

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

ELECTRICAL WORKERS PENSION FUND,	:	X	Civil Action No.
LOCAL 103, I.B.E.W., On Behalf of Itself and	:		
All Others Similarly Situated,	:		<u>CLASS ACTION</u>
	:		
Plaintiff,	:		COMPLAINT FOR VIOLATIONS OF
	:		FEDERAL SECURITIES LAWS
vs.	:		
	:		
NUVELO, INC., TED W. LOVE, GARY S.	:		
TITUS and SHELLY D. GUYER,	:		
	:		
Defendants.	:		
	:		
	:		<u>DEMAND FOR JURY TRIAL</u>

SUMMARY AND OVERVIEW

1. This is a securities class action on behalf of all purchasers of the publicly traded securities of Nuvelo, Inc. (“Nuvelo” or the “Company”) between 1/5/06 and 12/8/06, inclusive (the “Class Period”), including purchasers in Nuvelo’s 1/30/06 \$119 million follow-on offering (“Follow-On Offering”), against Nuvelo and certain of its key officers and directors for violations of the Securities Exchange Act of 1934 (the “Exchange Act”).

2. Nuvelo was founded in 1991. Nuvelo is a biopharmaceutical company engaged in the development and commercialization of acute cardiovascular and cancer therapies. During the Class Period, the Company’s drug development pipeline included three acute cardiovascular drugs under development: alfimeprase, recombinant nematode anticoagulant protein c2 (“rNAPc2”) and a thrombin inhibiting aptamer. However, the Company’s lead cardiovascular development program – which the market attributed 80% of the Company’s value to – was alfimeprase, a direct-acting thrombolytic agent, or blood clot dissolver. During the Class Period, Nuvelo conducted clinical trials for the use of alfimeprase for the treatment of acute peripheral arterial occlusion (“PAO”) and catheter occlusion (“CO”). Despite the fact they simply did not have the clinical data to back up their statements, ***and actually had clinical data they were concealing demonstrating alfimeprase lacked efficacy***, defendants repeatedly stated alfimeprase had already proved effective in clinical trials for the treatment of PAO and CO – and would undoubtedly beat the placebo in terms of efficacy in ongoing Phase III testing – leading to alfimeprase’s commercialization by 2008.

3. PAO, also known as “leg attack,” is the blocking of arterial blood flow to a distant part of the body by a clot. PAO usually occurs in the leg and is the result of underlying peripheral arterial disease (“PAD”), in which chronic fatty plaque buildup restricts blood flow. The classic early symptom of PAO is leg pain or fatigue during activity that subsides with rest. Continued restriction of blood flow leads to pain at rest and, if the condition continues, can lead to ulcers,

gangrene, tissue death and if untreated, foot or leg amputation. Bypass surgery and angioplasty are established treatments for PAO. However defendants claimed treatment with thrombolytic drug alteplase would present a less-invasive and more cost-effective alternative to surgery.

4. CO is the formation of blood clots in patients with catheters. COs are a problem in about a quarter of the 5 million cases where catheters are placed in patients each year.

5. In 1/01, Nuvelo Chairman and Chief Executive Officer (“CEO”) Ted W. Love (“Love”) joined the Company, then called Hyseq Pharmaceuticals Inc. (“Hyseq”). Hyseq had only \$2.7 million in cash when Love came on board. Amgen co-founder George Rathmann had just been named Chairman of the Hyseq Board and provided a \$20 million line of credit to the Company. Still, by 10/01 the Company’s prospects were growing dim. A \$15 million private placement in 4/01 kept it going, but the Company was running out of cash again and had no drugs ready to move into the clinic.

6. Researchers at big-pharma giant Amgen had initially developed alteplase, but found the protein to be unstable and were unable to commercialize it. Love sought to capitalize on the Company’s newfound relationship with Amgen, via Rathmann, by taking over the development and commercialization of alteplase.

7. Alteplase is a modified fibrinolytic that was once believed to dissolve (or “degrade”) fibrin, a protein that provides the scaffolding for blood clots, when delivered through a catheter at the site of a blood clot. Alteplase, a derivative of an enzyme found in the venom of the southern copperhead snake, was claimed to rapidly dissolve fibrin. Amgen conducted preclinical testing on Alteplase but found the protein had a tendency to fold up on itself, making it unstable and useless as a drug. Researchers at Amgen worked to alter alteplase to make it more stable, but Amgen still found no commercially viable use for the drug.

8. Knowing of Amgen's past failures, in 1/02 Love entered into a collaboration agreement with Amgen to co-develop and commercialize alfimeprase. Under the terms of Love's collaboration agreement with Amgen, Nuvelo would lead all clinical development activities and Amgen would be responsible for all manufacturing activities. Amgen neither promised nor delivered any up-front payments – Nuvelo was simply required to match Amgen's spending to date, and then to share all development costs thereafter equally. Nuvelo would need to fund all alfimeprase costs going forward until its investment reached the same level as Amgen's investment. Under the terms of the collaboration agreement, Amgen could then continue to jointly develop alfimeprase with Nuvelo or it could simply license alfimeprase to Nuvelo, requiring Nuvelo – a small company with virtually no revenue-producing products and nothing in its pipeline – to assume full financial responsibility for the commercialization of a drug which for years had already proven commercially non-viable.

9. Nonetheless, with alfimeprase in hand to build a pipeline around and his newfound relationship with Amgen to lend Hyseq credibility, Love turned his attention to raising money. The bubble that had made raising money easy for biotechnology companies had burst. Instead of turning to the capital markets, Love was forced to acquire Variagenics Inc., a pharmacogenomics company in Cambridge, Massachusetts, which had \$55.9 million in the bank. The merger served as a financing vehicle for Hyseq, which was renamed Nuvelo upon the completion of the merger in 2/03.

