NUVELO INC Form 424B5 February 02, 2005 Table of Contents

> Filed Pursuant to 424(B)(5) Registration No. 333-118821

PROSPECTUS SUPPLEMENT

(To Prospectus dated December 6, 2004)

8,500,000 Shares

Common Stock

We are offering all of the 8,500,000 shares of our common stock offered by this prospectus supplement. We will receive all of the net proceeds from the sale of such common stock.

Our common stock is quoted on The Nasdaq National Market under the symbol NUVO. The last reported sale price for our common stock on February 1, 2005 was \$7.99 per share.

Investing in our common stock involves a high degree of risk. Before buying any shares you should carefully read the discussion of material risks of investing in our common stock under the heading <u>Risk factors</u> beginning on page S-9 of this prospectus supplement and on page 1 of the accompanying prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus supplement or the accompanying prospectus are truthful or complete. Any representation to the contrary is a criminal offense.

	Per share	Total
Public offering price	\$7.50	\$63,750,000
Underwriting discounts and commissions	\$0.45	\$ 3,825,000
Proceeds, before expenses, to us	\$7.05	\$59,925,000

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The underwriters may also purchase up to an additional 1,275,000 shares of common stock from us at the public offering price, less underwriting discounts and commissions payable by us to cover over-allotments, if any, within 30 days from the date of this prospectus supplement. If the underwriters exercise the option in full, the total underwriting discounts and commissions will be \$4,398,750, and the total proceeds, before expenses, to us will be \$68,913,750.

The underwriters are offering the shares of common stock as set forth under Underwriting. Delivery of the shares will be made on or about February 7, 2005.

Sole Book-Running Manager

UBS Investment Bank

Deutsche Bank Securities

CIBC World Markets

Needham & Company, Inc.

The date of this prospectus supplement is February 1, 2005.

You should rely only on the information contained or incorporated by reference in this prospectus supplement and the accompanying prospectus. We have not, and the underwriters have not, authorized anyone to provide you with additional or different information. We are not making an offer of these securities in any jurisdiction where the offer is not permitted. You should assume that the information in this prospectus supplement is accurate only as of the date on the front of the document and that any information we have incorporated by reference is accurate only as of the date of the document incorporated by reference, regardless of the time of delivery of this prospectus supplement and the accompanying prospectus or of any sale of our common stock. Unless the context otherwise requires, references to we, or the company in this prospectus supplement and the accompanying prospectus mean Nuvelo, Inc. and its subsidiaries.

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We own or have rights to use trademarks or trade names that we use in conjunction with the operation of our business. Nuvelo is a registered trade and service mark of ours. All other trademarks, service marks and trade names referred to in this prospectus supplement or the accompanying prospectus are the property of their respective owners.

Prospectus supplement summary

This summary highlights information contained elsewhere or incorporated by reference in this prospectus supplement and the accompanying prospectus. This summary does not contain all of the information that you should consider before investing in our common stock. You should carefully read the entire prospectus supplement and the accompanying prospectus, including the Risk factors section, as well as the financial statements and the other information incorporated by reference herein before making an investment decision.

BUSINESS OVERVIEW

We are a biopharmaceutical company strategically focused on the discovery, development and commercialization of therapeutics for the treatment of acute cardiovascular indications and cancer.

We currently have three drug candidates in clinical trials. Our lead drug candidate, alfimeprase, is a thrombolytic agent, or blood clot dissolver. In 2004, we completed two separate Phase 2 clinical trials for alfimeprase for the treatment of acute peripheral arterial occlusion, or PAO, and catheter occlusion. We anticipate initiating a Phase 3 trial for alfimeprase in acute PAO in the first half of 2005 and a Phase 3 trial for alfimeprase in patients with occluded central venous catheters in the second half of 2005.

Our second drug candidate, recombinant nematode anticoagulant protein c2, or rNAPc2, is a recombinant version of a naturally occurring protein that has anticoagulant properties. These properties arise from its ability to block the factor VIIa/tissue factor protease complex, which is responsible for the initiation of the process leading to blood clot formation. rNAPc2 is currently undergoing a Phase 2a double-blind, placebo-controlled clinical trial for use in treating acute coronary syndromes, or ACS, including unstable angina, or UA, and non-ST segment elevation myocardial infarction, or NSTEMI. We expect to complete enrollment of this trial in the first half of 2005.

Our third drug candidate is ARC183, a novel thrombin inhibitor which is currently in a Phase 1 clinical development program for use as an anticoagulant in coronary artery bypass graft, or CABG, surgery. We entered into a 50/50 cost/profit sharing collaboration agreement with Archemix Corporation in January 2004 for the development and commercialization of ARC183. We anticipate completing enrollment of the Phase 1 clinical program for ARC183 in the first half of 2005.

We have exclusive worldwide rights to develop and commercialize alfimeprase and, for the indications we are currently pursuing, rNAPc2, and we share worldwide commercialization rights to ARC183 with Archemix.

In addition to our clinical and development stage drug candidates, we have an on-going discovery effort that is focused on therapeutic secreted proteins and antibody targets. Our secreted protein program includes our collaboration with the pharmaceutical division of Kirin Brewery Company, Ltd. and our internal discovery program. Our antibody program is focused on screening our proprietary gene sequence collection to identify proteins located on the surface of tumor cells that could be targeted by therapeutic monoclonal antibodies. We recently initiated pre-clinical studies on our first internally-discovered drug candidate, NU206. We expect to leverage discoveries in our research programs to extend and expand our drug pipeline and to create revenue-generating licensing and partnering arrangements.

