

NUVELO INC  
Form 10-Q  
November 07, 2007  
Table of Contents

---

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**  
**WASHINGTON, D.C. 20549**

\_\_\_\_\_  
**FORM 10-Q**  
\_\_\_\_\_

(Mark One)

**QUARTERLY REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934  
FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2007**

**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**  
(State or Other Jurisdiction of

**36-3855489**  
(I.R.S. Employer

Incorporation or Organization)

Identification Number)

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

(Address of Principal Executive Offices, including Zip Code)

**650-517-8000**

# Edgar Filing: NUVELO INC - Form 10-Q

(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  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  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

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, 2007: 53,388,525

---

---

**Table of Contents**

**Table of Contents**

**NUVELO, INC.**

**FORM 10-Q**

**FOR THE QUARTER ENDED SEPTEMBER 30, 2007**

	<b>PAGE</b>
Part I	
<u>Financial Information</u>	3
<u>Item 1. Condensed Consolidated Financial Statements (unaudited)</u>	3
<u>Condensed Consolidated Balance Sheets as of September 30, 2007 and December 31, 2006</u>	3
<u>Condensed Consolidated Statements of Operations for the Three and Nine Months Ended September 30, 2007 and 2006</u>	4
<u>Condensed Consolidated Statements of Cash Flows for the Nine Months Ended September 30, 2007 and 2006</u>	5
<u>Notes to Condensed Consolidated Financial Statements</u>	6
<u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	12
<u>Item 3. Quantitative and Qualitative Disclosures about Market Risk</u>	18
<u>Item 4. Controls and Procedures</u>	18
Part II	
<u>Other Information</u>	19
<u>Item 1. Legal Proceedings</u>	19
<u>Item 1A. Risk Factors</u>	19
<u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u>	37
<u>Item 3. Defaults Upon Senior Securities</u>	37
<u>Item 4. Submission of Matters to a Vote of Security Holders</u>	37
<u>Item 5. Other Information</u>	37
<u>Item 6. Exhibits</u>	37
<u>Signature</u>	39

**Table of Contents****PART I. FINANCIAL INFORMATION****ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
NUVELO, INC.****CONDENSED CONSOLIDATED BALANCE SHEETS****(unaudited)**

	September 30, 2007	December 31, 2006
	(In thousands)	
<b>ASSETS</b>		
Cash and cash equivalents	\$ 45,128	\$ 60,335
Short-term investments	66,126	92,791
Collaboration receivables	430	8,559
Other current assets	2,456	4,650
<b>Total current assets</b>	114,140	166,335
Restricted cash	6,000	
Equipment, leasehold improvements and software, net	9,461	11,978
Goodwill	4,671	4,671
Other assets	1,131	1,421
<b>Total assets</b>	\$ 135,403	\$ 184,405
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Accounts payable	\$ 2,217	\$ 7,026
Accrued employee liabilities	2,575	3,098
Accrued clinical trial and drug manufacturing costs	3,992	14,415
Current portion of deferred revenue	250	3,640
Current portion of deferred rent	1,386	1,342
Current portion of accrued facility exit costs	7,692	7,674
Accrued interest	2,254	2,172
Current portion of bank loans		1,367
Related party line of credit	229	2,292
Other current liabilities	810	813
<b>Total current liabilities</b>	21,405	43,839
Non-current portion of deferred revenue	16,125	44,533
Non-current portion of deferred rent	5,958	6,998
Non-current portion of accrued facility exit costs	14,398	18,942
Non-current portion of bank loans		125
Other liabilities	91	125
<b>Total liabilities</b>	57,977	114,562
Stockholders' equity:		
Preferred stock		
Common stock	53	53
Additional paid-in capital	536,245	527,992

Edgar Filing: NUVELO INC - Form 10-Q

Accumulated other comprehensive income	5	10
Accumulated deficit	(458,877)	(458,212)
<b>Total stockholders equity</b>	77,426	69,843
<b>Total liabilities and stockholders equity</b>	\$ 135,403	\$ 184,405

See accompanying notes to condensed consolidated financial statements.

**Table of Contents****NUVELO, INC.****CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS****(unaudited)**

	Three Months Ended		Nine Months Ended	
	September 30, 2007	September 30, 2006	September 30, 2007	September 30, 2006
	(In thousands, except per share data)			
Contract revenues	\$ 63	\$ 908	\$ 46,798	\$ 2,978
Operating expenses:				
Research and development	9,494	23,134	33,452	49,929
General and administrative	4,204	6,568	16,843	24,034
Restructuring	2,336		2,336	
Total operating expenses	16,034	29,702	52,631	73,963
Operating loss	(15,971)	(28,794)	(5,833)	(70,985)
Interest income	1,638	2,221	5,269	6,280
Interest expense	(25)	(95)	(101)	(512)
Net loss	\$ (14,358)	\$ (26,668)	\$ (665)	\$ (65,217)
Basic and diluted net loss per share	\$ (0.27)	\$ (0.51)	\$ (0.01)	\$ (1.28)
Weighted average shares used in computing basic and diluted net loss per share	53,361	52,022	53,310	50,943

See accompanying notes to condensed consolidated financial statements.

**Table of Contents****NUVELO, INC.****CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS****(unaudited)**

	<b>Nine Months Ended September 30,</b>	
	<b>2007</b>	<b>2006</b>
	<b>(In thousands)</b>	
<b>Cash flows from operating activities:</b>		
Net loss	\$ (665)	\$ (65,217)
<b>Adjustments to reconcile net loss to net cash used in operating activities:</b>		
Depreciation and amortization	1,761	2,403
Stock-based compensation expense	7,876	9,471
Non-cash facility exit costs	1,485	
Impairment of assets	1,117	
Change in fair value of warrant liability		2,791
Loss (gain) on sale or disposal of assets	5	(276)
Other non-cash items		(134)
<b>Changes in operating assets and liabilities:</b>		
Collaboration receivables	8,129	(6,962)
Clinical trial supplies		(5,448)
Other current assets	2,175	(3,440)
Other assets	290	(222)
Accounts payable	(4,809)	(363)
Accrued employee liabilities	(523)	528
Accrued clinical trial and drug manufacturing costs	(10,423)	5,360
Deferred revenue	(31,798)	47,270
Deferred rent	(996)	(5,720)
Accrued facility exit costs	(6,011)	
Accrued interest	82	(979)
Other liabilities	(5)	(1,152)
<b>Net cash used in operating activities</b>	<b>(32,310)</b>	<b>(22,090)</b>
<b>Cash flows from investing activities:</b>		
Maturities of short-term investments	119,578	54,862
Purchases of short-term investments	(92,912)	(77,369)
Increase in restricted cash	(6,000)	
Purchases of equipment, leasehold improvements and software	(353)	(1,897)
Proceeds from sale of assets		537
<b>Net cash provided by (used in) investing activities</b>	<b>20,313</b>	<b>(23,867)</b>
<b>Cash flows from financing activities:</b>		
Payments on bank loans, note payable and capital lease obligations	(1,524)	(5,181)
Payments on related party line of credit	(2,063)	(2,063)
Proceeds from issuance of common stock from public offerings, net		112,006
Proceeds from issuance of common stock upon exercise of options, warrants and under employee stock purchase plan	377	5,486
<b>Net cash provided by (used in) financing activities</b>	<b>(3,210)</b>	<b>110,248</b>

## Edgar Filing: NUVELO INC - Form 10-Q

Net increase (decrease) in cash and cash equivalents	(15,207)	64,291
Cash and cash equivalents at beginning of period	60,335	37,764
Cash and cash equivalents at end of period	\$ 45,128	\$ 102,055
Non-cash investing and financing activities:		
Acquisition of leasehold improvements under tenant improvement allowances	\$	\$ 992
Acquisition of equipment under capital leases		117
Capitalization of estimated future building restoration costs		19
See accompanying notes to condensed consolidated financial statements.		



---

**Table of Contents**

**NUVELO, INC.**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**September 30, 2007**

**(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 U.S. generally accepted accounting principles (GAAP) 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 GAAP for complete financial statements. The accompanying financial information is unaudited but includes all adjustments (consisting only 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, 2006 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. For further information, refer to the consolidated financial statements and footnotes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2006.

The unaudited condensed consolidated financial statements include the accounts of Nuvelo, Inc. and Hyseq Diagnostics, Inc., Nuvelo's wholly owned and inactive subsidiary. All inter-company transactions and accounts have been eliminated on consolidation. Nuvelo is focused on the discovery, development and commercialization of novel acute cardiovascular and cancer therapies. The Company's development pipeline includes alfimeprase, NU206, NU172 and a cancer antibody discovery program. Nuvelo has suspended development of rNAPc2 in all indications including cancer and acute coronary syndromes (ACS).

***Use of Estimates***

Conformity with GAAP requires the use of estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent amounts. 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 whether alternative future use exists for materials and equipment acquired for use in research and development, in estimating goodwill and long-lived asset impairment, facility exit costs, clinical trial accruals, stock-based compensation, income taxes and in determining revenue recognition.

On June 30, 2007, the Company entered into a Settlement Agreement with Avecia, its third-party alfimeprase manufacturer, in which the parties waived certain obligations and liabilities that arose between them prior to June 30, 2007. Specifically, the parties waived any obligations and liabilities between them for additional payment, refund, rework or replacement associated with batches of alfimeprase manufactured before June 30, 2007, with the exception of two batches that were to be released after June 30, 2007. The Company also agreed to pay Avecia for certain raw materials and other services. Pursuant to this Settlement Agreement, during the second quarter of 2007, the Company recorded a reversal of prior-period Avecia-related accruals, resulting in a \$2.0 million reduction of research and development expenses, net of cost sharing credits from the collaboration partner, which reduced the net loss per share by \$0.04 for the nine months ended September 30, 2007. During the three months ended September 30, 2007, the Company determined that one of the two batches mentioned above could not be released for clinical use and that it has no further payment obligation associated with this batch. Accordingly, the Company reversed a prior-period accrual related to this batch, resulting in a \$0.9 million reduction of research and development expenses and a decrease of net loss per share by \$0.02 for the three and nine months ended September 30, 2007.