10. Nuvelo began conducting clinical trials of alfimeprase as a treatment for PAO and CO. In 3/04, the Company was able to sell approximately 5.8 million shares of common stock for net proceeds of approximately \$69.5 million in a registered public stock offering. By 9/04, defendants would announce the successful completion of Phase II testing for alfimeprase, claiming that alfimeprase had demonstrated the potential to treat acute PAO by restoring blood flow to

patients within 4 hours of initiation of dosing, whereas most plasminogen activator type thrombolytic agents were requiring a prolonged infusion of 24 to 36 hours in patients with leg attack. More importantly, according to defendants, in the Phase II clinical trial *alfimeprase showed potential for thrombolysis (breaking up of a blood clot) at rates of up to 76% and restoration of arterial flow at rates of up to 60%, based on intention to treat analysis.*

11. By 11/04, the level of Nuvelo's financial investment in the development of alfimeprase had reached that of Amgen. Amgen then had an option to either pay 50% of the drug development costs going forward or to license alfimeprase to Nuvelo. Knowing that Nuvelo had been in discussions with the U.S. Food and Drug Administration ("FDA") regarding the next steps in the clinical approval process, the Phase III clinical trials, and knowing the FDA was going to require Nuvelo to demonstrate alfimeprase's efficacy by testing its results against a placebo, Amgen was not confident of the commercial viability of alfimeprase. Instead, based on internal information concerning alfimeprase's efficacy – or lack thereof – Amgen chose to license the drug to Nuvelo rather than continue investing in it. During the Company's 11/1/04 conference call announcing that Amgen was not going to participate in the ongoing development of alfimeprase, defendants were questioned specifically on the status of discussions with the FDA and the use of placebos in the Phase III clinical trial of alfimeprase to determine the drug's efficacy. Defendants were also quizzed on Amgen's decision not to move forward with the drug's development – specifically whether there was anything Amgen or defendants knew about the drug's commercial viability that was not being shared with the market:

CHARLES DUNCAN: And I know this is hard to bear, but you didn't feel there were any points of contention with regard to the way that you were interpreting safety and efficacy data and/or the outcome of those discussions versus your partner? This is purely a strategic decision on Amgen's part, not necessarily a decision regarding the drug or the client?

TED LOVE: *Absolutely right.*

12. Amgen's decision to pull out left Nuvelo with an incredible cash burn rate and no big-pharma investment partner. The Company ended fiscal 2004 with less than \$17 million in cash on its books. In 2/05 the Company would once again go back to the capital markets, selling approximately 9.8 million shares of common stock for net proceeds of approximately \$68.4 million. Still, less than \$38 million in cash remained on the Company's books by the close of the Company's fiscal year in 12/05. And with the loss of its big-pharma backer, Nuvelo's prospects looked bleak, making it almost impossible to raise the additional capital required to continue operations.

13. On 12/14/05, the Company announced it had received a Special Protocol Assessment ("SPA") agreement from the FDA for its second Phase III trial of alfimeprase for the treatment of acute PAO. Defendants promised that having the FDA SPA agreement in place "***solidifie[d] the regulatory pathway to approval for alfimeprase.***" In fact, investors had repeatedly been reassured of the Company's ability to demonstrate the drug's efficacy as compared to a placebo's, including a 5/2/05 statement at the Company's earnings conference, that would be reconfirmed repeatedly throughout the Class Period, that the Company's so-called "***power calculations***" had already established the Company's ability to determine efficacy as compared to a placebo and that "really the numbers in this trial are driven by the need to put in place a good size safety database ***rather the need to confirm the efficacy of this drug, which we are all very bullish on obviously.***"

14. But defendants still needed more money and needed another big-pharma partner to demonstrate credibility to the investment community. On 1/5/06, Nuvelo announced it had found another business partner and had entered into a new financial alliance – this time with Bayer Healthcare AG ("Bayer"). The Bayer deal, which included a \$50 million upfront payment to Nuvelo by Bayer, carried a ***potential*** total of up to \$385 million in fees and milestone payables to Nuvelo – ***if the Company met pre-ordained milestones.*** The milestones required Nuvelo to continue making

progress on the drug's development, including conducting multiple clinical trials, but did not require Nuvelo to demonstrate efficacy – at least initially. If Nuvelo met these milestones, Bayer would provide 40% of the Company's global development funding going forward *in exchange for the exclusive right to market alfimeprase outside of the United States*. Nuvelo retained only the exclusive right to market alfimeprase within the U.S. *Basically, defendants exchanged all of the drug's non-U.S. sales potential – while retaining the responsibility to pay all of Amgen's licensing fees, after hundreds of millions of dollars had been invested – for a \$50 million down-payment by Bayer and a promise to pay up to \$335 million more – if the drug turned out to be commercially viable. This was no endorsement by Bayer – it was gamble with huge upside (and little downside) potential for Bayer.*

15. During the Company's conference call held on 1/5/06, at the start of the Class Period, defendants stated they anticipated alfimeprase would reach the U.S. consumer market by 2008. Love predicted alfimeprase would generate \$500 million in annual sales for the treatment of PAO and CO in the U.S. alone, but stated that was just “the tip of the iceberg for the marketing opportunity for the drug.” Bayer stated it expected the drug to garner billions of dollars in sales outside of the U.S. Love stated Nuvelo would also start testing alfimeprase for the treatment of strokes later in 2006 and another clot condition known as deep vein thrombosis (“DVT”) in 2007, exponentially increasing the drug's potential global profitability. *The Company's stock price surged on the 1/5/06 announcement of the Bayer deal, increasing 41%, its largest increase in six years on extremely high volume.*

16. On 1/23/06, the Company announced it had been granted FDA “Fast Track Status” for alfimeprase. Love stated that “Fast track designation represent[ed] a further step in the achievement of [the Company's] regulatory strategy.” The next day the Company announced it

would conduct another public offering of 6.5 million shares, with up to an additional 825,000 shares to cover underwriter over-allotments. On 1/30/06, the Company issued and sold approximately 7.5 million shares of its common stock at \$16 per share in the Follow-On Offering, which was underwritten by JP Morgan, Lehman Bros. and Deutsche Bank Securities, Inc., receiving over \$119 million in proceeds.