OUR LEAD DRUG CANDIDATES

ALFIMEPRASE

Alfimeprase, our lead development candidate, recently completed Phase 2 clinical trials in two distinct indications, acute PAO and catheter occlusion. Alfimeprase is a thrombolytic agent, or blood clot dissolver, with a novel mechanism of action. It is a modified and recombinant version of fibrolase, a naturally occurring enzyme that directly degrades fibrin, the protein that provides the structural scaffold of blood clots. Thrombolytics currently on the market such as urokinase (Abbokinase) or alteplase (Activase), are plasminogen activators that work by activating plasminogen to form plasmin which, in turn, degrades fibrin. In contrast, alfimeprase directly degrades fibrin, creating the potential for more rapid clot dissolution or lysis. Alfimeprase is locally delivered at the site of the blood clot and is inactivated quickly by a naturally occurring protein in the bloodstream. We believe this clearance mechanism limits the amount of drug in systemic circulation and implies that patients may experience fewer associated side effects. Phase 2 clinical data suggest that alfimeprase has the potential to rapidly lyse clots while also reducing the bleeding complications resulting from currently available agents.

Alfimeprase was identified through a research program at Amgen Inc. In January 2002 we entered into a 50/50 cost/profit sharing arrangement with Amgen for the development and commercialization of alfimeprase. In October 2004, Amgen exercised its rights pursuant to the terms of this collaboration agreement to terminate its collaboration with us and enter instead into an exclusive license whereby we are granted the worldwide rights to develop and commercialize alfimeprase in exchange for the payment to Amgen of previously negotiated milestone payments and royalties. Under the terms of our license agreement with Amgen, Amgen will transfer the technology necessary for the manufacture of alfimeprase to us or to a manufacturer acceptable to Amgen. Amgen is required to continue to supply alfimeprase to us during the transition period. On January 21, 2005, we entered into an Interim Agreement with Avecia Limited for the manufacture of alfimeprase, and we are currently in negotiations with Avecia for a definitive agreement. In connection with the termination of the collaboration agreement with Amgen, we also entered into an opt-out, termination, settlement and release agreement with Amgen in October 2004, whereby we made a payment of \$8.5 million to Amgen, of which \$8.3 million was related to the remaining reimbursement of its manufacturing costs incurred under the collaboration agreement.

Alfimeprase in Acute Peripheral Arterial Occlusion (PAO)

Our lead medical indication for alfimeprase is acute PAO. Acute PAO is a significant cause of morbidity in the United States with over 100,000 cases reported annually. Acute PAO occurs when arterial blood flow is blocked to a distant part of the body, usually the leg, by a blood clot. Traditionally, bypass surgery and angioplasty have been used to treat acute PAO. However, thrombolytic agents such as urokinase (Abbokinase) or alteplase (Activase) have been increasingly used as a less-invasive alternative, even though they have not received regulatory approval to treat acute PAO. Studies have shown that patients receiving current thrombolytic therapies experience intracerebral hemorrhage at rates of between one to two percent. We believe alfimeprase has the potential to be a more effective agent than existing agents for use in treating acute PAO by reducing the treatment time and potential bleeding side effects.

We completed our Phase 2 alfimeprase trial in patients with acute PAO in the second quarter of 2004. This trial was a multi-center, open label, dose-escalation study to evaluate the safety and activity of alfimeprase, and involved 113 patients across centers in the United States, Western Europe, Hungary, Russia and South Africa. The Phase 2 results indicate that alfimeprase has the potential to offer significant advances in the rapid resolution of a clot while minimizing potentially fatal side effects such as hemorrhagic stroke and other bleeding complications. In analysis of the Phase 2 results, alfimeprase showed potential to break up blood clots within four hours of initiation of dosing with rates of up to 76 percent, and partial or complete clot lysis and restoration of arterial flow with rates of up to 60 percent. Up to 69 percent of study patients were able to avoid open vascular surgical intervention in

the 30 days following treatment with alfimeprase. Among the 113 patients enrolled, there were no intracerebral hemorrhages or deaths at 30 days. There were 7 major bleeding events reported.

Of these, only one was categorized by the investigator as possibly related to alfimeprase. Incidents of transient hypotension were also reported and were dose related.

We expect to initiate a multi-center, multi-national, randomized, double-blind, placebo-controlled Phase 3 program to determine the efficacy and safety of alfimeprase for the treatment of patients with acute PAO in the first half of 2005. This Phase 3 program, also known as NAPA-2, or Novel Arterial Perfusion with Alfimprase-2, will be led by Dr. Kenneth Ouriel, chairman of the division of surgery at the Cleveland Clinic and Dr. Gunnar Tepe, associate professor of radiology in the department of diagnostic radiology at the University of Tubingen, Germany. This program is expected to consist of two overlapping trials that will include a total of approximately 700 patients, who will be randomized to receive either 0.3 mg/kg of alfimeprase or placebo. The primary endpoint will be avoidance of open vascular surgery within 30 days. Secondary endpoints will include restoration of arterial blood flow and increase in ankle brachial index, which is a measure of ankle blood pressure. We have obtained orphan drug status for alfimeprase in the United States for the treatment of acute PAO, which may provide us with seven years of market exclusivity in the United States.

Alfimeprase in catheter occlusion

Our second medical indication for alfimeprase is catheter occlusion. Catheter occlusion is the obstruction of blood flow through a central venous catheter by a blood clot. It is estimated that about five million catheters are implanted in patients each year in the United States, and approximately 25% become occluded. Current treatment for catheter occlusion includes invasive surgery to remove and replace the catheter, or treatment with alteplase (Cathflo Activase). Based on clinical trial evidence of alfimeprase s activity, we believe alfimeprase has the potential to restore flow to these occluded catheters more rapidly than Cathflo Activase.