***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.



**Table of Contents****Significant Accounting Policies**

With the exception noted below, during the nine months ended September 30, 2007, there have been no changes to the accounting policies described in the Company's annual report on Form 10-K for the fiscal year ended December 31, 2006.

On January 1, 2007, the Company adopted the provisions of FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes - An Interpretation of FASB Statement No. 109* (FIN 48). FIN 48 provides detailed guidance for the financial statement recognition, measurement and disclosure of uncertain tax positions recognized in the financial statements in accordance with SFAS No. 109. Tax positions must meet a more-likely-than-not recognition threshold at the effective date to be recognized upon the adoption of FIN 48 and in subsequent periods. The adoption of FIN 48 did not have a material impact on the Company's results of operations or financial position.

The tax years 2003 through 2006 remain open to examination by the major taxing jurisdictions in which the Company operates. The Company does not expect any material changes to unrecognized tax positions within the next twelve months.

**Restricted Cash**

Restricted cash represents a certificate of deposit used to collateralize a letter of credit as required by the lease agreement for the unoccupied facility at 985 Almanor Avenue in Sunnyvale, California (see Note 5, Facility Exit Costs, for discussion of the related lease commitment).

**2. Net Loss Per Share**

The Company has computed net loss per common share according to Statement of Financial Accounting Standards No. 128, *Earnings Per Share*, which requires disclosure of basic and diluted earnings per share. Basic net loss per share is computed using the weighted-average number of common shares outstanding during the period. Diluted net loss per share reflects the potential dilution of securities by adding other potential common shares to the weighted-average number of common shares outstanding during the period, if dilutive.

In calculating diluted net loss per share, the Company excluded the following outstanding shares of common stock equivalents, as the effect would be anti-dilutive (in thousands):

	September 30,	
	2007	2006
Stock options and restricted stock units	7,572	8,270
Warrants	850	1,227
<b>Total</b>	<b>8,422</b>	<b>9,497</b>

**3. Stock-based Compensation**

Stock-based compensation expense related to employee stock options, restricted stock units and employee stock purchase plan purchase rights was as follows (in thousands):

	Nine Months Ended			
	Three Months Ended		September 30,	
	September 30,	September 30,	2007	2006
	2007	2006		
Research and development	\$ 783	\$ 1,087	\$ 2,924	\$ 3,668
General and administrative	1,170	1,325	4,023	5,465
Restructuring	926		926	
<b>Total</b>	<b>\$ 2,879</b>	<b>\$ 2,412</b>	<b>\$ 7,873</b>	<b>\$ 9,133</b>

## Edgar Filing: NUVELO INC - Form 10-Q

Stock-based compensation expense related to non-employees was negligible in these periods.

The Company has not recognized, and does not expect to recognize in the near future, any tax benefit related to employee stock-based compensation expense, as a result of the full valuation allowance on its net deferred tax assets.

**Table of Contents**

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,	
	2007	2006	2007	2006
Expected term	4.80 years	5.29 years	4.94 years	5.33 years
Expected volatility	0.92	0.58	0.88	0.61
Risk-free interest rate	4.50%	4.84%	4.66%	4.88%
Expected dividend yield				
Weighted-average grant date fair value per share	\$ 1.64	\$ 9.39	\$ 2.48	\$ 9.48

The Company granted options to purchase 61,200 and 1,577,750 shares of common stock with total estimated fair values of \$0.1 million and \$3.9 million in the three and nine months ended September 30, 2007, respectively, including options granted to a non-employee. The Company granted options to purchase 1,442,200 and 2,209,700 shares of common stock 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 options granted to non-employees. Of the options granted in the nine months ended September 30, 2007, options to purchase 95,000 shares vest immediately and options to purchase 1,307,750 shares vest ratably over a three-year period from the date of grant. There were a negligible number of options exercised in the nine months ended September 30, 2007.

The Company granted 183,000 restricted stock units during the nine months ended September 30, 2007, of which 97,000 were forfeited during the period, with all such units having a grant date fair value of \$3.54. The fair value of employee restricted stock units granted under the Company's stock incentive plans is equal to the average of the high and low prices of the Company's common stock on the date of grant, in accordance with the Company's normal stock award pricing practice. No restricted stock units vested during the nine months ended September 30, 2007. The unamortized compensation expense related to unvested restricted stock units as of September 30, 2007, excluding estimated forfeitures, was \$0.5 million. The weighted average period over which compensation expense related to these restricted stock units is expected to be recognized is 2.34 years.

The Company terminated two executives in connection with its reduction in force announced in August 2007 (see Note 6, Restructuring). The two former executives were entitled to a 12-month acceleration in vesting of their options in accordance with the Company's Executive Change in Control and Severance Benefit Plan. The Company recorded \$0.9 million of stock-based compensation expense as a result of this acceleration in vesting of options and classified this expense as part of restructuring costs.

On March 14, 2007, the 2004 Equity Incentive Plan and the Employee Stock Purchase Plan were amended by the Company's Board of Directors to increase the number of shares available for issuance under the plans by 2,000,000 and 500,000 shares, respectively. On May 31, 2007, the increases for the plans were approved by the Company's stockholders.

**4. 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		Nine Months Ended	
	September 30, 2007	September 30, 2006	September 30, 2007	September 30, 2006
Net loss, as reported	\$ (14,358)	\$ (26,668)	\$ (665)	\$ (65,217)
Change in unrealized gain (loss) on hedging instruments		72	(6)	780
Change in unrealized gain on available-for-sale securities	16	86	1	65
Comprehensive loss	\$ (14,342)	\$ (26,510)	\$ (670)	\$ (64,372)

**5. Facility Exit Costs**

## Edgar Filing: NUVELO INC - Form 10-Q

The Company currently has a lease commitment for a 139,000-square-foot facility at 985 Almanor Avenue, Sunnyvale, California, which expires on May 30, 2011. In September 2005, Nuvelo relocated the Company's headquarters to a facility located at 201 Industrial Road, San Carlos, California. Through December 2006, the Company retained the Sunnyvale facility as a storage location. In December 2006, the Company approved a plan to exit the Sunnyvale facility and restore the building for potential sublease. On December 31, 2006, the facility was exited and the Company accrued \$26.6 million to reflect the estimated present value of future lease-related payments less estimated net income from sublease rental. The future lease-related payments are scheduled to be made periodically until the lease expires.

**Table of Contents**

The balance of accrued facility exit costs represents the fair value of the lease liability based on assumptions regarding the vacancy period, sublease terms, and the probability of subleasing this space. The estimates and assumptions are re-evaluated each quarter and are based upon current market data, including vacancy rates and lease activities for similar facilities within the area. The following table summarizes the activity related to facility exit costs liabilities for the nine months ended September 30, 2007 (in thousands):

Balance as of December 31, 2006	\$ 26,616
Amounts paid during the period	(6,011)
Non-cash accretion	1,485
Balance as of September 30, 2007	\$ 22,090

The non-cash accretion totaling \$0.5 million and \$1.5 million was included in general and administrative expenses for the three and nine months ended September 30, 2007, respectively.

**6. Restructuring**

On August 1, 2007, the Company announced a reduction in its workforce by approximately 30 percent to realign its organization to focus on core development programs that it believes will produce nearest-term proof-of-concept data. In addition, the Company suspended development of rNAPc2 in all indications including cancer and ACS. As a result of the restructuring plan, the Company recorded a restructuring expense of \$2.3 million in the three and nine months ended September 30, 2007, including \$1.4 million of termination benefits and \$0.9 million of non-cash stock-based compensation expense. As of September 30, 2007, \$0.7 million of termination benefits remained unpaid, which were classified under accrued employee liabilities in the Condensed Consolidated Balance Sheet, and the Company substantially completed the restructuring plan as of that date.

**7. Borrowing Arrangements**

The Company had a Loan and Security Agreement in place with Silicon Valley Bank (SVB) under which it had a fully-utilized term loan facility of \$4.1 million and an \$8.0 million revolving credit line facility which expired on August 28, 2007. The term loan facility was utilized in two draw-downs, the first being for \$2.6 million, which was being repaid in 30 equal monthly installments, plus accrued interest of 6.43% per annum, through October 1, 2007; the second draw-down of \$1.5 million was being repaid in 36 equal monthly installments, plus accrued interest of 6.78% per annum, through March 1, 2008. The Company had not drawn down any of the funds available under the \$8.0 million revolving credit line, although \$6.0 million of this amount was 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 was reserved as collateral for foreign exchange hedging contracts with SVB and a portion was available for working capital and other general business needs. Any borrowings under this line bore interest at SVB's prime rate and would cause replacement collateral to be required for the items above. In September 2007, the Company repaid in full the remaining principal balance under the SVB term loan facility and did not renew the Loan and Security Agreement after its expiration. The \$6.0 million letter of credit is now being collateralized by a certificate of deposit of the same amount, which is recorded as restricted cash, and the Company has no outstanding foreign currency hedging contracts.

**8. Common Stock**

In August 2005, the Company entered into a Committed Equity Financing Facility (CEFF) with Kingsbridge Capital Ltd. (Kingsbridge), under which Kingsbridge 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. 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 eight-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, which occurred in October 2005, and to maintain its effectiveness. 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





**Table of Contents**

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 a further 568,247 shares for gross proceeds of \$10.0 million in October 2006, and may sell the balance of 5,667,353 shares to Kingsbridge through the expiration of the CEFF in October 2008, limited to the remaining \$50.6 million available under the facility, subject to the limitations discussed above.