17. On 2/27/06, the Company announced its fiscal 2005 results, explaining that the increase in its net loss of \$71.1 million for the year, or \$1.72 per share, compared to a corresponding net loss of \$40.6 million for fiscal 2004, was due in large part to “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.*” The Company also announced that morning it had begun patient enrollment in SONOMA-3, a second pivotal study of alfimeprase for the treatment of CO. On this and other positive statements made by defendants, analysts such as Caroline Stewart at Morgan Joseph & Company Inc. increased their price targets by **56%** – from \$16 to \$25 per share.

18. Shelly D. Guyer (“Guyer”) of JP Morgan joined Nuvelo in 3/06 as its Vice President of Business Development and Investor Relations. Guyer had walked away from a 17-year career as an investment banker at JP Morgan where she had served as the lead banker on Nuvelo’s 1/30/06 offering. Under defendant Guyer’s tutelage, defendants confirmed throughout the Class Period that they were executing their milestones with Bayer and were on track to commercialize alfimeprase for the treatment of PAO and CO by 2008.

19. However, before the start of trading on 12/11/06, the investment community would be shocked by Bayer’s announcement that alfimeprase had *completely failed* the clinical trials for both the treatment of PAO and for CO. The primary endpoint for the PAO treatment study was

preventing patients with blood clots in their legs from needing surgery within 30 days of taking the drug. *It didn't*. The primary endpoint for the CO treatment study was the ability to dissolve clots in catheters within 15 minutes of taking the drug. *It didn't*. The clinical trials also failed to reach *any* of their key secondary endpoints. During the conference call following the announcement, Love explained that some clots had been broken up, but admitted that alfimeprase failed to perform significantly better than the placebo and that the clots that were not *dissolved* by the drug, but had instead been *washed away* by having a solution shot at them through the artery. When pressed, Love and Michael Levy, Nuvelo's Senior Vice President of Research and Development, also admitted that *none of the Company's prior clinical testing had included the use of a placebo and that any past effectiveness of alfimeprase in "dissolving blood clots" was more likely than not simply attributable to the clots being broken up by having a solution shot out of a catheter directly into or at the clots – rather than any "dissolving" effect the drug had. Additionally, defendants now admitted that even if they could increase the dosage of alfimeprase to increase its efficacy, it could likely be prohibitively unsafe to do so as there was an increased incidence of bleeding in patients with alfimeprase as compared to the placebo.*

20. During the 12/11/06 conference call to discuss the failed Phase III results, Love was specifically questioned on whether the Phase II testing had *ever* demonstrated the drug was capable of "dissolving" rather than merely "disrupting" blood clots – and he was forced to admit it had not:

Jim Birchenough - Lehman Brothers - Analyst

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 - Nuvelo - Chairman and CEO

. . . I actually think it did probably happen in Phase II.

21. Bayer is now expected to abandon its investment in alfimeprase – just as Amgen did in 2004 – and Nuvelo is again without a big-pharma backer and is again without a viable means of support. On this news the Company’s stock price crashed by 80% erasing over \$800 million in market capitalization. Nuvelo’s stock closed at \$4.05 a share, down \$15.50 a share in unusually heavy trading of 90 million shares, more than 176 times the average daily trading volume of the stock. Even JP Morgan downgraded the stock to neutral from overweight, explaining that alfimeprase had been a key driver in Nuvelo’s investment value – and valued the Company at the \$3 per share cash it had on its books.

22. The true facts, which were known by each of the defendants but concealed from the investing public during the Class Period, were as follows:

(a) defendants had no reliable clinical data suggesting that alfimeprase “dissolved” blood clots when applied to them through a catheter – other than physically washing them away;

(b) defendants had no “power calculations” suggesting alfimeprase would outperform a placebo as required to demonstrate efficacy in the Phase III clinical trials required by the FDA to commercialize alfimeprase for the treatment of blood clots; and

(c) defendants in fact knew Amgen’s decision to walk away from its investment in alfimeprase in 12/04 was based on Amgen’s educated suspicion (based on clinical data also known to defendants) that alfimeprase would likely not pass FDA muster and thus was not a commercially viable drug candidate.

23. As a result of the defendants’ false statements, Nuvelo’s stock traded at inflated levels during the Class Period, trading as high as \$20.71 per share in 8/06, and the Company was able to sell \$119 million worth of Nuvelo securities in the Follow-On Offering.

JURISDICTION AND VENUE

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

25. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §1331 and §27 of the Exchange Act.

26. Venue is proper in this District pursuant to §27 of the Exchange Act. Many of the false and misleading statements were made in or issued from this District. 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.

THE PARTIES

27. Plaintiff Electrical Workers Pension Fund, Local 103, I.B.E.W. purchased Nuvelo securities as described in the attached certification and was damaged thereby.

28. Nuvelo was founded in 1991 and is incorporated in Delaware. The Company's common stock trades on the NASDAQ under the ticker symbol NUVO.

29. Defendant Ted W. Love ("Love") is, and at all relevant times has been, Chief Executive Officer ("CEO") and Chairman of the Board of Nuvelo.

30. Defendant Gary S. Titus ("Titus") was, at relevant times, Vice President of Finance and Chief Accounting Officer of Nuvelo. Titus resigned from his position as of 12/1/06. Titus sold approximately \$1.5 million worth of Nuvelo stock at inflated prices in 8/06.

31. Defendant Shelly D. Guyer ("Guyer") is Vice President of Business Development and Investor Relations at Nuvelo. Guyer, who has more than 17 years of experience in healthcare banking and management, joined Nuvelo in 3/06 as the member of its management team responsible

for leading business development and investor relations. Guyer was formerly an investment banker with JP Morgan, which served as the lead underwriter in the Company's 1/06 Follow-On Offering.

