NUVELO INC
Form 10-Q
November 08, 2006
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

x QUARTERLY REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2006

OR

¨ TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
FOR THE TRANSITION PERIOD FROM _____ TO _____

Commission File Number 000-22873

NUVELO, INC.

(Exact Name of Registrant as Specified in Its Charter)

DELAWARE	**36-3855489**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification Number)**

201 INDUSTRIAL ROAD, SUITE 310, SAN CARLOS, CA 94070-6211

(Address of Principal Executive Offices, including Zip Code)

650-517-8000

(Registrant s Telephone Number, including Area Code)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Sections 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No ¨

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act.

Large Accelerated Filer ¨ Accelerated Filer x Non-accelerated Filer ¨

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ¨ No x

Indicate the number of shares outstanding of each of the issuer s classes of common stock, as of the latest practicable date.

Class	**Number of Shares Outstanding**
Common Stock $0.001 par value	On October 31, 2006: 52,958,811

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NUVELO, INC.

FORM 10-Q

FOR THE QUARTER ENDED SEPTEMBER 30, 2006

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PART I. FINANCIAL INFORMATION

ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

NUVELO, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(unaudited)

	September 30, 2006	December 31, 2005
	(In thousands)	
ASSETS		
Cash and cash equivalents	$ 102,055	$ 37,764
Short-term investments	55,143	32,572
Collaboration receivables	8,169	1,207
Clinical trial supplies	18,436	12,261
Other current assets	5,438	1,961
Total current assets	189,241	85,765
Equipment, leasehold improvements and capitalized software, at cost	31,481	29,615
Accumulated depreciation and amortization	(15,713)	(14,450)
Equipment, leasehold improvements and capitalized software, net	15,768	15,165
Goodwill	4,671	4,671
Patents, licenses and other assets, net	2,425	2,445
Total assets	$ 212,105	$ 108,046
LIABILITIES AND STOCKHOLDERS EQUITY		
Accounts payable	$ 4,556	$ 4,919
Accrued employee liabilities	2,800	2,272
Accrued clinical trial and drug manufacturing costs	9,842	4,482
Current portion of deferred revenue	3,640	250
Current portion of deferred rent	5,260	9,936
Accrued interest	2,113	3,092
Current portion of bank loans	1,540	1,540
Note payable		4,000
Current portion of capital lease obligations	43	9
Current portion of related party line of credit	2,750	2,750
Other current liabilities	4,422	2,933
Total current liabilities	36,966	36,183
Non-current portion of deferred revenue	45,443	1,563
Non-current portion of deferred rent	9,341	9,393
Non-current portion of bank loans	337	1,492
Non-current portion of capital lease obligations	70	13
Non-current portion of related party line of credit	229	2,292
Other non-current liabilities	365	346

Total liabilities	92,751	51,282
Stockholders equity:		
Preferred stock, par value $0.001; 5,000,000 shares authorized; none issued and outstanding as of September 30, 2006 and December 31, 2005		
Common stock, par value $0.001; 100,000,000 shares authorized; 52,235,095 and 44,149,456 issued and outstanding as of September 30, 2006 and December 31, 2005, respectively	52	44
Additional paid-in capital	511,584	384,629
Accumulated other comprehensive income (loss)	594	(250)
Accumulated deficit	(392,876)	(327,659)
Total stockholders equity	119,354	56,764
Total liabilities and stockholders equity	$ 212,105	$ 108,046

See accompanying notes to condensed consolidated financial statements.

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NUVELO, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2006	2005	2006	2005
	(In thousands, except per share data)			
Contract revenue	$ 908	$ 123	$ 2,978	$ 362
Operating expenses:				
Research and development	23,134	14,798	49,929	40,341
General and administrative	6,840	4,175	24,310	11,139
Loss (gain) on sale or disposal of assets	(272)	2	(276)	25
Total operating expenses	29,702	18,975	73,963	51,505
Operating loss	(28,794)	(18,852)	(70,985)	(51,143)
Interest expense related party	(75)	(111)	(260)	(345)
Interest expense other	(20)	(143)	(252)	(414)
Interest income	2,221	639	6,276	1,617
Other income, net		8	4	157
Net loss	$ (26,668)	$ (18,459)	$ (65,217)	$ (50,128)
Basic and diluted net loss per share	$ (0.51)	$ (0.44)	$ (1.28)	$ (1.23)
Weighted average shares used in computing basic and diluted net loss per share	52,022	42,163	50,943	40,727

See accompanying notes to condensed consolidated financial statements.

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NUVELO, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(unaudited)

	Nine Months Ended September 30,	
	2006	2005
	(In thousands)	
Cash flows from operating activities:		
Net loss	$ (65,217)	$ (50,128)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	2,403	1,946
Loss (gain) on sale or disposal of assets	(276)	25
Write-off of clinical trial supplies	1,815	
Stock-based compensation expense	9,471	552
Change in fair value of warrant	2,791	(57)
Other non-cash items	(134)	207
Changes in operating assets and liabilities:		
Collaboration receivables	(6,962)	218
Clinical trial supplies	(7,263)	979
Other current assets	(3,440)	(1,076)
Other non-current assets	(222)	(282)
Accounts payable	(363)	(759)
Accrued employee liabilities	528	146
Accrued clinical trial and drug manufacturing costs	5,360	2,938
Deferred revenue	47,270	1,875
Deferred rent	(5,720)	988
Accrued interest	(979)	570
Other current liabilities	(1,152)	160
Net cash used in operating activities	(22,090)	(41,698)
Cash flows from investing activities:		
Maturities of short-term investments	54,862	47,506
Purchases of short-term investments	(77,369)	(55,672)
Purchases of equipment, leasehold improvements and software capitalization	(1,897)	(1,193)
Proceeds from sale of assets	537	
Net cash used in investing activities	(23,867)	(9,359)
Cash flows from financing activities:		
Proceeds from bank loans		1,500
Payments on bank loans	(1,155)	(683)
Payment of note payable	(4,000)	
Payments on capital lease obligations	(26)	(1,054)
Payments on related party line of credit	(2,063)	(2,063)
Proceeds from release of restricted cash		191
Proceeds from issuance of common stock from public offerings, net	112,006	68,448
Proceeds from issuance of common stock upon exercise of options, warrants and under employee stock purchase plan	5,486	1,457
Net cash provided by financing activities	110,248	67,796

Net increase in cash and cash equivalents	64,291	16,739
Cash and cash equivalents at beginning of period	37,764	16,811
Cash and cash equivalents at end of period	$ 102,055	$ 33,550
Supplemental disclosures of cash flow information:		
Interest paid	$ 1,498	$ 195
Non-cash investing and financing activities:		
Acquisition of leasehold improvements under tenant improvement allowances	$ 992	$ 8,856
Acquisition of equipment under capital leases	$ 117	$
Capitalization of estimated future building restoration costs	$ 19	$ 341
Fair value of warrant granted as equity financing cost	$	$ 2,078

See accompanying notes to condensed consolidated financial statements.

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NUVELO, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

September 30, 2006

(Unaudited)

1. Basis of Presentation and Significant Accounting Policies

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared by Nuvelo, Inc. (Nuvelo, or the Company) in accordance with accounting principles generally accepted in the United States of America for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by accounting principles generally accepted in the United States of America (GAAP) for complete financial statements. The accompanying financial information is unaudited, but includes all adjustments (consisting of normal recurring adjustments) that the Company considers necessary for a fair presentation of the financial position, operating results and cash flows for the periods presented. The condensed consolidated balance sheet as of December 31, 2005 is derived from the Company s audited financial statements. Certain prior period amounts have been reclassified to conform to the current period s presentation. The results of operations for the interim period shown herein are not necessarily indicative of operating results expected for the entire year.

The unaudited condensed consolidated financial statements include the accounts of Nuvelo, Inc. and Hyseq Diagnostics, Inc., Nuvelo s wholly owned and inactive subsidiary. All significant inter-company transactions and accounts have been eliminated on consolidation. Nuvelo is engaged in the discovery, development and commercialization of novel acute cardiovascular and cancer therapies. The Company s development pipeline includes three acute cardiovascular programs focused on alfimeprase, rNAPc2 and NU172, as well as an emerging oncology pipeline, which includes pre-clinical candidate NU206.

Use of Estimates

Conformity with GAAP requires the use of estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. The Company bases its estimates on historical experience and on assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for the judgments made about the carrying values of assets and liabilities that are not readily apparent from other sources. Future results may differ from these estimates. The Company believes significant judgment is involved in evaluating if there continues to be alternative future use or the need for reserves for capitalized clinical drug material, and in estimating goodwill and long-lived asset impairment, clinical trial accruals, stock-based compensation and in determining revenue recognition.

Liquidity and Concentration Risk

The Company s primary sources of liquidity are from financing activities and collaboration receipts. The Company plans to continue to raise funds through additional public and/or private offerings and collaboration activities in the future. The primary use of capital has been to fund operating activities, including research, clinical development and drug manufacturing expenses, license payments and spending on capital items.

The Company currently relies on Avecia Ltd. as a sole source for the manufacture of alfimeprase bulk drug substance and Baxter Pharmaceutical Solutions LLC (Baxter) as a sole source for its conversion into final drug product. If Avecia and Baxter are unable to produce alfimeprase in the quantities and with the quality required, the Company may incur significant additional expenses and efforts to complete clinical trials. Additionally, the potential approval to market alfimeprase could be significantly delayed.

Significant Accounting Policies

During the interim period, the Company has followed the accounting policies described in its Form 10-K for the fiscal year ended December 31, 2005. Additionally, the stock-based compensation policy has been updated as a result of the adoption by the Company of Statement of Financial Accounting Standards No. 123 (revised 2004), *Share-Based Payment,* on January 1, 2006. The updated policy is detailed hereunder.

Stock-Based Compensation

Effective January 1, 2006, the Company adopted the provisions of Statement of Financial Accounting Standards No. 123 (revised 2004), *Share-Based Payment* (SFAS 123(R)). SFAS 123(R) establishes accounting for stock-based awards exchanged for employee services. Under SFAS 123(R), employee stock-based compensation cost is generally measured at the grant date, based on the fair value of the award, and is recognized as an expense over the employee s requisite service period net of estimated forfeitures. The Company previously applied Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* (APB 25), and related Interpretations and provided the required pro forma disclosures of SFAS No. 123, *Accounting for Stock-Based Compensation* (SFAS 123). The Company has elected to adopt the modified prospective application method as provided by SFAS 123(R). Under the modified prospective method, the fair values of new and previously granted but unvested stock options are recognized as compensation expense in the statement of operations over the related vesting periods, and prior period results are not restated.

The Company has selected the Black-Scholes option pricing model as the most appropriate fair-value method for its stock-based awards. For options granted prior to January 1, 2006 and valued in accordance with SFAS 123, the Company continues to use the graded-vested (multiple-option) method for expense attribution. Prior to January 1, 2006, option forfeitures were recognized on a pro forma basis as they occurred, and subsequent to this date, the Company estimates forfeitures and only recognizes expense for those shares expected to vest. For options granted after January 1, 2006 and valued in accordance with SFAS 123(R), the Company is using the straight-line (single-option) method for expense attribution and estimates forfeitures and only recognizes expense for those shares expected to vest. See Note 2 for a more detailed discussion of SFAS 123(R).

The Company accounts for stock-based compensation expense for non-employees based on the fair values estimated using the Black-Scholes model on the date of grant and re-measured at each reporting date until vested, in compliance with Emerging Issues Task Force Issue No. 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services.*

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2. Stock-Based Compensation

Stock Plans

In May 2004, the Company adopted the 2004 Equity Incentive Plan (2004 Plan) to authorize the grant of stock options (including indexed options), stock appreciation rights, restricted stock purchase rights, restricted stock bonuses, restricted stock units, performance shares, performance units and deferred stock units. The 2004 Plan has since been amended, including amendments in May 2006 to increase the number of shares available for issuance under the plan by 4,700,000 shares and to remove the share reserve recycling features from the Plan such that shares no longer become re-available for issuance under the 2004 Plan in certain circumstances. Under the 2004 Plan, all awards may be granted to employees, directors and consultants of the Company, except for incentive stock options, which may be granted only to employees. The 2004 Plan supersedes all prior option plans (detailed below), and no new awards will be granted under the prior plans. As a result of the adoption of the 2004 Plan, all shares previously reserved for issuance under the prior plans and remaining for grant are now reserved for issuance under the 2004 Plan. Additionally, shares outstanding under the prior plans that are subject to options that expire or otherwise are forfeited become reserved for issuance under the 2004 Plan. For stock options, the 2004 Plan requires that the exercise price of each option may not be less than the fair market value of a share of common stock on the date of grant, and in the case of incentive stock options granted to an owner of more than 10% of the total combined voting power of all classes of the Company s stock (10% Owners), must have an exercise price equal to at least 110% of the fair market value on the date of grant. The maximum term of any option granted under the 2004 Plan is ten years, provided that incentive stock options granted to 10% Owners must have a term not exceeding five years. Options granted to employees generally vest over a four-year period and expire after ten years if not exercised. As of September 30, 2006, options to purchase 6,852,201 shares were outstanding under the 2004 Plan and 2,541,644 shares were reserved for future option grants.

In 1995, the Company s stockholders adopted the 1995 Employee Stock Option Plan (Employee Plan). Options granted under the Employee Plan were either incentive stock options or non-statutory stock options. Incentive stock options were granted to employees with exercise prices of not less than fair market value and non-statutory options were granted to employees at exercise prices of not less than par value of the common stock on the date of grant as determined by the Board of Directors. Options vest as determined by the Board of Directors (generally in four equal annual installments commencing one year after the date of grant), and expire ten years from the date of grant. As of September 30, 2006, options to purchase 313,497 shares were outstanding under the Employee Plan.

In 1997, the Company s stockholders adopted the Non-Employee Director Stock Option Plan (Directors Plan), which provided for periodic stock option grants to non-employee directors of the Company. Options under the Directors Plan, as amended, were granted at the fair market value of the Company s common stock on the date of the grant, with appointment grants vesting 50% one year after the grant date and 50% two years after the grant date and annual grants vesting fully on the date of grant. As of September 30, 2006, options to purchase 70,462 shares were outstanding under the Directors Plan.

In 1999, the Company adopted a Scientific Advisory Board/Consultants Stock Option Plan (SAB/Consultant Plan) that provided for periodic grants of non-qualified stock options to members of the Company s scientific advisory board and allowed the Board of Directors to approve grants of stock options to consultants. As of September 30, 2006, options to purchase 1,666 shares were outstanding under the SAB/Consultant Plan.

In 2002, the Company adopted the 2002 Equity Incentive Plan (2002 Plan) to grant stock options or make restricted stock awards to employees (including officers or employee directors) and consultants. The 2002 Plan authorized the grant of incentive stock options and restricted stock awards to employees and of non-qualified stock options and restricted stock awards to employees and consultants. The 2002 Plan required that the exercise price of options be not less than the fair value of the common shares at the grant date for those options intended to qualify as performance-based compensation and be not less than 110% of the fair value in the case of incentive stock options granted to 10% Owners. Options generally vest over a four-year period and are exercisable in installments beginning one year after the grant date and expire after ten years if not exercised. As of September 30, 2006, options to purchase 258,907 shares were outstanding under the 2002 Plan.

In February 2000, a former director of the Company was granted an option outside of any of the Company s stock option plans to purchase 333,333 shares of common stock at $95.06 per share, and in August 2001, was granted a further option to purchase 333,333 shares of common stock at $25.91 per share. In 2001, five employee officers were granted options outside of any option plan to purchase a total of 422,720 shares at prices between $29.87 and $37.69 per share. As of September 30, 2006, 773,539 options issued outside of any of the Company s stock option plans were outstanding.

The Directors Plan, the Employee Plan, the 2002 Plan, the 2004 Plan and the options granted to the former director to purchase 666,666 shares (as described above) provide for the acceleration of vesting of options upon certain specified events.

In December 2004, the Company s Board of Directors approved an Executive Change in Control and Severance Benefit Plan for executive officers and other eligible employees, which was amended and restated in May 2005. The purpose of the plan is to provide for the payment of severance benefits and/or change in control benefits to certain eligible employees, and the plan supersedes and replaces any change in control and/or severance plans adopted previously. The plan provides that, upon a change in control of the Company as defined under the plan, all Nuvelo stock options and stock awards held by a plan participant will become fully vested. Such shares held by a plan participant will also become fully vested if the participant is terminated without cause or constructively terminated within one month preceding a change in control. In addition, if a participant is terminated without cause or constructively terminated outside the context of change in control, he or she shall be credited with an additional year of vesting with respect to Nuvelo stock options and stock awards held. If a change in control occurs in the future, it is possible that material additional stock-based compensation expense could be incurred.

Under the Company s employee stock purchase plan (ESPP), eligible employees may elect to purchase shares of the Company s stock through payroll deductions at a price equal to the lower of 85% of the fair market value of the stock as of the first or last business day of each three-month period. As of September 30, 2006, there were 196,838 shares available for issuance under the ESPP.

Stock-Based Compensation Stock Options and ESPP

Effective January 1, 2006, the Company adopted the provisions of SFAS 123(R). Under the standard, stock-based compensation cost is generally to be measured at the grant date, based on the fair value of the award, and recognized as an expense over the employee s requisite service period. The Company calculates compensation cost on the date of grant using the Black-Scholes model, which requires assumptions to be made for the expected term of the awards, expected volatility of the Company s stock price, risk-free interest rates and expected dividend yields. The Company then amortizes compensation cost for awards expected to vest over the related vesting periods, generally four years for employee stock options.

For all option grants, the Company considers historical data, including post-vesting termination behavior, and the contractual term to estimate future exercises and cancellations, and therefore the expected term of each option. The risk-free interest rate assumptions are based on the yield of U.S. Treasury instruments with similar durations as the expected term of the related awards. The expected dividend yield assumption is based on the Company s historic and expected dividend payouts. For options granted prior to January 1, 2006 and valued in accordance with SFAS 123, the expected volatility was based solely on the historical volatility of the Company s common stock and option forfeitures were recognized on a pro forma basis as they occurred. The graded-vested (multiple-option) method continues to be used for expense attribution of these options that were unvested as of January 1, 2006. For options granted after January 1, 2006 and valued in accordance with SFAS 123(R), the Company is using a combination of historic and implied volatility of the Company s common stock to derive expected volatility. Forfeitures are estimated such that the Company only recognizes expense for those shares expected to vest, and adjustments are made if actual forfeitures differ from those estimates. The straight-line (single-option) method is being used for expense attribution of all awards granted on or after January 1, 2006.

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The fair values of employee stock options granted under the Company s stock option plans during the periods presented were estimated at the date of grant using the Black-Scholes model with the following assumptions and had the following estimated weighted-average grant date fair values per share:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2006	2005	2006	2005
Assumptions:				
Expected term	5.29 years	5.67 years	5.33 years	5.58 years
Expected volatility	0.58	0.77	0.61	0.82
Risk-free interest rate	4.84%	4.15%	4.88%	4.05%
Expected dividend yield				
Weighted-average grant date fair value per share	$ 9.39	$ 6.21	$ 9.48	$ 6.09

The fair values of purchase rights granted under the Company s ESPP during the periods presented were estimated at the date of grant using the Black-Scholes model with the following assumptions and had the following estimated weighted-average grant date fair values per share:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2006	2005	2006	2005
Assumptions:				
Expected term	0.25 years	0.25 years	0.25 years	0.25 years
Expected volatility	0.36	0.33	0.50	0.37
Risk-free interest rate	5.02%	3.52%	4.81%	3.05%
Expected dividend yield				
Weighted-average grant date fair value per share	$ 4.63	$ 2.11	$ 4.61	$ 1.84

The Company granted 1,442,200 and 2,209,700 options with total estimated fair values of $13.5 million and $21.0 million in the three and nine months ended September 30, 2006, respectively, including grants to non-employees. The total intrinsic value of options exercised was $3.8 million and $5.8 million for the three and nine months ended September 30, 2006, and $0.6 million and $0.7 million for the corresponding periods in 2005.