The fair value of the warrant issued to Kingsbridge on the date of grant of \$2.1 million was initially recorded as a deferred financing cost to additional paid-in capital, with the opposing entry being to other current liabilities in the balance sheet due to the existence of a cash payment feature in the agreement that compensates Kingsbridge based on any reduction in the fair value of shares held by Kingsbridge as a result of this agreement during a period in which Nuvelo fails to maintain the effectiveness of the abovementioned registration statement, or electively imposes a trading blackout (*i.e.*, a registration payment arrangement). The amount of compensation is payable in cash in both circumstances, or, at the sole discretion of Nuvelo, in shares of the Company's common stock in the event of a trading blackout. Through September 30, 2006, the current liability was marked-to-market at each quarter end, using the Black-Scholes option-pricing model, with the change being recorded to general and administrative expenses, which included a charge of \$0.4 million and \$2.8 million for the three and nine months ended September 30, 2006, respectively. On October 1, 2006, the Company adopted the provisions of FASB Staff Position No. EITF 00-19-2, *Accounting for Registration Payment Arrangements*, which requires that contingent obligations to make future payments under a registration payment arrangement be recognized and measured separately in accordance with Statement of Financial Accounting Standards No. 5, *Accounting for Contingencies*. The Company believes the likelihood of such a cash payment to be not probable and therefore does not need to recognize a liability for such obligations. Accordingly, on October 1, 2006, a cumulative-effect adjustment was recorded in the statement of operations to reflect the difference between the initial fair value of this warrant and its fair value as of this date, and the initial fair value of the warrant was reclassified from other current liabilities to additional paid-in capital in the balance sheet.

**9. Collaborative Agreements*****Bayer***

The Company and Bayer agreed to terminate their January 2006 license and collaboration agreement for the development and commercialization of alfimeprase effective June 30, 2007. The Company agreed to waive Bayer's obligation to provide Nuvelo 12 months' notice of termination in consideration of Bayer's agreement to pay Nuvelo a lump sum of \$15.0 million. Nuvelo has also granted Bayer the option to reacquire rights to alfimeprase upon the initiation of a pivotal stroke trial or upon Nuvelo's public announcement that it is discontinuing further development of alfimeprase in the stroke indication. The notice period during which Bayer may exercise the option begins upon the Company making certain information available to Bayer and lasts for 30 days after delivery of the information. If Bayer exercises the option, Bayer will make a \$15.0 million non-refundable payment to Nuvelo and the parties will enter into a new license and collaboration agreement on substantially the same terms as the original agreement, with the exception of the \$50.0 million upfront payment and the milestone payment related to a Phase 2 trial in a stroke indication that were part of the terms of the original agreement.

Under the original terminated agreement, Bayer had the right to commercialize alfimeprase in all territories outside the United States and, if commercialized, would pay tiered royalties on net sales of alfimeprase, if any. Nuvelo retained all commercialization rights and profits from any alfimeprase sales in the United States. The Company received a non-refundable, up-front cash payment from Bayer of \$50.0 million upon entry into the agreement. The \$50.0 million up-front cash payment was deferred upon receipt and was being recognized as revenue on a straight-line basis over the performance period under the agreement, estimated to be through September 2020. Nuvelo was responsible for 60 percent of any costs for alfimeprase global development programs, and Bayer was responsible for the remaining 40 percent, where global development programs refers to clinical trials conducted to support regulatory approval in major countries around the world.

As a result of the termination of the license and collaboration agreement, the Company recognized revenues of \$45.8 million, the remaining unamortized balance of the cash up-front payment, in the three months ended June 30, 2007, as the Company had no additional obligations or deliverables under the agreement. The \$15.0 million payment related to the termination was recorded as deferred revenue and will remain as such until the Bayer option is exercised or expires at the conclusion of the notice period.

Under the cost-sharing arrangement, the following amounts were billed to Bayer for Nuvelo's alfimeprase-related global development spending: \$0 million and \$3.0 million for the three and nine months ended September 30, 2007, and \$7.5 million and \$20.3 million for the three and nine months ended September 30, 2006, respectively. These amounts have been recorded as an offset to research and development expense in the statements of operations.

---

## **Table of Contents**

### ***Archemix***

In July 2006, Nuvelo entered into a collaboration agreement with Archemix Corporation. Under the 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 was recorded as a research and development expense, and is also funding at least \$5.25 million of Archemix's research over the first three years of the agreement. 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. At the initiation of the first Phase 3 study for any licensed compound, Archemix also 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. 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 total gross proceeds raised by Archemix in a qualified public offering of Archemix stock occurring within five years of the effective date of the collaboration agreement. On July 25, 2007, Archemix filed a registration statement for an initial public offering of its common stock with the Securities and Exchange Commission. On October 23, 2007, Archemix disclosed that it plans an initial public offering of 4.5 million shares of its common stock at an expected price between \$12 and \$14 per share. Concurrent with the closing of its initial public offering, the Company expects Archemix will offer shares of its common stock to the Company in a private placement, of which the total offering price is estimated to be approximately \$9.0 million if calculated at \$13 per share, the mid-point of the per share price range.

### ***Kirin Pharma Company, Limited***

In March 2005, Nuvelo entered into a collaboration agreement with the Kirin Pharma Company, Limited (Kirin) for the development and commercialization of NU206. In accordance with the terms of this agreement, the Company received a \$2.0 million upfront cash payment from Kirin in April 2005, which was deferred and is being recognized on a straight-line basis over the related performance period. Nuvelo leads 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 Nuvelo and 40 percent by Kirin. If this agreement is terminated, or Kirin or Nuvelo elects 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.

## **10. Transactions with Related Parties**

Dr. Rathmann, a former member of the Company's Board of Directors and currently 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 bore 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. As of September 30, 2007, the remaining principal and accrued interest to date totaled \$2.5 million, and the interest rate on the note on this date was 8.75%. The Company paid in full the remaining principal and accrued interest in October 2007.

## **11. 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.

---

## **Table of Contents**

### **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 drugs for acute cardiovascular disease, cancer and other debilitating medical conditions. Our development pipeline includes alfimeprase, a direct acting fibrinolytic in Phase 2 development for the potential treatment of thrombotic-related disorders including acute ischemic stroke and catheter occlusion (CO); preclinical candidate NU206 for the potential treatment of chemotherapy/radiation therapy-induced mucositis and inflammatory bowel disease; and preclinical candidate NU172, a direct thrombin inhibitor for use as a short-acting anticoagulant during medical or surgical procedures. In addition, we expect to continue our research programs in leukemia therapeutic antibodies and Wnt signaling pathway therapeutics to further expand our pipeline and create additional partnering and licensing opportunities.

On August 1, 2007, we announced a reduction in our workforce by approximately 30 percent to realign our organization to focus on core development programs that we believe will produce nearest-term proof-of-concept data. As a result of the reduction in workforce, we have less than 80 employees, a reduction of 45 percent from year end 2006. In addition, we announced the decision to suspend development of rNAPc2 in all indications including cancer and acute coronary syndromes.

As a result of the restructuring plan, we recorded a restructuring expense of \$2.3 million in the third quarter of 2007, and we have substantially completed the restructuring plan as of September 30, 2007. We expect this realignment of personnel and reprioritization of programs to result in reduced annual expenses of approximately \$15.0 million as compared to the expense level prior to this restructuring.

#### ***Alfimeprase***

Alfimeprase is a recombinant direct-acting fibrinolytic, or blood clot dissolver, that has the potential to rapidly and directly degrade fibrin, a protein that provides the scaffolding for blood clots, when delivered through a catheter at the site of a blood clot. In addition, alfimeprase's thrombolytic activity appears to be localized to the site of delivery because it is rapidly inactivated by alpha-2 macroglobulin, a naturally occurring protein in the blood, as it moves away from the site of delivery and into the general blood circulation. Alfimeprase is currently being evaluated as a potential treatment for acute ischemic stroke and CO.

**Acute Ischemic Stroke** The Phase 2 CARNEROS-1 (Catheter Directed Alfimeprase for Restoration of Neurologic Function and Rapid Opening of Arteries in Stroke) proof-of-concept trial with alfimeprase in acute ischemic stroke is expected to begin in the fourth quarter of 2007. CARNEROS-1 is a multi-center, open-label, dose escalation study beginning with doses of 1 mg, 5 mg and 10 mg, that will enroll up to 100 patients within 3-9 hours of stroke onset.

**CO** In August 2007, we re-initiated the SONOMA-3 trial with a modified protocol, evaluating a single 10 mg dose of alfimeprase with a concentration of 5 mg/mL in up to 100 patients. We expect to complete enrollment and provide top-line data from this trial in the first half of 2008. In addition, we will report full data from the first Phase 3 trial in the CO program, SONOMA-2, at the American Society of Hematology 49<sup>th</sup> Annual Meeting and Exposition in December 2007. In the SONOMA-2 trial, alfimeprase restored catheter function in patients with occluded catheters within 15 minutes with a p-value of 0.022. The data from SONOMA-2 did not, however, meet the more stringent p-value required for a single pivotal trial, less than 0.00125, nor did it meet the company's target product profile for commercial success. P-values are used to indicate the probability that results observed in two different samples are different due to chance alone, as opposed to a benefit due to the intervention, such as treatment with alfimeprase.