32. The individuals and entities named as defendants in ¶¶29-31 are referred to herein 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 but not to the public, 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 statements pleaded herein at ¶¶36, 38-42, 45-46, 48-49, 51-53, as those statements were each "group-published" information, the result of the collective actions of the Individual Defendants.

SCIENTER

33. In addition to the above-described involvement, each Individual Defendant had knowledge of Nuvelo's problems and was motivated to conceal such problems. Defendant Love, as Chairman and CEO, Titus, as Chief Accounting Officer, and Guyer, as VP of Investor Relations, were responsible for the reports and claims relating to alfimeprase as well as the press releases issued by the Company. Each Individual Defendant sought to demonstrate that he or she could lead the Company successfully and generate the successful commercialization of alfimeprase, including obtaining FDA approval.

34. Defendants knew throughout the Class Period, based on Love's prior experience at Genentech with that company's clinical Cardiovascular Thrombolytic to Open Occluded Lines (COOL) studies of alteprase, another snake-venom based blood clot-dissolving drug, completed in 1/01, that purported blood clot-dissolving drugs must be tested alongside a placebo for the clinical data to have any meaning. Love worked at Genentech from 1992 to 2001, including as a research physician and vice president of product development from 1992 to 1998, and was familiar with Genentech's development of alteprase. Gregory S. Yedinak, Nuvelo's Vice President of Manufacturing, also hailed from Genentech where he spent 15 years developing drugs before moving to Amgen and then to Nuvelo. Defendants knew that the COOL-1 study results showed that 74% of catheters (n = 74) responded to the first dose of alteprase compared to 17% of placebo (p < .001). If a second dose of drug was needed, both groups received alteprase. For these second doses defendants knew there was a 90% clearance rate in the alteprase set and 77% in the placebo group. Defendants knew how significant the placebo arm of the testing was and that Genentech had used a placebo-arm in its Phase II trials of alteprase. Defendants also knew, based upon their own clinical testing of alfineprase, that alfineprase would not demonstrate efficacy when tested against a placebo.

FRAUDULENT SCHEME AND COURSE OF BUSINESS

35. Each defendant is liable for (i) making false statements, *or* (ii) failing to disclose adverse facts known to him or her about Nuvelo. Defendants' fraudulent scheme and course of business that operated as a fraud or deceit on purchasers of Nuvelo securities was a success, as it (iii) deceived the investing public regarding Nuvelo's prospects and business; (iv) artificially inflated the prices of Nuvelo securities; (v) allowed defendants to obtain larger bonuses which were directly tied to the *perceived* successful efforts to bring the Company's drug closer to commercialization; (vi) allowed defendants to arrange to sell and actually sell \$119 million worth of Nuvelo securities at

artificially inflated prices in the Follow-On Offering; (vii) permitted defendant Titus to sell \$1.5 million worth of Nuvelo stock at inflated prices; and (viii) caused plaintiff and other members of the Class to purchase Nuvelo publicly traded securities at inflated prices.

DEFENDANTS' FALSE AND MISLEADING STATEMENTS ISSUED DURING THE CLASS PERIOD

36. Before the opening of trading on 1/5/06, Nuvelo and Bayer issued a release entitled "Nuvelo and Bayer HealthCare Enter Comprehensive Collaboration Agreement to Maximize Global Development and Commercialization of Alfimeprase," which stated in relevant part:

- 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 Alfimeprase for Stroke and Deep Vein Thrombosis
- Nuvelo to Host Conference Call/Webcast Today at 8:30 a.m. Eastern Time

. . . Nuvelo, Inc. today announced that it has entered into a collaboration agreement with Bayer HealthCare AG (BHC) to maximize the global development and commercialization of alfimeprase, Nuvelo's lead Phase 3 product candidate. *Alfimeprase, 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 alfimeprase sales in the United States. BHC will commercialize alfimeprase 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 alfimeprase.

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 alfimeprase 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 alfimeprase,” 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 alfimeprase’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 alfimeprase’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 alfimeprase 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 alfimeprase 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. Alfimeprase 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.

37. During an investor conference held on 1/5/06, Love presented very positive data on the status of the 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.

* * *

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.***

. . . 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.***

* * *

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.

* * *

MARK MONANE, ANALYST, NEEDHAM & COMPANY: . . . [W]hich 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.

38. On 1/5/06, defendants also announced Nuvelo would participate in the 24th Annual JP Morgan Healthcare Conference on 1/9/06. At the 1/9/06 conference, the Company provided the following clinical guidance for 2006:

Patient Enrollment in Alfimeprase Phase 3 Programs in Acute PAO and CO

The Company expects to complete patient enrollment in the second half of 2006 in two ongoing Phase 3 trials with alfimeprase: NAPA-2 (Novel Arterial Perfusion with Alfimeprase-2), the first of two Phase 3 trials for the treatment of acute PAO and SONOMA-2 (Speedy Opening of Non-Functional and Occluded Catheters with Mini-Dose Alfimeprase-2), the first of two Phase 3 trials for the treatment of CO. Nuvelo will initiate a second Phase 3 trial with alfimeprase in acute PAO (NAPA-3) in early 2006 and a second Phase 3 trial in CO (SONOMA-3) in the first half of 2006.

Pipeline Expansion: Cardiovascular Disease and Cancer

Nuvelo plans to expand the alfimeprase clinical development program by initiating a Phase 2 clinical trial for the treatment of stroke in the second half of 2006 and a Phase 2 clinical trial for the treatment of DVT in 2007.

* * *

“We intend to develop and commercialize best- and first-in-class compounds that have the potential to transform treatment paradigms in cardiovascular disease and cancer,” said Ted W. Love, M.D., chairman and chief executive officer of Nuvelo. “Through our focused research and development efforts, we are building a strong portfolio of products that address multiple indications, increasing the probability of success and the market opportunity for each of our compounds.”