Stock-based compensation expense related to employee stock options and ESPP purchase rights was $2.4 million and $9.1 million for the three and nine months ended September 30, 2006, of which $1.1 million and $3.7 million was recorded to research and development expense, and $1.3 million and $5.4 million was recorded to general and administrative expense, respectively. Stock-based compensation expense related to non-employees was $0.1 million and $0.3 million for the three and nine months ended September 30, 2006, and was negligible in the corresponding periods in 2005.

As a result of adopting SFAS 123(R), the Company s net loss for the three and nine months ended September 30, 2006 was $2.4 million and $9.1 million higher, respectively, than if it had continued to account for employee stock-based compensation under APB 25, as it did in the comparable prior year periods. Basic and diluted net loss per share for the three and nine months ended September 30, 2006 would have been $0.47 and $1.10 if SFAS 123(R) had not been adopted, compared to reported basic and diluted net loss per share of $0.51 and $1.28, respectively. The Company has not recognized, and does not expect to recognize in the near future, any tax benefit related to employee stock-based compensation cost, as a result of the full valuation allowance on its net deferred tax assets.

A summary of the Company s stock option activity for the nine months ended September 30, 2006, and related information as of the period end, is as follows:

	Number of Shares	Weighted-Average Exercise Price	Weighted-Average	Aggregate Intrinsic Value as of September 30, 2006

			Remaining Contractual Term (In years)	(In thousands)
Options outstanding at beginning of period	7,013,523	$ 15.11		
Options granted	2,209,700	16.47		
Options exercised	(581,738)	7.99		
Options forfeited	(302,658)	9.89		
Options expired	(68,555)	28.13		
Options outstanding at end of period	8,270,272	$ 16.06	8.12	$ 52,415
Options vested or expected to vest	7,675,952	$ 16.30	8.05	$ 49,289
Options exercisable at end of period	3,582,814	$ 20.90	6.95	$ 24,647

The following table summarizes information about stock options outstanding and exercisable as of September 30, 2006:

		Options Outstanding			Options Exercisable	
Range of Exercise Prices		Number of Shares	Weighted-Average Remaining Contractual Term (In years)	Weighted-Average Exercise Price	Number of Shares	Weighted-Average Exercise Price
$ 2.34	$ 7.18	906,927	7.58	$ 6.15	662,845	$ 6.00
7.46	8.86	600,155	8.57	8.38	174,053	8.41
8.87	9.17	1,445,339	8.82	9.16	389,172	9.16
9.21	9.83	1,034,652	8.07	9.64	668,773	9.63
9.83	10.18	1,059,835	7.81	10.08	529,844	10.09
10.19	16.67	605,356	8.87	14.45	197,665	12.86
16.73	16.73	898,233	9.84	16.74	27,587	16.74
16.74	25.91	1,154,790	8.18	19.83	367,890	25.66
26.01	132.38	563,985	3.77	73.35	563,985	73.35
285.56	285.56	1,000	3.41	285.56	1,000	285.56
2.34	285.56	8,270,272	8.12	16.06	3,582,814	20.90

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The fair value of options vested was $3.1 million and $8.7 million for the three and nine months ended September 30, 2006, and $3.1 million and $7.6 million for the corresponding periods in 2005. The unamortized compensation expense related to unvested options as of September 30, 2006, excluding estimated forfeitures, was $28.2 million. The weighted-average period over which compensation expense related to these options is expected to be recognized is 1.56 years.

The following table illustrates the pro forma effect under SFAS 123, of options and ESPP purchase rights granted, on the Company s net loss and net loss per share in the three and nine months ended September 30, 2005, net of related tax effects (in thousands, except for per share data):

	Three Months Ended September 30, 2005	Nine Months Ended September 30, 2005
Net loss, as reported	$ (18,459)	$ (50,128)
Add: Stock-based employee compensation expense included in reported net loss	216	394
Deduct: Total stock-based employee compensation expense determined under fair value-based method for all awards	(3,208)	(9,054)
Pro forma net loss	$ (21,451)	$ (58,788)
Basic and diluted loss per share:		
Total basic and diluted net loss per share, as reported	$ (0.44)	$ (1.23)
Pro forma basic and diluted net loss per share	$ (0.51)	$ (1.44)

3. Comprehensive Loss

The components of comprehensive loss for each period presented, net of any related tax effects, are as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2006	2005	2006	2005
Net loss, as reported	$ (26,668)	$ (18,459)	$ (65,217)	$ (50,128)
Unrealized gain on hedging instruments	72	82	780	82
Unrealized gain on available-for-sale securities	86	30	65	125
Comprehensive loss	$ (26,510)	$ (18,347)	$ (64,372)	$ (49,921)

4. Borrowing Arrangements

On May 31, 2006, the Company repaid the $4.0 million promissory note held by Affymetrix, Inc. in cash, as well as accrued interest of $1.4 million as of this date.

In August 2004, the Company entered into a Loan and Security Agreement (Loan Agreement) with Silicon Valley Bank (SVB) that originally provided a $6.0 million term loan facility and a $4.0 million revolving credit line, and grants SVB a security interest over certain of the Company s assets, excluding intellectual property. The Loan Agreement contains certain covenants and reporting requirements, with which the Company was in compliance as of September 30, 2006. Proceeds may be used solely for working capital or other general business needs.

In December 2004, the Company completed a $2.6 million initial draw-down and in March 2005 completed a $1.5 million second draw-down from this facility. On June 30, 2005, the remaining $1.9 million of the facility expired unused. The $2.6 million draw-down is being repaid in 30 equal monthly installments, plus accrued interest of 6.43% per annum, starting from May 1, 2005. The $1.5 million draw-down is being repaid in 36 equal monthly installments, plus accrued interest of 6.78% per annum, starting from April 1, 2005.

In August 2006, the Loan Agreement was amended to extend the revolving credit line facility through August 28, 2007. As of September 30, 2006, the Company has yet to draw-down any of the funds available under this facility. Of the $8.0 million total line, $6.0 million is currently being reserved to collateralize a letter of credit issued to The Irvine Company related to the lease for the facility at 985 Almanor Avenue in

Sunnyvale, California, and of the remaining $2.0 million, a portion is being reserved as collateral for foreign exchange hedging contracts with SVB (see Note 8) and a portion is available for working capital and other general business needs. Any borrowings under this line shall bear interest at SVB s prime rate, which was 8.25% as of September 30, 2006, and would cause replacement collateral to be required for the items above.

5. Facilities Lease Agreements

In January 2005, the Company entered into a seven-year facility lease agreement with BMR-201 Industrial Road LLC for 61,826 square feet of industrial space at 201 Industrial Road in San Carlos, California, at $2.35 per square foot per month, subject to annual increases. The lease commenced on September 1, 2005 and contains an option to cancel the lease after five years upon payment of certain amounts specified in the lease, two options to extend the lease for five additional years at 95% of the then-current fair market rental rate (but not less than the existing rental rate), rights of first refusal over all vacant space in the building during the first two years of the lease, and an expansion option for a specified amount of space. The lease contains a tenant improvement allowance of $8.9 million, which was fully utilized in 2005, and has been recorded to leasehold improvements and deferred rent, with the respective balances being charged to depreciation and credited to rent expense over the lease term. In March 2006, the lease on this property was amended to provide for the exercise of the Company s expansion option over 7,624 square feet of rentable space. The amendment allows for a tenant improvement allowance of $1.0 million, which was fully utilized as of September 30, 2006, and the related lease rental payments commenced in August of 2006.

As a result of the entry into the above lease, a review for impairment of leasehold improvements at 985 Almanor Avenue in Sunnyvale, California, took place in January 2005. As identifiable cash flows related to these assets are not independent of those of the Company as a whole, these assets were grouped with all the assets and liabilities of the Company for the purposes of the impairment review, and as a result, no impairment of these assets was identified, as the fair value of the net assets of the Company exceeds its carrying value. In accordance with Statement of Financial Accounting Standards No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets,* if the Company subleases or otherwise exits this facility, an impairment charge will be recorded based on the difference between the carrying value and fair value of the leasehold improvements at the time of the sublease or exit. The Company has estimated that it will incur future restoration costs for the premises at 985 Almanor Avenue with a current fair value of $0.4 million. Under Statement of Financial Accounting Standards No. 143, *Accounting for Asset Retirement Obligations,* this amount has been recorded as an increase to both leasehold improvements and other non-current liabilities in the balance sheet. Depreciation and interest accretion expense charged during the quarter was immaterial.

In August 2002, the lease on the property at 985 Almanor Avenue was amended to provide for a rent deferral of $4.9 million over the subsequent three years, retroactive to June 1, 2002. The Company is currently repaying the deferred rent liability, plus interest, over a four-year period beginning June 1, 2005, in equal monthly installments of $0.1 million. In October 2003, the lease was further amended to provide for an additional rent deferral of $2.9 million, to be repaid on May 30, 2011, the end of the lease term. In order to receive this rent deferral, the Company agreed to pre-pay $2.7 million of base rental payments in October 2003 to cover the nine-month period beginning October 1, 2003 and ending June 30, 2004, with no base rent being due for the period July 1, 2004 through March 30, 2005, and agreed to the

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early reinstatement of the original rental rates if the Company successfully raised $75.0 million in a single public or private offering, with the remaining amount of rent deferred under both lease amendments up to that date becoming due immediately. In September 2005, a third amendment to the lease was entered into to provide that if the Company raises $75.0 million or more in cash as a result of a single public or private offering, The Irvine Company will be paid the lesser of (i) 10% of any amount raised in excess of $75.0 million, or (ii) any remaining deferred rent obligation. The third amendment also required the Company to increase the letter of credit related to this lease from $4.0 million to $6.0 million (see Note 4), and released Dr. Rathmann from further obligations as a guarantor under the lease. As a result of the public offering in February 2006 (see Note 6), the Company paid The Irvine Company $3.7 million towards the remaining deferred rent obligation under the terms of this third amendment.

6. Common Stock

In June 2006, Nuvelo filed an automatic shelf registration statement with the U.S. Securities and Exchange Commission (SEC) under which the Company may, from time to time, offer to sell common stock, preferred stock, debt securities, warrants or any combination of these securities in amounts, at prices and on terms yet to be determined. The debt securities, warrants and preferred stock may be convertible into or exchangeable for common or preferred stock or other securities. The Company plans to use the net proceeds from any securities issued under the registration statement for working capital needs and other general corporate purposes, which may include funding the commercialization of alfimeprase and the advancement of drug candidates in clinical trials.

In February 2006, the Company raised $112.0 million in a public offering, after deducting underwriters fees and stock issuance costs of $7.6 million, from the sale of 7,475,000 shares of 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.

In August 2005, the Company entered into a Committed Equity Financing Facility (CEFF) with Kingsbridge Capital Ltd. (Kingsbridge), under which Kingsbridge has committed to purchase up to $75.0 million of the Company s common stock within a three-year period, subject to certain conditions and limitations. As part of the arrangement, the Company issued a warrant to Kingsbridge to purchase 350,000 shares of the Company s common stock at a price of approximately $12.07 per share, which is exercisable beginning six months after the date of grant and for a period of five years thereafter. The warrant s fair value on the date of grant of $2.1 million, being $5.94 per share, was recorded as a financing cost against additional paid-in capital. The opposing current liability has and will continue to be marked-to-market each quarter, with the change being recorded to general and administrative expenses. The fair value of the warrant as of September 30, 2006 was $4.3 million, and is included in other current liabilities in the balance sheet. Under the CEFF, the Company may require Kingsbridge to purchase newly-issued shares of common stock at prices between 90% and 94% of the volume weighted average price (VWAP) on each trading day during an 8-day pricing period. The value of the maximum number of shares the Company may issue in any pricing period is the lesser of 2.5% of the Company s market capitalization immediately prior to the commencement of the pricing period, or $10.0 million. The minimum VWAP for determining the purchase price at which the Company s stock may be sold in any pricing period is the greater of $2.50, or 85% of the closing price of the Company s common stock on the day prior to the commencement of the pricing period. The CEFF also required the Company to file a resale registration statement with respect to the resale of shares issued pursuant to the CEFF and underlying the warrant, to use commercially reasonable efforts to have the registration statement declared effective by the SEC, and to maintain its effectiveness. The registration statement was declared effective in October 2005. The Company may sell a maximum of 8,075,000 shares under the CEFF (exclusive of the shares underlying the warrant), which may further limit the potential proceeds from the CEFF. The Company is not obligated to sell any of the $75.0 million of common stock available under the CEFF, and there are no minimum commitments or minimum use penalties. Under the CEFF, the Company sold 1,839,400 shares for gross proceeds of $14.4 million in the fourth quarter of 2005, and may sell the balance of $60.6 million of common stock over the remainder of the three-year term of the CEFF, subject to the above limitations (see Note 11).

7. Collaborative and Manufacturing Agreements

In January 2006, the Company entered into a license and collaboration agreement with Bayer HealthCare AG (Bayer) for the global development and commercialization of alfimeprase. Under this agreement, Bayer has the right to commercialize alfimeprase in all territories outside the United States and will pay tiered royalties ranging from a minimum of 15 percent to a maximum of 37.5 percent of net sales. Nuvelo retains all commercialization rights and profits from alfimeprase sales in the United States and is eligible to receive up to $385.0 million in milestone payments from Bayer, including a $50.0 million up-front cash payment that was received in January 2006, $165.0 million in development milestones, and up to $170.0 million in sales and commercialization milestones over the course of the agreement. The $50.0 million up-front cash payment was deferred upon receipt and is being recognized as revenue on a straight-line basis over the performance period under the agreement, estimated to be through September 2020. In addition, Bayer is responsible for 40 percent of the costs for global development programs, and Nuvelo is responsible for the remaining 60 percent of the costs. Nuvelo will remain the lead for the design and conduct of the global development programs. Each party will bear its own expenses for any country-specific alfimeprase clinical trials it conducts, where the country-specific clinical trials are not part of the agreed global development program. Under the license agreement entered into in October 2004, Nuvelo will continue to bear sole responsibility for milestone payments and royalties owed to Amgen.

In June 2005, Nuvelo entered into a development and validation agreement with Avecia Limited for the scaled-up manufacturing process of alfimeprase. In accordance with the terms of this agreement, Avecia agreed to conduct process development and validation work for the manufacture of alfimeprase bulk drug substance, in accordance with FDA regulations. Nuvelo is to pay Avecia fees totaling £13.8 million ($24.2 million), for completion of this work, payable upon completion by Avecia of pre-negotiated milestones, including £3.8 million ($6.7 million) as a result of amendments to the work program to provide for additional process development and validation work. The milestone fees paid to date have been recorded as either research and development expenses in the statement of operations or clinical trial supplies in the balance sheet, depending on the nature of the milestone. The Company is also paying certain related fees and expenses including the cost of supplies, materials, specified subcontracted work and equipment. The agreement does not cover the commercial manufacture of alfimeprase drug substance, but the Company and Avecia are currently negotiating a commercial supply agreement.

In May 2006, the Company executed a drug product development and clinical supply agreement with Baxter for the lyophilization, filling, finishing, packaging and testing of alfimeprase, and process development related thereto. Under the terms of the agreement, the Company and Baxter will agree upon project plans, development plans and regulatory plans in accordance with which the work agreed upon by the parties will be conducted. In accordance with plans in effect as of September 30, 2006, Nuvelo expects to pay Baxter a total of $6.2 million, which is expected to increase as additional plans are executed by both parties. Nuvelo is also paying related fees and expenses, including the costs of supplies, materials, equipment and subcontracted work. The agreement does not cover the commercial lyophilization, filling, finishing, packaging or testing of alfimeprase.

In July 2006, Nuvelo entered into a new collaboration agreement with Archemix Corporation, a privately held biotechnology company located in Cambridge, Massachusetts, which replaces the former 50/50 collaboration agreement signed in January 2004. Under the new agreement, Archemix is responsible for the discovery of short-acting aptamers targeting the coagulation cascade for use in acute cardiovascular procedures, and Nuvelo is responsible for development and worldwide commercialization of these product candidates. Nuvelo made an upfront license fee payment to Archemix of $4.0 million in August 2006, which is included in research and development expense, and also agreed to fund at least $5.25 million of Archemix s research in the area of short-acting aptamer discovery over the next three years. In addition, Archemix may receive payments totaling up to $35.0 million per development compound on the achievement of specified development and regulatory milestones, along with potential royalty payments based on sales of licensed compounds. In addition, Nuvelo is obligated to purchase Archemix common stock having a value equal to the lesser of $10.0 million or 15 percent of the shares issued by Archemix in a qualified public offering of Archemix stock occurring within 5 years of the effective date of the new collaboration agreement. At the initiation of the first Phase 3 study for any licensed compound, Archemix has the option to elect to participate in profits from sales of the compound by funding its pro rata share of prior and future product development and commercialization expenses, in lieu of receiving milestone payments and royalties with respect to that compound. Upon signing of this new collaboration agreement, the parties agreed to dismiss the arbitration proceedings related to the original agreement initiated by Archemix in March 2006.

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8. Foreign Currency Derivatives

In June 2005, the Company entered into a development and validation agreement with Avecia Ltd. under which Nuvelo s payments to Avecia are denominated in British pounds. In order to reduce exposure to fluctuations in the British pound prior to any payment made under this contract, the Company has entered into a number of foreign currency forward hedging contracts, all maturing or having matured within one year, and all being designated as cash flow hedges under Statement of Financial Accounting Standards No. 133, *Accounting for Derivative Instruments and Hedging Activities,* (SFAS 133). In accordance with SFAS 133, all derivatives, such as foreign currency forward contracts, are recognized as either assets or liabilities in the balance sheet and measured at fair value. At hedge inception, critical terms in the derivative contract that may not precisely match the contract over its life are evaluated for effectiveness using regression analysis. Ongoing effectiveness is calculated by affirming the probability of the transaction and comparing, on a spot-to-spot basis, the change in fair value of the hedge contract to the change in fair value of the forecasted transaction (the underlying hedged item). The effective component of hedge gains and losses is recorded in other comprehensive income (loss) within stockholders equity in the balance sheet and reclassified to research and development expenses in the statement of operations when the forecasted transaction itself is recorded to the statement of operations. Any residual change in the fair value of the hedge contracts, such as ineffectiveness or time value excluded from effectiveness testing is recognized immediately as a general and administrative expense. In 2005 and the nine months ended September 30, 2006, immaterial amounts were recorded to general and administrative expense associated with the time value excluded from effectiveness testing. Should a hedge be de-designated or the hedge instrument terminated prior to recognition of the forecasted transaction, amounts accumulated in other comprehensive income (loss) will remain there until the hedged item impacts earnings. In the event the forecasted transaction is considered unlikely to occur or does not occur in the appropriate time frame, all gains and losses on the related hedge will be recognized immediately as a general and administrative expense.