---

**Table of Contents**

We agreed to terminate our license and collaboration agreement with Bayer for the development and commercialization of alfimeprase effective June 30, 2007. We waived Bayer's obligation to provide us 12 months' notice of termination in consideration of Bayer's agreement to pay Nuvelo a lump sum of \$15.0 million. We also granted Bayer the option to reacquire rights to alfimeprase upon the initiation of a pivotal stroke trial or upon our public announcement that we are discontinuing further development of alfimeprase in the stroke indication. If Bayer exercises the option, Bayer will make a \$15.0 million non-refundable payment to us and we and Bayer will enter into a new license and collaboration agreement on substantially the same terms as the original agreement, with the exception of the \$50.0 million upfront payment and the milestone payment related to a Phase 2 trial in a stroke indication that were part of the terms of the original agreement. Under the original terminated agreement, we were responsible for 60 percent of any costs for alfimeprase global development programs, and Bayer was responsible for the remaining 40 percent, where "global development programs" refers to clinical trials conducted to support regulatory approval in major countries around the world. For the nine months ended September 30, 2007, a total of \$3.0 million was billed to Bayer for our alfimeprase-related U.S. development spending as a result of this cost-sharing arrangement, which was recorded as an offset to research and development expense in the statement of operations. Our cost-sharing arrangement with Bayer ended as of June 30, 2007.

***NU206***

NU206 (R-spondin1) is a recombinant, secreted protein that acts as a highly specific and potent stimulator of gastrointestinal epithelial cells, as demonstrated in early animal studies. Preclinical studies suggest NU206 can promote growth and repair of these tissues in animal models of radiation treatment or chemotherapy for cancer, as well as in animal models of inflammatory bowel disease. We have successfully concluded our discussions with the FDA and now have regulatory clearance to begin clinical evaluation of NU206. We are actively working with a number of investigator sites and expect to enroll the first patient in our Phase 1 trial of NU206 in the first half of 2008.

In March 2005, we entered into a collaboration agreement with the Kirin Pharma Company, Limited for the development and commercialization of NU206. 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.

***NU172***

NU172 is an aptamer that was designed to directly inhibit thrombin's ability to generate fibrin, the protein that provides the scaffolding for blood clots. Data from early animal models suggest that NU172 has the potential to be a potent anticoagulant with predictable anticoagulant effects, rapid onset and offset of action, reduced bleeding complications compared to the current standard of care, which is the combination of heparin and its antidote, protamine, and no risk of heparin-induced thrombocytopenia. NU172 is currently being evaluated in IND-enabling studies, and we expect to initiate a Phase 1 trial with NU172 in the fourth quarter of 2007 or the first quarter of 2008. We expect to provide data from this trial in 2008.

We are developing NU172 through a collaboration with Archemix Corporation, under which we are responsible for development and worldwide commercialization of NU172 and other potential product candidates that may be developed under this collaboration. A \$1.0 million milestone fee will be payable to Archemix within 30 days of dosing the first patient in a Phase 1 trial for NU172.

**Results of Operations*****Contract Revenues***

Contract revenues were \$0.1 million and \$46.8 million in the three and nine months ended September 30, 2007, compared to \$0.9 million and \$3.0 million in the corresponding periods of 2006. The decrease in the three months and increase in the nine months ended September 30, 2007 was primarily due to the recognition of \$45.8 million of the \$50.0 million up-front license fee, which was received from Bayer in January 2006, as a result of the termination of the collaboration agreement in June 2007. The up-front license fee had been recorded as deferred revenue upon receipt and was being recognized on a straight-line basis over the performance period under the agreement, originally estimated to be through September 2020.

We expect the amortization of existing deferred revenue to be \$63,000 for the fourth quarter of 2007 due to the ongoing revenue recognition from an up-front license fee received from Kirin under the NU206 collaboration agreement. Our revenues may vary significantly from quarter to quarter as a result of any licensing or collaboration activities, or the termination of existing collaborations. 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.



**Table of Contents****Research and Development Expenses**

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

R&D expenses for our significant programs were as follows for the periods indicated (including upfront fees and collaboration cost-sharing credits, and excluding occupancy costs and stock-based compensation expense):

Program	Since Inception	Nine Months Ended	
		September 30, 2007	2006
(In millions)			
Alfimeprase	\$ 116.5	\$ 5.4	\$ 22.0
NU172	12.2	7.1	4.5
NU206	8.9	2.9	1.5

R&D expenses were \$9.5 million for the three months ended September 30, 2007 compared to \$23.1 million for the corresponding period in 2006, net of cost sharing credits billable to collaboration partners of \$0.3 million and \$8.1 million, respectively. The decrease of \$13.6 million in 2007 was primarily due to a decrease in expenses related to alfimeprase of \$9.4 million and NU172 of \$1.9 million, as well as reductions of \$1.0 million in occupancy costs and \$0.3 million in employees' stock-based compensation expense.

R&D expenses were \$33.5 million for the nine months ended September 30, 2007 compared to \$49.9 million for the corresponding period in 2006, net of cost sharing credits billable to collaboration partners of \$4.9 million and \$23.3 million, respectively. The decrease of \$16.4 million in 2007 was primarily due to a decrease in expenses related to alfimeprase of \$16.6 million and reductions of \$2.5 million in occupancy costs and \$0.7 million in employees' stock-based compensation expense, partially offset by increases in expenses related to NU172 and NU206 which totaled \$4.0 million.

The decrease in expenses related to alfimeprase in 2007 was largely due to a significant reduction in clinical trial related expenditures as our two alfimeprase Phase 3 trials were suspended during the first half of 2007. Additionally, the decrease in alfimeprase-related expenses in 2007 was due to the Settlement Agreement we entered into with our contract manufacturer in June 2007, pursuant to which certain obligations to this contract manufacturer we had previously accrued for were waived. Accordingly, we recorded a credit to R&D expenses of approximately \$2.0 million, net of cost sharing with our collaboration partner, in June 2007. During the three months ended September 30, 2007, we determined that one of the batches manufactured by this contract manufacturer could not be released for clinical use, and pursuant to the provisions of the Settlement Agreement, we have no further payment obligation associated with this failed batch. Accordingly, we recorded a credit to R&D expenses of approximately \$0.9 million.

We expect R&D expenses related to alfimeprase to increase from the current level for the remainder of 2007, as we have re-initiated the SONOMA-3 trial and expect to begin the Phase 2 CARNEROS-1 proof-of-concept trial in the second half of 2007. We expect to continue to invest significantly in NU206 and NU172 as we advance these drug candidates through clinical development.

The timing, cost of completing the clinical development of any product candidate, and any potential 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.

**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, professional fees, insurance, facilities and depreciation expenses, and various other administrative costs.

G&A expenses were \$4.2 million in the three months ended September 30, 2007, compared to \$6.6 million for the corresponding period in 2006. The decrease of \$2.4 million in 2007 was primarily due to a \$1.4 million decrease in personnel related costs, a \$0.4 million decrease in commercialization-related expenses for alfimeprase and a \$0.5 million decrease in occupancy costs as a result of the exit charges accrued in December 2006 related to the facility in Sunnyvale, California. The 2006 period also included a \$0.4 million charge due to the change in fair

## Edgar Filing: NUVELO INC - Form 10-Q

value of a warrant. The decrease was partially offset by a \$0.5 million non-cash accretion expense related to the exit charges accrued for the Sunnyvale facility.

**Table of Contents**

G&A expenses were \$16.8 million in the nine months ended September 30, 2007, compared to \$24.0 million for the corresponding period in 2006. The decrease of \$7.2 million was primarily due to a non-cash charge of \$2.8 million in the 2006 period for the change in fair value of a warrant, a decrease in personnel costs of \$2.7 million, of which \$1.4 million was employee stock-based compensation expense, and reductions of \$2.0 million in occupancy costs as a result of the exit charges accrued in December 2006 related to the facility in Sunnyvale, California, \$1.4 million in commercialization-related expenses for alimeprase and \$0.5 million in other consulting and professional fees. These decreases were partially offset by a \$1.1 million charge related to the impairment of software implementation costs and a \$1.5 million non-cash accretion expense related to the exit charges accrued for the Sunnyvale facility.

**Restructuring Expense**

As a result of the restructuring plan discussed above, we recorded a restructuring expense of \$2.3 million in the three months ended September 30, 2007, including \$1.4 million of termination benefits and \$0.9 million of non-cash stock-based compensation expense.

**Interest Income (Expense), Net**

We had net interest income of \$1.6 million and \$5.2 million in the three and nine months ended September 30, 2007, respectively, compared to \$2.1 million and \$5.8 million in the corresponding periods of 2006. Interest income has been decreasing due to declining cash and investment balances, offset by a reduction in interest expense as a result of reduced outstanding debt obligations.

**Net Loss**

Since our inception, we have incurred significant net losses, and as of September 30, 2007, our accumulated deficit was \$458.9 million. During the nine months ended September 30, 2007, we recorded a net loss of \$0.7 million, compared to a net loss of \$65.2 million in the corresponding period of 2006. The decrease in net loss was primarily due to the recognition of the remaining unamortized balance of the Bayer up-front license payment in the second quarter of 2007 and a reduction in R&D expenses noted above.

We expect to continue to incur significant losses from continuing operations for the foreseeable future, as we continue development of our drug candidates. In addition, we expect to incur significant costs as we further expand research and development of potential biopharmaceutical product candidates and potentially in-license other drug candidates.

**Liquidity and Capital Resources****Cash and Cash Equivalents, Short-term Investments and Restricted Cash**

	September 30,	December 31,
	2007	2006
	(In thousands)	
Cash and cash equivalents	\$ 45,128	\$ 60,335
Short-term investments	66,126	92,791
Restricted cash	6,000	
	\$ 117,254	\$ 153,126

As of September 30, 2007, we had total cash and cash equivalents, short-term investments and restricted cash of \$117.3 million, as compared to \$153.1 million as of December 31, 2006. The decrease of \$35.8 million resulted primarily from operating expenditures during the period.

As of September 30, 2007, all of our short-term investments in marketable securities 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*. 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.





