives, including its cardiovascular development and commercialization expertise, global reach and

ability to provide significant resources to rapidly develop Alfimeprase's full commercial potential. **In Bayer we have a partner who shares our vision for Alfimeprase and to seize its potential to transform the treatment of patients suffering from thrombotic-related disorders based on its demonstrated safety profile, ease of administration and ability to rapidly dissolve clots.**

Bayer has a strong global cardiology and hematology franchise, and is committed to bringing novel therapies for thrombotic diseases to market with late stage programs in venous, thromboembolism, and the prevention of stroke in atrial fibrillation. Nuvelo and Bayer will jointly engage in a comprehensive global development program to maximize the clinical and commercial potential of Alfimeprase. **Alfimeprase is currently in Phase III clinical trials for acute peripheral arterial occlusion or PAO, and catheter occlusion and may have utility in a wide range of additional thrombotic-related conditions, such as stroke, deep venous thrombosis and acute myocardial infarction. These disorders are among the most common causes of death and morbidity in the Western world.**

**In collaboration with Bayer we plan to expand beyond the current Phase III programs and initiate clinical programs with Alfimeprase in stroke and DVT. Specifically we plan to initiate a Phase II trial in stroke in the second half of 2006 and a Phase II trial in DVT sometime in 2007.**

**Alfimeprase is an enzyme produced by recombinant DNA technology that rapidly dissolves blood clots through a unique mechanism of action by directly degrading fibrin, a protein that provides the scaffolding for blood clots. In clinical studies to date Alfimeprase has been shown to have the potential to degrade clots within the arteries of the leg within four hours of initiation of dosing and to clear occluded catheters in 15 minutes or less.**

In addition its thrombolytic activity is localized to the site of delivery due to its rapid inactivation by alpha-2 macroglobulin, a naturally occurring protein in the blood. In clinical testing this clearance mechanism appears to minimize bleeding side effects. **Due to its unique clinical profile Alfimeprase has potential to establish a worldwide franchise that addresses the unmet medical need of the large number of patients with diseases caused by blood clot formation.**

**We initiated a development strategy and acute PAO in catheter occlusion to enable rapid market entry. Now with these clinical trials well underway we plan to initiate clinical programs to look at other strategic indications, including stroke and deep vein thrombosis which represent significantly larger market opportunities.**

**Our partnership with Bayer brings significant financial and human resources to the expanded development and commercial launch of Alfimeprase. This resource commitment demonstrates Bayer's confidence not only in the initial indications currently being pursued, but also in label expansion and the global market potential of additional indications. The depth of commercial experience and capability at Bayer positions us well to achieve our aggressive launch plans for Alfimeprase in multiple indications on a global scale.**

**\* \* \***

**2006 promises to be a transformational year for Nuvelo. We look forward to collaborating with Bayer to progress the Alfimeprase development programs. We will move forward with Alfimeprase in additional indications in stroke and DVT and plan to event all the programs in both our cardiovascular and oncology pipeline through 2006. Today's agreement with Bayer represents a major milestone. And it brings us closer to our goal of improving the lives of patients through the discovery, development and commercialization of novel drugs for acute cardiovascular and cancer therapy.**

**\* \* \***

**MARK MONANE, ANALYST, NEEDHAM & COMPANY:  
... Two questions please. One is which part of the Alfimeprase story was most attractive to the buyer? Was it the current Phase III trials underway, or was it really the promise of the future of going where class R like PE in stroke and MI?**

**DR. TED LOVE: Well, I think everyone that came in the door quite frankly was consistently impressed with the data that we generated with Alfimeprase, suggesting a dramatic feat of action and also its safety profile which emanates from the inactivation by alpha-2 macroglobulin. And it is really that profile and the confidence that that profile will be demonstrated in Phase III that generated excitement at Bayer and generated excitement quite frankly in every organization**

that we spoke with. So I think people really do see this as a transformational therapy, much like serotonin reuptake inhibitors were in Depression or the HMG-CoA reductase inhibitors were in the treatment of hyperlipidemia. So I think it really is looking forward recognizing that there are a great deal of thromboembolic disease out there, probably 10 million patients worldwide that really are not being well served with current therapies and Alfimeprase could deliver that unmet medical need.

**MARK MONANE:** That was helpful. One more question. Such a nice deal of course depends on the progress of the current Phase III trials. Could you -- would you be kind enough to update us on the current status of enrollment and how are the four Phase III trials moving along at this point?

**DR. TED LOVE:** What I will say to that is that obviously all the discussion that we had with potential partners was fully transparent about the conduct of the current trials. And I can tell you that all those efforts have been going extremely well. And very consistent with the promises that we've made to you and everyone. We will be giving you some updates on enrollment projections very soon.

\* \* \*

**CORY KASIMOV, ANALYST, OPPENHEIMER & CO: ...** You have long talked about the potential market opportunity for Alfimeprase and the number you've consistently thrown out there is greater than \$500 million in worldwide market potential. How does that change now with the confirmation that you will indeed be taking Alfimeprase into the clinic to evaluate it against both stroke and DVT?

**DR. TED LOVE:** The number certainly goes up quite dramatically. The \$500 million number that you reference is in fact an accurate number. We built that number off looking at two indications. And with the two indications that we had under study, that is acute PAO and catheter occlusion. It has been very clear to us from the very beginning that stroke and DVT are much larger market opportunities. But we did not start with those indications because of the development strategy was really focused on going after indications which will be rapid to market, which would demonstrate the superior advantage of the compound in terms of its fast speed of action and would provide a low-risk regulatory path for approval. **Now that we've got those**

**programs obviously well underway, we plan to turn our attention to DVT, stroke, other indications to really exploit the full commercial potential and the full medical benefit of the product.**

\* \* \*

LAUREN RICK, ANALYST, GOLDMAN SACHS: Just have a quick question, it's probably still early days but could you give us an idea of what you expect treatment timing to be for Alfimeprase in stroke, please?

DR. TED LOVE: It is a little early, but I think I could go back to a couple of reference points to give you some perspective. Obviously the time out for tPA is up to three hours. But as you probably know I was at Genentech when we did the filing for tPA with stroke. And it actually if you look at the data carefully, there is some evidence that tPA is active out as long as six hours. What happens, though, with plasminogen activators is that as time goes forward the risk of a hemorrhagic conversion increases with those drugs? **We think that Alfimeprase not having the systemic activity that we could extend that window somewhat by simply obliterating the systemic lytic activity that you generate with plasminogen activators.**

The second issue is as the occlusion remains in the brain you also now are increasing the risk of bleeding, and you obviously are minimizing the potential for benefit. **And so the speed of Alfimeprase is both potentially an advance on the safety side as well as the efficacy side.** So I think right now it is hard to be clear but I think we are looking at trying to get somewhere out into the range of nine hours or so. [Emphasis added.]

24. On January 23, 2006, Nuvelo issued a press release entitled “Nuvelo Receives FDA Fast Track Status for Alfimeprase.” Therein, the Company, in relevant part, stated:

Nuvelo Inc. (Nasdaq: NUVO) today announced that **it has been granted fast track designation by the U.S. Food and Drug Administration (FDA) for its lead product candidate, alfimeprase,** for the treatment of acute peripheral arterial occlusion (PAO), or "leg attack." **Fast track designation, which was mandated by the FDA Modernization Act of 1997, can potentially facilitate development and expedited review of Biologics License Applications (BLA). Fast track designation is reserved for new drugs that demonstrate the potential to**

**address an unmet medical need and are intended for the treatment of a serious or life-threatening condition.**

Alfimeprase is currently being studied in Phase 3 clinical trials for the potential treatment of acute PAO and catheter occlusion (CO), and may have utility in a wide range of additional thrombotic-related conditions such as stroke, deep venous thrombosis (DVT) and myocardial infarction. Collectively, these disorders are among the most common causes of death and morbidity in the Western world.

**"We recently received a special protocol assessment agreement for NAPA-3, our second pivotal Phase 3 trial in acute PAO. Fast track designation represents a further step in the achievement of our regulatory strategy for alfimeprase," said Ted W. Love, M.D., chairman and chief executive officer of Nuvelo. "With a more defined regulatory path, a Phase 3 program continuing to progress and a strong global commercialization partner in Bayer HealthCare AG, we believe we are progressing toward our goal of bringing this therapy to individuals suffering from clot related disorders."**

#### **Alfimeprase in Clinical Trials**

Alfimeprase is being studied in an ongoing Phase 3 program known as the NAPA (Novel Arterial Perfusion with alfimeprase) program, for the treatment of acute PAO. The program consists of two overlapping randomized, double-blind, multi-national trials comparing 0.3 mg/kg of alfimeprase versus placebo in a total of 600 patients. The primary endpoint in both trials is avoidance of open vascular surgery within 30 days of treatment. Open vascular surgery includes procedures such as surgical embolectomy, peripheral arterial bypass graft surgery and amputation, but does not include catheter-based procedures such as percutaneous angioplasty or stenting. A variety of secondary endpoints are also being evaluated, including safety endpoints such as the incidence of bleeding, and pharmacoeconomic endpoints such as length of hospital and intensive care unit (ICU) stay. The first trial in this program, NAPA-2, is expected to complete enrollment in the second half of 2006 and the second trial, NAPA-3, is expected to begin enrollment in early 2006.

Alfimeprase is also being studied in an ongoing Phase 3 clinical program known as the SONOMA (Speedy Opening of Non-functional and Occluded catheters with Mini-dose alfimeprase) program, for the treatment of CO. The program consists of two overlapping, multi-national trials. The first trial, SONOMA-2 is an

efficacy study comparing 3 mg of alfimeprase versus placebo in 300 patients with occluded central venous catheters, evaluating restoration of function to the catheters at 15 minutes. SONOMA-2 is expected to complete enrollment in the second half of 2006. The second trial, SONOMA-3, will be an open label, single-arm trial evaluating alfimeprase alone in 800 patients. This study's primary endpoint is safety; however efficacy will also be evaluated. SONOMA-3 is expected to begin enrollment in the first half of 2006. [Emphasis added.]

25. On February 27, 2006, Nuvelo issued a press release entitled "Nuvelo and Bayer HealthCare Begin SONOMA-3, Second Phase 3 Trial of Alfimeprase in Patients With Central Venous Catheter Occlusion." Therein, the Company, in relevant part, stated:

Nuvelo Inc. (Nasdaq: NUVO) and Bayer HealthCare (BHC) today announced that they have begun patient enrollment in a second pivotal Phase 3 clinical trial of lead product candidate, alfimeprase, for the treatment of central venous catheter occlusion (CO).