39. On 1/23/06, defendants issued a release entitled “Nuvelo Receives FDA Fast Track Status for Alfimeprase,” which stated in relevant part:

Nuvelo Inc. 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.”*

40. On 1/24/06, the Company announced it would conduct a follow-on stock offering of 6.5 million shares. On 1/30/06, the offering was priced and completed at \$16 per share, with the Company issuing and selling 6.5 million shares of its common stock and the exercise by the underwriters of their option to purchase an additional 975,000 shares solely to cover over-allotments. The gross proceeds, before deducting underwriting discounts and offering expenses, from the sale of the aggregate 7,475,000 shares were approximately \$119.6 million. The Company’s Registration Statement and Prospectus filed in connection with the 1/30/06 offering described the ongoing alfimeprase clinical testing and provided a chart purporting to depict the Company’s drug pipeline and the anticipated commercialization of alfimeprase:

Program/Product Candidate	Commercialization Rights	Research	Predinical	Phase 1	Phase 2	Phase 3	Biologics License Application
Cardiovascular Programs							
Alfimeprase (Fibrinolytic)	Nuvelo: U.S. rights Bayer: Ex-U.S. rights	Acute Peripheral Arterial Occlusion					
		Catheter Occlusion					
		Stroke (Expect to initiate Phase 2 program in second half of 2006)					
		Deep Venous Thrombosis (DVT) (Expect to initiate Phase 2 program in 2007)					
rNAPc2 (Tissue Factor Inhibitor)	Worldwide rights	Acute Coronary Syndromes					
Thrombin Inhibiting Aptamer	50/50 collaboration with Archemix	Coronary Artery Bypass Graft Surgery					
Oncology Programs							
NU206 (Potent Growth Factor)	60/40 collaboration with Kirin	Supportive Cancer Therapy (Mucositis)					
rNAPc2 (Tissue Factor Inhibitor)	Worldwide rights	Cancer					
Secreted Proteins and Cancer Antibody Programs		A Variety of Indications Including Cancer and Immune-related Diseases					

41. On 2/27/06, the Company and Bayer 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,” which stated in relevant part:

Nuvelo Inc. and Bayer HealthCare 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).

42. Also on 2/27/06, defendants issued a release entitled “Nuvelo Reports 2005 Fourth Quarter and Year End Results and Accomplishments and Provides 2006 Outlook,” which stated in relevant part:

Nuvelo, Inc. 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.

“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,” said Dr. Ted W. Love, chairman and chief executive officer of Nuvelo. ***“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.”

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 (see definition and reconciliation below).

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*

43. During the 2/27/06 conference call to discuss the Company's 4Q 05 and fiscal 2005 results, defendants provided a provided a very positive update on the status of the alfimeprase commercialization process:

MICHAEL LEVY, SVP, R&D, NUVELO, INC.: Thank you, Gary. For the next few minutes I will provide you with an update on our development pipeline. Focusing on our acute cardiovascular programs and on our emerging oncology programs and share with you our excitement about the progress we've made to date. Let's begin with an update on alfimeprase, our lead cardiovascular product candidate. We continue to execute our alfimeprase development strategy making significant progress with our Phase 3 programs in both acute PAO and catheter occlusion. And as recently announced expanding our development plans to include ischemic stroke and deep venous thrombosis.

Let's start with acute PAO also known as the NAPA program. Since patients enrollment has been tracking well, we were able to provide guidance on completion of enrollment in our NAPA-2 trial in January which was earlier than anticipated. We continue to be on track to complete enrollment in our first Phase 3 trial in this program NAPA-2 in the second half of 2006 and will provide top line data as soon as we can after completion of the last patient. Typically the time required to lock a database and then generate top line gain is a few months. Subsequently we expect that one of our investigators would present a more complete analysis of the full beta set at an appropriate medical conference as soon as possible thereafter.

Our second Phase 3 acute PAO NAA-3 is also progressing well. We were currently identifying and activating sites and expect to enroll the first patient in the Napa 3 trial soon. In addition to the progress we are making with our clinical trials, we have also been making progress on the regulatory front for alfimeprase. Obtaining orphan status in both the U.S. and EU, a special protocol assessment for NAPA-3 and most recently fast track designations for the NAPA program as a whole.

In November of last year, we were granted orphan drug designation by the EMEA for alfimeprase for the treatment of acute PAO. The designation provides several benefits including market exclusivity for ten years following market authorization. Note that we had previously obtained orphan drug designation in the U.S. from the FDA. In December of last year we received an SBA from the FDA. We have worked closely with the FDA on the design of the Napa program as a whole and are pleased to receive the FDA's formal approval of the NAPA-3 trial design as adequate in meeting their scientific and regulatory requirements.

As part of the SBA process, we have finalized the details of the NAPA-3 trial including the number of patients participating. This trial will closely replicate the NAPA-2 trial and will also be a randomized double blind study comparing 0.3 milligrams per kilogram of alfimeprase with placebo. It will enroll approximately 300 patients with the primary end point of avoidance of open vascular surgery within 30 days of treatment. We now expect to enroll a total of 600 patients into the acute PAO Phase 3 program as a whole.

Finally in January of this year, the FDA granted alfimeprase fast track designation. This designation is reserved for drugs that demonstrate the potential to address an unmet medical need and are intended for the treatment of a serious or life-threatening condition. In the case of acute PAO, there is no currently available FDA approved drug making it an unmet medical need and the Phase 2 data for alfimeprase has demonstrated that it has a real potential to transform the treatment of this condition. 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 the sponsor and the BLA may be submitted as a rolling submission which allow certain sections of the BLA to be submitted and reviewed while other sections are being finalized.