As of September 30, 2006, the Company had notional amounts outstanding of £3.0 million ($5.5 million) on these contracts and the outstanding contracts were in a fair value gain position of $37,000, which is recorded in other current assets in the balance sheet. The following table summarizes the activity in accumulated other comprehensive income (loss) related to derivatives classified as cash flow hedges held by the Company during the period presented (in thousands):

	Nine Months Ended September 30, 2006
Balance at beginning of period	$ (197)
Increase in fair value of derivatives, net	778
Reclasses to research and development expense from other comprehensive loss	1
Balance at end of period	$ 582

All unrealized gains reported in accumulated other comprehensive income (loss) as of September 30, 2006 are expected to be reclassified to the statement of operations within 12 months, as consistent with the classification of clinical trial supplies within current assets.

9. Transactions with Related Parties

Dr. Rathmann, a former member of the Company s board of directors and current chairman emeritus, provided a $20.0 million line of credit to the Company in August 2001, of which $11.0 million was drawn down, with the remaining $9.0 million having expired unused. The related promissory note bears interest at the prime rate plus 1%. In November 2003, the Company began repaying the outstanding balance over 48 months with equal monthly principal payments of $0.2 million. Accrued interest will be paid with the final payment in October 2007, unless both are repaid before then. As of September 30, 2006, the remaining principal and accrued interest to date totaled $5.1 million, and the interest rate on the note on this date was 9.25%. The outstanding principal and interest under the note may be repaid at any time in cash or upon mutual agreement, by conversion into shares of the Company s common stock at a price based upon the average price of Nuvelo s common stock over a 20-day period ending 2 days prior to the conversion or, if in connection with an equity financing, at the offering price. As of September 30, 2006, 265,875 shares would be issuable to fully repay the principal and interest outstanding upon conversion.

10. Segment Information

The Company is engaged in the discovery, development and commercialization of novel acute cardiovascular and cancer therapies. The Company has only one reportable segment and, therefore, all segment-related financial information required by Statement of Financial Accounting Standards No. 131, *Disclosures About Segments of an Enterprise and Related Information,* is included in the condensed

consolidated financial statements. The reportable segment reflects the Company s structure, reporting responsibilities to the chief executive officer and the nature of the products under development.

11. Subsequent Events

On October 13, 2006, under the CEFF with Kingsbridge, the Company sold 568,247 shares of the Company s common stock for gross proceeds of $10.0 million.

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ITEM 2. MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

This Management s Discussion and Analysis of Financial Condition and Results of Operations contains forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995. Forward-looking statements may be identified by words including will, anticipate, believe, intends, estimates, expect, should, may, potential and similar expressions. Such statements are based on management s current expectations and involve risks and uncertainties. Actual results and performance could differ materially from those projected in the forward-looking statements as a result of many factors discussed herein and elsewhere including, in particular, those factors described under the Risk Factors set forth below, and in our other periodic reports filed from time to time with the Securities and Exchange Commission, or SEC. Actual results and performance could also differ materially from time to time from those projected in our filings with the SEC.

Overview

We are a biopharmaceutical company dedicated to improving the lives of patients through the discovery, development and commercialization of novel acute cardiovascular and cancer therapies. Our development pipeline includes three acute cardiovascular programs: alfimeprase, a direct-acting thrombolytic in Phase 3 clinical trials for the treatment of thrombotic disorders; rNAPc2, an anticoagulant that inhibits the factor VIIa and tissue factor protease complex, which completed a Phase 2 clinical study for acute coronary syndromes (ACS); and NU172, a direct thrombin inhibitor for use as a short-acting anticoagulant during medical procedures, which is currently in pre-clinical development. We are also advancing an emerging oncology pipeline, which includes pre-clinical candidate NU206, for the potential treatment of chemotherapy/radiation therapy-induced mucositis, inflammatory bowel disease and short bowel syndrome, and rNAPc2, for potential use in a variety of cancers based on its apparent role in the cellular signaling related to metastasis and angiogenesis. In addition, we expect to leverage our expertise in secreted proteins and cancer antibody discovery to further expand our pipeline and create additional partnering and licensing opportunities.

Alfimeprase

Our lead product candidate, alfimeprase, is a thrombolytic agent with a novel mechanism of action. It is a modified and recombinant version of fibrolase, a naturally occurring enzyme that directly and rapidly degrades fibrin, the protein that provides the structural scaffold of blood clots. Currently, we have two Phase 3 programs in progress for alfimeprase, one in patients with acute peripheral arterial occlusion (PAO) and one in patients with occluded central venous catheters.

In April 2005, we commenced the first of two trials in the alfimeprase Phase 3 acute PAO program, known as NAPA (Novel Arterial Perfusion with Alfimeprase). The first trial in this program, known as NAPA-2, completed enrollment in September 2006, and we expect to report top-line data from this trial in late 2006 or early 2007. The second trial in this program, known as NAPA-3, began enrollment in April 2006. NAPA-2 was, and NAPA-3 is, a randomized, double-blind study comparing 0.3 mg/kg of alfimeprase versus placebo in 300 patients, with the primary endpoint being the 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 this program, including restoration of arterial blood flow, safety endpoints, such as the incidence of bleeding, and pharmacoeconomic endpoints, such as length of hospital stay and intensive care unit admission rates. NAPA-2 was, and NAPA-3 is, being conducted in approximately 100 centers worldwide. The NAPA-3 trial is under a special protocol assessment (SPA) agreement with the U.S. Food and Drug Administration (FDA). A SPA is a written agreement with the FDA that specifies the terms and conditions under which a trial will be conducted and analyzed in support of a regulatory submission. Alfimeprase has also received fast track designation from the FDA for acute PAO. Fast track designation can potentially facilitate development and expedite review of biologics license applications. Fast track designation is reserved for new drugs that demonstrate the potential to address an unmet medical need and are intended for treatment of a serious or life-threatening condition. In addition, we have obtained orphan drug status for alfimeprase in the United States and Europe for the treatment of acute PAO, which may provide us with up to seven and ten years of market exclusivity in the United States and Europe, respectively, following market authorization.

In September 2005, we commenced the first of two multi-national trials in the alfimeprase Phase 3 catheter occlusion program, known as SONOMA (Speedy Opening of Non-functional and Occluded catheters with Mini-dose Alfimeprase). The first trial, known as SONOMA-2, completed enrollment in September 2006, and we expect to report top-line data from this trial in late 2006 or early 2007. SONOMA-2 was a randomized, double-blind study comparing 3.0 mg of alfimeprase with placebo in 300 patients with occluded central venous catheters. Two-thirds of the patients received alfimeprase and the remainder received placebo. The study s primary endpoint is restoration of function to occluded central venous catheters at 15 minutes. The second trial, known as SONOMA-3, began patient enrollment in February 2006. This is an open label, single-arm study evaluating alfimeprase in 800 patients. This study s primary endpoint is safety, although we will be evaluating efficacy in these patients as well.

We intend to expand our alfimeprase development program by initiating a Phase 2 clinical trial in the fourth quarter of 2006 to evaluate the potential of alfimeprase in the treatment of acute ischemic stroke and another Phase 2 clinical trial in 2007 to evaluate the potential of alfimeprase to treat deep venous thrombosis (DVT). The Phase 2 acute ischemic stroke, or CARNEROS-1 (Catheter Directed Alfimeprase for Restoration of Neurologic Function and Rapid Opening of Arteries in Stroke) trial, will be an open label, dose escalation study in up to 90 patients with symptom onset within three to nine hours of enrollment in the trial. Primary endpoints will evaluate safety and re-canalization rates.

In January 2006, we entered into a license and collaboration agreement with Bayer HealthCare AG (Bayer) for the global development and commercialization of alfimeprase. Under this agreement, Bayer agreed to commercialize alfimeprase in all territories outside the United States and will pay us tiered royalties ranging from a minimum of 15 percent to a maximum of 37.5 percent of net sales. We retain all commercialization rights and profits from alfimeprase sales in the United States. We are eligible to receive up to $385.0 million in milestone payments from Bayer, including a $50.0 million up-front cash payment that we received in January 2006, $165.0 million in development milestones, and $170.0 million in sales and commercialization milestones over the course of the agreement. We expect to meet a $10.0 million development milestone in the fourth quarter of 2006 for the initiation of a Phase 2 trial for alfimeprase in acute ischemic stroke. In addition, Bayer is responsible for 40 percent of the costs for global alfimeprase development programs, and we are responsible for the remaining 60 percent of the costs. We will remain the lead for the design and conduct of the global development programs. Each party will bear its own expenses for any country-specific alfimeprase clinical trials it conducts, where the country-specific clinical trials are not part of the agreed global development program. In the first nine months of 2006, a total of $20.7 million was either billed or is billable to Bayer for our alfimeprase-related global development spending as a result of this cost-sharing arrangement.

In October 2004, we obtained worldwide rights to develop and commercialize alfimeprase from Amgen Inc., in exchange for the future payment to Amgen of previously negotiated milestone payments and royalties. As a result of dosing the first patient in the first Phase 3 clinical trial for alfimeprase, we paid a $5.0 million milestone fee to Amgen in the second quarter of 2005. Future milestone payments under the license agreement could total as much as $35.0 million, although we currently cannot predict if or when any of these additional milestones will be achieved. Under our agreement with Bayer, we will continue to bear sole responsibility for these milestone payments and royalties owed to Amgen.

In June 2005, we entered into a development and validation agreement with Avecia Limited for the scaled-up manufacturing process of alfimeprase. In accordance with the terms of this agreement, Avecia agreed to conduct process development and validation work for the manufacture of alfimeprase drug substance, in accordance with FDA regulations. In accordance with the terms of our license agreement with Amgen, Amgen has transferred the technology necessary for the manufacture of alfimeprase drug substance to Avecia. We are to pay Avecia fees totaling £13.8 million ($24.2 million) for completion of this work, payable upon completion by Avecia of pre-negotiated milestones, including £3.8 million ($6.7 million) as a result of amendments to the work program to provide for additional process development and validation work. Of the total commitment, £3.4 million ($6.3 million) had yet to be paid as of September 30, 2006.

In May 2006, we executed a drug product development and clinical supply agreement with Baxter Pharmaceutical Solutions LLC (Baxter) for the lyophilization, filling,

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finishing, packaging and testing of alfimeprase, and process development related thereto. Under the terms of the agreement, we and Baxter expect to agree upon project plans, development plans and regulatory plans in accordance with which the work agreed upon by the parties will be conducted. In accordance with current plans, we expect to pay Baxter $6.2 million, which is expected to increase as additional plans are executed by both parties. Nuvelo is also paying related fees and expenses, including the costs of supplies, materials, equipment and subcontracted work. The agreement does not cover the commercial lyophilization, filling, finishing, packaging or testing of alfimeprase.

rNAPc2

Our second drug candidate, rNAPc2, is a recombinant, modified version of a naturally occurring protein that has anticoagulant properties. Specifically, rNAPc2 has been shown to block the factor VIIa and tissue factor protease complex, which is responsible for the initiation of the process leading to blood clot formation and has also been shown to play a role in both metastasis, or local and distant spread of cancer cells, and angiogenesis, or the formation of new blood vessels, as they relate to tumor growth. In May 2005, we completed the dose escalation portion of a Phase 2 clinical trial, known as the ANTHEM (Anticoagulation with rNAPc2 To Help Eliminate MACE)/TIMI 32 trial, which showed that rNAPc2 has an acceptable safety profile and is well tolerated in doses up to ten micrograms/kg in patients being treated for non-ST-segment elevation acute coronary syndromes (NSTE-ACS). Based on these encouraging results, we initiated a heparin-replacement arm of the trial, which completed enrollment in June 2006. Results from both the dose escalation and heparin replacement portions of the trial were presented at the 2006 World Congress of Cardiology in September 2006. In this trial, treatment with higher dose rNAPc2 (greater than or equal to 7.5 micrograms/kg) reduced the incidence and duration of ischemia by more than 50% as compared to placebo in patients being treated with anti-thrombotics and an early invasive approach for NSTE-ACS, as measured by continuous electrocardiogram monitoring. In the heparin de-escalation arm, rNAPc2 (10 micrograms/kg) was shown to be able to reduce ischemia even in the absence of heparin and enoxaparin. In addition, rNAPc2 did not cause a statistically significant increase in major/minor bleeding (3.7% vs. 2.5%, p=NS) despite prolonging the time to clot formation in a dose-related fashion, as determined by the internationalized normalized ratio. Four cases of procedure-related thrombosis occurred among the no heparin treatment arm, and none occurred in the half-dose heparin arm. We are also investigating the potential of rNAPc2 as a cancer therapy and plan to initiate a Phase 2 trial with rNAPc2 in the first half of 2007. This trial will enroll up to 100 patients with metastatic colorectal cancer. Up to four ascending doses of rNAPc2 (up to 10 micrograms/kg) will be given twice weekly in addition to standard chemotherapy. Efficacy endpoints will include progression-free survival, metastasis-free survival and overall survival.

We have obtained exclusive worldwide rights to all indications of rNAPc2 and all other rNAPc molecules owned by Dendreon Corporation as a result of a licensing agreement entered into with them in February 2004. Future milestone payments to Dendreon could reach as much as $23.5 million if all development and commercialization milestones are achieved, although we currently cannot predict if or when any of these milestones will be achieved. If rNAPc2 is commercialized, we will also be responsible for paying royalties to Dendreon depending on sales of rNAPc2.

NU206

NU206 is a highly specific and potent gastrointestinal epithelial growth factor. It is active in multiple models of human disease, including radiation and chemotherapy-induced mucositis, inflammatory bowel disease and short bowel syndrome. We expect to initiate a Phase 1 single-center, double-blind, dose escalation study to evaluate the safety, tolerability and pharmacokinetics of single and multiple doses of NU206 in up to 80 healthy volunteers in the fourth quarter of 2006.

In March 2005, we entered into a collaboration agreement with the Pharmaceutical Division of Kirin Brewery Company, Ltd. (Kirin) for the development and commercialization of NU206. Under this agreement, we received a $2.0 million up-front cash payment from Kirin in April 2005, and we lead worldwide development, manufacturing and commercialization of the compound. All operating expenses and profits related to the development and commercialization of NU206 are being shared 60 percent by us and 40 percent by Kirin. If this agreement is terminated, or Kirin or we elect under certain circumstances to no longer actively participate in the collaboration, the relationship with respect to NU206 will convert from an expense and profit-sharing structure to a royalty-based structure.

NU172

Our newest drug candidate, NU172, is a short-acting aptamer that directly inhibits thrombin s ability to generate fibrin, the protein that provides the scaffolding for blood clots. NU172 is in pre-clinical development for potential use as an anticoagulant for patients undergoing acute cardiovascular procedures. Data from pre-clinical animal models suggest that NU172 is a potent anticoagulant with the potential to have predictable anticoagulant effects, rapid onset and offset of action, reduced bleeding complications and no risk of heparin-induced thrombocytopenia. We plan to commence IND-enabling studies with NU172 in the fourth quarter of 2006.

In July 2006, we expanded our collaboration with Archemix Corporation, a privately held biotechnology company located in Cambridge, Massachusetts, by entering into a new agreement with them, which replaces the former 50/50 collaboration signed in January 2004. Under the new agreement, Archemix is responsible for the discovery of short-acting aptamers targeting the coagulation cascade for use in acute cardiovascular procedures, and we will be responsible for development and worldwide commercialization of these product candidates. In August 2006, we made an upfront license fee payment to Archemix of $4.0 million. We also agreed to fund at least $5.25 million of Archemix s research in the area of short-acting aptamer discovery over the next three years. Archemix may receive payments totaling up to $35.0 million per development compound on the achievement of specified development and regulatory milestones, along with potential royalty payments based on sales of licensed compounds. In addition, Nuvelo is obligated to purchase Archemix common stock having a value equal to the lesser of $10.0 million or 15 percent of the shares issued by Archemix in a qualified public offering of Archemix stock occurring within 5 years of the effective date of the new collaboration agreement. At the initiation of the first Phase 3 study for any licensed compound, Archemix has the option to elect to participate in profits from sales of the compound by funding its pro rata share of prior and future product development and commercialization expenses, in lieu of receiving milestone payments and royalties with respect to that compound. Upon signing of this new collaboration agreement, the parties agreed to dismiss the arbitration proceedings related to the original agreement initiated by Archemix in March 2006.

Financing Activities

In June 2006, we filed an automatic shelf registration statement with the U.S. Securities and Exchange Commission under which we may, from time to time, offer to sell common stock, preferred stock, debt securities, warrants or any combination of these securities in amounts, at prices and on terms yet to be determined. The debt securities, warrants and preferred stock may be convertible into or exchangeable for common or preferred stock or other securities. We plan to use the net proceeds from any securities issued under the registration statement for working capital needs and other general corporate purposes, which may include funding the commercialization of alfimeprase and the advancement of drug candidates in clinical trials.

In February 2006, we raised $112.0 million in a public offering, after deducting underwriters fees and stock issuance costs of $7.6 million, from the sale of 7,475,000 shares of our common stock, including 975,000 shares from the exercise of an over-allotment option granted to the underwriters, at a public offering price of $16.00 per share. We plan to continue using the net proceeds from this offering for the advancement of our drug candidates in clinical trials, the development of a commercialization infrastructure, capital expenditures, and to meet working capital needs. The amounts and timing of the expenditures will depend on numerous factors, such as the timing and progress of our clinical trials and research and development efforts, technological advances and the competitive environment for our drug candidates. We expect from time to time to evaluate the acquisition of businesses, products and technologies for which a portion of the net proceeds may be used, although we currently are not planning or negotiating any such transactions. In addition, under our lease agreement for our facilities at 985 Almanor Avenue, Sunnyvale, California, as amended, in February 2006 we paid The Irvine Company $3.7 million from these proceeds, being ten percent of the net amount raised in excess of $75.0 million.

In August 2005, we entered into a Committed Equity Financing Facility (CEFF) with Kingsbridge Capital Ltd. (Kingsbridge), under which Kingsbridge has committed to purchase up to a total of $75.0 million of our common stock within a three-year period, subject to certain conditions and limitations. We plan to continue using the

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net proceeds from any securities issued under this agreement for general corporate purposes, including the advancement of our drug candidates in clinical trials, capital spending and working capital. As part of the arrangement, we issued a warrant to Kingsbridge to purchase 350,000 shares of our common stock at a price of $12.07 per share. As of September 30, 2006, we had $60.6 million remaining available under the CEFF, having sold 1,839,400 shares for gross proceeds of $14.4 million in the fourth quarter of 2005. On October 13, 2006, we sold a further 568,247 shares under this facility for gross proceeds of $10.0 million, leaving $50.6 million available under the CEFF.

Results of Operations

Contract Revenue

Contract revenues were $0.9 million and $3.0 million in the three and nine months ended September 30, 2006, compared to $0.1 and $0.4 million in the corresponding periods of 2005. The increases were primarily due to the recognition of revenue from the $50.0 million up-front license fee received from 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 performance period under the agreement, estimated to be through September 2020, when the last significant alfimeprase-related patent expires.