In the third quarter of 2004 we announced that we had closed patient enrollment in a Phase 2 multi-center, double-blind, randomized study in patients with occluded central venous catheters comparing three doses (0.3 mg, 1.0 mg and 3.0 mg) of alfimeprase against the approved dose of Cathflo Activase (2.0 mg). We treated 55 patients in this U.S. trial. The alfimeprase 3.0 mg dose produced cumulative flow rates of 50% at 15 minutes after the first dose, 60% at 120 minutes after the first dose, and 80% at 120 minutes after the second dose. This is compared to CathfloActivase (2.0 mg) which produced flow rates of 0% at 15 minutes after the first dose, 46% at 120 minutes after the first dose, and 62% at 120 minutes after the second dose. No major hemorrhagic events were reported in any treated patients and only one patient had a catheter-related infection. Results from this Phase 2 study support further evaluation of alfimeprase in fixed doses ranging from 1.0 mg to 3.0 mg for the treatment of occluded catheters. We expect to initiate a Phase 3 pivotal trial of alfimeprase in catheter occlusion in the second half of 2005.

rNAPc2

Our second drug candidate, rNAPc2, is a recombinant version of a naturally occurring protein that has anticoagulant properties. Specifically, rNAPc2 has been shown to block the factor VIIa/tissue factor protease complex, which is responsible for the initiation of the process leading to blood clot formation. Compared to other commercially available anticoagulants, which all exert their effects at later stages of the blood coagulation cascade, rNAPc2 is designed to block the first step in the clotting cascade. By blocking the coagulation cascade before amplification of the coagulation process, rNAPc2 could prove to be more effective in treating patients with conditions such as acute coronary syndrome or as a prophylactic against clot formation in conditions such as deep venous thrombosis.

ACS occurs when an atherosclerotic plaque ruptures in a coronary artery which triggers the coagulation cascade and results in the formation of a blood clot. The clot blocks the flow of blood to the heart

muscle, depriving it of oxygen and causing chest pain and, if severe, permanent heart muscle death. In the United States, ACS accounts for approximately 1.4 million hospital admissions annually. Patients with ACS are traditionally given aspirin and heparin, among other agents, to stabilize their medical condition. Recent guidelines also recommend the addition of the antiplatelet agent clopidogrel (Plavix) to the standard of care. However, based upon the significant number of patients with ACS who continue to experience poor outcomes such as recurrent angina, myocardial infarction or death, we believe there is a clear need for better antithrombotic therapy.

rNAPc2, given alone or with standard therapy, may reduce the risk of subsequent heart attack or death in patients suffering from ACS. Unlike aspirin and heparin, or current antithrombotic agents, which all exert their effects at later stages of the blood coagulation cascade, rNAPc2 blocks the first step in the clotting cascade. A medical regimen that includes rNAPc2 could, therefore, enable a multi-pronged attack at several points along the blood coagulation process. Alternatively, by stopping coagulation at the outset, rNAPc2 could also prove effective as a stand-alone therapy.

We licensed the worldwide rights for all indications of rNAPc2 and all of the rNAPc molecules owned by Dendreon Corporation in February 2004. The United States government may claim a non-exclusive right to use rNAPc2 with respect to the treatment of hemorrhagic fever. We don t currently contemplate development of rNAPc2 to treat hemorrhagic fever. To date, rNAPc2 has been shown to be well-tolerated in over 500 patients and healthy volunteers in several Phase 1 and 2 studies.

In May of 2004 we reinitiated a Phase 2a double-blind, placebo controlled clinical trial to determine a safe and effective dose of rNAPc2 in moderate to high-risk patients with ACS. The study is being conducted in three parts, each of which is investigating rNAPc2 in combination with current anticoagulant and antiplatelet therapies. Currently, the study is being conducted with the TIMI Study Group led by Dr. Eugene Braunwald of Brigham and Women s Hospital and Harvard Medical School. We plan to complete patient enrollment of the Phase 2a study in the first half of 2005.

ARC183

Our third drug candidate, ARC183, is a DNA aptamer, a single-stranded nucleic acid that binds to thrombin with high affinity and specificity. The key advantage of ARC183 compared to other thrombin inhibitors is its rapid onset of action and short half-life, giving it the potential to be highly effective for medical procedures that require rapid reversal of anticoagulation shortly after the procedure is completed.

In January of 2004 we announced a collaboration agreement with Archemix, a privately held biotechnology company, located in Cambridge, Massachusetts, for the development and commercialization of ARC183. Our lead indication for ARC183 is as a thrombin inhibitor for use in CABG surgery.

According to the American Heart Association, more than 500,000 CABG procedures are performed in the United States annually. Currently, heparin is used to limit blood clotting in this indication, but it is difficult to dose and can cause side effects such as bleeding and heparin-induced thrombocytopenia, or HIT. Moreover, the effect of heparin must be reversed with the use of an antidote called protamine. Protamine is not approved by the FDA for reversal of heparin in CABG surgery and is associated with significant complications including hypotension, platelet dysfunction, complement activation and thrombus formation. We believe that there is a significant unmet medical need for a safe, fast-acting anticoagulant for use in CABG surgery that is easier to administer, does not require a reversal agent and limits adverse side effects such as bleeding and HIT.

ARC183 has shown potential in pre-clinical studies to be equally effective, with fewer side effects, than heparin and protamine in combination. Due to its very short half-life, we believe ARC183 has the potential for more predictable dosing as well as reduced incidence of bleeding side effects compared to heparin.