Let's turn now to catheter occlusion our second development program for alfimeprase. For our Phase 3 catheter occlusion program we achieved our milestone of initiating the first catheter occlusion trial SONOMA-2 in the second half of 2005 and as announced today, we have just initiated enrollment in the second trial, SONOMA-3. The SONOMA-2 trial has been enrolling well, enabling us to share completion expectations earlier this year. And we continue to be on track to complete SONOMA-2 in the second half of 2006. We will provide top line data as soon as we

can after enrollment of the last patients and full data will be presented at an appropriate medical conference by one of our investigators.

Having made progress on our initial clinical programs in 2006 we will begin to implement our label expansion strategy for alfimeprase. *We have always known that alfimeprase holds the potential to treat a wide range of clot disorders and that acute PAO and catheter occlusion represented the most rapid and low risk market entry strategy for us. Now that we've advanced both of these initial programs, we are able to pursue follow-on opportunities for alfimeprase being ischemic stroke and NDBT. We believe that alfimeprase has the potential to transform both of these markets where currently there is little penetration by existing agents.*

Given alfimeprase's speed of action and safety profile, we believe it could be an ideal treatment for ischemic stroke providing the opportunity to decrease bleeding and expand the treatment window beyond the current three hour time frame. Both of these factors would enable a larger segment of stroke patients to receive treatment than is currently the case. We expect to initiate a Phase 2 trial with alfimeprase in stroke in the second half of 2006. For DBT the safety profile of plasminogen activators limits their use in its patient population. DBT is a significant but rarely life-threatening condition. So physicians are reluctant to administer plasminogen activators which expose patients to a significant bleeding risk. Given alfimeprase mechanism of action and safety profile to date we believe it has the potential to treat this patient population with a reduced bleeding risk. We plan to begin a Phase 2 trial in DBT in 2007.

* * *

[LOVE:] *Our partnership with Bayer is predicated on a belief that alfimeprase has the potential to transform treatment for the more than 10 million people in the western world who suffer from blood clot related conditions each year and that the market opportunity extends far beyond acute PAO and catheter occlusion. The Bayer partnership allows us to aggressively move alfimeprase into additional and higher value indications like stroke and DBT.* Accordingly, we plan to initiate a Phase 2 trial of alfimeprase in ischemic stroke in the second half of 2006. And we are also preparing for a Phase 2 trial in DBT that will begin in 2007.

After our announcement with Bayer in January, we have moved swiftly to kick off the partnership. *We are off to a great start and have been working to establish the appropriate joint committees between our companies. In other words, we've already started to put a solid foundation in place for our very successful collaboration and we continue to make excellent progress with alfimeprase development.*

* * *

MARK MONANE: And how about powering new opportunity to upsize the trial if it turns out.

MICHAEL LEVY: Well, *we don't believe that that will be necessary. As you know, the trial is highly overpowered. We have 90% power to detect a very small difference and we are looking for a large difference between placebo and alfimeprase.* And really the size of the trial is more predicated on putting together a good size patient safety database to go forward to BLA with so that we have experience with several hundred patients having received therapy.

44. On 3/23/06, the Company announced the appointment of Guyer as Vice President, Business Development and Investor Relations.

45. On 4/10/06, defendants, along with Bayer, issued a release entitled "Nuvelo and Bayer Healthcare Begin NAPA-3, Second Pivotal Phase 3 Trial of Alfimeprase for Acute Peripheral Arterial Occlusion," which stated in relevant part:

Nuvelo Inc. and Bayer HealthCare 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.

46. On 5/5/06, defendants issued a press release entitled “Nuvelo Reports First Quarter 2006 Financial Results and Accomplishments,” which stated in relevant part:

Nuvelo, Inc. 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.

"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," said Dr. Ted W. Love, chairman and chief executive officer of Nuvelo. "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."

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***

47. On 5/5/06, defendants held an earnings conference and provided positive data on the progress of the commercialization of alfimeprase:

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 your 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 veinous 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 alfimeprase.

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 alfimeprase 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 alfimeprase, 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 alfimeprase 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 alfimeprase 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: . . . 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

* * *

JIM: . . . [F]ocusing 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.*

* * *

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.

* * *

GARY TITUS: . . . *[W]e believe we still have overwhelming statistical power to detect the difference between and active therapy such as alfimeprase -- which is indeed very active based on our Phase 2 studies to date -- and placebo.*

48. On 7/6/06, the Company issued a release entitled "Nuvelo Announces Publication of Phase 2 Alfimeprase Study Results in Central Venous Catheter Occlusion," which stated in relevant part:

Nuvelo, Inc. 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.

49. On 8/03/06, defendants issued a release entitled “Nuvelo Reports Second Quarter 2006 Financial Results and Accomplishments,” which stated in relevant part:

Nuvelo, Inc. 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 alfimeprase and non-cash employee stock-based compensation expense of \$2.3 million.***

Net interest and other income for the second quarter of 2006 was \$2.1 million compared to \$0.4 million in the comparable period of 2005. The increase was primarily due to higher average cash and investment balances and applicable interest rates in the 2006 period.

For the six-month period ended June 30, 2006, the net loss was \$38.5 million, or \$0.76 per share, compared to a net loss of \$31.7 million, or \$0.79 per share, in the comparable period in 2005. Revenues for the first six months of 2006 were \$2.1 million compared to \$0.2 million in the same period of 2005. Total operating expenses for the six months ended June 30, 2006 and 2005 were \$44.3 million and \$32.5 million, respectively.

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.

“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, alfineprase, in stroke by year end; and we expect to complete enrollment in the first trial in each of our Phase 3 alfineprase 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,” said Dr. Ted W. Love, chairman and chief executive officer of Nuvelo. “Finally, as we continue to build our business and prepare for commercialization, we have added several key executives to our senior management team.”