We expect revenues to increase during the remainder of 2006 as compared to the same period of 2005, due to the ongoing revenue recognition from this up-front license fee. Our revenues may vary significantly from quarter to quarter as a result of this and other licensing or collaboration activities. In the future, we may not be able to maintain existing collaborations, obtain additional collaboration partners or obtain revenue from other sources, which could have a material adverse effect on our revenues, operating results and cash flows.

Research and Development Expenses

Research and development (R&D) expenses primarily consist of R&D personnel costs, including related stock-based compensation expense, clinical trial and drug manufacturing costs, license, collaboration and royalty fees and allocated facilities expenses.

R&D expenses were $23.1 million in the three months ended September 30, 2006, compared to $14.8 million in the corresponding period of 2005. The increase of $8.3 million was primarily due to a $12.5 million increase in consulting and outside service expenses related to clinical trials and drug manufacturing, and a $2.8 million increase in R&D personnel expenses in support of these activities, which includes a $1.1 million increase in employee stock-based compensation expense as a result of the implementation of Statement of Financial Accounting Standards No. 123 (revised 2004), *Share-Based Payment* (SFAS 123(R)). This increase also includes a $4.0 million up-front license fee we paid as a result of our entry into an expanded collaboration agreement with Archemix. These increases were largely offset by a $7.4 million increase in amounts billable to our collaboration partners under cost-sharing arrangements, primarily to Bayer, which is reimbursing 40 percent of alfimeprase-related global development spending.

R&D expenses were $49.9 million in the nine months ended September 30, 2006, compared to $40.3 million in the corresponding period of 2005. The increase of $9.6 million was primarily due to a $26.7 million increase in consulting and outside service expenses related to clinical trials and drug manufacturing, and a $8.4 million increase in R&D personnel expenses in support of expanding R&D activities, which includes a $3.7 million increase in employee stock-based compensation expense. This increase also includes a $4.0 million up-front license fee we paid as a result of our entry into an expanded collaboration agreement with Archemix. These increases were largely offset by a $20.9 million increase in amounts billable to our collaboration partners under cost-sharing arrangements, and a decrease due to the $5.0 million Amgen milestone payment expensed in 2005.

R&D expenses for our significant programs were as follows for the periods indicated (including upfront fees and net of collaboration cost-sharing):

Program	Nine Months Ended September 30, 2006	Since Inception
	(In millions)	
Alfimeprase	$ 10.6	$ 83.6
rNAPc2	1.7	11.1
NU206	0.4	4.2
NU172	4.5	4.5

We expect R&D spending to increase significantly during the remainder of 2006 as compared to the same period of 2005, as we intensify our alfimeprase Phase 3 clinical trial activity and increase alfimeprase manufacturing-related expenditures. The increase will be partially offset by amounts billable to our collaboration partners under cost-sharing arrangements.

The timing and cost of completing the clinical development of any product candidate, and potential for any future product revenues, will depend on a number of factors, including the disease or medical condition to be treated, clinical trial design and endpoints, availability of patients to participate in trials and the relative efficacy of the product versus treatments already approved. Due to these uncertainties, we are unable to estimate the length of time or the costs that will be required to complete the development of these product candidates. We do not expect to generate any product sales revenue until we reach the commercialization stage for any of our drug products, if this ever occurs.

General and Administrative Expenses

General and administrative (G&A) expenses primarily consist of G&A personnel and consulting costs, including related stock-based compensation expense, warrant revaluation expense, professional fees, insurance, facilities and depreciation expenses, and various other administrative costs.

G&A expenses were $6.8 million in the three months ended September 30, 2006, compared to $4.2 million in the corresponding period of 2005. The increase of $2.6 million was primarily due to a $1.9 million increase in G&A personnel costs, including a $1.3 million increase in employee stock-based compensation expense as a result of the implementation of SFAS 123(R), and a $0.8 million increase in facilities and IT-related expenses charged to G&A.

G&A expenses were $24.3 million in the nine months ended September 30, 2006, compared to $11.1 million in the corresponding period of 2005. The increase of $13.2 million was primarily due to a $7.3 million increase in G&A personnel costs, including a $5.4 million increase in employee stock-based compensation expense, $2.5 million related to the quarterly revaluation of the Kingsbridge warrant, a $2.1 million increase in facilities and IT-related expenses charged to G&A, and a $1.6 million increase in consulting and outside service expenses, primarily related to pre-commercialization activities for alfimeprase.

We expect G&A expenses to continue to increase in 2006 as compared to 2005 in order to support growth in our general operating activities and as we continue preparations for the planned commercial launch of alfimeprase.

Interest and Other Income (Expense), net

We had net interest and other income of $2.1 million and $5.8 million in the three and nine months ended September 30, 2006, compared to $0.4 million and $1.0 million in the corresponding periods of 2005. The increases were primarily due to an increase in interest income resulting from higher average cash and investment balances and higher interest rates in 2006.

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Net Loss

Since our inception, we have incurred significant net losses, and as of September 30, 2006, our accumulated deficit was $392.9 million. During the nine months ended September 30, 2006, we incurred a net loss of $65.2 million, compared to $50.1 million in the corresponding period of 2005. The $15.1 million increase in net loss resulted primarily from the increases in expenses noted above, including a $9.1 million increase in total employee stock-based compensation expense as a result of the implementation of SFAS 123(R) and $2.5 million related to the quarterly revaluation of the Kingsbridge warrant, being partially offset by higher revenues and interest income during the 2006 period.

We expect to continue to incur significant losses from continuing operations for the foreseeable future, which may increase substantially as we continue development of our clinical stage drug candidates, alfimeprase and rNAPc2, and our pre-clinical stage drug candidates, NU206 and NU172. In addition, we expect to incur significant costs as we continue preparations for the planned commercial launch of alfimeprase, further expand research and development of potential biopharmaceutical product candidates, and potentially in-license other drug candidates.

Liquidity and Capital Resources

Cash, cash equivalents and short-term investment balances as of the dates indicated were as follows:

	September 30, 2006	December 31, 2005
	(In thousands)	
Cash and cash equivalents	$ 102,055	$ 37,764
Short-term investments	55,143	32,572
Cash, cash equivalents and short-term investments	$ 157,198	$ 70,336

Cash flows from operating, investing and financing activities in the periods indicated were as follows:

	Nine Months Ended September 30,	
	2006	2005
	(In thousands)	
Net cash used in operating activities	$ (22,090)	$ (41,698)
Net cash used in investing activities	(23,867)	(9,359)
Net cash provided by financing activities	110,248	67,796
Net increase in cash and cash equivalents	$ 64,291	$ 16,739

Cash, Cash Equivalents and Short-Term Investments

As of September 30, 2006, we had total cash, cash equivalents and short-term investments of $157.2 million, as compared to $70.3 million as of December 31, 2005. The increase of $86.9 million resulted primarily from net cash proceeds of $112.0 million from a public offering in February 2006 and from a $50.0 million up-front cash payment received from Bayer in January 2006 upon entry into the license and collaboration agreement for alfimeprase. These inflows were partially offset by operating expenditures during the period.

As of September 30, 2006, all of our short-term investments in marketable securities have maturities of less than one year and have been classified as available-for-sale securities, as defined by Statement of Financial Accounting Standards No. 115, *Accounting for Certain Investments in Debt and Equity Securities* (SFAS 115). These securities are recorded at their fair value and consist of U.S. government agency and corporate debt, and asset-backed securities. We make our investments in accordance with our investment policy. The primary objectives of our investment policy are liquidity, safety of principal and diversity of investments.

Sources and Uses of Capital

Our primary sources of liquidity are from financing activities and collaboration receipts. We plan to continue to raise funds through additional public and/or private offerings and collaboration activities in the future.

In June 2006, we filed an automatic shelf registration statement with the U.S. Securities and Exchange Commission (SEC) under which we may, from time to time, offer to sell common stock, preferred stock, debt securities, warrants or any combination of these securities in amounts, at prices and on terms yet to be determined. The debt securities, warrants and preferred stock may be convertible into or exchangeable for common or preferred stock or other securities.

In February 2006, we raised $112.0 million in a public offering, after deducting underwriters fees and stock issuance costs of $7.6 million, from the sale of 7,475,000 shares of our common stock, including 975,000 shares from the exercise of an over-allotment option granted to the underwriters, at a public offering price of $16.00 per share.

In August 2005, we entered into a CEFF with Kingsbridge, under which Kingsbridge has committed to purchase up to a total of $75.0 million of our common stock within a three-year period, subject to certain conditions and limitations. As of September 30, 2006, we had $60.6 million remaining available under the CEFF, having sold 1,839,400 shares for gross proceeds of $14.4 million in the fourth quarter of 2005. On October 13, 2006, we sold a further 568,247 shares under this facility for gross proceeds of $10.0 million.

We have a Loan and Security Agreement in place with Silicon Valley Bank (SVB) under which we have a fully-utilized term loan facility of $4.1 million and an $8.0 million revolving credit line facility which expires on August 28, 2007. The term loan facility was utilized in two draw-downs, the first being for $2.6 million, which is being repaid in 30 equal monthly installments, plus accrued interest of 6.43% per annum, starting from May 1, 2005; the second draw-down of $1.5 million is being repaid in 36 equal monthly installments, plus accrued interest of 6.78% per annum, starting from April 1, 2005. We have yet to draw down any of the funds available under the $8.0 million revolving credit line, although $6.0 million of this amount is currently being reserved to collateralize a letter of credit issued to The Irvine Company related to the lease for the facility at 985 Almanor Avenue in Sunnyvale, California, and of the remaining $2.0 million, a portion is being reserved as collateral for foreign exchange hedging contracts with SVB and a portion is available for working capital and other general business needs. Any borrowings under this line shall bear interest at SVB s prime rate, and would cause replacement collateral to be required for the items above.

Dr. Rathmann, a former member of our board of directors and current chairman emeritus, provided us with a $20.0 million line of credit in August 2001, of which $11.0 million was drawn down, with the remaining $9.0 million having expired unused. The related promissory note bears interest at the prime rate plus 1%. In November

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2003, we began repaying the outstanding balance over 48 months with equal principal payments of $0.2 million. Accrued interest will be paid with the final payment in October 2007, unless both are repaid before then. As of September 30, 2006, the remaining principal and accrued interest to date totaled $5.1 million, and the interest rate on the note on this date was 9.25%. The outstanding principal and interest under the note may be repaid at any time in cash or upon mutual agreement, by conversion into shares of our common stock at a price based upon the average price of our common stock over a 20-day period ending 2 days prior to the conversion or, if in connection with an equity financing, at the offering price. As of September 30, 2006, 265,875 shares would be issuable to fully repay the principal and interest outstanding upon conversion.

In May 2006, we repaid a five-year promissory note held by Affymetrix. The cash payment consisted of $4.0 million for the principal and $1.4 million for the full amount of accrued interest through the date of the payment.

Our primary uses of capital resources to date have been to fund operating activities, including research, clinical development and drug manufacturing expenses, license payments, and spending on capital items.

Cash Used in Operating Activities

Net cash used in operating activities was $22.1 million in the nine months ended September 30, 2006, compared to $41.7 million in the corresponding period of 2005. The decrease of $19.6 million was primarily due to the $50.0 million up-front license fee received from Bayer in the 2006 period, partially offset by increases in spending primarily related to clinical trials and drug manufacturing for alfimeprase.

We expect operating spending to increase significantly during the remainder of 2006 as compared to the same period of 2005, as we advance our alfimeprase Phase 3 clinical trials, increase manufacturing expenditures, and incur additional general corporate expenses, including those for continued preparations for the planned commercial launch of alfimeprase. This increase in spending will be offset by the $50.0 million up-front payment received from Bayer in January 2006 upon entry into our license and collaboration agreement for alfimeprase, and by Bayer s quarterly 40 percent cost sharing reimbursements for global development spending. Our future milestone payments under current agreements with Amgen, Dendreon and Archemix could total $93.5 million, although we currently cannot predict with any certainty if or when any of these milestones will be achieved.

Cash Used in Investing Activities

Net cash used in investing activities was $23.9 million in the nine months ended September 30, 2006, compared to $9.4 million in the corresponding period of 2005. The increase of $14.5 million was primarily due to increased net purchases of short-term investments.

Cash Provided by Financing Activities

Net cash provided by financing activities was $110.2 million in the nine months ended September 30, 2006, compared to $67.8 million in the corresponding period of 2005. The amounts are primarily comprised of the net proceeds from public offerings of $112.0 million and $68.5 million in the 2006 and 2005 periods, respectively.

Our future capital requirements and the adequacy of available funds will depend on many factors, including those set forth under Risk Factors. We may not be able to secure additional financing to meet our funding requirements on acceptable terms, if at all. If we raise additional funds by issuing equity securities, substantial dilution to our existing stockholders may result. If we are unable to obtain additional funds, we will have to reduce our operating costs and delay our research and development programs. We believe that we have adequate cash, cash equivalent and investment balances to fund our operations for at least the next twelve months.

Contractual Obligations

The following table summarizes our significant contractual obligations as of September 30, 2006, and the effect such obligations are expected to have on our liquidity and cash flow in the remainder of 2006 and future periods (in thousands):

	2006	2007	2008	2009	2010	2011 and thereafter	Total
Contractual obligations:							

Operating lease obligations	$ 2,346	$ 9,533	$ 9,750	$ 8,333	$ 8,633	$ 6,523	$ 45,118
Bank loans (a)	414	1,420	126				1,960
Capital lease obligations (a)	10	48	33	33	1		125
Related party line of credit (b)	688	4,404					5,092
Facility restoration obligation (c)						366	366
Total contractual obligations	$ 3,458	$ 15,405	$ 9,909	$ 8,366	$ 8,634	$ 6,889	$ 52,661

(a) Includes interest payments at fixed rates of interest.

(b) Interest is accrued at a variable rate based on the current prime rate plus 1% and is due with the final line of credit payment in October 2007. Includes $2.1 million interest accrued as of September 30, 2006. The outstanding principal and interest may be repaid at any time in cash or upon mutual agreement, by conversion into shares of our common stock.

(c) Includes estimated interest accretion at 8.25% per annum.

The foregoing table does not include milestone payments potentially payable by us under our collaboration agreements and licenses. Such milestone payments are dependent upon the occurrence of specific milestones events and not the passage of time.

Critical Accounting Policies and Estimates

Our discussion and analysis of our operating results and financial condition is based upon our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of the financial statements requires us to make estimates, judgments, and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent amounts. While we believe our estimates, judgments and assumptions are reasonable, the inherent nature of estimates is that actual results will likely differ from the estimates made. We believe the following critical accounting policies, among others, affect the more significant judgments and estimates used in the preparation of our consolidated financial statements.

Clinical Trial Drug Manufacturing Expense and Clinical Trial Supplies Asset

In accordance with Statement of Financial Accounting Standards No. 2, *Accounting for Research and Development Costs* (SFAS 2), we capitalize clinical trial drug manufacturing costs as clinical trial supplies, a current asset on our balance sheet, as long as there are alternative future uses for the related clinical trial drug material in other indications not currently being studied, (e.g., for alfimeprase, these include deep venous thrombosis, acute ischemic stroke and acute myocardial infarction).

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We recognize clinical trial drug manufacturing expense when completed drug material is shipped from the manufacturing or storage facility for use in a clinical trial or for testing, or is otherwise consumed. On a quarterly basis, we evaluate whether there continues to be alternative future use for any capitalized drug material and if the material is obsolete or in excess of anticipated requirements. Any capitalized drug material will be written-off to research and development expense in the quarter in which there ceases to exist an alternative future use or if the material is obsolete or in excess of anticipated requirements, which may result in a significant adverse impact to our financial condition and results of operations.

Impairment or Disposal of Long-Lived Assets

Periodically, we determine whether any long-lived asset or related asset group has been impaired based on the criteria established in Statement of Financial Accounting Standards No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets* (SFAS 144). SFAS 144 requires, among other things, that impairment losses be recognized whenever the carrying amount of the asset or asset group exceeds its fair value. Intangibles with determinable useful lives and other long-lived assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable, and we perform an annual impairment review regardless of any such events or changes. Our judgments regarding the existence of impairment indicators are based on historical and projected future operating results, changes in the manner of our use of the acquired assets, our overall business strategy or market and economic trends. Events may occur that could cause us to conclude that impairment indicators exist and that certain long-lived assets or related asset groups are impaired, which may result in a significant adverse impact to our financial condition and results of operations. There were assessed to be no impairments to long-lived assets as of September 30, 2006. Additionally, in accordance with SFAS 144, we periodically examine the potential to sublease or otherwise exit our facility at 985 Almanor Avenue in Sunnyvale, California, which is currently being used for storage and for which we have a lease through May 30, 2011. If we sublease or otherwise exit this facility, an impairment charge, currently estimated at $3.2 million, would be recorded based on the difference between the carrying value and fair value of the leasehold improvements at the time of the sublease or exit. Furthermore, in accordance with Statement of Financial Accounting Standards No. 146, *Accounting for Costs Associated with Exit or Disposal Activities,* if the Company subleases or otherwise exits this facility, a significant charge to earnings could be incurred, based on the remaining lease rental expense reduced by the estimated income from sublease rental, if any. Currently, the remaining lease rental expense for this facility is approximately $26.3 million.

Goodwill

We applied the provisions of Statement of Financial Accounting Standards No. 142, *Goodwill and Other Intangible Assets* (SFAS 142), upon the completion of the merger with Variagenics in January 2003. SFAS 142 requires that goodwill and intangible assets with indefinite useful lives no longer be amortized but instead be tested for impairment at least annually in accordance with provisions of SFAS 142. SFAS 142 also requires that intangible assets with estimable useful lives be amortized over their respective estimated useful lives, and these assets will be reviewed for impairment in accordance with SFAS 144 as noted above.

The SFAS 142 goodwill impairment model involves a two-step process. First, we compare the fair value of the reporting unit with its carrying value, including goodwill. The estimated fair value of the reporting unit, in this case the Nuvelo business segment, being the only business segment in the company, is computed by multiplying the quoted market price of the company s common stock on the Nasdaq Global Market by the outstanding common stock of the company at that time. If the fair value of the reporting unit is determined to be more than its carrying value, including goodwill, no goodwill impairment is recognized. If the fair value of the reporting unit is determined to be less than its carrying value, goodwill impairment, if any, is computed using the second step. The second step requires the fair value of the reporting unit to be allocated to all the assets and liabilities of the reporting unit as if the reporting unit had been acquired in a business combination at the date of the impairment test and the fair value of the reporting unit was the price paid to acquire it. The excess of the fair value of the reporting unit over the amounts assigned to its assets and liabilities is the implied value of goodwill, which is used to determine the impairment amount.

We have designated October 31 as the annual impairment testing date for goodwill, although additional testing may be performed if circumstances warrant a re-evaluation. If it is determined that the carrying value of goodwill has been impaired, the value would be reduced by a charge to operations in the amount of the impairment, which may result in a significant adverse impact to our financial condition and results of operations. There was assessed to be no goodwill impairment based on the testing performed on October 31, 2006.