In August 2004 we and our partner, Archemix, initiated a Phase 1 clinical program for ARC183 for use in CABG surgery. These studies are evaluating the safety, tolerability, anticoagulation activity and titratability of ARC183. We expect to complete enrollment of the Phase 1 clinical program of ARC183 in the first half of 2005.

RESEARCH AND DEVELOPMENT PROGRAMS

In addition to our clinical and development stage drug candidates, we have an ongoing discovery program focused on the identification of novel human genes that encode proteins with therapeutic potential. Over the long-term, we intend to develop additional product opportunities from our ongoing discovery efforts focused on secreted proteins and antibody targets.

In the second half of 2004, we initiated pre-clinical studies for our first internally-generated drug candidate, NU206. In addition to the development of internal therapeutic candidates, we intend to leverage these discoveries to create revenue-generating licensing and partnering arrangements.

The secreted protein program includes our collaboration with Kirin and our internal discovery program. We have already advanced several secreted protein candidates to more extensive studies to better define their therapeutic utility based upon early findings in initial mouse models. Within our internal secreted protein discovery program, we have developed a fast and efficient method of expressing human secreted proteins in mice. This program could significantly bolster our ability to identify which secreted proteins within our patent estate have the greatest potential for therapeutic use.

The antibody program is focused on screening our proprietary gene sequence collection to identify proteins located on the surface of tumor cells that could be targeted by therapeutic monoclonal antibodies.

PRODUCT PIPELINE

The following table summarizes key information about our current product pipeline:

OUR STRATEGY

We are focused on building a successful biopharmaceutical business and committed to creating a valuable product-focused company that leverages our drug discovery and development expertise. Key elements of our strategy are to:

Successfully develop and commercialize our lead drug candidate, alfimeprase

We are seeking to successfully develop and commercialize our lead drug candidate, alfimeprase, for the treatment of acute PAO and catheter occlusion. We recently completed Phase 2 clinical trials in these two indications, and we expect to initiate pivotal, Phase 3 trials in both indications in 2005. We have acquired worldwide, exclusive rights to this compound and are currently exploring potential partnering opportunities that would enable us to participate in its commercialization, particularly in the United States.

Leverage our expertise in cardiovascular disease to advance our clinical development program

We are primarily focused on the development of acute, hospital-based, cardiovascular drug candidates. We believe this portfolio leverages our expertise in cardiovascular drug development, provides synergy with alfimeprase during both development and commercialization and enables us to pursue a more rapid path toward drug development.

Build a diversified pipeline of product candidates

We are pursuing several drug development candidates in various stages of clinical and pre-clinical development. We believe this strategy reduces our exposure to the impact of any single product failure and increases our flexibility to eliminate programs we deem less promising. By broadening our product portfolio, we intend to increase the probability of clinical and commercial success. In addition, we focus on molecules that we believe have a greater chance of success due to the predictability of pre-clinical models used in their development.

Opportunistically seek to license or acquire complementary products and technologies

We intend to supplement our internal drug discovery efforts through the acquisition of products and technologies that complement our development strategy. We continue to identify, evaluate and pursue the acquisition or licensing of strategically valuable product opportunities.

CORPORATE INFORMATION

We were incorporated as Hyseq, Inc. in Illinois in 1992 and reincorporated in Nevada in 1993. On January 31, 2003, we merged with Variagenics, Inc., a publicly traded Delaware corporation based in Massachusetts, and, in connection with the merger, changed our name to Nuvelo, Inc. On March 25, 2004, we reincorporated from Nevada to the State of Delaware. Our principal executive offices are located at 675 Almanor Avenue, Sunnyvale, California 94085 and our telephone number is (408) 215-4000. Our World Wide Web address is http://www.nuvelo.com. We have not incorporated by reference into this prospectus supplement or the accompanying prospectus the information contained on our website and you should not consider it to be part of this prospectus supplement or the accompanying prospectus.

The offering

Common stock we are offering	8,500,000 shares
Common stock to be outstanding after this offering	40,728,732 shares
Use of proceeds	We estimate the net proceeds to us from this offering will be approximately \$59.3 million, after payment of underwriting discounts and commissions and estimated expenses of this offering, or approximately \$68.3 million if the underwriters exercise their over-allotment option in full. We intend to use the net proceeds to us from this offering for general corporate purposes, including capital expenditures, working capital needs, current and future clinical trials of our lead drug candidate, alfimeprase, as well as other research and drug development activities. See Use of proceeds.
Nasdaq National Market Symbol	NUVO
Risk factors	See Risk factors beginning on page S-9 for a discussion of factors you should carefully consider before deciding to invest in shares of our common stock.

The number of shares of our common stock to be outstanding immediately after the closing of this offering is based on 32,228,732 shares of our common stock outstanding as of December 31, 2004, but excludes:

- Ø an aggregate of 3,871,594 shares of our common stock issuable upon exercise of stock options outstanding as of December 31, 2004, granted under our 2004 Equity Incentive Plan, 2002 Equity Incentive Plan, 1995 Stock Option Plan, Non-Employee Director Stock Option Plan, Scientific Advisory Board/Consultants Stock Option Plan and the Variagenics, Inc. Amended 1997 Employee, Director and Consultant Stock Option Plan, and as of December 31, 2004, an aggregate of 895,075 shares of common stock issuable upon the exercise of stock options granted outside of any of our stock option plans, with exercise prices of all outstanding options ranging from \$0.03 to \$304.31 per share and a weighted average exercise price of \$18.77 per share;
- Ø an aggregate of 3,760,298 shares of common stock reserved for issuance pursuant to future option grants under the 2004 Equity Incentive Plan, based on options outstanding as of December 31, 2004;

Ø an aggregate of 56,736 shares of common stock issuable under our Employee Stock Purchase Plan as of December 31, 2004;

- Ø an aggregate of 1,516,792 shares of our common stock issuable upon the exercise of warrants, with exercise prices ranging from \$4.05 to \$25.53 per share, and a weighted average exercise price of \$20.88 per share, outstanding as of December 31, 2004; and
- Ø 542,235 shares of common stock issuable at our option to repay our note held by Affymetrix and 907,113 shares of common stock issuable upon mutual agreement to convert the promissory note under the Rathmann line of credit, both as of December 31, 2004.