**The Phase 3 trial, known as SONOMA-3 (Speedy Opening of Non-functional and Occluded catheters with Mini-dose Alfimeprase-3), is the second of two overlapping, multi-national trials in the Phase 3 alfimeprase program for CO. This open-label, single-arm trial will evaluate the safety and efficacy of 3 mg of alfimeprase in 800 patients with occluded central venous catheters.**

**"We believe that alfimeprase has the potential to quickly dissolve clots and rapidly restore the ability to infuse critical therapy such as chemotherapy or antibiotics through once occluded catheters," said Steven R. Deitcher, M.D., vice president of medical sciences for Nuvelo and former principal investigator of the Phase 2 trial. "We look forward to completing the first trial in this program, SONOMA-2, later this year and expect the Phase 3 trial results to confirm the ability of alfimeprase to restore function to occluded catheters in 15 minutes or less, as demonstrated in our Phase 2 trial."**

**Previously announced results from a Phase 2 multi-center, randomized, double-blind study in 55 patients with occluded central venous catheters demonstrated that alfimeprase restored flow to 40 percent and 50 percent of occluded catheters 5 and 15 minutes after the first dose, respectively. By comparison, Cathflo(R)Activase(R) (alteplase) did not restore**

**flow at either time point. Alfimeprase also restored flow to 60 percent of occluded catheters at 120 minutes after the first dose and to 80 percent of occluded catheters at 120 minutes after the second dose compared with 46 percent at 120 minutes after the first dose and 62 percent at 120 minutes after the second dose with Cathflo(R)Activase(R).** [Emphasis added.]

26. Also on February 27, 2006, Nuvelo issued a second press release entitled “Nuvelo Reports 2005 Fourth Quarter and Year End Results and Accomplishments and Provides 2006 Outlook.” Therein, the Company, in relevant part, stated:

Nuvelo, Inc. (Nasdaq: NUVO) today announced 2005 fourth quarter and year end financial results and accomplishments and provided an outlook for 2006.

For the fourth quarter ended December 31, 2005, Nuvelo reported a net loss of \$20.9 million or \$0.49 per share compared to a net loss of \$13.0 million or \$0.40 per share for the same period in 2004. The loss from continuing operations during the fourth quarter was also \$20.9 million or \$0.49 per share in 2005, compared to \$10.8 million or \$0.33 per share in 2004. Revenues for the fourth quarter of 2005 were \$183,000, compared to revenues of \$43,000 for the same period in 2004.

For the year ended December 31, 2005, Nuvelo reported a net loss of \$71.1 million or \$1.72 per share, compared to a net loss of \$52.5 million or \$1.70 per share in 2004. The loss from continuing operations was also \$71.1 million or \$1.72 per share in 2005, compared to \$48.9 million or \$1.59 per share in 2004. Revenues for the year ended December 31, 2005 were \$545,000, compared to revenues of \$195,000 in 2004.

**The increase in loss from continuing operations of \$10.1 million and \$22.2 million for the quarter and year ended December 31, 2005, respectively, was primarily due to increases in development expenses related to clinical trials, including outside services and the use of previously manufactured alfimeprase drug product, increased personnel costs in support of these activities, and higher general and administrative expenses incurred to build the infrastructure necessary to support the Company’s growth and begin preparations for the planned commercial launch of alfimeprase.**

As of December 31, 2005, Nuvelo had \$70.3 million in cash, cash equivalents and short-term investments compared to \$50.6 million at December 31, 2004. For the quarter and year ended December 31, 2005, our net cash used in operating activities was \$17.2 million and \$58.9 million respectively, and our “Cash Burn,” a non-GAAP financial measure, (see definition and reconciliation below) was \$19.4 million and \$64.6 million respectively.

**In January 2006, we received a \$50.0 million up-front cash payment from Bayer HealthCare upon entry into our license and collaboration agreement for alfimeprase, and in February 2006, we raised approximately \$111.9 million in a public offering, after deducting underwriters’ fees and stock issuance costs of approximately \$7.7 million, from the sale of 7,475,000 shares of our common stock, including 975,000 shares related to the exercise of an over-allotment option granted to the underwriters, at a public offering price of \$16.00 per share.**

\* \* \*

#### **Recent Corporate Accomplishments**

- **Enrolled the first patient in the second Phase 3 alfimeprase trial in patients with catheter occlusion, SONOMA-3.**
- **Successfully completed a secondary offering with gross proceeds of \$119.6 million, putting the Company in the strongest financial position in its history.**
- **Granted fast track status by the U.S. Food and Drug Administration (FDA) and orphan drug designation from the European Medicines Evaluation Agency (EMA) for alfimeprase for the treatment of acute peripheral arterial occlusion (PAO).**
- **Entered into a global collaboration agreement with Bayer to optimize the worldwide development and commercialization of alfimeprase while retaining rights to alfimeprase within the United States and securing a \$50.0 million up front payment, up to \$335.0 million in additional potential milestone payments, 40 percent of development funding and up to 37.5 percent in tiered royalties for sales outside of the U.S.**

- **Received a Special Protocol Assessment (SPA) agreement from the FDA for NAPA-3, the second pivotal Phase 3 trial evaluating alfimeprase for the treatment of acute PAO.**
- **Presented Phase 2a ANTHEM/TIMI 32 study results at the American Heart Association's Scientific Sessions 2005 showing that rNAPc2 has an acceptable safety profile and is well tolerated at the highest dose tested in patients being treated for ACS.**

#### **2006 Guidance and Key Milestones**

In 2006, Nuvelo expects to use cash in operating activities of between \$30.0 million and \$38.0 million and to have a Cash Burn of between \$33.5 and \$43.5 million.

**In 2006, Nuvelo anticipates accomplishing the following:**

- **Enrollment of the first patient in the second Phase 3 alfimeprase trial in acute PAO, NAPA-3, in early 2006;**
- **Completion of patient enrollment in the first Phase 3 alfimeprase trial in acute PAO, NAPA-2, in the second half of 2006;**
- **Completion of patient enrollment in the first Phase 3 alfimeprase trial in catheter occlusion, SONOMA-2, in the second half of 2006;**
- **Initiation of a Phase 2 trial of alfimeprase in ischemic stroke in the second half of 2006;**
- **Completion of a Phase 2 rNAPc2 heparin replacement study in patients with ACS in the first half of 2006;**
- **Presentation of efficacy data from our Phase 2a rNAPc2 trial in patients with ACS at a medical meeting in the second half of 2006;**
- **Initiation of a Phase 1 study of NU206 for the treatment of cancer therapy-induced mucositis in the second half of 2006. [Internal citations omitted, Emphasis added.]**

27. Commenting on the Company's results, Defendant Love stated:

**2005 was a foundation building year for Nuvelo. We executed plans to achieve all of our key strategies and goals. We launched our initial Phase 3 programs for alfimeprase, enhanced the Company's financial strength and obtained a strong international partner willing to commit its significant capabilities and resources to the successful development and commercialization of our lead compound. ... Already in 2006 we are making significant progress building on this solid foundation, and it should be a transformational year for us as we prepare to complete the first of our Phase 3 trials with alfimeprase and expand the program into stroke. In addition, we expect to generate proof-of-concept data from our Phase 2 rNAPc2 trial in acute coronary syndrome (ACS) and expand the program into cancer. [Emphasis added.]**

28. On April 10 2006, Nuvelo issued a press release entitled "Nuvelo and Bayer Healthcare Begin NAPA-3, Second Pivotal Phase 3 Trial of Alfimeprase for Acute Peripheral Arterial Occlusion." Therein, the Company, in relevant part, stated:

Nuvelo Inc. (Nasdaq: NUVO) and Bayer HealthCare (BHC) today announced that they have begun patient enrollment in a second pivotal Phase 3 clinical trial of alfimeprase for the treatment of acute peripheral arterial occlusion (PAO), or "leg attack." This Phase 3 trial, known as NAPA-3 (Novel Arterial Perfusion with Alfimeprase-3), recently received a Special Protocol Assessment (SPA) agreement from the U.S. Food and Drug Administration (FDA).

NAPA-3 is the second of two overlapping multi-national trials in the Phase 3 alfimeprase program for acute PAO. Both trials are randomized, double-blind studies comparing 0.3 mg/kg of alfimeprase with placebo in a total of 600 patients between the two studies. **The primary endpoint in both trials is avoidance of open vascular surgery within 30 days of treatment.** Open vascular surgery includes procedures such as surgical embolectomy, peripheral arterial bypass graft surgery and amputation, but does not include catheter-based procedures such as percutaneous angioplasty or stenting. **A variety of secondary endpoints are also being evaluated in the two trials, including safety endpoints, such as the incidence of bleeding, and pharmacoeconomic endpoints, such as length of hospital and intensive care unit (ICU) stay.**

**"We recently announced that we have received fast track designation from the FDA for the NAPA program and that we**

**expect to complete enrollment in the first trial in this program, NAPA-2, in the second half of this year," said Michael D. Levy, M.D., senior vice president of research and development for Nuvelo. "Now that we have initiated NAPA-3 and have plans to initiate additional trials in stroke and deep venous thrombosis (DVT), we are well on our way to bringing this potentially transformational therapy to the millions of patients suffering from clot related disorders."**

**Previously announced results from the NAPA-1 trial, a Phase 2 dose- escalation study, demonstrated that alfimeprase can restore arterial blood flow within four hours of initiation of dosing, has a favorable safety profile with minimal bleeding complications, and resulted in a majority of patients avoiding open vascular surgery within 30 days of treatment. [Emphasis added.]**

29. On May 5, 2006, Nuvelo issued a press release entitled "Nuvelo Reports First Quarter 2006 Financial Results and Accomplishments." Therein, the Company, in relevant part, stated:

Nuvelo, Inc. (Nasdaq: NUVO) today announced first quarter 2006 financial results and accomplishments.

For the three months ended March 31, 2006, Nuvelo reported a net loss of \$19.7 million or \$0.40 per share compared to a net loss of \$14.7 million or \$0.39 per share for the same period in 2005.

**Revenues for the first quarter of 2006 were \$1.1 million, compared to revenues of \$42,000 for the same period in 2005. The increase was primarily due to the recognition of \$0.8 million of revenue from the up-front license fee of \$50.0 million received from Bayer HealthCare AG (Bayer) in January 2006.** The up-front license fee was recorded as deferred revenue upon receipt and is being recognized on a straight-line basis over the term of the agreement, estimated to be through September 2020, when the last significant alfimeprase-related patent expires. Any other amounts billable to Bayer for milestones achieved or for sales of alfimeprase to Bayer for use in their country-specific trials or commercial sale outside of the United States will be recognized on a similar basis. Once the development of alfimeprase has been substantially completed, any remaining deferred revenue will be recognized at that point, and any milestones and sales of alfimeprase that are billable to Bayer after that point will be recognized as earned. We are continuing to evaluate the

appropriate revenue recognition for royalty payments we anticipate receiving in future years.