Recent Corporate Accomplishments

- ***Initiated the second Phase 3 alfineprase trial in acute peripheral arterial occlusion (PAO), NAPA-3;***
- ***Published data from the Phase 2 alfineprase 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)*

50. During the 8/3/06 conference call to discuss the 2Q 06 financial results, Love reassured investors that the Company's "collaboration with Bayer HealthCare to develop and commercialize alfimeprase *continues to go very well*, and [that Nuvelo was] tracking to [its] goals and milestones laid out for the program." Love also stated that Bayer's decision to do presentations concerning alfimeprase "emphasize[d] the importance Bayer attribute[d] to this program." Defendants highlighted the progress they were making on the commercialization of alfimeprase and touted Bayer's continuing support, but refused to discuss the clinical data:

On the clinical front, with the initiation of NAPA-3, we now have four phase III alfimeprase 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 alfimeprase 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 this 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.

The symposium will feature Dr. Gunnar Tepe, Associate Professor Radiology at the University of Tübingen, Germany, Dr. Barry Katzen, Clinical Professor of Radiology at the University of Miami, and Dr. Steven Deitcher, Vice President of Medical Sciences here at Nuvelo.

Additionally, Bayer is hosting an international press conference on October 31st entitled, Perspectives on Innovation, which will also feature a presentation on alfimeprase. More information on each of these events will be available as the dates approach.

* * *

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 alfineprase 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.

51. On 9/5/06, defendants issued a press release entitled "Nuvelo Announces Completion of Patient Enrollment in SONOMA-2, First Phase 3 Trial of Alfineprase in Central Venous Catheter Occlusion," which stated in relevant part that:

Nuvelo, Inc. today announced that it has completed patient enrollment in the first Phase 3 clinical trial of alfineprase 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 Alfineprase-2), is the first of two ongoing, multi-national trials in the Phase 3 alfineprase program for CO. This randomized, double-blind trial compared the efficacy and safety of 3 mg of alfineprase 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 alfineprase 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 alfineprase 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.

52. On 9/5/06, defendants issued a release entitled “Nuvelo Announces Completion of Patient Enrollment in NAPA-2, First Phase 3 Trial of Alfimeprase in Acute Peripheral Arterial Occlusion,” which stated in relevant part:

Nuvelo, Inc. 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.

53. On 11/2/06, defendants issued a release entitled “Nuvelo Reports Third Quarter 2006

Financial Results and Accomplishments,” which stated in relevant part:

Nuvelo, Inc. 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.***

Net interest and other income for the third quarter of 2006 was \$2.1 million compared to \$0.4 million in the comparable period of 2005. The increase was primarily due to higher average cash and investment balances and applicable interest rates in the 2006 period.

For the nine-month period ended September 30, 2006, the net loss was \$65.2 million, or \$1.28 per share, compared to a net loss of \$50.1 million, or \$1.23 per share, in the comparable period in 2005. Revenues for the first nine months of 2006 were \$3.0 million compared to \$0.4 million in the same period of 2005. Total

operating expenses for the nine months ended September 30, 2006 and 2005 were \$74.0 million and \$51.5 million, respectively.

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.

“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,” said Dr. Ted W. Love, chairman and chief executive officer of Nuvelo. ***“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).”***

Recent Corporate Accomplishments

- ***Completed enrollment in the first Phase 3 alfimeprase trial in acute PAO, NAPA-2;***
- ***Completed enrollment in the first Phase 3 alfimeprase trial in CO, SONOMA-2;***

* * *

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

54. During the 11/2/06 conference call to discuss the 3Q 06 results, the Company provided further positive guidance on the status of the alfimeprase commercialization process, including the following statements concerning expanding its use to treat strokes and DVT:

[W]e 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.

55. During the conference call, defendants were specifically asked to reveal more data on the NAPA-1 Phase II trial of alfimeprase in acute PAO. Defendants did not deny having more information, but refused to disclose more:

CHRIS DIMITROPOULOS: Hi. Just if you can give us some more color on the AHA presentation of NAPA-1, specifically what incremental data might we see there in terms of end points?

DR. TED W. LOVE: I am actually not intimately familiar with that presentation. I'll actually be going to the meeting, but I don't expect there will be a great deal of incremental data. I think it'll probably be some additional data, but mostly sharing the data with a broader audience.

* * *

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.

JIM BIRCHENOUGH: And just as a frame of reference, I can't remember the STILE or TOPAS study where the protocol was amended, very early on, because of excess bleeding, where heparin was removed. I just want to confirm that that hasn't happened in this case and does that provide some reassurance that we shouldn't see excess bleeding, at least in ICH with alfimeprase.

DR. MICHAEL LEVY: Well, I can answer your question very factually that no, we have not removed the heparin treatment from the trials. We think that's very important. Obviously alfimeprase is a thrombolytic and it removes the acute clots, but you need onboard anticoagulants to prevent the formation of new clots in the future. But beyond that, I wouldn't read too much into that.

The good news is that the first trial, as Ted mentioned, is complete and hopefully the end of this year, beginning of next year we'll be able to share the data with you and won't need to speculate.

56. Then, before the opening of trading on 12/11/06, defendants and Bayer suddenly issued a 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," which stated in relevant part:

Nuvelo, Inc. 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.

These data will be submitted for presentation at the next appropriate medical meetings.

“These outcomes are disappointing particularly for patients with acute PAO, who have few treatment options,” said Dr. Ted W. Love, chairman and chief executive officer of Nuvelo. “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.”

57. Bayer is now expected to walk away from its investment in alfimeprase – just as Amgen did in 2004. The Company’s stock price crashed on 12/11/06 by approximately 80% – erasing over \$800 million in market capitalization. Nuvelo’s stock closed at \$4.05 a share, down \$15.50 a share in unusually heavy trading of 90 million shares, more than 176 times the average daily trading volume. Nuvelo’s stock had been trading an average of 450,000 shares a day in recent weeks. Even JP Morgan downgraded the stock to neutral from overweight, explaining that alfimeprase had been a key driver in Nuvelo’s investment value.