Unless otherwise stated, all information contained in this prospectus supplement assumes that the underwriters do not exercise their over-allotment option to purchase up to an additional 1,275,000 shares of common stock and all currency amounts are in United States dollars.

Summary consolidated financial data

The tables below present summary consolidated statement of operations and balance sheet data. The summary financial data for the years ended December 31, 2001 through December 31, 2003 are derived from our audited consolidated financial statements for those periods. The summary data for the nine month period ended September 30, 2004, is derived from our unaudited condensed consolidated financial statements for that period. This information is only a summary and should be read in conjunction with our historical consolidated financial statements and related notes contained in our annual reports, quarterly reports and recent current reports on file with the SEC incorporated by reference in this prospectus supplement and the accompanying prospectus. For more details on how you can obtain our SEC filings, you should read the section of this prospectus supplement entitled Incorporation by reference beginning on page S-43. Our consolidated balance sheet data gives effect to the sale by us of 8,500,000 shares of our common stock in this offering, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

	Year ended December 31,			Nine months ended September 30,	
Consolidated statement of operations data:	2001	2002 (in thousar	2003 nds, except per s	2003 share data)	2004
Revenue	\$ 24,590	\$ 26,433	\$ 2,290	\$ 1,940	\$ 2,219
Research and development expenses	46,506	50,157	33,084	26,421	34,845
General and administrative expenses	13,452	18,108	17,223	14,384	6,667
Total operating expenses	60,783	70,368	51,532	42,017	41,487
Interest income (expense), net	(572)	(1,155)	(945)	(720)	(239)
Net loss	(36,472)	(44,978)	(50,187)	(40,797)	(39,507)
Net loss per common share, basic and diluted	\$ (6.78)	\$ (6.24)	\$ (2.37)	\$ (2.08)	\$ (1.30)
Shares used in computation of basic and diluted net loss per share	5,386	7,220	21,054	19,656	30,427

September 30, 2004

Consolidated balance sheet data:	Actual (unau	As adjusted dited)
Cash, cash equivalents and short-term investments	\$ 70,671	\$ 129,976
Working capital	53,663	112,968
Total assets	100,339	159,644
Current portion of capital lease, note and line of credit obligations	6,698	6,698
Non-current portion of capital lease, note and line of credit obligations	9,886	9,886
Accumulated deficit	(243,066)	(243,066)
Total stockholders equity	58,516	117,821

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Risk factors

Investing in our common stock involves a high degree of risk. You should consider carefully the risk factors described below, in the accompanying prospectus and all other information contained in or incorporated by reference in this prospectus supplement and the accompanying prospectus before deciding to invest in our common stock. If any of the following risks actually occur, they may materially harm our business, financial condition, operating results and cash flow. As a result, the market price of our common stock could decline, and you could lose all or part of your investment. Additional risks and uncertainties that are not yet identified or that we think are immaterial may also materially harm our business, operating results and financial condition and could result in a complete loss of your investment.

RISKS RELATED TO OUR BUSINESS

Development of our products will take years, and our products require regulatory approval before they can be sold.

We have three clinical stage drug candidates. All of our other potential products currently are in research or pre-clinical development and revenues from the sales of any products resulting from this research and development may not occur for several years, if at all. We cannot be certain that any of our products will be demonstrated to be safe and effective or that we will obtain regulatory approvals. We cannot predict whether we will be able to develop and commercialize any of our drug candidates successfully. If we are unable to obtain regulatory approval and successfully commercialize our potential products, our business, results of operations and financial condition will be affected in a materially adverse manner.

We do not yet have products in the commercial markets. We must demonstrate that our product candidates satisfy rigorous standards of safety and efficacy before the FDA and comparable agencies in foreign markets. We cannot apply for regulatory approval of our potential products until we have performed significant additional research and development and testing. We cannot be certain that we, or our strategic partners, will be permitted to undertake clinical testing of our potential products or continue clinical testing of alfimeprase, rNAPc2, or ARC183. If we are successful in initiating clinical trials, we may experience delays in conducting them. Our clinical trials may not demonstrate the safety and efficacy of our potential products, and we may encounter unacceptable side effects or other problems in the clinical trials that may prevent or limit the use of our products. Should this occur, we may have to delay or discontinue development of the potential product that causes the problem. After a successful clinical trial, we cannot market products in the United States until we receive regulatory approval. Even if we are able to gain regulatory approval of our products after successful clinical trials and then commercialize and sell those products, we may be unable to manufacture enough products to maintain our business, which could have a negative impact on our financial condition.

Our clinical trials may not yield results that will enable us to obtain regulatory approval for our products.