**The increase in net loss of \$5.0 million was primarily due to an increase in general and administrative expenses of \$6.4 million, including \$1.8 million of non-cash stock-based compensation expense related to the implementation of SFAS 123(R), a non-cash charge of \$2.9 million for the quarterly revaluation of the Kingsbridge Capital Limited warrant issued in connection with our Committed Equity Financing Facility, and other expenses primarily related to the growth in our infrastructure and pre-commercialization activities for alfimeprase. The increase in research and development expenses was primarily due to increased clinical trial and drug manufacturing activity and related personnel costs, including \$1.3 million of stock-based compensation expense under SFAS 123(R). These increases were largely offset by a \$5.9 million increase in amounts billable to our collaboration partners under cost-sharing arrangements, primarily with Bayer. We expect to receive Bayer's reimbursement for 40 percent of our first quarter's alfimeprase-related global development spending in the second quarter.**

**As of March 31, 2006, Nuvelo had \$200.3 million in cash, cash equivalents and short-term investments compared to \$70.3 million at December 31, 2005. The amount as of March 31, 2006 includes the \$50.0 million up-front cash payment received from Bayer in January 2006 and \$112.0 million from our public offering in February 2006, after deducting underwriters' fees and stock issuance costs of \$7.6 million, in which we sold 7,475,000 shares of our common stock at a public offering price of \$16.00 per share.**

For the quarter ended March 31, 2006, our net cash provided by operating activities was \$18.1 million, which includes the \$50.0 million up-front license fee payment received from Bayer. With the \$50.0 million receipt included, our Cash Burn, a non-GAAP financial measure (see definition and reconciliation below), was a \$17.9 million increase in cash. Excluding the effect of this receipt, our "Cash Burn" would have been a \$32.1 million decrease in cash. Key drivers behind our spending in the quarter were the ramp up of our clinical development operations for our alfimeprase Phase 3 programs in acute peripheral arterial occlusion (PAO) and catheter occlusion (CO). Additionally, we continue to incur costs associated with our ongoing programs with rNAPc2, NU206 and our thrombin inhibiting aptamer program, and we also paid \$3.7

million towards the remaining deferred rent obligation under the lease for our facility in Sunnyvale, California.

### **Recent Corporate Accomplishments**

- **Entered into a global collaboration agreement with Bayer for the worldwide development and commercialization of alfimeprase while retaining rights to alfimeprase within the United States and securing a \$50 million up-front payment, up to \$335 million in additional potential milestone payments, 40 percent of development funding and up to 37.5 percent in tiered royalties for sales outside of the United States;**
- **Successfully completed a secondary offering with net proceeds of \$112 million;**
- **Initiated the second Phase 3 alfimeprase trial in patients with acute PAO, NAPA-3;**
- **Initiated the second Phase 3 alfimeprase trial in patients with CO, SONOMA-3;**
- **Granted fast track status by the U.S. Food and Drug Administration (FDA) for alfimeprase for the treatment of acute PAO;**
- **Appointed Shelly Guyer vice president, business development and investor relations.**

### **Upcoming Milestones**

In the remainder of 2006, Nuvelo anticipates accomplishing the following:

- **Completion of the first Phase 3 alfimeprase trial in acute PAO, NAPA-2, in the second half of 2006;**
- **Completion of the first Phase 3 alfimeprase trial in catheter occlusion, SONOMA-2, in the second half of 2006;**
- **Initiation of a Phase 2 trial of alfimeprase in ischemic stroke in the second half of 2006;**

- Completion of a Phase 2 rNAPc2 heparin replacement study in patients with acute coronary syndromes (ACS) in the second quarter of 2006;
- Presentation of efficacy data from our Phase 2a rNAPc2 trial and our Phase 2 heparin replacement trial in patients with ACS at a medical meeting in the second half of 2006;
- Initiation of a Phase 1 study of NU206, which is being developed for the treatment of cancer therapy-induced mucositis in the second half of 2006. [Emphasis added.]

30. Commenting on these developments, Defendant Love stated:

**We are off to a great start with Bayer, and are working together on our global development programs including preparations for our planned Phase 2 trial in ischemic stroke, as well as collaborating on manufacturing efforts as we prepare for the commercial production of alfimeprase. Additionally, we finished the first quarter with \$200 million in cash, putting us in a position of financial strength as we progress four Phase 3 trials of alfimeprase and prepare to initiate a Phase 2 trial in ischemic stroke and a Phase 1 trial of NU206.** [Emphasis added.]

31. Also on May 5, 2006, Defendants held a conference call to discuss the recent developments with regard to alfimeprase. On the call, Defendants stated:

**DR. TED W. LOVE, CHAIRMAN & CEO, NUVELO, INC.:**  
**... Last month, we initiated the NAPA-3 trial with alfimeprase, the second of two Phase 3 trails in our acute peripheral arterial occlusion. or PAO program. We also initiated SONOMA-3 trail last quarter, the second Phase 3 catheter occlusion trial. With the start of these two trails, we now have four trails Phase 3 trial ongoing with alfimeprase.** In February, we successfully completed a secondary offering, with gross proceeds of approximately \$120 million. On the regulatory front, alfimeprase was granted fast track status by the U.S. Food and Drug Administration. And finally, in January, Nuvelo and Bayer HealthCare entered into a global collaboration agreement to develop and commercialize alfimeprase. With this agreement, Nuvelo retained full U.S. commercialization rights and received a \$50 million upfront payment from Bayer.

\* \* \*

GARY TITUS, ACTING CFO & CHIEF ACCOUNTING OFFICER, NUVELO, INC.: Thanks, Ted. Hello, everyone. The first quarter has been exciting financially for Nuvelo. As Ted mentioned, we completed a successful public offering in February and executed a collaboration agreement with Bayer. These accomplishments have been instrumental in achieving our goal of building financial strength. Let me begin by reviewing our cash balance, run rate, recent collaboration and financing events. We began the first quarter with approximately \$7 million and ended the quarter with approximately \$200 million in cash and investment balances.

\* \* \*

**DR. MICHAEL LEVY, SVP OF R&D, NUVELO, INC.:** Thank you, Gary. Over the next few minutes, I'll provide you with an update of our development pipeline, focusing on our acute cardiovascular programs and emerging oncology programs, as well as share with you our excitement about the progress we've made. Let's begin with an update on alfimeprase, our lead cardiovascular product candidate. We started the first quarter of 2006 with the announcement of our global collaboration agreement with Bayer in January. The companies entered into this partnership with a shared vision of alfimeprase's potential to change the treatment paradigm for a wide range of conditions due to thrombosis, including acute peripheral arterial occlusion, or PAO, catheter occlusion, stroke and deep venous thrombosis. We are well on our way to achieving this vision and are off to a great start our new partner.

The [UN] committees are meeting regularly, and we're actively working with Bayer on our new global development programs, including preparing for the Phase 2 stroke trial, as well as collaborating on them with our manufacturing efforts as we prepare for the commercial production of alfimeprase. In addition, we've transitioned responsibility to Bayer for managing activities relating to the [EAA] and other foreign regulatory agencies after having received confirmation from the [EAA] that our Phase 3 program in acute PAO is appropriate for drug registration in Europe. On the clinical front, with the initiation of NAPA-3, we now have four Phase 3 alfimeprase trials ongoing and are on track to complete the first of these trials, NAPA-2 and SONOMA-2, in the second half of this year. As Ted mentioned, NAPA-3, which started

**this April, is the second of two Phase 3 trials in our acute PAO program for alfineprase.**

Under our Special Protocol Assessment, or SPA, with the FDA, NAPA-3 will essentially replicate the NAP-2 trial, and is also a randomized double blind study containing 0.3 milligrams per kilogram of alfineprase with placebo. It will enroll 300 patients with the primary end point gain of [INAUDIBLE] open vascular surgery within thirty days of treatment. The NAPA program, which as a whole enrolled 600 patients, received fast track designation from the FDA in 2006. Fast track is designed to facilitate drug development and can lead to a priority review of a biologic license application, or BLA, which according to the FDA may reduce the total review time from the standard 12 months to 6 months.

In addition, under the fast track program, the FDA is committed to working more closely with a sponsor, and the BLA can be submitted as a rolling submission, which allows certain sections of the BLA to be submitted and reviewed while other sections are being finalized. We continue to be on track to complete enrollment in NAPA-2, the first Phase 3 trial in this program, in the second half of 2006. Typically, the time required to lock the data base, analyze the data and then provide top line results is a few months. And subsequently, we expect that one of our investigators would present a more complete analysis of the full data at an appropriate medical conference as soon as possible thereafter. Our second target indication for alfineprase, catheter occlusion, is also progressing well.

We achieved our milestone of initiating the second Phase 3 catheter occlusion trial, SONOMA-3, in the first half of 2006. This open label single arm trial will evaluate the safety and efficacy of 3 milligrams of alfineprase in 800 patients with occluded central unit catheters. We continue to be on track to complete Sonoma-2, the first trial in this program, in the second half of 2006; and depending on the exact timing of the completion of SONOMA-2, we expect to be able to provide top line data shortly after enrollment of the last patient, and full data to be presented at an appropriate medical conference by one of our investigators. Finally, we're working closely with the FDA and our partner Bayer on a Phase 2 of alfineprase in stroke and remain on target to begin enrollment in the second half of 2006. In addition, a Phase 2 trial in deep venous thrombosis, or DVT, is scheduled to begin in 2007.

\* \* \*

**MARK MONANE, ANALYST, NEEDHAM & COMPANY:** ... And then I have a more concrete follow-up question on alfimeprase. It seems to me that the CO program is actually moving on very successfully. And it could be a possibility CO could with lap PAO, potentially with some -- with some good results. Is the Company indifferent to which indication is [INAUDIBLE] different? It's interesting, it seems that everything might come together about the same time. How do you view the ongoing race and/or completion of these trials?

**DR. MICHAEL LEVY:** Hi, Mark, Michael Levy here. Thanks for the question. You're right, the CO program is progressing well, but then so is the PAO program. They're both progressing well, I'm pleased to report. And at this time, it still looks as though they'll complete around the same time. And it's very difficult to say which will complete first. With respect to Bayer and our ourselves, we view both programs as important, both goaled towards meeting an unmet medical need, and we'll progress each of them as rapidly as we can as priorities for both companies.

\* \* \*

**JIM, ANALYST:** Hi, guys, just got a few questions. Just first, just wondering whether you can give us any further detail on timelines for completion of enrollment in NAPA-2 and SONOMA-2, whether we should expect that in 3Q or 4Q '06?

**DR. TED W. LOVE:** Hi, Jim, thanks for the question. So what we've said so far is that it will definitely be the second haft of the year, and we really haven't given guidance beyond that; so those are still our expectations for both trials.

**JIM:** And then just focusing on PAO specifically, could you just describe what measures you've taken in that trial to make sure docs stick to protocol when it comes to deciding who gets open vascular surgery? Whether there's been some assumptions based into the trial around protocol violaters and whether there's been any [AA] surprises in the terms of the percent of docs that are sticking to protocol here?