Clinical Trial and Drug Manufacturing Accruals

We accrue costs for clinical trial and drug manufacturing activities based upon estimates of the services received and related expenses incurred that have yet to be invoiced by the contract research organizations (CROs), clinical study sites, drug manufacturers, collaboration partners, laboratories, consultants, or otherwise. Related contracts vary significantly in length and may be for a fixed amount, a variable amount based on actual costs incurred, capped at a certain limit, or for a combination of these elements. Activity levels are monitored through close communication with the CROs and other vendors, including detailed invoice and task completion review, analysis of expenses against budgeted

amounts, and pre-approval of any changes in scope of the services to be performed. Each CRO or significant vendor provides an estimate of costs incurred but not invoiced at the end of each period for each individual trial or project. The estimates are reviewed and discussed with the CRO or vendor as necessary and are included in research and development expenses for the related period or capitalized as clinical trial supplies, as necessary. For clinical study sites, which are paid at least quarterly, an estimated amount is accrued based on patient enrollment or progress made against specified targets in each period. All estimates may differ significantly from the actual amounts subsequently invoiced. No adjustments for material changes in estimates have been recognized in any period presented.

Revenue Recognition

We recognize revenue in accordance with Staff Accounting Bulletin No. 104, *Revenue Recognition* (SAB 104) when (i) persuasive evidence of an arrangement exists, (ii) delivery has occurred or services have been rendered, (iii) the price is fixed and determinable, and (iv) collectibility is reasonably assured. In situations where we have no continuing performance obligations, or our continuing obligations are perfunctory or inconsequential, we recognize up-front non-refundable fees as revenues on the effective date of the related agreement. Up-front non-refundable licensing fees that require continuing involvement in the form of development, manufacturing or other commercialization efforts by us are recognized as revenue ratably over the performance period.

Stock-Based Compensation

Effective January 1, 2006, we adopted the provisions of Statement of Financial Accounting Standards No. 123 (revised 2004), *Share-Based Payment* (SFAS 123(R)). SFAS 123(R) establishes accounting for stock-based awards exchanged for employee services. Under SFAS 123(R), employee stock-based compensation cost is generally measured at the grant date, based on the fair value of the award, and is recognized as an expense over the employee s requisite service period net of estimated forfeitures. We previously applied Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* (APB 25), and related Interpretations and provided the required pro forma disclosures of SFAS No. 123, *Accounting for Stock-Based Compensation* (SFAS 123). We have elected to adopt the modified prospective application method as provided by SFAS 123(R). Under the modified prospective method, the fair values of new and previously granted but unvested stock options are recognized as compensation expense in the statement of operations over the related vesting periods, and prior period results are not restated.

We have selected the Black-Scholes option pricing model as the most appropriate fair-value method for our stock-based awards, which requires assumptions to be made for the expected term of the awards, expected volatility of our stock price, risk-free interest rates and expected dividend yields. These assumptions are highly subjective and involve inherent uncertainties and are based on management s best estimates and judgment. If alternative assumptions had been used instead of those presented in the notes to the financial statements, stock-based compensation expense could have been materially different from amounts recorded in the financial statements under SFAS 123(R) and disclosed on a pro forma basis under SFAS 123. In addition, under SFAS 123(R) we are required to estimate the expected forfeiture rate of awards and only recognize expense for those awards expected to vest. If the actual forfeiture rate is materially different from the estimate, the stock-based compensation expense could be materially different from amounts recorded in the financial statements.

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For all option grants we use historical data, including post-vesting termination behavior, and the contractual term to estimate future exercises and cancellations, and therefore the expected term of the option. The risk-free interest rate assumptions are based on the yield of U.S. Treasury instruments with similar durations as the expected term of the related awards. The expected dividend yield assumption is based on our historic and expected dividend payouts. For options granted prior to January 1, 2006, and valued in accordance with SFAS 123, the expected volatility was based solely on the historical volatility of our common stock and option forfeitures were recognized on a pro forma basis as they occurred. The graded-vested (multiple-option) method continues to be used for expense attribution of these options that were unvested as of January 1, 2006. For options granted after January 1, 2006 and valued in accordance with SFAS 123(R), we are using a combination of historic and implied volatility of our common stock in deriving expected volatility. Forfeitures are estimated such that we only recognize expense for those shares expected to vest, and adjustments are made if actual forfeitures differ form those estimates. The straight-line (single-option) method is being used for expense attribution of all awards granted on or after January 1, 2006.

We account for stock-based compensation expense for non-employees based on the fair values estimated using the Black-Scholes model on the date of grant and re-measured at each reporting date until vested, in compliance with Emerging Issues Task Force No. 96-18 *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services.*

Income Taxes

Income taxes are accounted for under the asset and liability method pursuant to Statement of Financial Accounting Standards No. 109, *Accounting for Income Taxes* (SFAS 109). Under SFAS 109, deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date.

We record a valuation allowance to reduce deferred income tax assets to an amount that is more likely than not to be realized. Assessment of the realization of deferred income tax assets requires that estimates and assumptions be made as to the taxable income of future periods. Our deferred tax assets have been reduced to zero, as management believes that it is more likely than not that the deferred tax assets will not be realized. Projection of future period earnings is inherently difficult as it involves consideration of numerous factors such as our overall strategies and estimates of new product development and acceptance, product lifecycles, selling prices and volumes, responses by competitors, manufacturing costs and assumptions as to operating expenses and other industry specific and macro- and micro-economic factors. In addition, consideration is also given to ongoing and constantly evolving global tax laws and our own tax minimization strategies.

Foreign Currency Transactions and Contracts

We use foreign exchange forward contracts, and similar instruments, to mitigate the currency risk associated with the acquisition of goods and services under agreements with vendors that are denominated in foreign currency. Contracts for anticipated transactions are designated and documented as cash flow hedges under Statement of Financial Accounting Standards No. 133, *Accounting for Derivative Instruments and Hedging Activities* (SFAS 133), at hedge inception and are evaluated for effectiveness at least quarterly. We only hedge exposures that can be confidently identified and quantified and do not enter into speculative foreign currency transactions. All contracts have maturities of one year or less. In accordance with SFAS 133, all derivatives, such as foreign currency forward contracts, are recognized as either assets or liabilities in the balance sheet and measured at fair value. The effective component of the hedge gains and losses are recorded in other comprehensive income (loss) within stockholders equity in the balance sheet and reclassified to research and development expenses in the statement of operations when the forecasted transaction itself is recorded to the statement of operations. Any residual change in the fair value of the hedge contracts, such as ineffectiveness or time value excluded from effectiveness testing, is recognized immediately as a general and administrative expense.

Off-Balance Sheet Arrangements

We have not participated in any transactions with unconsolidated entities, such as special purpose entities, which would have been established for the purpose of facilitating off-balance sheet arrangements.

Indemnifications

In the ordinary course of business, we enter into contractual arrangements under which we may agree to indemnify certain parties from any losses incurred relating to the services they perform on our behalf or for losses arising from certain events as defined within the particular contract. Such indemnification obligations may not be subject to maximum loss clauses. Historically, payments made related to these indemnifications have been immaterial. In addition, we have entered into indemnity agreements with each of our directors and officers. Such

indemnity agreements contain provisions, which are in some respects broader than the specific indemnification provisions contained in Delaware law. We also maintain an insurance policy for our directors and executive officers insuring against certain liabilities arising in their capacities as such.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Risk

We place our investments with high quality issuers and, by policy, limit the amount of credit exposure with any one issuer. We do not use derivative financial instruments in our investment portfolio. We are averse to principal loss and strive to ensure the safety and preservation of our invested funds by limiting default, market and reinvestment risk.

We have exposure to changes in interest rates on our cash equivalents, which are held primarily in money market funds and debt securities with original maturities of 90 days or less and that earn interest at variable rates.

Changes in interest rates do not affect interest income on our existing short-term investments as they are maintained in U.S. government agency and corporate debt and asset-backed securities with fixed rates and original maturities of less than 24 months.

Changes in interest rates do not affect interest income on any restricted cash we may hold, as it is generally maintained in commercial paper with fixed rates and original maturities of less than 90 days.

Changes in interest rates do not affect interest expense on our outstanding bank loans and capital leases, as they bear fixed rates of interest.

We have exposure to changes in interest rates on our revolving bank line of credit with Silicon Valley Bank, which bears interest at their prime rate. No draw-downs have been made on this line of credit to date.

We have exposure to changes in interest rates on our line of credit with Dr. George Rathmann, which bears interest at the prime rate plus 1%. Our interest rate exposure is mitigated by our ability to repay amounts outstanding under the line of credit with our common stock.

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A hypothetical 10% change in market interest rates is not expected to have a material effect on our near-term financial condition or results of operations.

There were no significant changes in our market risk exposures through the third quarter of 2006 since our Form 10-K filing on March 15, 2006.

Foreign Exchange Risk

Some payments to overseas suppliers of goods or services are denominated in foreign currencies. Accordingly, as part of our corporate risk management strategy, we have implemented a policy of hedging significant foreign currency exposures that can be confidently identified and quantified, in order to mitigate the impact of currency rate fluctuations on our cash outflows. We do not enter into speculative foreign currency transactions. In June 2005, we entered into a development and validation with Avecia Ltd. under which payments for their services are denominated in British pounds. As a result, our financial results could be adversely affected by future changes in the British pound exchange rate. In order to reduce our exposure to fluctuations in the British pound prior to any payment made under this contract, we entered into a number of foreign currency forward hedging contracts in 2005 and the nine months ended September 30, 2006, all maturing within one year and being designated as cash flow hedges under SFAS 133. The table below provides information about the open derivative contracts as of September 30, 2006, with amounts in U.S. dollar equivalents (in thousands, except for average contract rate):

	September 30, 2006		
	Notional Amount	Average Contract Rate	Fair Value Gain (Loss)
British pounds	$ 5,533	0.54	$ 37

We have no investments denominated in foreign currencies, and therefore our investments are not subject to foreign currency exchange risk. However, at each quarter end, we may have liabilities for costs incurred by overseas providers that are denominated in foreign currencies that are not hedged because of their small size, uncertainty of payment date, and/or short time until settlement. An increase or decrease in exchange rates on these unhedged exposures may affect our operating results.

ITEM 4. CONTROLS AND PROCEDURES

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in the reports that we file under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosures. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

As required by Rule 13a-15(b) of the Securities Exchange Act of 1934, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the quarter covered by this report. Based on the foregoing, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level.

We continue to review and improve the design and effectiveness of our internal controls over financial reporting in order to remain in compliance with Section 404 of the Sarbanes-Oxley Act of 2002. There has been no change in our internal controls during our fiscal quarter ended September 30, 2006 that has materially affected, or is reasonably likely to materially affect, our internal controls over financial reporting.

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PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

On or about December 6, 2001, Variagenics, Inc. was sued in a complaint filed in the United States District Court for the Southern District of New York naming it and certain of its officers and underwriters as defendants. The complaint purportedly is filed on behalf of persons purchasing Variagenics stock between July 21, 2000 and December 6, 2000 and alleges violations of Sections 11, 12(a)(2) and 15 of the Securities Act of 1933, as amended and Section 10(b) of the Securities Exchange Act of 1934, as amended, and Rule 10b-5 promulgated thereunder.

The complaint alleges that, in connection with Variagenics July 21, 2000 initial public offering, or IPO, the defendants failed to disclose additional and excessive commissions purportedly solicited by and paid to the underwriter defendants in exchange for allocating shares of Variagenics stock to preferred customers and alleged agreements among the underwriter defendants and preferred customers tying the allocation of IPO shares to agreements to make additional aftermarket purchases at predetermined prices. Plaintiffs claim that the failure to disclose these alleged arrangements made Variagenics registration statement on Form S-1 filed with the SEC in July 2000 and the prospectus, a part of the registration statement, materially false and misleading. Plaintiffs seek unspecified damages. On or about April 19, 2002, an amended complaint was filed which makes essentially the same allegations. On or about July 15, 2002, Variagenics and the individuals filed a motion to dismiss. We are involved in this litigation as a result of our merger with Variagenics in January 2003.

On July 16, 2003, Nuvelo s Board of Directors approved a settlement proposal initiated by the plaintiffs. The final terms of the settlement are still being negotiated. We believe that any loss or settlement amount will not be material to our financial position or results of operations and that any settlement payment and attorneys fees accrued with respect to the suit will be paid by our insurance provider. However, it is possible that the parties may not reach agreement on the final settlement documents or that the Federal District Court may not approve the settlement in whole or part. We could be forced to incur material expenses in the litigation if the parties do not reach agreement of the final settlement documents, and in the event there is an adverse outcome, our business could be harmed.

On March 24, 2006, we were notified that Archemix had filed with Judicial Arbitration and Mediation Services, Inc. (JAMS) a Statement of Claim requesting the initiation of an arbitration pursuant to our January 12, 2004 Collaboration Agreement. As a result of the entry into a new collaboration agreement with Archemix on July 31, 2006, the parties agreed to dismiss this arbitration proceeding, and the arbitration has now been dismissed.

ITEM 1A. RISK FACTORS

We operate in a rapidly changing environment that involves a number of risks, some of which are beyond our control. The following discussion highlights some of these risks. Those risk factors that reflect substantive changes from the risk factors included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2005 are marked with an asterisk(*).

RISKS RELATED TO OUR BUSINESS

We may not be able to develop and commercialize our lead product candidate, alfimeprase, or any of our other drug candidates successfully.*

We currently have two 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 may not occur for several years, if at all. If we are unable to successfully develop and commercialize alfimeprase and our other potential products, our business, results of operations and financial condition will be affected in a materially adverse manner.

FDA and international regulatory approval of our lead product candidate, alfimeprase, and our other 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 regulations, or cGMP, and that the process for manufacturing the product has been validated in accordance with the requirements of the FDA and comparable agencies in other countries.

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 and international regulatory 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:

- a drug candidate may not be safe or effective;
- the 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;
- 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
- the FDA or comparable international regulatory officials may change their approval polices or adopt new regulations.

In addition, in order to market any products outside of the United States, we and our collaborators must establish and comply with numerous and varying regulatory requirements of other jurisdictions, including the European Medicines Evaluation Agency, or EMEA, regarding safety and efficacy. Approval procedures vary among countries and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries differs from that required to obtain FDA approval. The regulatory approval process in other countries can include all of the risks detailed above regarding FDA approval in the United States as well as other risks. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in others. Failure to obtain regulatory approval in other countries or any delay or setback in obtaining such approval could have the same adverse effects detailed above regarding FDA approval in the United States.

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

- warning letters;
- fines;
- civil penalties;

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injunctions;

recall or seizure of products;

total or partial suspension of production;

refusal of the government to grant approvals; or

withdrawal of approvals and criminal prosecution.

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

would adversely affect our ability to generate product, milestone and royalty revenues;

could impose significant additional costs on us or our collaboration partners;

could diminish competitive advantages that we may attain;

would adversely affect the marketing of our products; and

could cause the price of our shares to decline.

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.

Our near-term success is dependent on the success of our lead product candidate, alfimeprase.

Alfimeprase is currently being evaluated in Phase 3 clinical trials for the treatment of each of acute PAO and catheter occlusion and will require the successful completion of these or other planned Phase 3 clinical trials before we are able to submit a biologics license application, or BLA, to the FDA for approval. If our Phase 3 or other clinical trials fail to demonstrate that alfimeprase is safe and effective, it will not receive regulatory approval. Even if alfimeprase receives FDA approval, it may never be successfully commercialized. We also may have inadequate financial or other resources to pursue this product candidate through the clinical trial process or through commercialization. If we are unable to successfully commercialize or obtain regulatory approval for alfimeprase, we may not be able to generate revenue, become profitable or continue our operations. One of our Phase 3 trials of alfimeprase, NAPA-3, is the subject of a special protocol assessment agreement with the FDA. Under this agreement, the FDA provides guidance on the design of a trial prior to its initiation. We have also been granted fast track designation by the FDA for alfimeprase in acute PAO. The special protocol assessment agreement and the fast track designation do not offer any assurance that alfimeprase will receive FDA approval, and the FDA is in no way constrained by the agreement or the designation in its ability to deny approval for alfimeprase.

Our clinical trials for alfimeprase and our other products may not yield results that will enable us to obtain the regulatory approvals necessary to sell them.

We, and our collaborators, will only receive regulatory approval for alfimeprase and our other drug candidates 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 current 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. We have spent, and expect to continue to spend, significant amounts of time and money in the clinical development of our product candidates. It will take us several years to complete our testing, and failure can occur at any stage of testing. The results we obtain in pre-clinical testing and early clinical 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 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 and in foreign countries, including those for informed consent and good clinical practices. We may not be able to comply with these requirements and the FDA, a similar foreign authority, 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.

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 market price of our common stock 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 or condition under investigation. We, or our collaborators, 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:

- design of the protocol;
- the size of the patient population;
- eligibility criteria for the study in question;
- perceived risks and benefits of the drug under study;
- availability of competing therapies;
- efforts to facilitate timely enrollment in clinical trials;
- the success of our personnel in making the arrangements with potential clinical trial sites necessary for those sites to begin enrolling patients;

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patient referral practices of physicians;

availability of clinical trial sites; and

other clinical trials seeking to enroll subjects with similar profiles.

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, milestone and royalty revenues and could impose significant additional costs on us or on our collaborators.

If we fail to maintain existing licenses and collaborations, or fail to develop new collaborations, our business will be harmed.*

The success of our business is dependent, in significant part, upon our ability to maintain current licensing and collaborative relationships, and to enter into multiple new licenses and collaboration agreements. We also must manage effectively the numerous issues that arise from such arrangements and agreements. Management of our relationships with these third parties has required and will require:

a significant amount of our management team s time and effort;

effective allocation of our and third-party resources to multiple projects;

agreements with third parties as to ownership of proprietary rights and development plans, including clinical trials or regulatory approval strategy; and

the recruitment and retention of management, scientific and other personnel.

In January 2006, we entered into a license and collaboration agreement with Bayer for the development and commercialization of alfimeprase internationally. Under the agreement, Bayer will commercialize alfimeprase in all territories outside the United States and will pay us tiered royalties ranging from a minimum of 15 percent to a maximum of 37.5 percent of net sales. We will retain all commercialization rights and profits from alfimeprase sales in the United States. We received an up-front cash payment from Bayer of $50.0 million upon entry into the agreement, and are eligible to receive up to an additional $335.0 million in milestone payments, including $165.0 million in development milestones and $170.0 million in sales and commercialization milestones, over the course of the agreement. In addition, Bayer will be responsible for 40 percent of the costs for global development programs. We will be responsible for 60 percent of the costs and will remain the lead for the design and conduct of the global development programs. Each party will solely bear the expense of any country-specific alfimeprase clinical trials conducted by it, where the country-specific clinical trials are not part of the agreed global development program. If we fail to maintain a successful collaboration with Bayer, Bayer could terminate our agreement, which could force us to expend additional amounts to obtain regulatory approval, delay the commercial launch of alfimeprase outside the United States, delay our ability to obtain regulatory approval for alfimeprase in the stroke, deep venous thrombosis or other indications, and have a negative impact on the success of alfimeprase s commercial launch, all of which would have a material, adverse effect on our business.

In October 2004, we obtained worldwide rights to develop and commercialize alfimeprase from Amgen in exchange for payment to Amgen of future development milestones and royalties. Future milestone payments under the license agreement could total as much as $35.0 million. Under our agreement with Bayer, we retain sole responsibility for making these payments to Amgen. In accordance with the terms of the license agreement, Amgen has transferred the technology necessary for the manufacture of alfimeprase drug substance to our designated manufacturer, Avecia.

In February 2004, we entered into a license agreement with Dendreon relating to rNAPc2, in accordance with which we are to make milestone payments, ranging from $2.0 million to $6.0 million, upon dosing of the first patient in a Phase 3 clinical trial, upon submission of an NDA and upon first commercial sale, for both the first and second indications of rNAPc2. If these and other milestones are all achieved, total milestone payments to Dendreon may reach as much as $23.5 million.