We will only receive regulatory approval for a drug candidate if we can demonstrate in carefully designed and conducted clinical trials that the drug candidate is safe and effective. We do not know whether our pending or any future clinical trials will demonstrate sufficient safety and efficacy to obtain the requisite regulatory approvals or will result in marketable products. Clinical trials are lengthy, complex, and expensive processes with uncertain results. It will take us several years to complete our testing, and failure can occur at any stage of testing. Results attained in pre-clinical testing and early clinical studies, or trials, may not be predictive of results that are obtained in later studies. We may suffer significant setbacks in advanced clinical trials, even after promising results in earlier studies. Based on results at any stage of clinical trials, we may decide to repeat or redesign a trial or discontinue development of one or more of our drug candidates. If we fail to adequately demonstrate the safety and efficacy of our products

Risk factors

under development, we will not be able to obtain the required regulatory approvals to commercialize our drug candidates, and our business, results of operations and financial condition will be materially adversely affected.

Clinical trials are subject to continuing oversight by governmental regulatory authorities and institutional review boards, or IRBs, and must meet the requirements of these authorities in the United States, including those for informed consent and good clinical practices. We may not be able to comply with these requirements and the FDA, an IRB or we may suspend or terminate clinical trials at any time.

Administering our drug candidates to humans may produce undesirable side effects. These side effects could interrupt, delay or halt clinical trials of our drug candidates and could result in the FDA or other regulatory authorities denying approval of our drug candidates for any or all targeted indications.

We rely on third parties, including contract research organizations and outside consultants, to assist us in managing and monitoring clinical trials. Our reliance on these third parties may result in delays in completing, or in failing to complete, these trials if they fail to perform with the speed and competency we expect.

If clinical trials for a drug candidate are unsuccessful, we will be unable to commercialize the drug candidate. If one or more of our clinical trials are delayed, we will be unable to meet our anticipated development or commercialization timelines. Either circumstance could cause the price of our shares to decline.

If we encounter difficulties enrolling patients in our clinical trials, our trials could be delayed or otherwise adversely affected.

Clinical trials for our drug candidates require that we identify and enroll a large number of patients with the disorder under investigation. We may not be able to enroll a sufficient number of patients to complete our clinical trials in a timely manner.

Patient enrollment is affected by factors including:

Ø design of the protocol;

- Ø the size of the patient population;
- Ø eligibility criteria for the study in question;

- Ø perceived risks and benefits of the drug under study;
- Ø availability of competing therapies;
- Ø efforts to facilitate timely enrollment in clinical trials;
- Ø patient referral practices of physicians; and
- Ø availability of clinical trial sites.

If we have difficulty enrolling a sufficient number of patients to conduct our clinical trials as planned, we may need to delay or terminate ongoing or planned clinical trials, either of which would have a negative effect on our business. Delays in enrolling patients in our clinical trials would also adversely affect our ability to generate product and royalty revenues and could impose significant additional costs on us or our collaborators. In addition, we have never conducted Phase 3 clinical trials, and we may be unable to successfully conduct multiple Phase 3 clinical trials involving the numbers of clinical sites and the numbers of patients planned for our alfimeprase Phase 3 clinical trials.

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Risk factors

We face heavy government regulation, and FDA regulatory approval of our products is uncertain.

The research, testing, manufacturing and marketing of drug products such as those proposed to be developed by us or our collaboration partners are subject to extensive regulation by federal, state and local governmental authorities, including the FDA, and comparable agencies in other countries. To obtain regulatory approval of a drug product, we or our collaboration partners must demonstrate to the satisfaction of the applicable regulatory agency, among other things, that the product is safe and effective for its intended uses. In addition, we must show that the manufacturing facilities used to produce the products are in compliance with current Good Manufacturing Practices, or cGMP, requirements.

The process of obtaining FDA and other required regulatory approvals and clearances typically takes several years and will require us to expend substantial capital and resources. Despite the time and expense expended, regulatory approval is never guaranteed. The number of pre-clinical and clinical tests that will be required for FDA approval varies depending on the drug candidate, the disease or condition that the drug candidate is in development for, and the regulations applicable to that particular drug candidate. The FDA or comparable international regulatory authorities can delay, limit or deny approval of a drug candidate for many reasons, including:

- Ø a drug candidate may not be safe or effective;
- Ø FDA or comparable international regulatory authorities may interpret data from pre-clinical and clinical testing in different ways than we and our collaboration partners interpret them;
- Ø the FDA or comparable international regulatory authorities may not approve our manufacturing processes or facilities or the processes or facilities of our collaboration partners; or
- \emptyset the FDA or comparable international regulatory officials may change their approval polices or adopt new regulations.

Moreover, if and when our products do obtain such approval or clearances, the marketing, distribution and manufacture of such products would remain subject to extensive ongoing regulatory requirements. Failure to comply with applicable regulatory requirements could result in:

- Ø warning letters;
- Ø fines;
- Ø civil penalties;
- Ø injunctions;
- Ø recall or seizure of products;

- Ø total or partial suspension of production;
- Ø refusal of the government to grant approvals; or
- Ø withdrawal of approvals and criminal prosecution.

Any delay or failure by us or our collaboration partners to obtain regulatory approvals for our product candidates:

- Ø would adversely affect our ability to generate product and royalty revenues;
- Ø could impose significant additional costs on us or our collaboration partners;
- Ø could diminish competitive advantages that we may attain;
- Ø would adversely affect the marketing of our products; and
- \emptyset could cause the prices of our shares to decline.

Risk factors

Even if we do receive regulatory approval for our drug candidates, the FDA or international regulatory authorities may impose limitations on the indicated uses for which our products may be marketed, subsequently withdraw approval or take other actions against us or our products that are adverse to our business. The FDA and comparable international regulatory authorities generally approve products for particular indications. An approval for a limited indication reduces the size of the potential market for the product. Product approvals, once granted, may be withdrawn if problems occur after initial marketing.