**DR. TED W. LOVE:** So you asked two questions. I'll answer the statistical one first. Yes, we took a very conservative case when we prepared the trial. Obviously in an ideal world, everyone who received placebo wouldn't respond to therapy

**and require surgery, and the vast components of people who received alfimeprase would respond. But we took a conservative case scenario and allowed for a certain percentage of patients to be deemed to respond to placebo; and as we've discussed in past conferences in particular, the statistical power is still overwhelming for this trial, and we have 90% [INAUDIBLE], 22% difference in the ultimate rate between the two therapies, placebo and alfimeprase.**

So in terms of making sure that doctors follow the guidelines, what we've done for Phase 3 is, first of all, of course, been very careful in our site selection that we have -- that we're working with the best and most appropriate sites. And we've also got the sites to agree to work with the task guidelines, which are international consensus guidelines developed by American and European Vascular Surgery Societies detailing what sort of lesions require what sort of treatment. And so far we are very pleased that physicians are following the guidelines appropriately.

\* \* \*

**JASON ZANE, ANALYST, PRUDENTIAL EQUITY GROUP:** Thanks. Questions on the regulatory front alfimeprase PAO managed. I know you are going to complete the trial completion phase second half and hopefully [INAUDIBLE], since we don't have a very long follow I think the data should be pretty soon after patients are getting through the trial. But you are still going to do the second phase three although you have the fast track, what's your thinking right now? Do you need to have two trials definitely to get a drug approved, or is there any some alternative path that you are thinking or what's the balance between you and the FDA?

**GARY TITUS:** Thanks for the question. We get asked that question a lot. And we believe that the prudent case to plan for is two trials for approval. That's typically what's required by the FDA. And really the driver here is not the statistical power for approving efficacy, because we believe that can be done with a relatively small patient sample; but we need to generate a reasonable size patient safety database to seek approval. So that's certainly the way we're planning.

JASON ZANE: So, in other words, you are really trying to finish the trials and then –

GARY TITUS: That's our best thinking, yes.

\* \* \*

**GARY TITUS:** So, I mean, the thing to remember with **alfimeprase** is that it is an acute thrombolytic. But sometimes upon treatment of an acute problem you can highlight and discover underlying peripheral vascular disease above and beyond what was seen, and that's because from a treatment standpoint **alfimeprase** can act as a diagnostic agent by clearing away the key problems that are masking underlying issues. And so in those cases, patients may still sometimes require surgery even though the acute clot is removed.

**JASON ZANE:** Right.

**GARY TITUS:** Now, on the other hand with placebo patients, sometimes for whatever reason, you know, before surgery is performed, the surgeon or the family may decide that the patient because of, for example, other medical conditions, is a poor surgical risk and avoid surgery and take a wait and see attitude, even though there is an underlying issue, just because of the risks of surgery. Those are the sort of things that can make our results deviate from an ideal world. But as I've mentioned, even taking those issues into account, we believe we still have overwhelming statistical power to detect the difference between active therapy such as **alfimeprase** -- which is indeed very active based on our Phase 2 studies to date -- and placebo. [Emphasis added.]

32. On July 6, 2006, Nuvelo issued a press release entitled "Nuvelo Announces Publication of Phase 2 **Alfimeprase** Study Results in Central Venous Catheter Occlusion."

Therein, the Company, in relevant part, stated:

Nuvelo, Inc. (Nasdaq: NUVO) today announced the publication of Phase 2 clinical trial results in the July 1st issue of the Journal of Clinical Oncology (JCO), demonstrating that **alfimeprase** can quickly restore function to occluded central venous access devices (CVADs).

**This Phase 2 randomized, double-blind, controlled, dose-ranging study compared the safety and activity of three fixed doses of **alfimeprase** (0.3 mg, 1 mg and 3 mg) against the approved dose of **Cathflo(R)Activase(R)** (alteplase). Fifty-five patients were treated to re-establish patency to their occluded CVADs. Catheter patency was assessed at 5, 15, 30 and 120**

**minutes after drug was given. If patency was not achieved at 120 minutes after the first dose of either alfimeprase or CathfloActivase, patients received a second dose. Adverse events, including bleeding events, were assessed for a 30-day period after exposure to study drug. The results demonstrated that at the highest dose of 3 mg, alfimeprase produced cumulative patency rates of 40% at 5 minutes, 50% at 15 minutes and 60% at 30 and 120 minutes after the first dose, as well as 80% at 120 minutes after the second dose. By comparison, CathfloActivase produced patency rates of 0% at 5 and 15 minutes, 23% at 30 minutes and 46% at 120 minutes after the first dose, as well as 62% at 120 minutes after the second dose. No major hemorrhagic events were reported in any treated patients.**

"Restoration of CVAD function within minutes is important because it may facilitate timely delivery of prescribed therapies or enable early identification of CVAD obstructions that require prompt catheter replacement," said Steven R. Deitcher, M.D., vice president, medical sciences for Nuvelo and former principal investigator (PI) for the trial. "The ability to rapidly restore catheter function also may reduce patient anxiety related to missed or delayed treatment and improve treatment center efficiency."

**"Based on these promising Phase 2 results, we have initiated two overlapping, multi-national Phase 3 trials evaluating the 3 mg dose of alfimeprase in catheter occlusion. We anticipate data from the first of these trials, the SONOMA-2 trial, in the second half of this year, and hope to confirm the ability of alfimeprase to restore function to occluded catheters in 15 minutes or less," said Ted W. Love, M.D., chairman and CEO of Nuvelo. [Emphasis added.]**

33. On August 3, 2006, Nuvelo issued a press release entitled "Nuvelo Reports Second Quarter 2006 Financial Results and Accomplishments." Therein, the Company, in relevant part, stated:

Nuvelo, Inc. (Nasdaq: NUVO) today announced second quarter 2006 financial results and accomplishments.

For the second quarter ended June 30, 2006, Nuvelo reported a net loss of \$18.9 million, or \$0.36 per share, compared to a net loss of \$17.0 million, or \$0.40 per share, for the same period in 2005. As of June 30, 2006, the company had cash, cash equivalents and short-term investments of \$179.6 million.

Revenues for the second quarter of 2006 were \$1.0 million compared to second quarter 2005 revenues of \$0.2 million. The increase was primarily due to the recognition of revenue from the up-front license fee of \$50.0 million received from Bayer HealthCare (Bayer) in January 2006. The up-front license fee was recorded as deferred revenue upon receipt and is being recognized as revenue on a straight-line basis over the term of the agreement.

**Total second quarter 2006 operating expenses were \$22.0 million compared to \$17.6 million in the prior year period. Research and development expenses were \$14.7 million for the three months ended June 30, 2006 compared to \$14.5 million for the second quarter of 2005. These amounts are net of credits for cost-sharing amounts billable to collaboration partners of \$8.2 million and \$1.2 million in the respective periods. Increases in research and development expenses due to clinical trial, drug manufacturing and personnel costs, including \$1.3 million of non-cash employee stock-based compensation expense under SFAS 123(R), were largely offset by the collaboration cost-sharing credits and a \$5.0 million decrease in milestone payment expense. General and administrative expenses were \$7.3 million for the three months ended June 30, 2006 and \$3.2 million for the same period in 2005. The increase was primarily due to expenses related to the growth in our infrastructure, pre-commercialization activities for alfineprase and non-cash employee stock-based compensation expense of \$2.3 million.**

\* \* \*

For the three months ended June 30, 2006, our net cash used in operating activities was \$16.1 million. Cash provided by operating activities was \$1.9 million in the six-month period. Our cash burn, a non-GAAP measure, as defined and reconciled below, was \$20.6 million and \$2.9 million in the three and six months ended June 30, 2006, respectively, both including a \$5.4 million cash payment in May 2006 to settle a five-year promissory note that was issued to Affymetrix in November 2001, consisting of \$4.0 million of principal and \$1.4 million of accrued interest. Cash burn in the six-month period includes the receipt of the \$50.0 million up-front payment from Bayer in the first quarter of 2006. Due to the \$5.4 million cash payment to settle the Affymetrix note and the \$4.0 million up-front license fee to be paid as a result of our entry into an expanded collaboration agreement with Archemix, we are updating our guidance, and expect to use cash in operating

activities in the range of \$38.0 million to \$46.0 million and cash burn to be in the range of \$43.0 million to \$53.0 million for the full year 2006.

\* \* \*

### **Recent Corporate Accomplishments**

- **Initiated the second Phase 3 alfimeprase trial in acute peripheral arterial occlusion (PAO), NAPA-3;**
- **Published data from the Phase 2 alfimeprase study in central venous catheter occlusion in the July issue of the *Journal of Clinical Oncology*;**
- Successfully completed the Phase 2 heparin replacement trial evaluating rNAPc2 in acute coronary syndromes (ACS);
- Signed new collaboration agreement with Archemix and designated NU172, a direct thrombin inhibitor, as a development candidate for potential use as a short-acting anticoagulant for patients undergoing acute cardiovascular procedures;
- Expanded management team with H. Ward Wolff as senior vice president, finance and chief financial officer; Jill M. Pergande as vice president, human resources; Gregory S. Yedinak as vice president, manufacturing and process sciences; and Ralph J. Zitnik, M.D., as vice president, development;
- Appointed James R. Gavin III, M.D., Ph.D. to Nuvelo's board of directors;
- Hosted our first Research and Development Day in New York.

### **Upcoming Milestones**

In the remainder of 2006, Nuvelo anticipates accomplishing the following:

- **Completion of the first Phase 3 alfimeprase trial in acute PAO, NAPA-2;**

- **Completion of the first Phase 3 alfimeprase trial in catheter occlusion, SONOMA-2;**
- **Initiation of the Phase 2 alfimeprase trial in acute ischemic stroke, CARNEROS-1 (Catheter directed Alfimeprase for Restoration of Neurologic function and Rapid Opening of arteries in Stroke);**
- Presentation of efficacy data from Phase 2a rNAPc2 trial and Phase 2 heparin replacement trial in patients with ACS at the World Congress of Cardiology, Barcelona, Spain, in September 2006;
- Initiation of a Phase 1 study of NU206, which is being developed for the treatment of cancer therapy-induced mucositis. [Emphasis added.]

34. Commenting on these results, Defendant Love stated:

**Over the past several months, we have made significant progress in the expansion of our pipeline and the execution of our milestones. In our acute cardiovascular programs, we have designated NU172, a short-acting anticoagulant, as our newest development candidate; we plan to initiate a Phase 2 trial with our most advanced candidate, alfimeprase, in stroke by year end; and we expect to complete enrollment in the first trial in each of our Phase 3 alfimeprase programs in the second half of the year. In cancer, we are preparing to initiate a Phase 1 trial with NU206, which is being developed for cancer-therapy induced mucositis, and have begun to lay the groundwork for a Phase 2 trial with rNAPc2 in colorectal cancer, based on the role that the factor VIIa/tissue factor protease complex plays in the cellular signaling of metastasis and angiogenesis in a variety of cancers. ... Finally, as we continue to build our business and prepare for commercialization, we have added several key executives to our senior management team.** [Emphasis added.]