In March 2005, we entered into a collaboration agreement with the Pharmaceutical Division of Kirin for the development and commercialization of NU206. All operating expenses and profits related to the development and commercialization of NU206 will be shared 60 percent by us and 40 percent by Kirin. If this agreement is terminated, or we or Kirin elect under certain circumstances to no longer actively participate in the collaboration, the relationship with respect to NU206 will convert from an expense and profit sharing structure to a royalty-based structure. Our 2001 collaboration agreement with Kirin for research and development of secreted proteins expired in December 2005 in accordance with its terms.

On July 31, 2006, we expanded our collaboration with Archemix Corporation, a privately held biotechnology company located in Cambridge, Massachusetts, by entering into a new agreement with them, which replaces the former 50/50 collaboration signed in January 2004, under which we shared equally all research and development costs and revenues for the research and development of a thrombin inhibiting aptamer subsequent to our initial funding of $4.0 million of those costs. Under the new agreement, Archemix will be responsible for the discovery of short-acting aptamers targeting the coagulation cascade for use in acute cardiovascular procedures, and we will be responsible for development and worldwide commercialization of these product candidates. Under the new collaboration agreement, we made an upfront license fee payment to Archemix of $4.0 million. We will also fund at least $5.25 million of Archemix s research in the area of short-acting aptamer discovery over the next three years. In addition, Archemix may receive payments totaling up to $35.0 million per development compound on the achievement of specified development and regulatory milestones, along with potential royalty payments based on sales of licensed compounds. In addition, Nuvelo is obligated to purchase Archemix common stock having a value equal to the lesser of $10.0 million or 15 percent of the shares issued by Archemix in a qualified public offering of Archemix stock occurring within 5 years of the effective date of the new collaboration agreement. At the initiation of the first Phase 3 study for any licensed compound, Archemix has the option to elect to participate in profits from sales of the compound by funding its pro rata share of prior and future product development and commercialization expenses, in lieu of receiving milestone payments and royalties with respect to that compound.

Our efforts to manage simultaneously a number of collaboration arrangements may not be successful, and our failure to manage effectively such collaborations would significantly harm our business, financial condition and results of operations.

Due to these factors and other possible disagreements with current or potential collaborative partners, we may be delayed or prevented from developing or commercializing alfimeprase, rNAPc2, NU206, NU172, or other pre-clinical product candidates, or we may become involved in litigation or arbitration, which would be time-consuming or expensive and could have a material adverse effect on our stock price.

In addition to our existing collaborations, we will focus on effecting new collaborative arrangements where we would share costs of identifying, developing and marketing drug candidates. We cannot assure you that we will be able to negotiate new collaboration arrangements of this type on acceptable terms, or at all.

We are heavily dependent upon third parties for a variety of functions, including clinical trials management and manufacturing. Our current and future arrangements with these third parties may not provide us with the benefits we expect.*

We currently rely upon third parties to perform administrative functions and functions related to the research, development, pre-clinical testing and clinical trials of our drug candidates. Our reliance on third party contract research organizations and consultants that manage and monitor our clinical trials may result in delays in completing, or in failing to complete, our clinical trials if they fail to perform with the speed and competency we expect. Our reliance on third-party contract research organizations to conduct research and testing, including GLP toxicology studies necessary to gather the data necessary to file INDs with the FDA, for any of our drug

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candidates may result in delays in our regulatory filings if they do not conduct their research or testing properly, or if they fail to complete their contract research or testing on the anticipated schedule. In either case, the progress of our clinical programs may be delayed and our research and development costs may increase, which may in turn have a material adverse affect on our business.

We do not have the resources, facilities or experience to manufacture our drug candidates on our own. We rely, and will continue to rely, on third parties, such as contract research and manufacturing organizations, to manufacture our drug candidates for clinical trials, and, if our products are approved, in quantities for commercial sales. We currently rely on a number of sole-source service providers and suppliers to manufacture bulk compound, fill finish our products, and label and package them, and we do not have long-term supply agreements with these third-party manufacturers. We may not be able to finalize contractual arrangements, transfer technology or maintain relationships with such organizations in order to file an investigational new drug application, or IND, with the FDA, and proceed with clinical trials for any of our drug candidates.

Our drug candidates have never been manufactured on a commercial scale. Until recently, we have relied on Amgen to manufacture our lead clinical drug product, alfimeprase. In June 2005, we entered into a definitive agreement with Avecia for the scale up and validation of the manufacturing process for alfimeprase drug substance, in anticipation of the potential commencement of the manufacture of commercial quantities. We have transitioned the process of alfimeprase manufacture from Amgen to Avecia, but do not yet have a definitive agreement with Avecia for the manufacture of commercial quantities of alfimeprase drug substance. In May 2006, we executed a drug product development and clinical supply agreement with Baxter for the lyophilization, filling, finishing, packaging and testing of alfimeprase, and process development related thereto. We do not have an agreement in place for the commercial-scale manufacture of alfimeprase final drug product. We also may need to conduct comparative studies or utilize other means to determine bioequivalence between alfimeprase manufactured by Avecia and Baxter and that previously manufactured by Amgen.

While we currently believe we have enough supplies of alfimeprase for phase 3 trials for the treatment of acute PAO and catheter occlusion, additional supplies may be necessary for these trials and for anticipated trials in other indications, and we are not yet certain that Avecia and Baxter will succeed in manufacturing additional supplies of alfimeprase for such trials. If Avecia and Baxter are unable to manufacture clinical or commercial grade alfimeprase for us, or we are unable to complete commercial arrangements with Avecia and Baxter, we may not have adequate supplies of alfimeprase to complete our clinical trials or to obtain regulatory approvals for alfimeprase on our anticipated schedule. If Avecia and Baxter are unable to produce alfimeprase in the quantities and with the quality we need, when we need it, we may incur significant additional expenses, and our and Bayer s efforts to complete our clinical trials and obtain approval to market alfimeprase could be significantly delayed.

With respect to rNAPc2, we received a supply of rNAPc2 from Dendreon, which is being used in our research and development activities. We are currently engaging third party manufacturers to produce additional supplies of rNAPc2 for future clinical trials. Third-party manufacturers may not be able to manufacture the bulk drug substance and final drug product at a cost, in quantities or with the quality necessary to make this drug commercially viable.

If and when any of our other drug candidates, such as NU206 and NU172, enter the clinical trial phase, we will initially depend on third-party contract manufacturers to develop the necessary production processes, and produce the volume of cGMP-grade material needed to complete such trials. We have entered into, and intend to enter into contractual relationships with third parties in order to (i) complete the Good Laboratory Practices, or GLP, toxicology and other studies necessary to file an IND with the FDA, (ii) produce a sufficient volume of cGMP-grade material in order to conduct clinical trials of these other drug candidates, and (iii) fill and finish, and label and package our material. We cannot be certain that we will be able to complete these tasks on a timely basis or that we will be able to obtain sufficient quantities of material or other manufacturing services on commercially reasonable terms. In addition, the failure of any of these third parties to perform their obligations may delay our filing for an IND or impede our progress through the clinical trial phase. Any significant delay or interruption would have a material adverse effect on our ability to file an IND with the FDA and/or proceed with the clinical trial phase for any of our drug candidates.

Moreover, contract manufacturers that we may use must continually adhere to cGMP enforced by the FDA through a facilities inspection program. If one of our contract manufacturers fails to maintain compliance, the production of our product candidates could be interrupted, resulting in delays, additional costs and potentially lost revenues. In addition, if the facilities of such manufacturers do not pass a pre-approval plant inspection, the FDA will not grant pre-market approval of our products.

Our reliance on these relationships poses a number of risks, including:

Ineffective clinical trials management or monitoring resulting in delays in or interruptions to, our clinical trials;

delays in, or failures to achieve, scale-up to commercial quantities, or changes to current raw material suppliers or product manufacturers (whether the change is attributable to us or the supplier or manufacturer), resulting in delayed clinical studies, regulatory submissions and commercialization of our drug candidates;

inability of third parties to manufacture, including filing and finishing, and labeling and packaging, our drug candidates in a cost-effective or timely manner or in quantities needed for clinical trials or commercial sales;

our inability to effectively control the resources devoted by our partners to our programs or products;

disagreements with third parties that could disrupt our operation or delay or terminate the research, development or manufacturing of drug candidates, or result in litigation or arbitration;

inadequate contractual protection or difficulty in enforcing the contracts if one of our partners fails to perform;

failure of these third parties to comply with regulatory requirements;

conflicts of interest between third parties work for us and their work for another entity or entities, and the resulting loss of their services;

failure to identify acceptable manufacturers or other suppliers or enter into favorable long-term agreements with them; and

lack of all necessary intellectual property rights to manufacture and sell our drug candidates.

Given these risks, our current and future arrangements with third parties may not be successful. If these efforts fail, we would be required to devote additional internal resources to the activities currently performed, or to be performed, by third parties, to seek alternative third-party sources, or to delay our product development or commercialization.

We may not achieve our projected development goals in the time frames we announce and expect.

We set goals for and make public statements regarding the timing of certain accomplishments, such as the commencement and completion of clinical trials, anticipated regulatory approval dates and time of product launch, which we sometimes refer to as milestones. These milestones may not be achieved, and the actual timing of these events can vary dramatically due to a number of factors such as delays or failures in our clinical trials, disagreements with current or future clinical development collaborative partners, the uncertainties inherent in the regulatory approval process and manufacturing scale-up and delays in achieving manufacturing or marketing

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arrangements sufficient to commercialize our products. There can be no assurance that our clinical trials will be completed, that we will make regulatory submissions or receive regulatory approvals as planned or that we will be able to adhere to our current schedule for the launch of any of our products. If we fail to achieve one or more of these milestones as planned, our business will be materially adversely affected and the price of our shares will decline.

We are dependent on key personnel and we must attract and retain qualified employees, collaborators and consultants.

The success of our business is highly dependent on the principal members of our scientific and management staff, including our senior management team. The loss of the services of any such individual might seriously harm our product development and commercialization efforts. In addition, we will require additional skilled personnel in areas such as clinical development. Retaining and training personnel with the requisite skills is challenging and extremely competitive, particularly in Northern California, where we are located.

Our success will depend on our ability to attract and retain qualified employees to help develop our potential products and execute our research, development and commercialization strategy. We have programs in place to retain personnel, including programs to create a positive work environment and competitive compensation packages. Because competition for employees in our field is intense, however, we may be unable to retain our existing personnel or attract additional qualified employees. Our success also depends on the continued availability of outside scientific collaborators, including collaborators at research institutions, to perform research and develop processes to advance and augment our internal research efforts. Competition for collaborators is intense. We also rely on services provided by outside consultants. Attracting and retaining qualified outside consultants is competitive, and, generally, outside consultants can terminate their relationship with us at will. If we do not attract and retain qualified personnel, outside consultants and scientific collaborators, or if we experience turnover or difficulties recruiting new employees or outside consultants, our research, development and commercialization programs could be delayed and we could experience difficulties in generating sufficient revenue to maintain our business.

We currently have limited sales, marketing and distribution capability. As the potential commercialization of our products approaches, we intend to hire marketing and sales personnel to enable us to participate in the commercialization of our products in the United States. If we are unsuccessful in hiring and retaining sales and marketing personnel with appropriate qualifications and talent, our ability to generate product revenues will be adversely affected.

We are expanding our operations, and any difficulties managing this growth could disrupt our business.*

The implementation of our business strategy requires us to expand our operations, including expanding our facility, which will place and places additional demands on our financial, administrative and information technology resources and increase the demands on our financial systems and controls. We have begun the process of hiring a commercial organization and putting the infrastructure in place to support a potential commercial launch of alfimeprase. Our strategy also calls for us to undertake increased research and development activities, and to manage an increasing number of relationships with collaborators and other third parties. As our operations grow, we must expand and enhance our financial, administrative and information technology infrastructures. We also may need to continue to expand our office and laboratory facilities to accommodate any future growth, but may be unable to lease additional space at or close to our current San Carlos facility at commercially reasonable rates, if at all. We may be required to seek additional facilities. If we are unable to effectively manage the growth of our operations, we may not be able to implement our business strategy, and our financial condition and results of operations may be adversely affected.

The success of our potential products in research and pre-clinical studies does not guarantee that these results will be replicated in humans.

Our internal drug development programs are currently in the research stage or in pre-clinical development. Although our clinical development-stage drug candidates have shown favorable results in pre-clinical studies, these results may not be replicated in our clinical trials with humans. None of our potential therapeutic protein candidates from our own portfolio has advanced to Phase 1 clinical trials. Before we make any products available to the public from our internal research and development programs, we or our collaboration partners will need to conduct further research and development and complete laboratory testing and animal studies. These programs may not move beyond their current stages of development. Even if our internal research does advance, we will need to engage in certain additional pre-clinical development efforts to determine whether a product is sufficiently safe and effective to enter clinical trials. We have little experience with these activities with respect to protein candidates and may not be successful in developing these products. Consequently, there is no assurance that the results in our research and pre-clinical studies are predictive of the results that we may see in our clinical trials with humans or that they are predictive of whether any resulting products will be safe and effective in humans.

We have not yet commercialized any of our drug candidates; our ability to commercialize products is unproven.*

We have not yet commercialized any of our in-licensed therapeutic product candidates. Our commercialization of products is subject to several risks, including but not limited to:

- the possibility that a product is toxic, ineffective or unreliable;
- failure to obtain regulatory approval for the product;
- difficulties in manufacturing the product on a large scale;
- difficulties in planning, coordinating and executing the commercial launch of the product;
- difficulties in marketing, distribution or sale of the product;
- the possibility of a failure to comply with laws and regulations related to the marketing sale and reimbursement of the product;
- competition from superior products; or
- third-party patents that preclude us from marketing a product.

Any regulatory approvals that we or our collaboration partners receive for our product candidates may be subject to limitations on the intended uses for which the product candidates may be marketed or contain requirements for potentially costly post-marketing follow-up studies. The labeling, packaging, adverse event reporting, storage, advertising, promotion and record-keeping for any approved product will be subject to extensive regulatory requirements. Additionally, we, our collaborators and our suppliers, may not be able to produce any products in commercial quantities at a reasonable cost or may not be able to successfully market such products. If we do not develop a commercially viable product, then we will suffer significant harm to our business, financial condition and operating results.

Even if a product candidate such as alfimeprase or rNAPc2 were approved for commercial sale, significant strategic planning and resources will be necessary to effectively coordinate commercial launch of the product in the approved indication or indications, and to effectively market, distribute and sell the product for use in the approved indication or indications. We currently have limited sales, marketing and distribution capability. As the potential commercialization of our products approaches, we intend to hire additional marketing and sales personnel to enable us to participate in the commercialization of our products in the United States. If we are unsuccessful in hiring and retaining sales and marketing personnel with appropriate technical and sales expertise or in developing an adequate distribution capability to support them, our ability to generate product revenues will be adversely affected.

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In addition, the marketing, distribution, sale and reimbursement of pharmaceutical products is heavily regulated, and we must comply with all such applicable laws and regulations, or incur costs, fees and other liabilities associated with non-compliance. If our or a collaboration partner s commercial launch of a product approved for commercial sale were to be unsuccessful, or if we or a collaboration partner were to fail in our or their efforts to properly market, distribute or sell any product approved for sale, our business, financial condition and operating results would suffer significant harm.

Our products may not be accepted in the marketplace, and we may not be able to generate significant revenue, if any.

Even if they are approved for marketing, our products, if any, may never achieve market acceptance among physicians, patients and the medical community. The degree of market acceptance of any products developed by us, alone, or in conjunction with our collaboration partners, will depend on a number of factors, including:

the establishment and demonstration of the clinical efficacy and safety of the products;

convenience and ease of administration;

cost-effectiveness;

our products potential advantages over alternative treatment methods;

marketing, sales and distribution support of our products; and

reimbursement policies of government and third-party payers.

Physicians, patients or the medical community in general may not accept and utilize any of the products that we alone, or in conjunction with our collaboration partners, develop. In practice, competitors may be more effective in marketing their drugs. The lack of such market acceptance would significantly harm our business, financial condition and results of operations.

Even if our product candidates are approved for marketing and are accepted by physicians, patients and the medical community, the size of the market for these products may be insufficient to sustain our business, or may not provide an acceptable return on our investment in the development of these products. For example, our lead product candidate, alfimeprase, is undergoing clinical trials for the treatment of acute PAO. There are currently no thrombolytic agents specifically approved for the treatment of acute PAO in the United States or overseas, and as a result there is currently limited market data available for us to use in judging the market size for a therapeutic product of this nature. The number of incidents of acute PAO that are treatable with an approved thrombolytic agent may not be sufficient to create a sustainable market for alfimeprase, if approved. As a result, the commercialization of alfimeprase for the treatment of acute PAO, or any of our other product candidates, could fail even if we receive marketing approval from the FDA or similar foreign authority, and acceptance by the medical and patient communities.

We face intense competition.*

The biopharmaceutical industry is intensely competitive and is accentuated by the rapid pace of technological development. Our products, if successfully developed, will compete with a number of traditional drugs and therapies and with new products currently under development. We also expect to face increased competition in the future as new companies enter our markets. Research and discoveries by others may result in breakthroughs that render our potential products obsolete even before they begin to generate any revenue. Our competitors include major pharmaceutical, medical device and biotechnology firms, many of which have substantially greater research and product development capabilities and financial, scientific, marketing and human resources than we have. Our lead product candidate, alfimeprase, if approved, will face competition in the catheter occlusion indication from alteplase, an approved Genentech, Inc. product, and will potentially face competition in the acute PAO indication from medical devices and product candidates currently being developed and/or marketed.

Our competitors may obtain patents and regulatory approvals for their competing products more rapidly than we, or our collaboration partners, or develop products that are more effective than those developed by us, or our collaboration partners. All of our products will face competition from companies developing similar products as well as from companies developing other forms of treatment for the same conditions.

Many of the companies developing competing products have greater expertise than our collaboration partners have, in discovery, research and development, manufacturing, pre-clinical and clinical testing, obtaining regulatory approvals and marketing. Other smaller companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These companies and institutions compete with us in recruiting and retaining qualified scientific and management personnel as well as in acquiring technologies complementary to our programs. We will face competition with respect to:

product efficacy and safety;

the timing and scope of regulatory approvals;

availability of resources;

reimbursement coverage; and

price and patent position, including the potentially dominant patent positions of others.

There can be no assurance that research and development by others will not render the products that we may develop obsolete or uneconomical, or result in treatments or cures superior to any therapy developed by us or that any therapy we develop will be preferred to any existing or newly-developed alternative products.

We face uncertainty with respect to coverage, pricing, third-party reimbursements and healthcare reform.

Our ability to collect significant revenues from our products may depend on our ability, and the ability of our collaboration partners or customers, to obtain adequate levels of coverage for our products and reimbursement from third-party payers such as:

government health administration authorities;

private health insurers;

health maintenance organizations;

pharmacy benefit management companies; and

other healthcare-related organizations.