We also are subject to numerous federal, state and local laws, regulations and recommendations relating to safe working conditions, laboratory and manufacturing practices, the experimental use of animals, the environment and the use and disposal of hazardous substances used in connection with our discovery, research and development work, including radioactive compounds and infectious disease agents. In addition, we cannot predict the extent of government regulations or the impact of new governmental regulations that might significantly harm the discovery, development, production and marketing of our products. We may be required to incur significant costs to comply with current or future laws or regulations, and we may be adversely affected by the cost of such compliance.

If we fail to maintain existing third-party arrangements and collaborative agreements or fail to develop new collaborative arrangements, our business will be harmed.

 In reliance on the reviews and discussions referred to above, the Committee recommended to the Board of Directors, and the Board has approved, that the audited financial statements be included in the Company's Annual Report on Form 10-K for the year ended December 31, 2001. The Committee also recommended and the Board approved the reappointment of Ernst & Young, LLP as the Company's independent auditors for the year ending December 31, 2002.

Respectfully Submitted by:

Charlie Bass Burnett Donoho Leon Malmed

CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

 The following is a description of transactions during the past three fiscal years to which we have been a party, in which the amount involved exceeded \$60,000 and in which any director, executive officer or beneficial holder of more than 5% of our outstanding capital stock had or will have a direct or indirect material interest.

 We had outstanding accounts payable to the Impact Zone, an engineering design and consulting services company, of \$18,688, \$29,400 and \$2,500 at December 31, 2001, 2000 and 1999, and received services from Impact Zone during the years ended December 31, 2001, 2000 and 1999 valued at \$234,838, \$163,500 and \$21,300. The Company had no outstanding accounts receivable due from the Impact Zone at December 31, 2001 and

recognized revenues from sales to Impact Zone during the year ended December 31, 2001 of \$18,118. The Impact Zone's principal stockholder, Dale Gifford, is a sibling of Micheal L. Gifford, Executive Vice President and Director of the Company.

 On October 5, 2000, we acquired 3rd Rail Engineering. Paul Hughes, formerly President of 3rd Rail Engineering, became our Vice President of Operations, and Robert Miller, former Chief Technical Officer of 3rd Rail Engineering, became our Vice President of Engineering. Neither individual had any relationship with us prior to the acquisition. Paul Hughes and Robert Miller each received 282,045 common shares of Socket and cash of \$432,785 in payment for their equity interests in 3rd Rail Engineering. We also executed employment agreements with each individual. These agreements are described more fully above under "Executive Compensation - Employment Contracts and Change-in Control Arrangements."

 In March 2002 we completed a private placement of 381,760 shares of our common stock to increase our working capital and cash balances. The offering was sold at a price of \$1.59 per share of common stock and resulted in gross proceeds of approximately \$607,000, and net proceeds after costs and expenses of approximately \$420,000. In connection with the offering, we issued warrants to investors in the offering and Socket's placement agent in the offering to purchase an aggregate of 118,344 shares of common stock at a price of \$1.59 per share (subject to adjustment in the event of dilutive issuances). The warrants have a term of five years, and could result in additional proceeds if exercised. Pursuant to a Registration Rights Agreement, we agreed to file no later than May 1, 2002 a registration statement on Form S-3 to enable the resale of the shares issued in this offering and the shares issuable on exercise of the warrants issued to investors in this offering. Two members of Socket's Board of Directors, Charlie Bass and Enzo Torresi, invested \$100,000 and \$30,000, respectively, in this offering. Mr. Bass acquired 62,893 shares of our common stock and warrants to purchase an additional 15,723 shares of our common stock, and Dr. Torresi acquired 18,867 shares of our common stock and warrants to purchase an additional 4,716 shares of our common stock.

 See also "Executive Compensation - Employment Contracts and Change-in Control Arrangements."

PERFORMANCE GRAPH

 The following graph shows a five-year comparison of cumulative total stockholder return, calculated on a dividend reinvestment basis and based on a \$100 investment, from December 31, 1996 through December 31, 2001 comparing the return on the Company's Common Stock with the Russell 2000 Index, the JP Morgan H & Q Technology Index and the Nasdaq Computer & Data Processing Index. No dividends have been declared or paid on the Company's Common Stock during such period. Historical stock price performance is not necessarily indicative of future stock price performance.

COMPARISON OF 5 YEAR CUMULATIVE TOTAL RETURN* AMONG SOCKET COMMUNICATIONS, INC., THE RUSSELL 2000 INDEX, THE JP MORGAN H & Q TECHNOLOGY INDEX AND THE NASDAQ COMPUTER &

DATA PROCESSING INDEX

OTHER MATTERS

 The Company knows of no other matters to be submitted at the Annual Meeting. If any other matters properly come before the Annual Meeting, it is the intention of the persons named in the enclosed form of proxy to vote the shares they represent as the Board of Directors may recommend.

THE BOARD OF DIRECTORS

Dated: May 10, 2002

APPENDIX A

AUDIT COMMITTEE CHARTER OF THE BOARD OF DIRECTORS OF SOCKET COMMUNICATIONS, INC.

PURPOSES:

 The Audit Committee will make such examinations as are necessary to monitor the corporate financial reporting and the internal and external audits of the corporation, to provide to the Board of Directors the results of its examinations and recommendations derived therefrom, to outline to the Board improvements made, or to be made, in internal accounting controls, to nominate independent auditors, and to provide to the Board such additional information and materials as it may deem necessary to make the Board aware of significant financial matters that require Board attention.