35. Also on August 3, 2006, Defendants held a conference call to discuss the Company's recent developments with regard to alfimeprase. On the call, Defendants stated:

**TED LOVE, CHAIRMAN AND CEO, NUVELO, INC.: ... Finally, our collaboration with Bayer HealthCare to develop and commercialize alfimeprase continues to go very well, and we are tracking to our goals and milestones laid out for the**

**program.** Bayer will highlight alfineprase in two events this fall, a satellite symposium at the Cardiovascular and Interventional Radiological Society in Europe, known as CIRSE, held in September, and during Bayer's international news conference, entitled Perspectives on Innovation, in Germany this October.

We are very pleased that alfineprase will be included in these events, which emphasize the importance Bayer attributes to this program. Let me now turn the call over to Ward to discuss the specifics of our second quarter 2006 financial results.

WARD WOLFF SVP, FINANCE AND CFO, NUVELO, INC.: Thank you, Ted, and good afternoon, everyone. I am very pleased to have recently joined Nuvelo and to participate for the first time on this quarterly call. This afternoon, we released our financial results for the second quarter, ended June 30, 2006, and I will cover some of the highlights of those results.

\* \* \*

MICHAEL LEVY, SVP, R&D, NUVELO, INC.: Thank you, Ward. Over the next few minutes, I will provide you with an update of our development pipeline, focusing our acute cardiovascular and emerging oncology programs, as well as share with you our excitement about the progress we've made. Let's begin with an update on alfineprase, our lead cardiovascular product candidate.

**On the clinical front, with the initiation of NAPA-3, we now have four phase III alfineprase trials ongoing in our acute peripheral arterio-occlusion and cath through occlusion programs and are on track to expand the development program this year with the initiation of a phase II trial in stroke.**

NAPA-3, which started this April, is the second of two phase III trials in our acute [KO] program. Under our special protocol assessment, or SPA, with the FDA, NAPA-3 will essentially replicate the NAPA-2 trial. It too is a randomized, double-blind study, comparing 0.3 milligrams per kilogram of alfineprase with placebo, and it too will enroll 300 patients with the primary endpoint of avoidance of open vascular surgery within 30 days of treatment.

A variety of secondary endpoints are also being evaluated, including restoration of blood flow, which is a key measure

physicians use in determining success of treatment. Safety endpoints, such as the incidence of bleeding and pharmacoeconomic endpoints, such as length of hospital and ICU stay. We continue to be on track to complete enrollment in NAPA-2, the first phase III trial in this program in the second half of 2006.

**Typically, the time required to lock the database, analyze the data and then provide top-line results in several months. Subsequently, we expect that one of our investigators would submit a more complete analysis of the full data at an appropriate medical conference as soon as possible thereafter.**

**Moving now to our second target indication, catheter occlusion. We are pleased to announce that results from our phase II trial of alfimeprase in its indication were published in the July 1st issue of the Journal of Clinical Oncology. In addition, our phase III program in this indication is progressing well. We achieved our milestone of initiating the second phase III catheter occlusion trial, SONOMA-3, in the first half of 2006. This open-label single-arm trial is evaluating the safety and efficacy of three milligrams of alfimeprase in 800 patients with occluded central venous catheters.**

**We also continue to be on track to complete enrollment in SONOMA-2, the first trial in this program, in the second half of 2006, and expect to provide top-line results several months afterwards. More complete analysis of the data will be presented at an appropriate medical conference as soon as possible thereafter.**

**At our first R&D day in June, we shared with you the progress we've made on our third target indication for alfimeprase, acute ischemic stroke. We've met with the FDA and with our partner Bayer and have agreed upon the design of our phase II trial. And in keeping with our theme of California wine regions, the alfimeprase stroke trial has been designated the CARNEROS-1 trial. This will be an open-label dose-escalation study in up to 90 patients within three to nine hours of stroke onset and will measure safety and arterial re-[catalyzation] rate.**

**We expect to initiate this trial the second half of this year. At our R&D day, we also had a chance to expand on the potential for alfimeprase in deep venous thrombosis for DVT. At that meeting, we highlighted that the unfavorable risk to benefit ratio for plasminogen activators has limited their use in this patient population. In contrast, the speed and safety profile we've seen**

**today with alfimeprase in our acute PAO and catheter occlusion trials makes it a compelling candidate, potentially, to treat DVT. And we continue to be on track to initiate a phase II trial in DVT in 2007.**

**On the manufacturing side, we are completing commercial-scale process validation and are planning to initiate commercial production runs early next year.** As Ted mentioned, Bayer will be sponsoring a satellite symposium at the CIRSE meeting in Rome, Italy, in September entitled, Advances in Thrombolytic Therapy, a Focus on Alfimeprase.

\* \* \*

**TED LOVE: Thank you, Michael. As you can see, we have a number of exciting milestones coming up, including for alfimeprase, completion of patient enrollment in both the NAPA-2 and SONOMA-2 trials and initiation of CARNEROS-1, our phase II trial in ischemic stroke, all expected to occur in the second half of 2006.**

\* \* \*

JIM BIRCHENOUGH: And just one other question, just on the type of patients that may come in to the trial with an acute occlusive event. I'm imagining that for PAO they may be a bit of a heterogeneous group with some patients that may have enlarged fixed [inaudible] occlusion already and then a minor thrombus on top of it, a direct fibrinolytic might not help that much, whereas a patient with a small fixed lesion and a large thrombus may derive more of a benefit.

Can you just talk about the heterogeneity of the patients that you expect in this trial and how you I guess avoid the risk of patients coming in with enlarged fixed lesions that you might be able to help much with a thrombolytic.

MICHAEL LEVY: So, as you suggest, the group of patients that present are heterogeneous. Almost all the patients, if not all the patients, do have some sort of underlying fixed peripheral vascular disease, and that a thrombus generally forms on top of that when flow is diminished to a critical stage. We do of course select in this trial for patients who have had an acute occlusion of less than 14 days. That's one thing we do. And obviously I have no data to share with you about this particular trial, but **I can say that we were very gratified in phase to find that alfimeprase worked**

very well on big clots and on small clots, and we've discussed that in the past, that we've had some examples of very large clots, clots up to 60 centimeters in length, that we've dissolved rapidly.

And it's worked on what we thought were new clots and old clots, based on the angiograms that we read showing extensive collateralizations, which tend to be evidence of an older clot. And on top of that, in phase I, we looked at patients who had chronic peripheral vascular disease where the burden of their illness was fixed disease and very little was acute thrombus. And we were gratified that in 40% of those patients as well we could see improvements on the angiogram and restoration of blood flow. [Emphasis added.]

36. On September 5, 2006, Nuvelo issued a press release entitled "Nuvelo Announces Completion of Patient Enrollment in SONOMA-2, First Phase 3 Trial of Alfimeprase in Central Venous Catheter Occlusion." Therein, the Company, in relevant part, stated:

Nuvelo, Inc. (Nasdaq: NUVO) today announced that it has completed patient enrollment in the first Phase 3 clinical trial of alfimeprase for the treatment of central venous catheter occlusion (CO).

The Phase 3 trial, known as SONOMA-2 (Speedy Opening of Non-functional and Occluded catheters with Mini-dose Alfimeprase-2), is the first of two ongoing, multi-national trials in the Phase 3 alfimeprase program for CO. This randomized, double-blind trial compared the efficacy and safety of 3 mg of alfimeprase with placebo in a 2:1 ratio in approximately 300 patients with occluded central venous catheters. The study's primary endpoint is restoration of function to occluded central venous catheters at 15 minutes.

**"Catheter occlusion is a widespread problem which can result in delayed administration of critical therapies such as cancer chemotherapy or antibiotics, and we are optimistic that alfimeprase will more rapidly restore delivery of these life-saving medications than existing treatments," said Steven R. Deitcher, M.D., vice president and chief medical scientist for Nuvelo and former principal investigator of Nuvelo's Phase 2 alfimeprase catheter occlusion trial. "We thank the many patients, physicians, and health care workers who participated in this trial and look forward to sharing top-line data within the next several months."**

The second Phase 3 trial, known as SONOMA-3, was initiated in February 2006 and is ongoing. This open-label, single-arm trial will evaluate the safety and efficacy of 3 mg of alfimeprase in 800 patients with occluded central venous catheters.

37. Also on September 5, 2006, Nuvelo issued a press release entitled "Nuvelo Announces Completion of Patient Enrollment in NAPA-2, First Phase 3 Trial of Alfimeprase in Acute Peripheral Arterial Occlusion." Therein, the Company, in relevant part, stated:

Nuvelo, Inc. (Nasdaq: NUVO) today announced that it has completed patient enrollment in the first Phase 3 clinical trial of alfimeprase for the treatment of acute peripheral arterial occlusion (PAO), or "leg attack."

The Phase 3 trial, known as NAPA-2 (Novel Arterial Perfusion with Alfimeprase-2), is the first of two multi-national trials in the Phase 3 alfimeprase program for acute PAO. This randomized, double-blind study compared the efficacy and safety of 0.3 mg/kg of alfimeprase versus placebo in approximately 300 patients in over 100 centers worldwide. The study's primary endpoint is avoidance of open vascular surgery within 30 days of treatment. Open vascular surgery includes procedures such as surgical embolectomy and peripheral arterial bypass graft surgery as well as amputation, but does not include catheter-based procedures such as percutaneous angioplasty or stenting. A variety of secondary endpoints are also being evaluated, including restoration of arterial blood flow, safety endpoints such as the incidence of bleeding and pharmacoeconomic endpoints such as length of hospital and intensive care unit (ICU) stay.

**"We'd like to thank the patients, investigators, and coordinators at our trial sites for helping us to reach this important milestone," said Michael D. Levy, M.D., senior vice president, research and development for Nuvelo. "We look forward to announcing top-line data within the next several months and are hopeful that these data will confirm our Phase 2 study, which demonstrated the ability to restore arterial blood flow within four hours of initiation of dosing with a favorable safety profile."**

The second Phase 3 trial, known as NAPA-3, was initiated in April 2006 and is ongoing. This trial essentially replicates the NAPA-2 study design and is being conducted under a special protocol assessment (SPA) agreement with the U.S. Food and Drug Administration (FDA).

In addition, the FDA granted alfimeprase fast track designation for the treatment of acute PAO, which can potentially facilitate development and expedited review of a Biologics License Application (BLA). Fast track designation is reserved for new drugs that demonstrate the potential to address an unmet medical need and are intended for the treatment of a serious or life-threatening condition. Alfimeprase also has received orphan drug designation from both the FDA and the Committee for Orphan Medicinal Products of the European Medicines Agency for the treatment of acute PAO. [Emphasis added.]

38. On November 2, 2006, Nuvelo issued a press release entitled “Nuvelo Reports Third Quarter 2006 Financial Results and Accomplishments.” Therein, the Company, in relevant part, stated:

Nuvelo, Inc. (Nasdaq: NUVO) today announced third quarter 2006 financial results and accomplishments.