**Table of Contents****Cash Flows from Operating, Investing and Financing Activities**

	Nine Months Ended	
	September 30, 2007	September 30, 2006
	(In thousands)	
Net cash provided by (used in):		
Operating activities	\$ (32,310)	\$ (22,090)
Investing activities	20,313	(23,867)
Financing activities	(3,210)	110,248
Net increase (decrease) in cash and cash equivalents	\$ (15,207)	\$ 64,291

Net cash used in operating activities was \$32.3 million in the nine months ended September 30, 2007, compared to \$22.1 million in the corresponding period of 2006. The increase of \$10.2 million was primarily due to the \$50.0 million up-front license fee received from Bayer in the 2006 period, partially offset by the \$15 million received from Bayer related to the termination of the collaboration agreement and an overall reduction in operating expenses in the 2007 period.

Net cash provided by investing activities was \$20.3 million in the nine months ended September 30, 2007, compared to \$23.9 million used in investing activities in the corresponding period of 2006. The change of \$44.2 million was primarily due to an increase in maturities, net of purchases, of short-term investments.

Net cash used in financing activities was \$3.2 million in the nine months ended September 30, 2007, compared to \$110.2 million provided by financing activities in the corresponding period of 2006. The change of \$113.4 million was primarily due to net proceeds of \$112.0 million from a public offering in the 2006 period.

**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 August 2005, we entered into a Committed Equity Financing Facility (CEFF) with Kingsbridge Capital Ltd. (Kingsbridge), under which Kingsbridge committed to purchase up to a total of \$75.0 million of our common stock, not to exceed 8,075,000 shares, within a three-year period, subject to certain conditions and limitations. Under the CEFF, we sold 1,839,400 shares for gross proceeds of \$14.4 million in the fourth quarter of 2005, and a further 568,247 shares for gross proceeds of \$10.0 million in October 2006, and may sell the balance of 5,667,353 shares to Kingsbridge through the expiration of the CEFF in October 2008, limited to the remaining \$50.6 million available under the facility, and subject to certain other limitations (see Note 8 to the Condensed Consolidated Financial Statements elsewhere in this filing).

We had a Loan and Security Agreement in place with Silicon Valley Bank (SVB) under which we had a fully-utilized term loan facility of \$4.1 million and an \$8.0 million revolving credit line facility which expired on August 28, 2007. The term loan facility was utilized in two draw-downs, the first being for \$2.6 million, which was being repaid in 30 equal monthly installments, plus accrued interest of 6.43% per annum, through October 1, 2007; the second draw-down of \$1.5 million was being repaid in 36 equal monthly installments, plus accrued interest of 6.78% per annum, through March 1, 2008. We had not drawn down any of the funds available under the \$8.0 million revolving credit line, although \$6.0 million of this amount was 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 was reserved as collateral for foreign exchange hedging contracts with SVB and a portion was available for working capital and other general business needs. The borrowings under this line bore interest at SVB's prime rate and would cause replacement collateral to be required for the items above. In September 2007, we repaid in full the remaining principal balance of \$0.3 million under the SVB term loan facility and did not renew the Loan and Security Agreement after its expiration. The \$6.0 million letter of credit is now being collateralized by a certificate of deposit of the same amount, which is recorded as restricted cash, and we have no outstanding foreign currency hedging contracts.

Dr. Rathmann, a former member of our Board of Directors and currently 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 bore

## Edgar Filing: NUVELO INC - Form 10-Q

interest at the prime rate plus 1%. In November 2003, we began repaying the outstanding balance over 48 months with equal principal payments of \$0.2 million. As of September 30, 2007, the remaining principal and accrued interest to date totaled \$2.5 million, and the interest rate on the note on this date was 8.75%. We paid in full the remaining principal and accrued interest in October 2007.

---

## **Table of Contents**

In July 2006, Nuvelo entered into a collaboration agreement with Archemix. Under the 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. In accordance with the agreement, Nuvelo is obligated to purchase Archemix common stock having a value equal to the lesser of \$10.0 million or 15 percent of the total gross proceeds raised by Archemix in a qualified public offering of Archemix stock occurring within five years of the effective date of the collaboration agreement. On July 25, 2007, Archemix filed a registration statement for an initial public offering of its common stock with the Securities and Exchange Commission. On October 23, 2007, Archemix disclosed that it plans an initial public offering of 4.5 million shares of its common stock at an expected price between \$12 and \$14 per share. Concurrent with the closing of its initial public offering, we expect Archemix will offer shares of its common stock to us in a private placement, of which we estimate the total offering price to be approximately \$9.0 million if calculated at \$13 per share, the mid-point of the per share price range.

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.

Our future capital requirements and the adequacy of available funds will depend on many factors, including those set forth under Part II, Item 1A. 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.

### **Critical Accounting Policies and Estimates**

There have been no material changes to our critical accounting policies and estimates as described in our Annual Report on Form 10-K for the year ended December 31, 2006, except as noted below.

On January 1, 2007, we adopted the provisions of FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes - An Interpretation of FASB Statement No. 109* (FIN 48). FIN 48 provides detailed guidance for the financial statement recognition, measurement and disclosure of uncertain tax positions recognized in the financial statements in accordance with SFAS No. 109. Tax positions must meet a more-likely-than-not recognition threshold at the effective date to be recognized upon the adoption of FIN 48 and in subsequent periods. The adoption of FIN 48 did not have a material impact on our results of operations or financial condition.

The tax years 2003 through 2006 remain open to examination by the major taxing jurisdictions in which we operate. We do not expect any material changes to unrecognized tax positions within the next twelve months.

### **Recent Accounting Pronouncements**

In September 2006, the FASB issued Statement of Financial Accounting Standards No. 157, *Fair Value Measurements* (SFAS 157). SFAS 157 defines fair value, establishes a framework for measuring fair value in accordance with generally accepted accounting principles, and expands disclosures about fair value measurements. SFAS 157 is effective for fiscal years beginning after November 15, 2007. We are evaluating the potential impact of the implementation of SFAS 157 on our financial position and results of operations.

In February 2007, the FASB issued Statement of Financial Accounting Standards No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities* (SFAS 159). SFAS 159 permits entities to choose to measure many financial instruments and certain other items at fair value. The standard requires that unrealized gains and losses on items for which the fair value option has been elected be reported in earnings. SFAS 159 is effective for fiscal years beginning after November 15, 2007. We are evaluating the potential impact of SFAS 159 on our financial position and results of operations.

In June 2007, the FASB issued EITF Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities* (EITF 07-3). EITF 07-3 requires that non-refundable advance payments for future research and development activities be deferred and capitalized until the goods have been delivered or the related services have been performed. If an entity does not expect the goods to be delivered or services to be rendered, the capitalized advance payment should be charged to expense. EITF 07-3 is effective for fiscal years beginning after December 15, 2007, and will apply only to new contracts entered into on or after the effective date. Early adoption is not permitted. We are evaluating the potential impact of EITF 07-3 on our financial position and results of operations.



## **Table of Contents**

### **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 insignificant. 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**

There have been no material changes in the reported interest rate risk or foreign currency exchange risk from those reported under Item 7A, Quantitative and Qualitative Disclosures About Market Risk in our Annual Report on Form 10-K for the year ended December 31, 2006.

### **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, 2007 that has materially affected, or is reasonably likely to materially affect, our internal controls over financial reporting.

**Table of Contents****PART II. OTHER INFORMATION****ITEM 1. LEGAL PROCEEDINGS**

On February 9, 2007, Nuvelo, Inc. and certain of our former and current officers and directors were named as defendants in a purported securities class action lawsuit filed in the United States District Court for the Southern District of New York. The suit alleges violations of the Securities Exchange Act of 1934 related to the clinical trial results of alfimeprase, which we announced on December 11, 2006, and seeks damages on behalf of purchasers of our common stock during the period between January 5, 2006 and December 8, 2006. Specifically, the suit alleges that we misled investors regarding the efficacy of alfimeprase and the drug's likelihood of success. The plaintiff seeks unspecified damages and injunctive relief. Six additional lawsuits were filed in the Southern District of New York on February 16, 2007, March 1, 2007 and March 6, 2007, respectively. On April 10, 2007, six separate motions to consolidate the cases, appoint lead plaintiff, and appoint lead plaintiff's counsel were filed. On April 18, 2007, we filed a motion to transfer the four cases to the Northern District of California. The Court granted our motion to transfer the cases to the Northern District of California in July 2007. Plaintiffs have filed motions for consolidation, lead plaintiff and lead plaintiff's counsel in the Northern District of California. We currently cannot determine the impact that this litigation will have on our business, results of operations or financial condition.

On March 19, 2007, we received a summons related to a derivative suit that had been filed in the Superior Court for California, San Mateo County, by an alleged individual stockholder of Nuvelo, purportedly on behalf of Nuvelo against certain of Nuvelo's current and former officers and directors. The complaint alleges among other claims, that the defendants breached their fiduciary duties to Nuvelo by issuing or failing to prevent the issuance of purportedly false and misleading statements between January 5, 2006 and December 11, 2006 relating to the clinical trial results of alfimeprase, which we announced on December 11, 2006, and that certain defendants benefited from these actions. On April 18, 2007, we filed a demurrer to the complaint on the ground that plaintiff was not excused from issuing a demand to the board prior to filing the lawsuit. Plaintiffs filed oppositions to our demurrer, and we have subsequently filed replies to Plaintiffs' oppositions. The Court heard this motion on July 30, 2007, and granted our demurrer, but also granted plaintiffs the opportunity to file an amended complaint. Plaintiffs filed an amended complaint on October 15, 2007. We currently cannot determine the impact that this litigation will have on our business, results of operations or financial condition.