Third-party payers may deny coverage or offer inadequate levels of reimbursement if they determine that a prescribed product has not received appropriate clearances from the FDA or other government regulators, is not used in accordance with cost-effective treatment methods as determined by the third-party payer, or is

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experimental, unnecessary or inappropriate. If third-party payers deny coverage or offer inadequate levels of reimbursement, we may not be able to market our products effectively. We also face the risk that we will have to offer our products at prices lower than anticipated as a result of the current trend in the United States towards managed healthcare through health maintenance organizations. Currently, third-party payers are increasingly challenging the prices charged for medical products and services. Prices could be driven down by health maintenance organizations that control or significantly influence purchases of healthcare services and products. Existing U.S. laws, such as the Medicare Prescription Drug and Modernization Act of 2003, or future legislation to reform healthcare or reduce government insurance programs could also adversely affect prices of our approved products, if any. The cost-containment measures that healthcare providers are instituting and the results of potential healthcare reforms may prevent us from maintaining prices for our products that are sufficient for us to realize profits and may otherwise significantly harm our business, financial condition and operating results. In addition, to the extent that our products are marketed outside of the United States, foreign government pricing controls and other regulations may prevent us and our collaboration partners from maintaining prices for our products that are sufficient for us to realize profits and may otherwise significantly harm our business, financial condition and operating results.

We may merge with or acquire other companies, and our failure to receive the anticipated benefits in these transactions could harm our business.

In January 2003, we merged with Variagenics, and we may merge with or acquire other companies in the future. The success of any merger or acquisition depends, in part, on our ability to realize the anticipated synergies, cost savings and growth opportunities from integrating the business of the merged or acquired company with our business. The integration of two independent companies is a complex, costly and time-consuming process. The difficulties of combining the operations of the companies and/or our subsidiary include, among others:

- consolidating research and development operations;
- retaining key employees;
- consolidating corporate and administrative infrastructures;
- preserving the research and development and other important relationships of the companies;
- integrating and managing the technology of two companies;
- using the merged or acquired company s liquid capital and other assets efficiently to develop the business of the combined company;
- minimizing the diversion of management s attention from ongoing business concerns; and
- coordinating geographically separate organizations.

We cannot assure you that we will receive all of the anticipated benefits of any mergers or acquisitions, or that any of the risks described above will not occur. Our failure to receive anticipated benefits of, and our exposure to inherent risks in, any such merger or acquisition transaction could significantly harm our business, financial condition and operating results.

We are subject to the risk of natural disasters.

Our facilities are located in Northern California. If a fire, earthquake, flood or other natural disaster disrupts our research or development efforts, our business, financial condition and operating results could be materially adversely affected. Although we maintain personal property and general business interruption coverage, we do not maintain earthquake or flood insurance coverage for personal property or resulting business

interruption.

RISKS RELATED TO OUR CAPITAL STRUCTURE AND FINANCIAL RESULTS

We have not been profitable, anticipate continuing losses and may never become profitable.*

We had net losses of $52.5 million in 2004, $71.6 million in 2005 and $65.2 million in the nine months ended September 30, 2006. As of September 30, 2006, we had an accumulated deficit of $392.9 million.

All of our product candidates are in various stages of product development, and some are still in research or in early development. None of them are approved for sale. The process of developing our drug products will require significant additional research and development, pre-clinical testing, clinical trials and regulatory approvals.

These activities, together with drug manufacturing, commercialization, general administrative and other expenses, are expected to result in operating losses for the foreseeable future. To date, we have not generated any revenues from product sales. We do not expect to achieve significant product sales or royalty revenue from product sales for several years, and we may never do so. We expect to incur additional operating losses in the future, and these losses may increase significantly as we continue pre-clinical research and clinical trials, apply for regulatory approvals, develop our drug candidates, expand our operations and develop systems that support commercialization of our potential products. These losses, among other things, have caused and may cause our stockholders equity and working capital to decrease. We may not be successful in developing our drug candidates, obtaining regulatory approvals and commercializing our products, and our operations may not be profitable even if any of our drug candidates are commercialized. We may never generate profits and, as a result, the market price of our common stock could decline.

Moreover, utilization of our net operating loss carry forwards and credits may be subject to an annual limitation due to the change in ownership provisions of the Internal Revenue Code of 1986 and similar state law provisions. It is possible that certain transactions that we have entered into, including our merger with Variagenics in January 2003, when considered in connection with other transactions, may result in a change in ownership for purposes of these provisions.

In January 2005, we entered into a lease agreement for 61,826 square feet of industrial space in San Carlos, California. In connection with our lease of this new facility, we are examining the potential to sublease or otherwise exit our facility at 985 Almanor Avenue in Sunnyvale, California, which is currently being used for storage and for which we have a lease through May 30, 2011. In accordance with Statement of Financial Accounting Standards No. 146, Accounting for Costs Associated with Exit or Disposal Activities, if we sublease or otherwise exit this facility, we could incur a significant charge to our earnings based on the remaining lease rental expense for this facility, reduced by the estimated income from sublease rental, if any. As of September 30, 2006, the remaining lease rental expense for this facility was $26.3 million. Similarly, in accordance with Statement of Financial Accounting Standards No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets, if we sublease or otherwise exit this facility, we could also incur a significant charge to our earnings for the impairment of leasehold improvements related to this facility, based on the difference between their carrying value and fair value at the time of the sublease or exit. As of September 30, 2006, this difference was estimated to be $3.2 million.

We are potentially subject to additional non-cash charges, which can negatively impact our results of operations. For example, as a result of our adoption of SFAS 123(R), we must measure compensation cost for stock-based awards made to employees at the grant date, based on the fair value of the award, and recognize the cost as an expense over the employee s requisite service period. As the variables that are used as a basis for valuing future awards change over time, the magnitude of the expense that we must recognize may increase significantly. In addition, in August 2005, in connection with our entry into a Committed Equity Financing Facility, we

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issued a warrant to Kingsbridge Capital Ltd. to purchase 350,000 shares of our common stock. The warrant s fair value was recorded as a financing cost to additional paid-in capital, and the opposing current liability has and will continue to be marked-to-market each quarter, with the change being recorded as a charge to our general and administrative expenses. Changes in the price of our common stock over time have and may continue to cause significant charges to expense. Our results of operations could be materially and adversely affected by these or other non-cash charges that we may incur in the future.

We will need to raise additional capital, and such capital may be unavailable to us when we need it or not available on acceptable terms.*

We will need to raise significant additional capital to finance the research and clinical development of our drug products. If future securities offerings are successful, they could dilute our current shareholders equity interests and reduce the market price of our common stock. Financing may be unavailable when we need it or may not be available on acceptable terms. The unavailability of financing may require us to delay, scale back or eliminate expenditures for our research, development and marketing activities necessary to commercialize our potential biopharmaceutical products. We may also be required to raise capital by granting rights to third parties to develop and market drug candidates that we would prefer to develop and market on our own, potentially reducing the ultimate value that we could realize from these drug candidates.

If we are unable to obtain additional financing when we need it, the capital markets may perceive that we are not able to raise the amount of financing we desire, or on the terms that we desire. This perception, if it occurs, may negatively affect the market price of our common stock. If sufficient capital is not available, we may be forced to delay, reduce the scope of, eliminate or divest one or more of our research or development programs. Any such action could significantly harm our business, financial condition and results of operations.

Our future capital requirements and the adequacy of our currently available funds will depend on many factors, including, among others, the following:

- our ability to maintain, and the financial commitments involved in, our existing collaborative and licensing arrangements;
- the success of our collaboration with Bayer, in accordance with the alfimeprase license and collaboration agreement we entered into in January 2006;
- progress in current and anticipated clinical studies of our products, including alfimeprase, rNAPc2, NU206 and NU172;
- the cost of manufacturing our material for pre-clinical, clinical and commercial purposes;
- our ability to establish new collaborative relationships with other companies to share costs and expertise of identifying and developing drug candidates;
- the magnitude and scope of our research and development programs, including development of product candidates;
- continued scientific progress in our research and development programs, including progress in our research and pre-clinical studies;
- the cost involved in any facilities expansion to support research and development of our product candidates;
- the cost of prosecuting and enforcing our intellectual property rights;

the time and cost involved in obtaining regulatory approvals;

our need to develop, acquire or license new technologies or products;

competing technological and market developments;

our ability to use our common stock to repay our line of credit with Dr. George Rathmann;

future funding commitments to our collaborators;

current conditions and the uncertainty of future conditions in the financial markets and in the biotech sector;

other factors not within our control.

We may face fluctuations in operating results.*

Our operating results may rise or fall significantly from period to period as a result of many factors, including:

the amount of research and development we engage in;

the number of product candidates we have, their progress in research, pre-clinical and clinical studies and the costs involved in manufacturing them;

our ability to expand our facilities to support our operations;

our ability to maintain existing and enter into new strategic relationships;

the scope, duration and effectiveness of our licensing and collaborative arrangements;

the costs involved in prosecuting, maintaining and enforcing patent claims;

the possibility that others may have or obtain patent rights that are superior to ours;

changes in government regulation;

changes in the price of our common stock or other variables used as a basis for valuing stock-based awards;

changes in accounting policies or principles; and

release of successful products into the market by our competitors.

In addition, as a result of our adoption of FAS 123(R), we must measure compensation cost for stock-based awards made to employees at the grant date of the award, based on the fair value of the award, and recognize the cost as an expense over the employee s requisite service period. As the variables that we use as a basis for valuing future awards change over time, the magnitude of the expense that we must recognize may vary significantly. Any such variance from one period to the next could cause a significant fluctuation in our operating results.

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Excluding our two clinical stage drug candidates, our 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. A high percentage of our expenses are fixed costs such as lease obligations, and certain charges to our statement of operations are dependent on movements in the price of our common stock, which historically has been and is likely to remain highly volatile. As a result, we may experience fluctuations in our operating results from quarter to quarter and continue to generate losses. Quarterly comparisons of our financial results may not necessarily be meaningful, and investors should not rely upon such results as an indication of our future performance. In addition, investors may react adversely if our reported operating results are less favorable than in a prior period or are less favorable than those anticipated by investors or the financial community, which may result in a drop in the market price of our common stock.

Our stock price has historically been and is likely to remain highly volatile, and an investment in our stock could suffer a decline in value.

Stock prices and trading volumes for many biopharmaceutical companies fluctuate widely for a number of reasons, including factors which may be unrelated to their businesses or results of operations, such as media coverage, legislative and regulatory measures and the activities of various interest groups or organizations. This market volatility, as well as general domestic or international economic, market and political conditions, could materially and adversely affect the market price of our common stock and the return on your investment.

Historically, our stock price has been extremely volatile. Between January 1, 2005 and December 31, 2005, the price ranged between a high of $10.35 per share and a low of $5.75 per share, and between January 1, 2006 and September 30, 2006, the price ranged between a high of $20.98 per share and a low of $8.16 per share. Significant market price fluctuations of our common stock can be due to a variety of factors, including:

- the depth of the market for the common stock;
- the experimental nature of our potential products;
- actual or anticipated fluctuations in our operating results;
- sales of our common stock by existing holders, or sales of shares issuable upon exercise of outstanding options and warrants, or upon repayment of our line of credit with Dr. George Rathmann;
- market conditions relating to the biopharmaceutical and pharmaceutical industries;
- any announcements of technological innovations, new commercial products or collaborations, or clinical progress or lack thereof by us, our collaborative partners or our competitors;
- announcements concerning regulatory developments, developments with respect to proprietary rights and our collaborations;
- changes in or our failure to meet market or, to the extent securities analysts follow our common stock, securities analysts expectations;
- loss of key personnel;
- changes in accounting principles;

general market conditions; and

public concern with respect to our products.

In addition, the stock market in general, and the market for biotechnology and other life science stocks in particular, has historically been subject to extreme price and volume fluctuations. This volatility has had a significant effect on the market prices of securities issued by many companies for reasons unrelated to the operating performance of these companies. In the past, following periods of volatility in the market price of a company s securities, class action securities litigation has often been instituted against such a company. Any such litigation instigated against us could result in substantial costs and a diversion of management s attention and resources, which could significantly harm our business, financial condition and operating results.

Future sales or the possibility of future sales of our common stock may depress the market price of our common stock.*

Sales in the public market of substantial amounts of our common stock could depress prevailing market prices of our common stock. As of September 30, 2006, we had 52,235,095 shares of our common stock outstanding. All of these shares are freely transferable without restriction or further registration under the Securities Act, except for shares held by our directors, officers and other affiliates and unregistered shares held by non-affiliates. As of September 30, 2006, our directors, officers and greater than five percent stockholders held approximately 15 percent of the shares of our outstanding common stock. Although we do not believe that our directors, officers and greater than five percent stockholders have any present intentions to dispose of large amounts of any shares of common stock owned by them, there can be no assurance that such intentions will not change in the future. The sale of these additional shares could depress the market price of our common stock.

Under registration statements on Form S-8 under the Securities Act, as of September 30, 2006, we have also registered approximately 11,008,754 shares of our common stock which may be issued 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, stock option agreements entered into outside of any of our stock option plans, and our Employee Stock Purchase Plan. Included in the 11,008,754 shares, as of September 30, 2006, are (i) 7,496,733 shares of our common stock issuable under outstanding options to purchase our common stock under the specified plans, (ii) 773,539 shares of our common stock issuable under stock option agreements entered into outside of any of our stock option plans, (iii) 2,541,644 shares of our common stock reserved for future option grants under our 2004 Equity Incentive Plan, and (iv) 196,838 shares of our common stock reserved for future issuance under our Employee Stock Purchase Plan. As of September 30, 2006, 3,582,814 of the shares issuable upon exercise of our outstanding options were exercisable. Once these shares are exercised, such shares are available for sale in the open market without further registration under the Securities Act. The existence of these outstanding options and share reserves may negatively affect our ability to complete future equity financings at acceptable prices and on acceptable terms. The exercise of those options, and the prompt resale of shares of our common stock received, may also result in downward pressure on the price of our common stock.

As of September 30, 2006, 1,227,323 shares of our common stock were issuable upon the exercise of outstanding warrants, which were all exercisable as of this date. Once a warrant is exercised, the holder can arrange for the resale of shares either by invoking any applicable registration rights, causing the shares to be registered under the Securities Act and thus freely transferable, or by relying on an exemption to the Securities Act. If these registration rights, or similar registration rights that may apply to securities we may issue in the future, are exercised, it could result in additional sales of our common stock in the market, which may have an adverse effect on our stock price.

As of September 30, 2006, $5.1 million of our common stock was issuable, upon mutual agreement, to convert the remaining amount due on the promissory note under our line of credit with Dr. George Rathmann, including accrued interest, at a conversion price equal to the average price of our common stock over a 20-day period, ending two days prior to conversion, or, if in connection with an equity financing, at the offering price. If we agree to repay this note with our common stock, whether pursuant to acceleration of the note or otherwise, the resale of shares of our common stock received by Dr. Rathmann may also result in significant downward pressure on the market price of our common stock.

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In June 2006, we filed an automatic shelf registration statement with the SEC on Form S-3, which became immediately effective upon filing. Under this shelf registration, we may, from time to time, offer to sell common stock, preferred stock, debt securities, warrants or any combination of these securities in amounts, at prices and on terms yet to be determined. The debt securities, warrants and preferred stock may be convertible into or exchangeable for common or preferred stock or other securities. Should we sell any securities under this shelf, it could have a dilutive effective on the holdings of our current stockholders, and may result in downward pressure on the market price of our common stock.

Under the August 2005 committed equity financing facility, or CEFF, that we entered into with Kingsbridge Capital Ltd., and related stock purchase and registration rights agreements, we may periodically sell up to $75.0 million in shares of our common stock to Kingsbridge over a three-year period, subject to certain conditions and restrictions. In the fourth quarter of 2005, under this CEFF, we sold 1,839,400 shares for gross proceeds of $14.4 million, and in October 2006 we sold 568,247 shares for gross proceeds of $10.0 million. We may sell the balance of $50.6 million of shares of our common stock over the remainder of the three-year term of the CEFF. Should we sell further securities under the CEFF, it could have a dilutive effective on the holdings of our current stockholders, and may result in downward pressure on the market price of our common stock.

We will need to raise significant additional capital to finance the research, development and commercialization of our drug products. If future securities offerings are successful, they could dilute our current stockholders equity interests and reduce the market price of our common stock.

We do not intend to pay cash dividends on our common stock in the foreseeable future.

We do not anticipate paying cash dividends on our common stock in the foreseeable future. Any payment of cash dividends will depend upon our financial condition, results of operations, capital requirements and other factors and will be at the discretion of our board of directors. Under our August 31, 2004 Loan and Security Agreement with Silicon Valley Bank, as amended, we cannot pay dividends without Silicon Valley Bank s prior written consent, except for dividends paid in shares of our capital stock. Furthermore, we may incur additional indebtedness that may severely restrict or prohibit the payment of dividends.

We face exposure to currency fluctuations for transactions denominated in foreign currencies, which may adversely affect our results of operations.

To mitigate the impact of currency exchange rate fluctuations on our cash outflows for certain foreign currency-denominated purchases, we have developed and implemented a foreign exchange risk management policy utilizing forward contracts to hedge against this exposure. For example, we have entered into a number of foreign exchange hedge contracts with Silicon Valley Bank in relation to our development and validation agreement with Avecia, pursuant to which we are required to make payments to Avecia in British pounds. Although we use forward contracts, when appropriate, to reduce the impact of foreign currency fluctuations on our future results, these efforts may not be successful, and any such fluctuations could adversely affect our results of operations.

The committed equity financing facility with Kingsbridge may not be available to us when we desire to draw upon it, may require us to make additional blackout payments to Kingsbridge, and may result in dilution to our stockholders.

In August 2005, in connection with a committed equity financing facility, or CEFF, we entered into a stock purchase agreement and related registration rights agreement with Kingsbridge Capital Ltd. The CEFF entitles us to sell and obligates Kingsbridge to purchase, from time to time over a period of three years, shares of our common stock for cash consideration up to an aggregate of $75.0 million, subject to certain conditions and restrictions. In the fourth quarter of 2005, under this stock purchase agreement, we sold 1,839,400 shares for gross proceeds of $14.4 million and in October 2006 we sold 568,247 shares for gross proceeds of $10.0 million. The balance of $50.6 million remains available for use by us over the remainder of the three-year period. Kingsbridge will not be obligated to purchase shares under the CEFF unless certain conditions are met, which include a minimum price for our common stock; the accuracy of representations and warranties made to Kingsbridge; compliance with laws; effectiveness of a registration statement to register such shares for resale by Kingsbridge; and the continued listing of our stock on the Nasdaq Global Market. In addition, Kingsbridge is permitted to terminate the CEFF if it determines that a material and adverse event has occurred affecting our business, operations, properties or financial condition. If we are unable to access funds through the CEFF, or if the CEFF is terminated by Kingsbridge, we may be unable to access capital on favorable terms or at all.

We are entitled in certain circumstances, to deliver a blackout notice to Kingsbridge to suspend the use of the registration statement under which shares sold under the CEFF are registered for resale, thereby prohibiting Kingsbridge from selling shares. If we deliver a blackout notice in the 15 trading days following the settlement of a sale of shares under the CEFF, or if the registration statement is not effective in circumstances not permitted by our agreement with Kingsbridge, then we must make a payment to Kingsbridge, or issue Kingsbridge additional shares in lieu of this payment, calculated on the basis of the number of shares held by Kingsbridge and the change in the market price of our common stock during the period in which the use of the registration statement is suspended. If the market price of our common stock declines during a

suspension of the registration statement, the blackout payment could be significant.