For the third quarter ended September 30, 2006, Nuvelo reported a net loss of \$26.7 million, or \$0.51 per share, compared to a net loss of \$18.5 million, or \$0.44 per share, for the same period in 2005. As of September 30, 2006, the company had cash, cash equivalents and short-term investments of \$157.2 million.

Revenues for the third quarter of 2006 were \$0.9 million compared to third quarter 2005 revenues of \$0.1 million. The increase was primarily due to the recognition of revenue from the up-front license fee of \$50.0 million received from Bayer HealthCare (Bayer) in January 2006. The up-front license fee was recorded as deferred revenue upon receipt and is being recognized as revenue on a straight-line basis over the term of the agreement.

Total third quarter 2006 operating expenses were \$29.7 million compared to \$19.0 million in the prior year period. Research and development expenses were \$23.1 million for the three months ended September 30, 2006 compared to \$14.8 million for the third quarter of 2005. These amounts are net of credits for cost-sharing amounts billable to collaboration partners of \$7.9 million and \$0.5 million in the respective periods. Research and development expenses increased primarily due to clinical trial and drug manufacturing activities, a \$4.0 million up-front license fee paid as a result of our entry into an expanded collaboration agreement with Archemix, and personnel costs, including \$1.1 million of non-cash employee stock-based compensation expense under SFAS 123(R),

which were partially offset by the increase in cost-sharing credits noted above. General and administrative expenses were \$6.8 million for the three months ended September 30, 2006 and \$4.2 million for the same period in 2005. The increase was primarily due to expenses related to the growth in our infrastructure, pre-commercialization activities for alfineprase and non-cash employee stock-based compensation expense of \$1.3 million.

\* \* \*

For the three and nine months ended September 30, 2006, our net cash used in operating activities was \$24.0 million and \$22.1 million, respectively. Our cash burn, a non-GAAP measure, as defined and reconciled below, was \$22.5 million and \$25.3 million in the three and nine months ended September 30, 2006, respectively, both including the \$4.0 million up-front license fee paid to Archemix. Additionally, cash burn in the nine-month period includes the receipt of the \$50.0 million up-front payment from Bayer in the first quarter and the \$5.4 million cash payment in the second quarter to settle the principal and interest on a promissory note issued to Affymetrix.

\* \* \*

### **Recent Corporate Accomplishments**

- **Completed enrollment in the first Phase 3 alfineprase trial in acute PAO, NAPA-2;**
- **Completed enrollment in the first Phase 3 alfineprase trial in CO, SONOMA-2;**
- Presented Phase 2 efficacy data from the ANTHEM (Anticoagulation with rNAPc2 To Help Eliminate MACE)/TIMI 32 trial evaluating rNAPc2 in patients with acute coronary syndromes (ACS) at the World Congress of Cardiology in Barcelona and at the Transcatheter Cardiovascular Therapeutics 2006 Conference in Washington, D.C.;
- Signed a new collaboration agreement with Archemix and designated NU172, a short-acting, direct thrombin inhibiting aptamer, as a development candidate for potential use as an anticoagulant for patients undergoing acute medical or surgical procedures;

- Expanded management team with Ward Wolff as senior vice president, finance and chief financial officer, and Jill Pergande as vice president, human resources.

### **Upcoming Milestones**

In the remainder of 2006 and into early 2007, Nuvelo anticipates accomplishing the following:

- **Presentation of Phase 2 alfimeprase and rNAPc2 data at the American Heart Association Scientific Sessions 2006 in November;**
- **Release of top-line data from both the NAPA-2 and SONOMA-2 trials;**
- **Initiation of a Phase 2 alfimeprase trial in acute ischemic stroke, CARNEROS-1 (Catheter directed Alfimeprase for Restoration of Neurologic function and Rapid Opening of arteries in Stroke) in the fourth quarter of 2006;**
- Initiation of a Phase 1 study evaluating NU206 in the fourth quarter of 2006;
- Initiation of IND-enabling studies for NU172 in the fourth quarter of 2006. [Emphasis added.]

39. Commenting on the recent developments, Defendant Love stated:

**In the third quarter, we achieved two significant milestones in the Company's history by completing enrollment in the first trial in both Phase 3 alfimeprase programs. We also advanced our pipeline by presenting positive results from a Phase 2 proof-of-concept trial evaluating the potential of rNAPc2 in the treatment of patients with acute coronary syndromes (ACS), nominating a new product candidate, NU172, and expanding our agreement with Archemix for the discovery of short-acting anticoagulants. Over the next several months, we will remain focused on our key value-driving deliverables – execution of our milestones, and producing and announcing top-line alfimeprase data in acute peripheral arterial occlusion (PAO) and catheter occlusion (CO). [Emphasis added.]**

40. Also on November 2, 2006, Defendants held a conference call to discuss the Company's recent developments with regard to alfimeprase. On the call, Defendants stated:

DR. TED W. LOVE, MD, PRESIDENT AND CEO, NUVELO:  
Thank you all for joining us today. We are very pleased to share with you our third quarter financial results and accomplishments.

\* \* \*

**Over the past months, we've been focused on the execution of our milestones, particularly with regards to our alfimeprase Phase III programs and the development of our pipeline. Let me quickly review the most recent corporate accomplishments.**

**In September, we were very pleased to announce the completion of patient enrollment in the first trial of each Phase III alfimeprase programs. This includes NAPA-2, which is evaluating alfimeprase for the treatment of acute peripheral arterial occlusion (or PAO), and SONOMA-2, which is evaluating alfimeprase for the treatment of catheter occlusion (or CO).**

\* \* \*

Let me now turn the call over to Ward to discuss the specifics of our third quarter 2006 financial results.

WARD WOLFF, SVP FINANCE AND CFO, NUVELO: Thank you, Ted, and good afternoon, everyone. After the close of the market today, we released our financial results for the third quarter ended September 30, 2006 and I will cover some of the highlights of those results.

\* \* \*

To elaborate on those activities, I will turn the call over to Dr. Michael Levy, Senior Vice President of R&D.

DR. MICHAEL LEVY, SVP, R&D, NUVELO: ... Over the next few minutes, I will provide you with an update of our development pipeline, focusing on our acute cardiovascular and emerging oncology programs, as well as share with you our excitement about the progress we've made.

**Let's begin with an update on alfimeprase, our lead cardiovascular product candidate.**

**As announced in September, we've completed enrollment in the first trial in both our Phase III alfimeprase programs for**

**acute PAO and CO. These are important milestones for us. We are now working hard to collect and process the data in a high-quality, efficient manner and are on track to announce top line data from each trial before year-end or early in 2007.**

**In addition to the two trials we've completed, we have ongoing Phase III trials in acute PAO and CO, known as NAPA-3 and SONOMA-3, respectively. NAPA-3 started this April and the trial is designed to essentially replicate NAPA-2.**

**Earlier this year, we gained agreement from the FDA to transfer select high-quality sites from the NAPA-2 trial to the NAPA-3 trial upon completion of the first study and in fact, we've already begun that process.**

**As we did with NAPA-2, we plan to announce guidance on when we expect to complete this trial when we have more experience with the trial accrual rate.**

**SONOMA-3 began this February and is an open label, single arm trial evaluating the safety and efficacy of 3.0-mg of alfimeprase in 800 patients with occluded central venous catheters. As with NAPA-3, we plan to provide guidance on when we expect to complete this trial, when we have sufficient experience with the trial accrual rate.**

**Moving on to the potential use of alfimeprase in stroke, we remain optimistic that alfimeprase's speed of action and safety profile give us the ideal profile to study in the treatment of acute ischemic stroke. Alfimeprase may be able to rapidly restore blood flow, decrease bleeding complications and side effects, and expand the treatment window beyond the current three-hour timeframe.**

**We continue to make progress with our clinical plan and expect to initiate the Phase II trial, known as CARNEROS-1, in the fourth quarter of this year. This will be an open label, dose escalation study in up to 90 patients within three-to-nine hours of stroke onset and the primary end points will focus on safety as well as arterial recanalization and reperfusion rates.**

**Alfimeprase's speed and safety profile also make it a compelling candidate to study for the treatment of deep venous thrombosis (or DVT) and we continue to be on track to initiate a Phase II trial in DVT in 2007.**

**In keeping with our efforts to educate physicians about our alfimeprase clinical trial results, we continue to make presentations at relevant scientific meetings. The next such presentation will be at the American Heart Association (AHA) Scientific Sessions 2006, where we will be presenting data from the previous NAPA-1 Phase II trial of alfimeprase in acute PAO.**

\* \* \*

DR. TED W. LOVE: Thank you, Michael. Over the next several months, we will remain focused on our key value-driving deliverables, execution of our milestones, and producing and announcing top line alfimeprase results in acute PAO and CO.

For our cardiovascular pipeline, our upcoming milestones include presentations of alfimeprase and rNAPc2 at the AHA in November. This will include data from the NAPA-1 Phase II trial of alfimeprase in acute PAO and further safety and efficacy results from the Phase II ANTHEM TIMI-32 trial, evaluating rNAPc2 in patients with ACS.

Second, the release of top line data results from both the NAPA-2 and SONOMA-2 by the end of this year or early in 2007. Third, the initiation of CARNEROS-1, our Phase 2 trial evaluating alfimeprase in acute ischemic stroke, in the fourth quarter of 2006 and last, the initiation of a Phase 2 trial evaluating alfimeprase in deep venous thrombosis in 2007.

For our oncology pipeline, initiation of an NU206 Phase I study in the fourth quarter of 2006 and initiation of a Phase II program evaluating rNAPc2 in metastatic colorectal cancer in the first half of 2007.

**In closing, we remain on track to successfully complete each of the milestones that we established in 2006. We look forward to updating you on our progress on our next quarterly call.**

\* \* \*

MAGED SHENOUDA, ANALYST, UBS: Sure, thanks for taking my questions. **First, just as a market question, can you help us size the DVT opportunity relative to the PAO opportunity?** And also, what are you thinking, at least at this very early stage, in terms of dosing and pricing? And then also, could you just elaborate on NU172 a little bit?

DR. MICHAEL LEVY: Thanks for the question. Let me start off, then, with the question about the DVT opportunity. **Looking strictly in terms of the epidemiology, clearly there are a lot more DVT patients diagnosed and ready for treatment in the United States every year than there are acute PAO patients and it's difficult to estimate exactly how big the DVT opportunity is in terms of patients. It depends a bit on diagnosis.**

But the best conservative estimates indicate that something like 650,000 patients are diagnosed in the United States every year and treated and with acute PAO, it's more like 100,000 to 125,000, so a bigger unmet medical need, in terms of the patient load. And we think that translates into the size of the market opportunity as well.

As you know, typically you don't finalize decisions on pricing until after the Phase III trials are complete and you move forward with discussions with various governmental agencies around the world. And we're just not at a stage yet where we can share much information with you, with regard to pricing.