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. However, because of a recent court ruling, the settlement class, as defined in the settlement papers, is no longer feasible. One of the avenues currently being considered by the parties is whether there is another mechanism by which the settlement can be achieved. However, there is no assurance that this can be accomplished. We and other defendant issuers have been advised that the plaintiffs intend to file second, amended, consolidated complaints against us and the other defendant issuers at some point. If such a complaint is filed, we intend to file another motion to dismiss. We believe that any attorneys' fees, loss or settlement payment with respect to this suit will be paid by our insurance provider. However, it is possible that we could be forced to incur material expenses in the litigation if the parties cannot achieve a settlement, and, in the event of an adverse outcome, our business could be harmed.

**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, 2006 are marked with an asterisk(\*).





---

**Table of Contents**

**RISKS RELATED TO OUR BUSINESS**

**We may not be able to develop and commercialize any of our drug candidates successfully.\***

Our clinical-stage drug candidate, alfimeprase, did not meet its primary endpoint in the first of two planned Phase 3 trials for the treatment of acute peripheral arterial occlusion, or PAO, and in the first of two planned Phase 3 trials for the treatment of catheter occlusion, or CO. All clinical trials for alfimeprase were suspended in December 2006. In the second quarter of 2007, we reported our decision to pursue alfimeprase for the treatment of stroke in a Phase 2 clinical trial and for the treatment of CO in a Phase 2 trial using a single, higher and more concentrated dose of alfimeprase. We also reported our decision to close the suspended PAO trial. If we are unable to further develop alfimeprase for any reason, our business, results of operations and financial condition may be affected in a materially adverse manner.

In August 2007, we announced the suspension of our clinical development of our second drug candidate, rNAPc2, for the treatment of metastatic colorectal cancer and acute coronary syndromes. In November 2007, we announced that we have successfully concluded our discussions with the FDA and now have regulatory clearance to begin clinical evaluation of NU206. All of our other potential products are currently in research or preclinical 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 our products, our business, results of operations and financial condition will be affected in a materially adverse manner.

**Our success is dependent on the proper management of our current and future business operations, and the expenses associated with them.\***

Our business strategy requires us to manage our operations to provide for the continued development and potential commercialization of our drug candidates. 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, while simultaneously managing the expenses generated by these activities. In August 2007, we announced a reduction of approximately 30% of our workforce, across our research, clinical development and administrative functions. This reduction in force was a part of our efforts to reduce our operating expenses through prioritization of our development portfolio and streamlining our infrastructure. As a result of the reduction in force, we recorded a restructuring charge of approximately \$2.3 million in the third quarter of 2007. We continue to believe that strict cost containment in the near term is essential if our current funds are to be sufficient to allow us to continue our currently planned operations.

If we are unable to effectively manage our current operations, we may not be able to implement our business strategy and our financial condition and results of operations may be adversely affected. If we are unable to effectively manage our expenses, we may find it necessary to reduce our expenses through another reduction in our workforce, which could adversely affect our operations.

**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 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;

## Edgar Filing: NUVELO INC - Form 10-Q

availability of competing therapies, including the off-label use of therapies approved for related indications;

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;

patient referral practices of physicians;

availability of clinical trial sites; and

other clinical trials seeking to enroll subjects with similar profiles.

---

## **Table of Contents**

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.

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

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. In January 2003, we merged with Variagenics, and we may merge with or acquire other companies in the future. 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;

diverting 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.

### **Our clinical trials for our products may not yield results that will enable us to further develop our products and obtain the regulatory approvals necessary to sell them.\***

We, and our collaborators, will only receive regulatory approval for our 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 preclinical 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. For example, in December 2006, we announced that alfimeprase did not meet its primary endpoint in the first of two planned Phase 3 trials for the treatment of acute PAO and in the first of two planned Phase 3 trials for the treatment of CO. 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

## Edgar Filing: NUVELO INC - Form 10-Q

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 would be materially adversely affected.

In the second quarter of 2007, we reported our decision to pursue alfimeprase for the treatment of stroke in a Phase 2 clinical trial, and for the treatment of CO in a Phase 2 trial using a single, higher and more concentrated dose of alfimeprase. We have never completed a successful trial in the stroke indication, and may be unable to do so. Similarly, we cannot predict whether our use of a single higher and more concentrated dose of alfimeprase in the treatment of CO will result in a positive Phase 2 trial in CO. In the second quarter of 2007, we also reported our decision to close the suspended PAO trial.

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.

---

**Table of Contents**

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 timelines. Either circumstance could cause the market price of our common stock to decline. For example, in December 2006, after we announced that alfimeprase did not meet its primary endpoint in Phase 3 trials for the treatment of PAO and a Phase 3 trial for CO, the closing price of our common stock was \$4.05 on the day of the announcement, as compared to \$19.55 on the trading day prior to the announcement.

**If we fail to maintain existing licenses, 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 June 2007, we agreed to terminate our January 2006 collaboration with Bayer for the development and commercialization of alfimeprase. We agreed to waive Bayer's obligation to provide us twelve-months' notice of termination in consideration of Bayer's agreement to pay us a lump sum of \$15.0 million. Under the terminated agreement, Bayer had the right to commercialize alfimeprase in all territories outside the United States and, if commercialized, would have paid us tiered royalties on net sales of alfimeprase. We retained 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. We were responsible for 60 percent of any costs for US development programs associated with alfimeprase and solely bore the expense of any country-specific alfimeprase clinical trials conducted by us where the country-specific clinical trials was not part of the agreed global development program. As a result of the termination of the Agreement, we are now responsible for all costs and expenses associated with the development of alfimeprase.

As part of our termination agreement with Bayer, we also have granted Bayer the one-time option to reacquire rights to alfimeprase upon the initiation of a pivotal stroke trial or upon our public announcement that we are discontinuing further development of alfimeprase in the stroke indications. The period during which Bayer may exercise the one-time option begins upon the Company making certain information available to Bayer and lasts for 30 days after delivery of the information. If Bayer exercises this option, Bayer shall make a \$15.0 million non-refundable payment to us and we and Bayer will enter into a new license and collaboration agreement on substantially the same terms as the original agreement, with the exception of the \$50.0 million upfront payment and the milestone payment related to a Phase 2 trial in a stroke indication that were part of the terms of the original agreement.

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 terminated agreement with Bayer, we retained sole responsibility for making these payments to Amgen.

In February 2004, we entered into a license agreement with Dendreon relating to rNAPc2. We have suspended our clinical development of rNAPc2, which could negatively impact our relationship and license with Dendreon.

## Edgar Filing: NUVELO INC - Form 10-Q

In March 2005, we entered into a collaboration agreement with the Kirin Pharma Company, Limited for the development and commercialization of NU206. In November 2007, we announced that we have successfully concluded our discussions with the FDA and now have regulatory clearance to begin clinical evaluation of NU206. 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 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.

---

**Table of Contents**

On July 31, 2006, we entered into an agreement with Archemix Corporation. Under the agreement, Archemix is responsible for the discovery of short-acting aptamers targeting the coagulation cascade for use in acute cardiovascular procedures, and we are responsible for development and worldwide commercialization of these product candidates. Under the agreement, we made an upfront license fee payment to Archemix of \$4.0 million. We are also funding at least \$5.25 million of Archemix's research in the area of short-acting aptamer discovery over the first six years of the agreement. In addition, we may have to make payments to Archemix 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. Nuvelo also is obligated to purchase Archemix common stock having a value equal to the lesser of \$10.0 million or 15 percent of the total gross proceeds raised by Archemix in a qualified public offering of Archemix stock occurring within five years of the effective date of the new collaboration agreement. On July 25, 2007, Archemix filed an S-1 registration statement with the SEC, a preliminary prospectus for an initial public offering. 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. On October 23, 2007, Archemix disclosed that it plans an initial public offering of 4.5 million shares of its common stock at a price between \$12 and \$14 per share. Concurrent with the closing of its initial public offering, we expect Archemix will offer shares of its common stock to us in a private placement, of which we estimate the total offering price to be approximately \$9.0 million if calculated at \$13 per share, the mid-point of the per share price range.

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

In addition to our existing collaborations, we may enter into 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 manufacturing and a variety of other functions, including clinical trials management. Our current and future arrangements with our manufacturers and other third parties may not provide us with the benefits we expect.\***

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 drug substance, fill and finish our drug 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.

While we currently believe we have enough supplies of alfimeprase to complete our ongoing and anticipated near-term trials, additional supplies may be necessary for trials in other indications. We do not have an agreement in place for the commercial-scale manufacture of alfimeprase final drug product. On June 30, 2007, we entered into an agreement with Avecia, our third-party alfimeprase manufacturer, in which we and Avecia waived any obligations and liabilities between us for additional payment, refund, rework or replacement associated with batches of alfimeprase manufactured before June 30, 2007, with the exception of two batches. We subsequently determined that one of the two batches could not be released for clinical use. We have not yet determined whether we will continue the manufacture of clinical supplies of alfimeprase with Avecia. Additionally, we are evaluating third-party manufacturers for the clinical filling and finishing of future supplies of alfimeprase. If we are unable to have Avecia or another third-party manufacture clinical or commercial grade alfimeprase for us if and when we need it, we may not have adequate supplies to complete our future trials, or to obtain regulatory approvals for alfimeprase. If we are unable to have third parties produce alfimeprase final drug product in the quantities and with the quality we need, when we need it, we may incur significant additional expenses, and our efforts to complete our ongoing and anticipated clinical trials, and obtain approval to market alfimeprase could be significantly delayed. We also may need to conduct comparative studies or utilize other means to determine bioequivalence between alfimeprase manufactured by the current manufacturer and any subsequent manufacturers.