Should we sell additional shares to Kingsbridge under the CEFF, or issue shares in lieu of any blackout payment, it will have a dilutive effective on the holdings of our current stockholders, and may result in downward pressure on the market price of our common stock. If we draw down under the CEFF, we will issue shares to Kingsbridge at a discount of up to ten percent from the volume weighted average price of our common stock. If we draw down amounts under the CEFF when our share price is decreasing, we will need to issue more shares to raise the same amount than if our share price was higher. Issuances in the face of a declining share price will have an even greater dilutive effect than if our share price were stable or increasing, and may further decrease our share price.

We have implemented anti-takeover provisions that could discourage, prevent or delay a takeover, even if the acquisition would be beneficial to our stockholders.

The existence of our stockholder rights plan and provisions of our certificate of incorporation and bylaws, as well as provisions of Delaware law, could make it more difficult for a third party to acquire us, even if doing so would benefit our stockholders. These provisions:

- establish a classified board of directors so that not all members of our board may be elected at one time;
- authorize the issuance of up to 5,000,000 shares of preferred stock that could be issued by our board of directors to increase the number of outstanding shares and hinder a takeover attempt;
- limit who may call a special meeting of stockholders;
- prohibit stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders; and
- establish advance notice requirements for nominations for election to our board of directors or for proposing matters that can be acted upon at a stockholder meeting.

Specifically, our certificate of incorporation provides that all stockholder action must be effected at a duly called meeting, and not by a written consent. The by-laws provide, however, that our stockholders may call a special meeting of stockholders only upon a request of stockholders owning at least 50 percent of our common stock. These provisions of our certificate of incorporation and our by-laws could discourage potential acquisition proposals and could delay or prevent a change in control. We designed these provisions to reduce our vulnerability to unsolicited acquisition proposals and to discourage certain tactics that may be used in proxy fights. These

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provisions, however, could also have the effect of discouraging others from making tender offers for our shares. As a consequence, they also may inhibit fluctuations in the market price of our shares that could result from actual or rumored takeover attempts. Such provisions also may have the effect of preventing changes in our management.

We are permitted to issue shares of our preferred stock without stockholder approval upon such terms as our board of directors determines. Therefore, the rights of the holders of our common stock are subject to, and may be adversely affected by, the rights of the holders of our preferred stock that may be issued in the future. In addition, the issuance of preferred stock could have a dilutive effect on the holdings of our current stockholders.

On June 5, 1998, our board of directors adopted a rights plan and declared a dividend with respect to each share of our common stock then outstanding. This dividend took the form of a right, which entitles the holders to purchase one one-thousandth of a share of our Series A junior participating preferred stock at a purchase price that is subject to adjustment from time to time. These rights have also been issued in connection with each share of our common stock issued after June 15, 1998. The rights are exercisable only if a person or entity or affiliated group of persons or entities acquires, or has announced its intention to acquire, 15 percent (27.5 percent in the case of certain approved stockholders) or more of our outstanding common stock. The adoption of the rights plan makes it more difficult for a third party to acquire control of us without the approval of our board of directors. This rights agreement was amended on March 19, 2004, to reflect our reincorporation under Delaware law.

We are subject to the Delaware anti-takeover laws regulating corporate takeovers. These anti-takeover laws prevent a Delaware corporation from engaging in a merger or sale of more than ten percent of its assets with any stockholder, including all affiliates and associates of the stockholder, who owns 15 percent or more of the corporation s outstanding voting stock, for three years following the date that the stockholder acquired 15 percent or more of the corporation s stock unless:

- the board of directors approved the transaction where the stockholder acquired 15 percent or more of the corporation s stock;
- after the transaction in which the stockholder acquired 15 percent or more of the corporation s stock, the stockholder owned at least 85 percent of the corporation s outstanding voting stock, excluding shares owned by directors, officers and employee stock plans in which employee participants do not have the right to determine confidentially whether shares held under the plan will be tendered in a tender or exchange offer; or
- on or after this date, the merger or sale is approved by the board of directors and the holders of at least two-thirds of the outstanding voting stock that is not owned by the stockholder.

The provisions of our governing documents, stockholder rights plan and current Delaware law may, collectively:

- lengthen the time required for a person or entity to acquire control of us through a proxy contest for the election of a majority of our board of directors;
- discourage bids for our common stock at a premium over market price; and
- generally deter efforts to obtain control of us.

We have adopted an Executive Change in Control and Severance Benefit Plan that could discourage, prevent or delay a takeover, even if the acquisition would be beneficial to our stockholders.

In December 2004, our board of directors approved an Executive Change in Control and Severance Benefit Plan for our executive officers and other eligible employees, which was amended and restated in May 2005. The purpose of the plan is to provide for the payment of severance benefits and/or change in control benefits to certain of our eligible employees, and the plan supersedes and replaces any change in control and/or

severance plans adopted by us previously. All of our executive employees at the level of Vice President or above have been designated as participants in the plan and our board of directors may designate other eligible individuals as participants. The plan provides that, upon a change in control of the company as defined under the plan, all Nuvelo stock options and stock awards held by a plan participant will become fully vested. Such shares held by a plan participant will also become fully vested if the participant is terminated without cause, or constructively terminated, within one month preceding our change in control. If a participant is terminated without cause or constructively terminated one month before or one year after our change in control, he or she will also be entitled to certain cash severance and continued medical benefits. The change in control and severance benefits for certain of our employees provided for under this plan could make it more difficult and expensive, or less desirable, for a third party to acquire us, even if doing so would benefit our stockholders.

RISKS RELATED TO INTELLECTUAL PROPERTY AND OTHER LEGAL MATTERS

The commercial success of our products will depend upon our ability to protect the intellectual property rights associated with our products and drug candidates.

Our competitive success will depend, in part, on our ability to obtain and maintain patent protection for our inventions, technologies and discoveries, including intellectual property that we license. The patent positions of biotechnology companies involve complex legal and factual questions, and we cannot assure you that our patents and licenses will successfully preclude others from using our technology. We could incur substantial costs in seeking enforcement of our proprietary rights against infringement.

We currently have, or have in-licensed, issued patents and pending patent applications that include claims to our in-licensed clinical products. We obtained exclusive worldwide rights to alfimeprase from Amgen in October 2004. We obtained exclusive worldwide rights for all indications of rNAPc2 and all of the rNAPc molecules owned by Dendreon 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 also currently have patents that cover some of our technological discoveries and patent applications that we expect to protect some of our gene, protein and technological discoveries. We will continue to apply for patents for our discoveries. We cannot assure you that any of our applications, or our licensors applications, will issue as patents, or that any patent issued or licensed to us will not be challenged, invalidated, circumvented or held unenforceable by way of an interference proceeding or litigation.

The timing of the grant of a patent cannot be predicted. Patent applications describing and seeking patent protection of methods, compositions, or processes relating to proprietary inventions involving human therapeutics could require us to generate data, which may involve substantial costs. Our pending patent applications may lack priority over others applications or may not result in the issuance of patents. Even if issued, our patents may not be sufficiently broad to provide protection against competitors with similar technologies and may be challenged, invalidated or circumvented.

In addition to patents, we rely on a combination of trade secrets, copyright and trademark laws, nondisclosure agreements, licenses and other contractual provisions and technical measures to maintain and develop our competitive position with respect to intellectual property. Nevertheless, these measures may not be adequate to safeguard the technology underlying our products. For example, employees, consultants and others who participate in the development of our products may breach their agreements with us regarding our intellectual property and we may not have adequate remedies for the breach. Our trade secrets could become known through other unforeseen means. We depend on our collaborators and other third parties that license intellectual property to us to protect our licensed intellectual property. These collaborators and other third parties could fail to take a necessary step to protect our licensed intellectual property, which could seriously harm our intellectual property position.

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We also may not be able to effectively protect our intellectual property rights in some foreign countries, as many countries do not offer the same level of legal protection for intellectual property as the United States. Furthermore, certain of the patent applications describing our proprietary methods are filed only in the United States. Even where we have filed our patent applications internationally, for some cases and in certain countries, we have chosen not to maintain foreign patent protection by opting not to enter national phase or opting not to pay maintenance annuities.

Notwithstanding our efforts to protect our intellectual property, our competitors may independently develop similar or alternative technologies or products that are equal or superior to our technology. Our competitors may also develop similar products without infringing on any of our intellectual property rights or design around our proprietary technologies.

If the manufacture, use or sale of our products infringe on the intellectual property rights of others, we could face costly litigation, which could cause us to pay substantial damages or licensing fees and limit our ability to sell some or all of our products.

Extensive litigation regarding patents and other intellectual property rights has been common in the biopharmaceutical industry. Litigation may be necessary to assert infringement claims, enforce patent rights, protect trade secrets or know-how and determine the enforceability, scope and validity of certain proprietary rights. The defense and prosecution of intellectual property lawsuits, United States Patent and Trademark Office interference proceedings, and related legal and administrative proceedings in the United States and internationally involve complex legal and factual questions. As a result, such proceedings are costly and time-consuming to pursue and their outcome is uncertain.

Regardless of merit or outcome, our involvement in any litigation, interference or other administrative proceedings could cause us to incur substantial expense and could significantly divert the efforts of our technical and management personnel. An adverse determination may subject us to the loss of our proprietary position or to significant liabilities, or require us to seek licenses that may include substantial cost and ongoing royalties. Licenses may not be available from third parties, or may not be obtainable on satisfactory terms. An adverse determination or a failure to obtain necessary licenses may restrict or prevent us from manufacturing and selling our products, if any. These outcomes could materially harm our business, financial condition and results of operations.

Our market success depends in part on us neither infringing valid, enforceable patents or proprietary rights of third parties, nor breaching any licenses that may relate to our technologies and products. We are aware of third-party patents and proprietary rights that may relate to our technology. We may be required to obtain licenses to patents or other proprietary rights of others for ourselves, our collaboration partners and our service providers in order to conduct research, development or commercialization of some or all of our programs. We plan to seek licenses, as we deem appropriate, but it is possible that we may infringe upon these patents or proprietary rights of third parties. If we do not obtain these licenses, we may encounter delays in product market introductions, incur substantial costs while we attempt to design around existing patents or not be able to develop, manufacture or sell products. In response, third parties may assert infringement or other intellectual property claims against us, our collaboration partners or our service providers. We may consequently be subjected to substantial damages for past infringement or be required to modify our products if it is ultimately determined that our products infringe a third party s proprietary rights. Further, we may be prohibited from selling our products before we obtain a license, which, if available at all, may require us to pay substantial royalties, which could adversely impact our product costs and have an impact on our business. Further, if we do obtain these licenses, the agreed terms may necessitate reevaluation of the potential commercialization of any one of our programs. Failing to obtain a license could result in litigation. Even if these claims are without merit, defending a lawsuit takes significant time, may be expensive and may divert management attention from other business concerns. Any public announcements related to litigation or interference proceedings initiated or threatened against us could cause our stock price to decline.

We face product liability exposure and potential unavailability of insurance.

We risk financial exposure to product liability claims in the event that the use of products developed by us, or our collaboration partners, if any, result in personal injury.

We may experience losses due to product liability claims in the future. We have obtained limited product liability insurance coverage. Such coverage, however, may not be adequate or may not continue to be available to us in sufficient amounts or at an acceptable cost, or at all. We may not be able to obtain commercially reasonable product liability insurance for any product approved for marketing. A product liability claim or other claim, product recalls, as well as any claims for uninsured liabilities or in excess of insured liabilities, may significantly harm our business, financial condition and results of operations.

We face heavy government regulation, and any disputes relating to business practices or improper handling, storage or disposal of hazardous materials, chemicals and patient samples could be time consuming and costly. *

Our research and development and production activities involve the controlled use of hazardous or radioactive materials, chemicals, including oxidizing and reducing reagents, infectious disease agents, patient tissue and blood samples. We, our collaborators and service providers, are subject to federal, state and local laws and regulations governing the use, storage, handling and disposal of these materials and certain waste products. We could be liable for accidental contamination or discharge or any resultant injury from hazardous materials, and conveyance, processing, and storage of and data on patient samples. If we, or our collaborators or service providers, fail to comply with applicable laws or regulations, we could be required to pay penalties or be held liable for any damages that result and this liability could exceed our financial resources. Further, future changes to environmental health and safety laws could cause us to incur additional expense or restrict our operations. In addition, our collaborators and service providers may be working with hazardous materials, including viruses and hazardous chemicals, in connection with our collaborations. In the event of a lawsuit or investigation, we could be held responsible for any injury caused to persons or property by exposure to, or release of, patient samples that may contain viruses and hazardous materials. The cost of this liability could exceed our resources.

We also are subject to numerous federal, state and local laws, regulations and recommendations relating to safe working conditions, laboratory and manufacturing practices, general business practices, the experimental use of animals, and the environment. 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.

Variagenics has been named as a defendant in a class action suit and defending this litigation could hurt our business.

Variagenics has been named as a defendant in a securities class action lawsuit alleging the failure to disclose additional and excessive commissions purportedly solicited by and paid to underwriters who are also named defendants in the lawsuit. Plaintiffs in the suit allege that underwriters took these commissions and in exchange allocated shares of Variagenics stock to their preferred customers through alleged agreements with these preferred customers that tied the allocation of initial public offering shares to agreements by the customers to make additional aftermarket purchases at pre-determined prices. As a result of our merger with Variagenics, we are obligated to continue to defend against this litigation. Currently we are in the process of approving a settlement by and between the issuers that are defendants in the lawsuit, the insurers of those issuers, and the plaintiffs. We believe that any loss or settlement amount will not be material to our financial position or results of operation, and that any settlement payment and attorneys fees accrued with respect to the suit will be paid by our insurance provider. However, we cannot assure you that this will be the case until a final settlement is executed. Failure to finalize a settlement could require us to pay substantial damages.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

Not applicable.

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ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

Not applicable.

ITEM 5. OTHER INFORMATION

On August 29, 2006, we entered into a Second Amendment to the Loan and Security Agreement with Silicon Valley Bank entered into on August 31, 2004, as amended by the first amendment thereto dated July 18, 2005. Under this Second Amendment, the revolving credit line facility provided for under the Loan and Security Agreement was extended by one year, through August 28, 2007. A copy of the Second Amendment to the Loan and Security Agreement is attached as an exhibit to this Quarterly Report on Form 10-Q.

ITEM 6. EXHIBITS

Exhibit

Number	**Description**
2.1	Agreement and Plan of Merger between Hyseq, Inc., Vertical Merger Corp. and Variagenics, Inc. dated November 9, 2002.(5)
2.2	Agreement and Plan of Merger between Nuvelo, Inc. and Nuvelo, Inc., a Nevada corporation and Nuvelo, Inc. s predecessor in interest dated March 19, 2004.(7)
2.3	Stock Purchase Agreement between SBH Genomics, Inc., Radoje Drmanac, Snezana Drmanac, Nuvelo, Inc., and Affymetrix, Inc. dated December 3, 2004.(8)
3.1	Amended and Restated Certificate of Incorporation of Nuvelo, Inc.(7)
3.2	Amended and Restated By-Laws of Nuvelo, Inc.(10)
4.1	Form of Nuvelo, Inc. Common Stock Certificate.(7)
4.2	Certificate of Designations of Series A Junior Participating Preferred Stock.(7)
4.3	Rights Agreement between Hyseq, Inc. and U.S. Stock Transfer Corporation dated June 5, 1998.(1)
4.4	Amendment to Rights Agreement between Hyseq, Inc. and U.S. Stock Transfer Corporation dated November 9, 2002.(6)
4.5	Amendment to Rights Agreement between Nuvelo, Inc. and U.S. Stock Transfer Corporation dated March 19, 2004.(7)
4.6	Form of Warrant to purchase 1,491,544 shares of Common Stock of Hyseq, Inc. dated January 8, 2002.(2)
4.7	Form of Warrant dated April 5, 2002.(4)
4.8	Replacement Warrant to purchase 195,130 shares of Common Stock of Nuvelo, Inc. dated January 20, 2005.(9)
4.9	Replacement Warrant to purchase 200,000 shares of Common Stock of Nuvelo, Inc. dated January 20, 2005.(9)
4.10	Replacement Warrant to purchase 50,000 shares (pre split) of Common Stock of Nuvelo, Inc. dated June 7, 2005.(11)
4.11	Warrant to purchase 350,000 shares of Common Stock of Nuvelo, Inc. dated August 4, 2005.(12)
4.12	Registration Rights Agreement by and between Nuvelo, Inc. and Kingsbridge Capital Limited dated August 4, 2005.(12)
4.13	Replacement Warrant to purchase 109,607 shares (pre split) of Common Stock of Nuvelo, Inc. dated July 15, 2005.(13)
4.14	Replacement Warrant to purchase 222,536 shares (pre split) of Common Stock of Nuvelo, Inc. dated July 15, 2005.(13)
4.15	Reference is made to Exhibits 3.1 and 3.2.

10.57	Base Salaries for Named Executive Officers, effective August 1, 2006. (14)
10.59*§	Amended and Restated Collaboration and License Agreement dated July 31, 2006 between Nuvelo, Inc. and Archemix Corp.
10.60*	Second Amendment to Loan and Security Agreement dated August 29, 2006 between Silicon Valley Bank and Nuvelo, Inc.
31.1*	Certificate of Chief Executive Officer pursuant to Rule 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certificate of Chief Financial Officer pursuant to Rule 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. sec. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

* Filed herewith.
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(1) Previously filed with the SEC as an Exhibit to and incorporated herein by reference from Hyseq, Inc. s Form 8-K, filed on July 31, 1998, File No. 00-22873.

(2) Previously filed with the SEC as an Exhibit to and incorporated herein by reference from Hyseq, Inc. s Form 10-K filed April 2, 2001, File No. 000-22873.

(3) Previously filed with the SEC as an Exhibit to and incorporated herein by reference from Hyseq, Inc. s Form 10-K, filed on April 1, 2002, File No. 000-22873.

(4) Previously filed with the SEC as an Exhibit to and incorporated herein by reference from Hyseq, Inc. s Form S-3, filed on June 14, 2002, File No. 333-90458.

(5) Previously filed with the SEC as an Exhibit to and incorporated herein by reference from Hyseq, Inc. s Form 8-K, filed on November 12, 2002, File No. 000-22873.

(6) Previously filed with the SEC as an Exhibit to and incorporated herein by reference from Hyseq, Inc. s Form S-4, filed on November 27, 2002, File No. 333-101503.

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(10) Previously filed with the SEC as an Exhibit to and incorporated herein by reference from Nuvelo, Inc. s Form 10-Q, filed on May 10, 2005, File No. 000-22873.

(11) Previously filed with the SEC as an Exhibit to and incorporated herein by reference from Nuvelo, Inc. s Form S-3, filed on July 14, 2005, File No. 333-126591.

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(13) Previously filed with the SEC as an Exhibit to and incorporated herein by reference from Nuvelo, Inc. s Form S-3, filed on September 14, 2005, File No. 333-128316.

(14) Previously filed with the SEC as an Exhibit to and incorporated herein by reference from Nuvelo, Inc. s Form 8-K, filed August 3, 2006, File No. 000-22873.

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SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Nuvelo, Inc. (Registrant)

By: /s/ H. WARD WOLFF
H. Ward Wolff
Senior Vice President, Finance and Chief Financial Officer
(Duly Authorized and Principal Financial Officer)

Dated: November 8, 2006

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