**But we think DVT is a huge opportunity for us and when you run through the math, even on the back of an envelope, you can see that you don't have to have a very large share of the market before it becomes a very big commercial opportunity indeed.**

\* \* \*

JIM BIRCHENOUGH, ANALYST, LEHMAN BROTHERS: Hi guys, just a couple of questions in looking ahead to the NAPA-2 results. **What do you think an acceptable excess bleeding rate is or is there any acceptable excess bleeding rate and in particular, when we think about intracerebral hemorrhage, is there any acceptable rate? Or should we expect to see really none with alfimeprase?**

DR. MICHAEL LEVY: Well, that's a very good question and let me tell you what we're aiming for. Obviously we're aiming to develop a compound that has the best possible profile in terms of the risk/benefit ratio in particular and what we'll do is look at the data in its totality. **So we need to look at how fast and efficacious alfimeprase is and then we need to look at the side effect profile.**

**But at this time, we're very confident and optimistic that we'll be able to show in Phase III that we have a drug that has a great risk/benefit profile and that it has the potential to be an important new treatment.** [Emphasis added.]

41. The statements contained in ¶¶ 22 – 40 were materially false and misleading when made because Defendants failed to disclose or indicate the following: (1) that the clinical trial information regarding multiple alfimeprase studies was inaccurate; (2) specifically, clinical data from testing failed to show that alfimeprase, when administered through a catheter, could dissolve blood clots; (3) that no reliable data existed to show that alfimeprase would meet the high standards for efficacy for FDA approval; (4) that such information, as described above, was known to Defendants as early as December 2004, when Amgen discontinued its investment in alfimeprase; and (5) that, as a result of the above, the Company's statements concerning alfimeprase and its clinical trials were lacking in any reasonable basis when made.

### **The Truth Begins to Emerge**

42. On December 11, 2006, Nuvelo shocked investors by issuing a press release entitled “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.” Therein, the Company, in relevant part, revealed:

**Nuvelo, Inc. (Nasdaq: NUVO) and Bayer HealthCare today announced 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.** [Emphasis added.]

43. Commenting on the revelation, Defendant Love stated:

These outcomes are disappointing particularly for patients with acute PAO, who have few treatment options. ... We and our partner Bayer will conduct further analyses and have discussions with the Data Safety and Monitoring Board members, outside experts and regulatory authorities to determine how to proceed with the development of alfimeprase, including the possibility of alternative dosing and delivery.”

44. During the December 11, 2006 conference call to discuss the Company’s recent shocking revelations with regard to alfimeprase, Defendant Love stated:

**DR. TED W. LOVE, CHAIRMAN AND CEO, NUVELO: Thanks to all of you for joining us today. Here with me today are members of the Nuvelo senior management team. As you are now aware, we and Bayer announced top-line data demonstrating that the Phase III clinical trial of alfimeprase in acute peripheral arterial occlusion, RPAO, known as NAPA-2, did not meet its primary endpoint of avoidance of open vascular surgery at 30 days of treatment.**

**In addition, the Phase III trial in catheter occlusion, or CO, known as SONOMA-2, did not meet the endpoint of restoration of function at 15 minutes. We have also temporarily suspended enrollment in the ongoing Phase III trials NAPA-3 and SONOMA-3 until further analysis and discussion with outside experts and regulatory agencies are completed.**

**To be clear, we are not ending either of the ongoing trials at this time. We were obviously disappointed in the outcomes of the NAPA-2 and SONOMA-2 trials particularly for the patients with acute PAO who have few treatment options. The NAPA-2 trial also did not meet its secondary efficacy and safety endpoints.**

We are confident that the NAPA-2 study compliance and conduct were excellent. **One of the key observations from the trial suggest the possibility that a significant number of patients**

**mechanical manipulation resulted in disruption of the clot allowing runoff of alteplase beyond the clot with an activation by alpha-2 macroglobulin.** This may have negatively impacted the alteplase ARM.

**While the data from the SONOMA-2 trial show a statistically significant difference in the rate at which alteplase and placebo dissolved clots in venous catheters at 15 minutes, this result did not meet the high threshold established by the FDA for regulatory approval based on only one control trial.** We and our partner Bayer will conduct further analysis and have discussions with the data safety monitoring board members, outside experts, and regulatory authorities to determine how to proceed with the development of alteplase in these indications including the possibility of alternative dosing and delivery.

\* \* \*

**JIM BIRCHENOUGH, ANALYST, LEHMAN BROTHERS:** Hi, Ted. Just I guess the first question is whether there was any evidence of thrombolytic effect of alteplase in either NAPA-2 or SONOMA-2 and what that evidence of thrombolytic effect was? I'm somewhat baffled based on the prior Phase II results that we wouldn't have seen any thrombolytic effect here. I'm just wondering whether you can characterize any positives that you saw in the trial results?

**DR. TED W. LOVE:** Hi, Jim. I'd be happy to try to do that. We don't want to get into too many of the details until we obviously have a DSMB go through all of this. But to get to your point, we definitely did see thrombolytic effect. We saw it at what would traditionally be considered a statistically significant rate in the SONOMA trial. But we had an agreement with the FDA that the P-value would be far lower than .05 which would be the traditional number. We were below that number. So we did see thrombolytic effect in catheter occlusion.

**In PAO, we actually saw a very profound effect of placebo. And in fact I think the best we can guess at this point is that the mechanical disruption of the clot facilitated a very high rate of clot dissolution and clot resolution. And it may have also facilitated very rapid washout of alteplase really allowing it not to demonstrate any particular advantage over the placebo.**

**JIM BIRCHENOUGH:** So based on that assessment, could you comment on where you stand for pursuing alteplase in

stroke and DVT, whether we should expect continued development in those areas?

**DR. TED W. LOVE:** I think what we want to do at this point is complete the analysis of all the data that we've got both efficacy and safety in making informed decisions. We obviously have suspended the enrollment in SONOMA-3 and NAPA-3 and obviously would not initiate enrollment in any other program until we've worked through all of these questions.

\* \* \*

KIM LEE, ANALYST, PACIFIC GROWTH EQUITIES: Thanks for taking the question. What is the status of initiation of the Phase II trials in stroke and DVT?

**DR. TED W. LOVE:** So as I mentioned we put the enrollment of all the trials with alfimeprase on hold. And we really want to work carefully through all the data that we've got before we move forward with any of the -- any further enrollment in NAPA-3 or SONOMA-3 or any of the other programs. So all those programs will wait for review of all the data.

\* \* \*

**JIM BIRCHENOUGH:** So I'm just trying to understand why that might not have happened in the Phase II experience where it seems that you had higher thrombolysis rates?

**DR. TED W. LOVE:** I think it probably did but that's the kind of stuff we need to go through. I actually think it did probably happen in Phase II. And when we were seeing it, when we were seeing high rates of opening, we expected that was all due to drug. [Emphasis added.]

45. On the release of this shocking news, shares of Nuvelo plummeted \$15.50, or 79 percent, to close, on December 11, 2006, at \$4.05 per share, on unusually high trading volume.

46. The market's reaction to the Company's release of this unexpected and shocking revelation may best be summed up by the views stated by the biotechnology analysts that followed Nuvelo. In their research reports released immediately following the Company's shocking news, the analysts, in relevant parts, stated:

- Miller Johnson Steichen Kinnard analyst Carl Byrnes:

**NAPA-2 and SONOMA-2 Trials Fail to Meet Primary and Secondary Endpoints**

**The failure of the NAPA-2 and SONOMA-2 trials is a stunning setback.** While it is possible that alternative dosing or delivery may offer some hope for future development progression of alfimeprase, **we assess these prospects as being very low at this juncture.** [Emphasis added.]

- Prudential analyst Jason Zhang, Ph.D.:

**Sometimes, when a stock is hammered badly after failure of a key clinical trial, it could be a good buying opportunity if the trial could be salvaged or if the drug is in other clinical trials that could yield positive data to support further development or approval. We believe that is not the case here. Alfimeprase is the main drug from Nuvelo's pipeline and represents more than 80% of the company's value. Without a reasonable expectation this drug would be approved for the two indications the company sought, the stock is unlikely to recover anytime soon.** [Emphasis added.]

- Wachovia analysts George Farmer, Ph.D. and Francine Pollack, CFA:

**Following disappointing Phase III results on alfimeprase, we await additional data and guidance from management to better assess this program. We view only modest value in the remainder of the pipeline.** [Emphasis added.]

**PLAINTIFF'S CLASS ACTION ALLEGATIONS**

47. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased the

securities of Nuvelo between January 5, 2006 and December 8, 2006, inclusive (the “Class Period”) and who were damaged thereby. Excluded from the Class are Defendants, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.

48. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Nuvelo’s securities were actively traded on NASDAQ under the symbol “NUVO.” While the exact number of Class members is unknown to Plaintiff at this time and can only be ascertained through appropriate discovery, Plaintiff believes that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Nuvelo or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

49. Plaintiff’s claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants’ wrongful conduct in violation of federal law that is complained of herein.

50. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation.

51. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

- a. whether the federal securities laws were violated by Defendants’ acts as alleged herein;

- b. whether statements made by Defendants to the investing public during the Class Period misrepresented material facts about the business, operations and management of Nuvelo; and
- c. to what extent the members of the Class have sustained damages and the proper measure of damages.

52. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

#### **UNDISCLOSED ADVERSE FACTS**

53. The market for Nuvelo's securities was open, well-developed and efficient at all relevant times. As a result of these materially false and misleading statements and failures to disclose, Nuvelo's securities traded at artificially inflated prices during the Class Period. Plaintiff and other members of the Class purchased or otherwise acquired Nuvelo securities relying upon the integrity of the market price of Nuvelo's securities and market information relating to Nuvelo, and have been damaged thereby.

54. During the Class Period, Defendants materially misled the investing public, thereby inflating the price of Nuvelo's securities, by publicly issuing false and misleading statements and omitting to disclose material facts necessary to make Defendants' statements, as set forth herein, not false and misleading. Said statements and omissions were materially false and misleading in that they failed to disclose material adverse information and misrepresented

the truth about the Company, its business and operations, as alleged herein.

55. At all relevant times, the material misrepresentations and omissions particularized in this Complaint directly or proximately caused or were a substantial contributing cause of the damages sustained by Plaintiff and other members of the Class. As described herein, during the Class Period, Defendants made or caused to be made a series of materially false or misleading statements about Nuvelo's business, prospects and operations. These material misstatements and omissions had the cause and effect of creating in the market an unrealistically positive assessment of Nuvelo and its business, prospects and operations, thus causing the Company's securities to be overvalued and artificially inflated at all relevant times. Defendants' materially false and misleading statements during the Class Period resulted in Plaintiff and other members of the Class purchasing the Company's securities at artificially inflated prices, thus causing the damages complained of herein.