---

## **Table of Contents**

Since NU206 is moving into the clinical trial phase, and if and when NU172 or any of our other drug candidates 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 additional contractual relationships with third parties in order to (i) complete the Good Laboratory Practices, or GLP, toxicology and other studies necessary to file INDs 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 candidate 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.

We also currently rely upon third parties to perform administrative functions and functions related to the research, development, preclinical 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 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.

Our reliance on these manufacturing and other contract services relationships poses a number of risks, including:

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;

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;

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

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 of our drug candidates resulting in delayed regulatory submissions and commercialization of our drug candidates;

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;



## Edgar Filing: NUVELO INC - Form 10-Q

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; 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.

---

## **Table of Contents**

### **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 efforts. 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 and development 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 qualified individuals to fill open positions. In addition, in August 2007 we reduced our workforce by approximately 30 percent as part of our efforts to reduce our operating expenses through prioritization of our development portfolio and streamlining our infrastructure. This reduction in our workforce may impair our ability to recruit and retain qualified employees and to effectively complete administrative and development functions. If we need to rehire terminated individuals or hire individuals with similar skills, we may be unable to do so. 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 retain qualified personnel, outside consultants and scientific collaborators, or if we experience turnover or difficulties recruiting new employees or outside consultants, our research and development programs could be delayed, and we could experience difficulties in generating sufficient revenue to maintain our business.

### **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, 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 collaborative partners, the uncertainties inherent in the regulatory approval process and manufacturing scale-up and delays in achieving manufacturing or marketing arrangements sufficient to commercialize our products. There can be no assurance that our clinical trials will be completed, or that we will make regulatory submissions or receive regulatory approvals as planned. 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.

### **The success of our potential products in research and preclinical studies does not guarantee that these results will be replicated in humans.**

Several of our drug development programs are currently in the research stage or in preclinical development. Although our clinical development-stage drug candidates have shown favorable results in preclinical 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 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 research does advance, we will need to engage in certain additional preclinical 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 preclinical 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.

### **FDA and international regulatory approval of our products is uncertain.**

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

## **Table of Contents**

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 preclinical 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 preclinical 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 policies 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;

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.

**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;

**Table of Contents**

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 is 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. 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, fines 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.

**Even if approved, 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. As a result, the commercialization of any of our product candidates could fail even if we receive marketing approval from the FDA or similar foreign authorities, and acceptance by the medical and patient communities.

**We face intense competition.**

The biopharmaceutical industry is intensely competitive, which 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. The competitors for our drugs currently in development will vary depending on the particular indication pursued, and may include major pharmaceutical, medical device and

---

## **Table of Contents**

biotechnology firms, many of which have substantially greater research and product development capabilities and financial, scientific, marketing and human resources than we have. Our clinical-stage product candidate, alfineprase, is a clot dissolver. If approved, it could face competition from other drugs and devices that are used to dissolve clots. Competition differs depending on the indication and includes, for example, alteplase, an approved Genentech, Inc. product, reteplase, an approved PDL BioPharma Inc. product and devices such as Possis Medical Inc.'s AngioJet® and Concentric Medical Inc.'s MerC® Retriever.

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 we or our collaboration partners have in discovery, research and development, manufacturing, preclinical 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 as well as other organizations compete with us in recruiting and retaining qualified scientific and management personnel as well as in acquiring technologies complementary to our programs. We may 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 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 AND STOCK PRICE VOLATILITY**

#### **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 stockholders' 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. As an example, if the minimum volume weighted-average price for our common stock is below \$2.50 per share, which was the case as of September 28, 2007, we may be unable to sell stock to Kingsbridge Limited under the CEFF. The unavailability of financing may require us to delay, scale back or eliminate expenditures for the research and development of 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.

## Edgar Filing: NUVELO INC - Form 10-Q

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. As an example, in August 2007, we announced that we suspended the clinical development of rNAPc2. Any such action could significantly harm our business, financial condition and results of operations.



**Table of Contents**

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, including our ability to continue to receive cost-sharing reimbursements from Kirin;

progress in current and anticipated clinical studies of our products, including alfimeprase, NU206 and NU172;

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

future funding commitments to new and existing collaborators, such as Archemix, from which Nuvelo is obligated to purchase Archemix common stock having a value equal to the lesser of \$10.0 million or 15 percent of the total gross proceeds raised by Archemix in a qualified public offering;

the cost of manufacturing our material for preclinical and clinical purposes;

our ability to establish new collaborative relationships with other companies to share costs and expertise of identifying, developing and commercializing 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 preclinical studies;

the cost involved in maintaining facilities 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;

competing technological and market developments;

our ability to use our committed equity financing facility with Kingsbridge Capital;

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

other factors not within our control.

**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 any investment in our company.

Historically, our stock price has been extremely volatile. Between January 1, 2006 and December 31, 2006, the price ranged between a high of \$20.98 per share and a low of \$3.35 per share. In December 2006, after we announced that alfimeprase did not meet its primary endpoint in Phase 3 trials for the treatment of acute peripheral arterial occlusion and catheter occlusion, the closing price of our common stock was \$4.05 on the day of the announcement, as compared to \$19.55 on the trading day prior to the announcement. Between January 1, 2007 and September 30, 2007, the price ranged between a high of \$6.63 per share and a low of \$1.52 per share. Significant market price fluctuations of our common stock can be due to a variety of factors, including:

the depth of demand for our common stock;

the experimental nature of, and public concern or expectations with respect to, our product candidates;

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;

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 or developments with respect to proprietary rights;

changes in our collaborative arrangements;

**Table of Contents**

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; and

general market conditions.

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.

**We have a significant accumulated deficit and anticipate continuing losses.\***

We have incurred significant net losses, including \$71.6 million in 2005 and \$130.6 million in 2006 and \$0.7 million in the nine months ended September 30, 2007. As of September 30, 2007, we had an accumulated deficit of \$458.9 million and we anticipate continuing losses for the foreseeable future.

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, preclinical testing, clinical trials and regulatory approvals.

These activities, together with drug manufacturing, 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 preclinical research and clinical trials, apply for regulatory approvals and develop our drug candidates. 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 and obtaining regulatory approvals. 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 have resulted in a change in ownership for purposes of these provisions.

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. 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 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;

## Edgar Filing: NUVELO INC - Form 10-Q

if Nuvelo is obligated to purchase Archemix common stock having a value equal to the lesser of \$10.0 million or 15 percent of the total gross proceeds, in accordance with the collaboration agreement with Archemix;

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

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

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

our ability to maintain our facilities to support our operations;

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;

**Table of Contents**

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.

Excluding alfimeprase, our potential products currently are in research or preclinical development, and revenues from the sales of any products resulting from this research and development may not occur for several years, if at all. We have a significant amount of 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.

**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, 2007, we had 53,388,525 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, 2007, our directors, officers and greater than five percent stockholders held approximately 31 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.

As of September 30, 2007, we had approximately 13,048,034 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 these 13,048,034 shares are (i) 6,712,332 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) 86,000 shares of our common stock issuable under restricted stock units, (iv) 4,935,904 shares of our common stock reserved for future grants under our 2004 Equity Incentive Plan, and (v) 540,259 shares of our common stock reserved for future issuance under our Employee Stock Purchase Plan. As of September 30, 2007, outstanding options to purchase 4,810,186 shares of common stock were exercisable, and no restricted stock units have been vested. If and when these options 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, 2007, 850,224 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.

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, not to exceed 8,075,000 shares, 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. If we can satisfy certain conditions and requirements, we may sell the balance of 5,667,353 shares to Kingsbridge through the expiration of the CEFF in October 2008, limited to the remaining \$50.6 million available under the facility. Should we sell further securities under the CEFF, it could have a dilutive effect on the holdings of our current stockholders and may result in downward pressure on the market price of our common stock.



---

**Table of Contents**

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.

**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, not to exceed 8,075,000 shares, subject to certain conditions and restrictions. Kingsbridge is not obligated to purchase shares under the CEFF unless certain conditions are met, which include a minimum volume weighted average price for our common stock of \$2.50 per share; 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. 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. If the previously discussed conditions are met, we may sell the balance of 5,667,353 shares to Kingsbridge through the expiration of the CEFF in October 2008, limited to the remaining \$50.6 million available under the facility.

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 effect 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 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. Furthermore, we may incur additional indebtedness that may severely restrict or prohibit the payment of dividends.

**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;

---

**Table of Contents**

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 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 six 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.

**Table of Contents****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 August 2007. 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****We are party to securities litigation and a shareholder derivative suit, and defending these lawsuits could hurt our business. The volatility of the market price of our securities could engender additional class action securities litigation.\***

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. This risk is especially acute for us, because biotechnology companies have experienced greater than average stock price volatility in recent years and, as a result, have been subject to, on average, a greater number of securities class action claims than companies in other industries. 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. For example, in December 2006, after we announced that alfimeprase did not meet its primary endpoint in the first of two planned Phase 3 trials for the treatment of acute peripheral arterial occlusion and in the first of two planned Phase 3 trials for the treatment of catheter occlusion, the closing price of one share of our common stock was \$4.05 on the day of the announcement, as compared to a closing price of \$19.55 on the trading day prior to the announcement. On February 9, 2007, Nuvelo, Inc. and certain of our former and current officers and directors were named as defendants in a purported securities class action lawsuit filed in the United States District Court for the Southern District of New York. The suit alleges violations of the Securities Exchange Act of 1934 related to the clinical trial results of alfimeprase, which we announced on December 11, 2006, and seeks damages on behalf of purchasers of our common stock during the period between January 5, 2006 and December 8, 2006. Specifically, the suit alleges that we misled investors regarding the efficacy of alfimeprase and the drug's likelihood of success. The plaintiff seeks unspecified damages and injunctive relief. Six additional lawsuits were filed in the Southern District of New York on February 16, 2007, March 1, 2007 and March 6, 2007, respectively. On April 10, 2007, six separate motions to consolidate the cases, appoint lead plaintiff, and appoint lead plaintiff's counsel were filed. On April 18, 2007, we filed a motion to transfer the four cases to the Northern District of California. The Court granted our motion to transfer the cases to the Northern District of California in July, 2007. Plaintiffs have filed motions for consolidation, lead plaintiff and lead plaintiff's counsel in the Northern District of California. We currently cannot determine the impact that this litigation will have on our business, results of operations or financial condition.