58. The true facts, which were known by each of the defendants but concealed from the investing public during the Class Period, were as follows:

(a) defendants had no reliable clinical data suggesting that alfimeprase “dissolved” blood clots when applied to them through a catheter – other than physically washing them away;

(b) defendants had no “power calculations” suggesting alfimeprase would outperform a placebo as required to demonstrate efficacy in the Phase III clinical trials required by the FDA to commercialize alfimeprase for the treatment of blood clots; and

(c) defendants in fact knew Amgen's decision to walk away from its investment in alfimeprase in 12/04 was based on Amgen's educated suspicion (based on clinical data also known to defendants) that alfimeprase would likely not pass FDA muster and thus was not a commercially viable drug candidate.

59. As a result of the defendants' false statements, Nuvelo's stock traded at inflated levels during the Class Period, trading as high as \$20.71 per share in 8/06, and the Company was able to sell \$119 million worth of Nuvelo securities in the Follow-On Offering.

LOSS CAUSATION/ECONOMIC LOSS

60. By concealing problems with the alfimeprase, the defendants presented a misleading picture of Nuvelo's business and prospects. Thus, instead of truthfully disclosing during the Class Period that Nuvelo's business was not as healthy as represented, Nuvelo concealed problems it knew would prevent FDA approval of alfimeprase.

61. These concealments and claims of future profitability caused and maintained the artificial inflation in Nuvelo's stock price throughout the Class Period and until the truth was revealed to the market.

62. Defendants' false and misleading statements had the intended effect and caused Nuvelo stock to trade at artificially inflated levels throughout the Class Period, reaching as high as \$20.71 per share in 8/06.

63. On 12/11/06, the Company disclosed that alfimeprase had *completely failed* the clinical trials for the treatment of both PAO and CO.

64. As a direct result of defendants' admissions and the public revelations regarding the truth about alfimeprase and about Nuvelo's overstatement of its actual business prospects going forward, Nuvelo's stock dropped 80% on 12/11/06, erasing over \$800 million in market

capitalization. This drop removed the inflation from Nuvelo's stock price, causing real economic loss to investors who had purchased the stock during the Class Period.

COUNT I

For Violation of §10(b) of the Exchange Act and Rule 10b-5 Against All Defendants

65. Plaintiff incorporates ¶¶1-64 by reference.

66. During the Class Period, defendants disseminated or approved the false statements specified above, which they knew or deliberately disregarded were misleading in that they contained misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

67. Defendants violated §10(b) of the Exchange Act and Rule 10b-5 in that they:

(a) Employed devices, schemes, and artifices to defraud;

(b) Made untrue statements of material facts or omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; or

(c) Engaged in acts, practices, and a course of business that operated as a fraud or deceit upon plaintiff and others similarly situated in connection with their purchases of Nuvelo publicly traded securities during the Class Period.

(d) Plaintiff and the Class have suffered damages in that, in reliance on the integrity of the market, they paid artificially inflated prices for Nuvelo publicly traded securities. Plaintiff and the Class would not have purchased Nuvelo publicly traded securities at the prices they paid, or at all, if they had been aware that the market prices had been artificially and falsely inflated by defendants' misleading statements.

68. As a direct and proximate result of these defendants' wrongful conduct, plaintiff and the other members of the Class suffered damages in connection with their purchases of Nuvelo publicly traded securities during the Class Period.

COUNT II

For Violation of §20(a) of the Exchange Act Against All Defendants

69. Plaintiff incorporates ¶¶1-68 by reference.

70. The Individual Defendants acted as controlling persons of Nuvelo within the meaning of §20(a) of the Exchange Act. By reason of their positions as officers and/or directors of Nuvelo, and their ownership of Nuvelo stock, the Individual Defendants had the power and authority to cause Nuvelo to engage in the wrongful conduct complained of herein. Nuvelo controlled each of the Individual Defendants and all of its employees. By reason of such conduct, the Individual Defendants and Nuvelo are liable pursuant to §20(a) of the 1934 Act.

CLASS ACTION ALLEGATIONS

71. Plaintiff brings this action as a class action pursuant to Rule 23 of the Federal Rules of Civil Procedure on behalf of all persons who purchased Nuvelo publicly traded securities on the open market or in a registered stock offering during the Class Period (the "Class"). Excluded from the Class are defendants.

72. The members of the Class are so numerous that joinder of all members is impracticable. The disposition of their claims in a class action will provide substantial benefits to the parties and the Court. Nuvelo had approximately 53 million shares of stock outstanding, owned by hundreds if not thousands of persons.

73. There is a well-defined community of interest in the questions of law and fact involved in this case. Questions of law and fact common to the members of the Class which predominate over questions which may affect individual Class members include:

- (a) Whether the Exchange Act was violated by defendants;
- (b) Whether defendants omitted and/or misrepresented material facts;
- (c) Whether defendants' statements omitted material facts necessary to make the statements made, in light of the circumstances under which they were made, not misleading;
- (d) Whether defendants knew or deliberately disregarded that their statements were false and misleading;
- (e) Whether the prices of Nuvelo publicly traded securities were artificially inflated; and
- (f) The extent of damage sustained by Class members and the appropriate measure of damages.

74. Plaintiff's claims are typical of those of the Class because plaintiff and the Class sustained damages from defendants' wrongful conduct.

75. Plaintiff will adequately protect the interests of the Class and has retained counsel who are experienced in class action securities litigation. Plaintiff has no interests which conflict with those of the Class.

76. A class action is superior to other available methods for the fair and efficient adjudication of this controversy.

PRAYER FOR RELIEF

WHEREFORE, plaintiff prays for judgment as follows:

- A. Declaring this action to be a proper class action pursuant to FRCP 23;
- B. Awarding plaintiff and the members of the Class damages, including interest;

- C. Awarding plaintiff reasonable costs and attorneys' fees; and
- D. Awarding such equitable/injunctive or other relief as the Court may deem just and

proper.

JURY DEMAND

Plaintiff demands a trial by jury.

DATED: December __, 2006

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