 In addition, the Audit Committee will undertake those specific duties and responsibilities listed below and such other duties as the Board of Directors from time to time prescribe.

MEMBERSHIP:

 The Audit Committee will consist of three (3) members of the Board, all of whom shall be independent directors, in accordance with NASD Rules. The members of the Audit Committee will be appointed by and will serve at the discretion of the Board of Directors.

RESPONSIBILITIES:

 The responsibilities of the Audit Committee shall include:

 1. Nominating the independent auditors;

 2. Reviewing the plan for the audit and related services;

 3. Reviewing audit results and financial statements;

 4. Overseeing the adequacy of the corporation's system of internal accounting controls, including obtaining from the independent auditors management letters or summaries on such internal accounting controls;

 5. Overseeing compliance with the Foreign Corrupt Practices Act;

 6. Overseeing compliance with SEC requirements for disclosure of auditor's services including auditor independence and audit committee members and activities; and

 7. Reviewing related party transactions for potential conflicts of interest.

 In addition to the above responsibilities, the Audit Committee will undertake such other duties as the Board of Directors delegates to it, and will report, at least annually, to the Board regarding the Committee's examinations and recommendations including recommending to the Board of Directors approving the filing of the Company's annual report to the Securities and Exchange Commission on Form 10-K.

MEETINGS:

 The Audit Committee will meet at least one time per year with the Auditors and with management to review the audit results and the audited financial statements, to discuss with the auditors the matters required by Statement on Auditing Standards No. 61, and to review and discuss with the Auditors the matters required by Independence Standards Board Statement No. 1 and consider the compatibility of non-audit services with the Auditor's independence.

 The Audit Committee will also meet quarterly, or will designate one of its members to meet quarterly, with the Auditors and with management to review the quarterly financial statements prior to their filing with the Securities and Exchange Commission.

 The Audit Committee shall insure open communications between the Auditors and the Audit Committee at all times.

REPORTS:

 The Audit Committee shall prepare a written report to the Board of Directors based on its meeting with the Auditors and its review of the audited financial statements, which report shall be incorporated into the Board minutes and shall be printed in the Annual Meeting Proxy to the stockholders of the Company.

MINUTES:

 The Audit Committee will maintain written minutes of its meetings, which minutes will be filed with the minutes of the meetings of the Board of Directors.

This Proxy is solicited on behalf of the Board of Directors of Socket Communications, Inc.

2002 ANNUAL MEETING OF STOCKHOLDERS

The undersigned stockholder of SOCKET COMMUNICATIONS, INC., a Delaware corporation, hereby acknowledges receipt of the Notice of Annual Meeting of Stockholders and Proxy Statement, each dated May 10, 2002, and hereby appoints Kevin Mills and David Dunlap, and each of them, proxies and attorneys-in-fact, with full power to each of substitution, on behalf and in the name of the undersigned, to represent the undersigned at the 2002 Annual Meeting of Stockholders of SOCKET COMMUNICATIONS, INC. to be held on Wednesday, June 20, 2002 at 9:00 a.m. local time, at the Company's headquarters at 37400 Central Court, Newark, California 94560, and at any adjournment or adjournments thereof, and to vote all shares of Common Stock which the undersigned would be entitled to vote if then and there personally present, on the matters set forth below:

1. ELECTION OF SEVEN DIRECTORS.

// FOR all nominees listed // Withhold Authority to vote for ALL Nominees Listed

Nominees: Charlie Bass, Kevin Mills, Michael Gifford, Gianluca Rattazzi, Leon Malmed, Enzo Torresi, Peter Sealey

If you wish to withhold authority to vote for any individual nominee, strike a line through that nominee's name in the list below:

Charlie Bass; Kevin Mills; Michael Gifford; Gianluca Rattazzi; Leon Malmed; Enzo Torresi; Peter Sealey

- PROPOSAL TO RATIFY A PRIVATE PLACEMENT OF SHARES OF THE COMPANY'S COMMON STOCK AND WARRANTS 2. TO PURCHASE COMMON STOCK.
 - 11 FOR 11 AGAINST 11 ABSTAIN
- PROPOSAL TO RATIFY THE APPOINTMENT OF ERNST & YOUNG, LLP AS INDEPENDENT PUBLIC ACCOUNTANTS OF 3. THE COMPANY FOR THE FISCAL YEAR ENDING DECEMBER 31, 2002.
 - FOR 11 AGAINST ABSTAIN 11 11

In their discretion, the Proxies are entitled to vote upon such other matters as may properly come before the meeting or any adjournments thereof.

THIS PROXY WILL BE VOTED AS DIRECTED OR, IF NO CONTRARY DIRECTION IS INDICATED, WILL BE VOTED FOR THE ELECTION OF DIRECTORS, FOR THE RATIFICATION OF ERNST & YOUNG LLP AS INDEPENDENT PUBLIC ACCOUNTANTS, FOR THE APPROVAL OF THE SALE AND ISSUANCE OF THE COMPANY'S COMMON STOCK AND WARRANTS TO PURCHASE COMMON STOCK AND AS SAID PROXIES DEEM ADVISABLE ON SUCH OTHER MATTERS AS MAY PROPERLY COME BEFORE THE MEETING.

Signature

Signature

(This Proxy should be marked, dated and signed by the stockholder(s) exactly as his or her name appears hereon, and returned promptly in

the enclosed envelope. Persons signing in a fiduciary capacity should so indicate. If shares are held by joint tenants or as community property, both should sign.)

Date: _____, 2002