On March 19, 2007, we received a summons related to a derivative suit that had been filed in the Superior Court for California, San Mateo County, by an alleged individual stockholder of Nuvelo, purportedly on behalf of Nuvelo against certain of Nuvelo's current and former officers and directors. The complaint alleges among other claims, that the defendants breached their fiduciary duties to Nuvelo by issuing or failing to prevent the issuance of purportedly false and misleading statements between January 5, 2006 and December 11, 2006 relating to the clinical trial results of alfimeprase, which we announced on December 11, 2006, and that certain defendants benefited from these actions. On April 18, 2007, we filed a demurrer to the complaint on the ground that plaintiff was not excused from issuing a demand to the board prior to filing the lawsuit. Plaintiffs filed oppositions to our demurrer, and we have subsequently filed replies to Plaintiff's oppositions. The Court heard this motion on July 30, 2007, and granted our demurrer, but also granted plaintiffs the opportunity to file an amended complaint. Plaintiff's filed an amended complaint on October 15, 2007. We currently cannot determine the impact that this litigation will have on our business, results of operations or financial condition.

In addition, 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. We believe that any loss or settlement amount will not be material to our financial position or results of operations,



---

## **Table of Contents**

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. Because of a recent court ruling, the settlement class, as defined in the settlement papers, is no longer feasible. The parties are exploring whether there is another mechanism by which the settlement can be achieved but there is no assurance that this can be accomplished. We and other defendant issuers have been advised that the plaintiffs intend to file second, amended, consolidated complaints against us and the other defendant issuers at some point. If such a complaint is filed, we intend to file another motion to dismiss.

### **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 alimeprase 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.

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.

---

## **Table of Contents**

### **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, 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.



**Table of Contents**

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.

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

Not applicable.

**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**

Not applicable.

**ITEM 6. EXHIBITS**

**Exhibit**

<b>Number</b>	<b>Description</b>
2.1	Agreement and Plan of Merger between Hyseq, Inc., Vertical Merger Corp. and Variagenics, Inc. dated November 9, 2002.(4)
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.(6)
2.3	Stock Purchase Agreement between SBH Genomics, Inc., Radoje Drmanac, Snezana Drmanac, Nuvelo, Inc., and Affymetrix, Inc. dated December 3, 2004.(7)
3.1	Amended and Restated Certificate of Incorporation of Nuvelo, Inc.(6)
3.2	Amended and Restated By-Laws of Nuvelo, Inc.(9)
4.1	Form of Nuvelo, Inc. Common Stock Certificate.(6)
4.2	Certificate of Designations of Series A Junior Participating Preferred Stock.(6)
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.(5)
4.5	Amendment to Rights Agreement between Nuvelo, Inc. and U.S. Stock Transfer Corporation dated March 19, 2004.(6)
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.(3)

## Edgar Filing: NUVELO INC - Form 10-Q

- 4.8 Replacement Warrant to purchase 195,130 shares of Common Stock of Nuvelo, Inc. dated January 20, 2005.(8)
- 4.9 Replacement Warrant to purchase 200,000 shares of Common Stock of Nuvelo, Inc. dated January 20, 2005.(8)
- 4.10 Replacement Warrant to purchase 50,000 shares (pre split) of Common Stock of Nuvelo, Inc. dated June 7, 2005.(10)
- 4.11 Warrant to purchase 350,000 shares of Common Stock of Nuvelo, Inc. dated August 4, 2005.(11)
- 4.12 Registration Rights Agreement by and between Nuvelo, Inc. and Kingsbridge Capital Limited dated August 4, 2005.(11)



**Table of Contents**

**Exhibit**

<b>Number</b>	<b>Description</b>
4.13	Replacement Warrant to purchase 109,607 shares (pre split) of Common Stock of Nuvelo, Inc. dated July 15, 2005.(12)
4.14	Replacement Warrant to purchase 222,536 shares (pre split) of Common Stock of Nuvelo, Inc. dated July 15, 2005.(12)
4.15	Reference is made to Exhibits 3.1 and 3.2.
10.65	Base Salary for Named Executive Officer, effective August 1, 2007.(13)
10.66 *	Amended and Restated Addendum to Employment Agreement between Nuvelo, Inc. and Ted W. Love dated April 30, 2007.
10.67 *	Amended Executive Change in Control and Severance Benefit Plan.
31.1*	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) or 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*	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) or 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.

Compensatory plan or agreement.

- (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 S-3, filed on June 14, 2002, File No. 333-90458.
- (4) 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.
- (5) 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.
- (6) Previously filed with the SEC as an Exhibit to and incorporated herein by reference from Nuvelo, Inc. s Form 8-K, filed March 26, 2004, File No. 000-22873.
- (7) Previously filed with the SEC as an Exhibit to and incorporated herein by reference from Nuvelo, Inc. s Form 8-K, filed December 9, 2004, File No. 000-22873.

## Edgar Filing: NUVELO INC - Form 10-Q

- (8) Previously filed with the SEC as an Exhibit to and incorporated herein by reference from Nuvelo, Inc. s Form 10-K, filed on March 16, 2005, File No. 000-22873.
- (9) 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.
- (10) 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.
- (11) Previously filed with the SEC as an Exhibit to and incorporated herein by reference from Nuvelo, Inc. s Form 8-K, filed August 5, 2005, File No. 000-22873.
- (12) 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.
- (13) Previously filed with the SEC as an Exhibit to and incorporated herein by reference from Nuvelo, Inc. s Form 8-K, filed on September 19, 2007, File No. 000-22873.

**Table of Contents**

**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/ LEE BENDEKGEY**  
**Lee Bendekgey**  
*Senior Vice President and Chief Financial Officer*  
*(Duly Authorized and Principal Financial and*  
*Accounting Officer)*

Dated: November 7, 2007

**Table of Contents****EXHIBIT INDEX****Exhibit**

<b>Number</b>	<b>Description</b>
2.1	Agreement and Plan of Merger between Hyseq, Inc., Vertical Merger Corp. and Variagenics, Inc. dated November 9, 2002.(4)
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.(6)
2.3	Stock Purchase Agreement between SBH Genomics, Inc., Radoje Drmanac, Snezana Drmanac, Nuvelo, Inc., and Affymetrix, Inc. dated December 3, 2004.(7)
3.1	Amended and Restated Certificate of Incorporation of Nuvelo, Inc.(6)
3.2	Amended and Restated By-Laws of Nuvelo, Inc.(9)
4.1	Form of Nuvelo, Inc. Common Stock Certificate.(6)
4.2	Certificate of Designations of Series A Junior Participating Preferred Stock.(6)
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.(5)
4.5	Amendment to Rights Agreement between Nuvelo, Inc. and U.S. Stock Transfer Corporation dated March 19, 2004.(6)
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.(3)
4.8	Replacement Warrant to purchase 195,130 shares of Common Stock of Nuvelo, Inc. dated January 20, 2005.(8)
4.9	Replacement Warrant to purchase 200,000 shares of Common Stock of Nuvelo, Inc. dated January 20, 2005.(8)
4.10	Replacement Warrant to purchase 50,000 shares (pre split) of Common Stock of Nuvelo, Inc. dated June 7, 2005.(10)
4.11	Warrant to purchase 350,000 shares of Common Stock of Nuvelo, Inc. dated August 4, 2005.(11)
4.12	Registration Rights Agreement by and between Nuvelo, Inc. and Kingsbridge Capital Limited dated August 4, 2005.(11)
4.13	Replacement Warrant to purchase 109,607 shares (pre split) of Common Stock of Nuvelo, Inc. dated July 15, 2005.(12)
4.14	Replacement Warrant to purchase 222,536 shares (pre split) of Common Stock of Nuvelo, Inc. dated July 15, 2005.(12)
4.15	Reference is made to Exhibits 3.1 and 3.2.
10.65	Base Salary for Named Executive Officer, effective August 1, 2007.(13)
10.66 *	Amended and Restated Addendum to Employment Agreement between Nuvelo, Inc. and Ted W. Love dated April 30, 2007.
10.67 *	Amended Executive Change in Control and Severance Benefit Plan.
31.1*	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) or 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*	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) or 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.

Compensatory plan or agreement.

**Table of Contents**

- (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 S-3, filed on June 14, 2002, File No. 333-90458.
- (4) 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.
- (5) 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.
- (6) Previously filed with the SEC as an Exhibit to and incorporated herein by reference from Nuvelo, Inc. s Form 8-K, filed March 26, 2004, File No. 000-22873.
- (7) Previously filed with the SEC as an Exhibit to and incorporated herein by reference from Nuvelo, Inc. s Form 8-K, filed December 9, 2004, File No. 000-22873.
- (8) Previously filed with the SEC as an Exhibit to and incorporated herein by reference from Nuvelo, Inc. s Form 10-K, filed on March 16, 2005, File No. 000-22873.
- (9) 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.
- (10) 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.
- (11) Previously filed with the SEC as an Exhibit to and incorporated herein by reference from Nuvelo, Inc. s Form 8-K, filed August 5, 2005, File No. 000-22873.
- (12) 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.
- (13) Previously filed with the SEC as an Exhibit to and incorporated herein by reference from Nuvelo, Inc. s Form 8-K, filed on September 19, 2007, File No. 000-22873.