#### **LOSS CAUSATION**

56. Defendants' wrongful conduct, as alleged herein, directly and proximately caused the economic loss suffered by Plaintiff and the Class.

57. During the Class Period, Plaintiff and the Class purchased securities of Nuvelo at artificially inflated prices and were damaged thereby. The price of Nuvelo securities declined when the misrepresentations made to the market, and/or the information alleged herein to have been concealed from the market, and/or the effects thereof, were revealed, causing investors' losses.

#### **SCIENTER ALLEGATIONS**

58. As alleged herein, Defendants acted with scienter in that Defendants knew that the public documents and statements issued or disseminated in the name of the Company were

materially false and misleading; knew that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the federal securities laws. As set forth elsewhere herein in detail, Defendants, by virtue of their receipt of information reflecting the true facts regarding Nuvelo, their control over, and/or receipt and/or modification of Nuvelo's allegedly materially misleading misstatements and/or their associations with the Company which made them privy to confidential proprietary information concerning Nuvelo, participated in the fraudulent scheme alleged herein.

59. Additionally, during the Class Period and with the Company's stock trading at artificially inflated prices, Defendants acted with further scienter in that they knew that their false and misleading statements would continue to support an artificially inflated stock price. Based on this increased value in the stock price, Nuvelo was able to generate significantly superior amounts of capital through their financing and stock offering activities. For example, the Company was able to successfully complete a Follow-On Offering in 2006, yielding them \$119 million. Additionally, the Company was able to partner with Bayer to receive an immediate capital influx of \$50 million to stabilize their anemic operations, with the ability to earn hundreds of millions of dollars more contingent upon the achievement of certain milestones.

60. These false and misleading statements also enabled the Defendants to secure higher bonus payments, which were directly based upon their success in bringing alfimeprase to the commercial market.

61. Moreover, Defendant Gary Titus was able to cash in on the Company's artificially inflated stock price by selling 75,831 shares of Nuvelo for gross proceeds of \$1,521,360.00. His inside trading during the class period is evidenced by the following chart:

Date	Inside Seller	# Shares	Price	Gross proceeds
August 30, 2006	TITUS, GARY	14,000	\$20.70	\$289,800
August 29, 2006	TITUS, GARY	6,831	\$20.65	\$141,060
August 25, 2006	TITUS, GARY	40,000	\$19.88 - \$20.00	\$798,000
August 24, 2006	TITUS, GARY	15,000	\$19.50	\$292,500

**TOTAL SALES: 75,831 \$1,521,360**

**Applicability of Presumption of Reliance:  
Fraud On The Market Doctrine**

62. At all relevant times, the market for Nuvelo securities was an efficient market for the following reasons, among others:

- a. Nuvelo stock met the requirements for listing, and was listed and actively traded on NASDAQ, a highly efficient and automated market;
- b. As a regulated issuer, Nuvelo filed periodic public reports with the SEC and NASDAQ;
- c. Nuvelo regularly communicated with public investors via established market communication mechanisms, including through regular disseminations of press releases on the national circuits of major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services; and
- d. Nuvelo was followed by several securities analysts employed by major brokerage firms who wrote reports which were distributed to the sales force and certain customers of their respective brokerage firms. Each of these reports was publicly available and entered the public marketplace.

63. As a result of the foregoing, the market for Nuvelo securities promptly digested

current information regarding Nuvelo from all publicly-available sources and reflected such information in Nuvelo's stock price. Under these circumstances, all purchasers of Nuvelo securities during the Class Period suffered similar injury through their purchase of Nuvelo securities at artificially inflated prices and a presumption of reliance applies.

### **NO SAFE HARBOR**

64. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false statements pleaded in this complaint. Many of the specific statements pleaded herein were not identified as "forward-looking statements" when made. To the extent there were any forward-looking statements, there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. Alternatively, to the extent that the statutory safe harbor does apply to any forward-looking statements pleaded herein, Defendants are liable for those false forward-looking statements because at the time each of those forward-looking statements was made, the particular speaker knew that the particular forward-looking statement was false, and/or the forward-looking statement was authorized and/or approved by an executive officer of Nuvelo who knew that those statements were false when made.

### **FIRST CLAIM** **Violation of Section 10(b) of** **The Exchange Act and Rule 10b-5** **Promulgated Thereunder Against All Defendants**

65. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

66. During the Class Period, Defendants carried out a plan, scheme and course of conduct which was intended to and, throughout the Class Period, did: (i) deceive the investing

public, including Plaintiff and other Class members, as alleged herein; and (ii) cause Plaintiff and other members of the Class to purchase Nuvelo securities at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Defendants, and each of them, took the actions set forth herein.

67. Defendants (a) employed devices, schemes, and artifices to defraud; (b) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements not misleading; and (c) engaged in acts, practices, and a course of business which operated as a fraud and deceit upon the purchasers of the Company's securities in an effort to maintain artificially high market prices for Nuvelo securities in violation of Section 10(b) of the Exchange Act and Rule 10b-5. All Defendants are sued either as primary participants in the wrongful and illegal conduct charged herein or as controlling persons as alleged below.

68. Defendants, individually and in concert, directly and indirectly, by the use, means or instrumentalities of interstate commerce and/or of the mails, engaged and participated in a continuous course of conduct to conceal adverse material information about the business, operations and future prospects of Nuvelo as specified herein.

69. These Defendants employed devices, schemes and artifices to defraud, while in possession of material adverse non-public information and engaged in acts, practices, and a course of conduct as alleged herein in an effort to assure investors of Nuvelo's value and performance and continued substantial growth, which included the making of, or the participation in the making of, untrue statements of material facts and omitting to state material facts necessary in order to make the statements made about Nuvelo and its business operations and future prospects in light of the circumstances under which they were made, not misleading, as set forth more particularly herein, and engaged in transactions, practices and a course of

business which operated as a fraud and deceit upon the purchasers of Nuvelo securities during the Class Period.

70. Each of the Individual Defendants' primary liability, and controlling person liability, arises from the following facts: (i) the Individual Defendants were high-level executives and/or directors at the Company during the Class Period and members of the Company's management team or had control thereof; (ii) each of these Defendants, by virtue of his responsibilities and activities as a senior officer and/or director of the Company was privy to and participated in the creation, development and reporting of the Company's internal budgets, plans, projections and/or reports; (iii) each of these Defendants enjoyed significant personal contact and familiarity with the other Defendants and was advised of and had access to other members of the Company's management team, internal reports and other data and information about the Company's finances, operations, and sales at all relevant times; and (iv) each of these Defendants was aware of the Company's dissemination of information to the investing public which they knew or recklessly disregarded was materially false and misleading.

71. The Defendants had actual knowledge of the misrepresentations and omissions of material facts set forth herein, or acted with reckless disregard for the truth in that they failed to ascertain and to disclose such facts, even though such facts were available to them. Such Defendants' material misrepresentations and/or omissions were done knowingly or recklessly and for the purpose and effect of concealing Nuvelo's operating condition and future business prospects from the investing public and supporting the artificially inflated price of its securities. As demonstrated by Defendants' overstatements and misstatements of the Company's business, operations and earnings throughout the Class Period, Defendants, if they did not have actual knowledge of the misrepresentations and omissions alleged, were reckless in failing to obtain

such knowledge by deliberately refraining from taking those steps necessary to discover whether those statements were false or misleading.

72. As a result of the dissemination of the materially false and misleading information and failure to disclose material facts, as set forth above, the market price of Nuvelo securities was artificially inflated during the Class Period. In ignorance of the fact that market prices of Nuvelo's publicly-traded securities were artificially inflated, and relying directly or indirectly on the false and misleading statements made by Defendants, or upon the integrity of the market in which the securities trades, and/or in the absence of material adverse information that was known to or recklessly disregarded by Defendants but not disclosed in public statements by Defendants during the Class Period, Plaintiff and the other members of the Class acquired Nuvelo securities during the Class Period at artificially high prices and were damaged thereby.

73. At the time of said misrepresentations and omissions, Plaintiff and other members of the Class were ignorant of their falsity, and believed them to be true. Had Plaintiff and the other members of the Class and the marketplace known the truth regarding the problems that Nuvelo was experiencing, which were not disclosed by Defendants, Plaintiff and other members of the Class would not have purchased or otherwise acquired their Nuvelo securities, or, if they had acquired such securities during the Class Period, they would not have done so at the artificially inflated prices which they paid.

74. By virtue of the foregoing, Defendants have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

75. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases and sales of the Company's securities during the Class Period.

**SECOND CLAIM**  
**Violation of Section 20(a) of**  
**The Exchange Act Against the Individual Defendants**

76. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

77. The Individual Defendants acted as controlling persons of Nuvelo within the meaning of Section 20(a) of the Exchange Act as alleged herein. By virtue of their high-level positions, and their ownership and contractual rights, participation in and/or awareness of the Company's operations and/or intimate knowledge of the false statements filed by the Company with the SEC and disseminated to the investing public, the Individual Defendants had the power to influence and control and did influence and control, directly or indirectly, the decision-making of the Company, including the content and dissemination of the various statements which Plaintiff contends are false and misleading. The Individual Defendants were provided with or had unlimited access to copies of the Company's reports, press releases, public filings and other statements alleged by Plaintiff to be misleading prior to and/or shortly after these statements were issued and had the ability to prevent the issuance of the statements or cause the statements to be corrected.

78. In particular, each of these Defendants had direct and supervisory involvement in the day-to-day operations of the Company and, therefore, is presumed to have had the power to control or influence the particular transactions giving rise to the securities violations as alleged herein, and exercised the same.

79. As set forth above, Nuvelo and the Individual Defendants each violated Section 10(b) and Rule 10b-5 by their acts and omissions as alleged in this Complaint. By virtue of their positions as controlling persons, the Individual Defendants are liable pursuant to Section 20(a) of

the Exchange Act. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and other members of the Class suffered damages in connection with their purchases of the Company's securities during the Class Period.

**WHEREFORE**, Plaintiff prays for relief and judgment, as follows:

- a. Determining that this action is a proper class action under Rule 23 of the Federal Rules of Civil Procedure;
- b. Awarding compensatory damages in favor of Plaintiff and the other Class members against all Defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;
- c. Awarding Plaintiff and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and
- d. Such other and further relief as the Court may deem just and proper.

**JURY TRIAL DEMANDED**

Plaintiff hereby demands a trial by jury.

Respectfully submitted,

Dated:

\_\_\_\_\_  
Evan J. Smith  
240 Mineola Boulevard  
Mineola, NY 11501  
Telephone: (516) 741 – 4977  
Facsimile: (516) 741 – 0626

**SCHIFFRIN & BARROWAY  
TOPAZ & KESSLER, LLP**  
Richard A. Maniskas  
D. Seamus Kaskela

280 King of Prussia Rd.  
Radnor, PA 19087  
(610) 667-7706  
Telephone: (610) 667 – 7706  
Facsimile: (610) 667 – 7056

**Attorneys for Plaintiff**