

NUVELO INC
Form 10-Q
May 10, 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 MARCH 31, 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)

Edgar Filing: NUVELO INC - Form 10-Q

650-517-8000

(Registrant's Telephone Number, including Area Code)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Sections 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes 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 April 30, 2007: 53,303,668

Table of Contents

Table of Contents

NUVELO, INC.

FORM 10-Q

FOR THE QUARTER ENDED MARCH 31, 2007

	PAGE
Part I	
<u>Financial Information</u>	3
<u>Item 1. Condensed Consolidated Financial Statements (unaudited)</u>	3
<u>Condensed Consolidated Balance Sheets as of March 31, 2007 and December 31, 2006</u>	3
<u>Condensed Consolidated Statements of Operations for the Three Months Ended March 31, 2007 and 2006</u>	4
<u>Condensed Consolidated Statements of Cash Flows for the Three Months Ended March 31, 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>	9
<u>Item 3. Quantitative and Qualitative Disclosures about Market Risk</u>	13
<u>Item 4. Controls and Procedures</u>	13
Part II	
<u>Other Information</u>	14
<u>Item 1. Legal Proceedings</u>	14
<u>Item 1A. Risk Factors</u>	14
<u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u>	27
<u>Item 3. Defaults Upon Senior Securities</u>	27
<u>Item 4. Submission of Matters to a Vote of Security Holders</u>	27
<u>Item 5. Other Information</u>	27
<u>Item 6. Exhibits</u>	27
<u>Signature</u>	29

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

	March 31, 2007	December 31, 2006
ASSETS		
Cash and cash equivalents	\$ 66,855	\$ 60,335
Short-term investments	67,951	92,791
Collaboration receivables	3,311	8,559
Other current assets	3,292	4,650
Total current assets	141,409	166,335
Equipment, leasehold improvements and software, net	11,607	11,978
Goodwill	4,671	4,671
Other assets	1,209	1,421
Total assets	\$ 158,896	\$ 184,405
LIABILITIES AND STOCKHOLDERS EQUITY		
Accounts payable	\$ 1,903	\$ 7,026
Accrued employee liabilities	1,739	3,098
Accrued clinical trial and drug manufacturing costs	12,081	14,415
Current portion of deferred revenue	3,640	3,640
Current portion of deferred rent	1,357	1,342
Current portion of accrued facility exit costs	7,580	7,674
Accrued interest	2,215	2,172
Current portion of bank loans	1,107	1,367
Related party line of credit	1,604	2,292
Other current liabilities	810	813
Total current liabilities	34,036	43,839
Non-current portion of deferred revenue	43,623	44,533
Non-current portion of deferred rent	6,651	6,998
Non-current portion of accrued facility exit costs	17,594	18,942
Non-current portion of bank loans		125
Other liabilities	114	125
Total liabilities	102,018	114,562
Stockholders' equity:		
Preferred stock		
Common stock	53	53
Additional paid-in capital	530,389	527,992
Accumulated other comprehensive gain (loss)	(3)	10
Accumulated deficit	(473,561)	(458,212)

Edgar Filing: NUVELO INC - Form 10-Q

Total stockholders equity	56,878	69,843
Total liabilities and stockholders equity	\$ 158,896	\$ 184,405

See accompanying notes to condensed consolidated financial statements.

Table of Contents

NUVELO, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(unaudited)

	Three Months Ended	
	March 31, 2007	March 31, 2006
	(In thousands, except per share data)	
Contract revenues	\$ 910	\$ 1,065
Operating expenses:		
Research and development	12,725	12,099
General and administrative	5,366	10,201
Total operating expenses	18,091	22,300
Operating loss	(17,181)	(21,235)
Interest income	1,881	1,813
Interest expense	(49)	(229)
Net loss	\$ (15,349)	\$ (19,651)
Basic and diluted net loss per share	\$ (0.29)	\$ (0.40)
Weighted average shares used in computing basic and diluted net loss per share	53,252	48,913

See accompanying notes to condensed consolidated financial statements.

Table of Contents

NUVELO, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(unaudited)

	Three Months Ended March 31,	
	2007	2006
	(In thousands)	
Cash flows from operating activities:		
Net loss	\$ (15,349)	\$ (19,651)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Non-cash facility exit costs	526	
Depreciation and amortization	586	772
Stock-based compensation expense	2,231	3,264
Change in fair value of warrant liability		2,877
Other non-cash items	(1)	(22)
Changes in operating assets and liabilities:		
Collaboration receivables	5,248	(5,470)
Clinical trial supplies		(2,315)
Other current assets	1,357	(2,120)
Other assets	212	(365)
Accounts payable	(5,123)	(1,341)
Accrued employee liabilities	(1,359)	(790)
Accrued clinical trial and drug manufacturing costs	(2,334)	(728)
Deferred revenue	(910)	49,090
Deferred rent	(332)	(4,333)
Accrued facility exit costs	(1,968)	
Accrued interest	43	172
Other liabilities	(4)	(948)
Net cash provided by (used in) operating activities	(17,177)	18,092
Cash flows from investing activities:		
Maturities of short-term investments	48,932	16,878
Purchases of short-term investments	(24,100)	(18,543)
Purchases of equipment, leasehold improvements and software	(218)	(504)
Proceeds from sale of assets		7
Net cash provided by (used in) investing activities	24,614	(2,162)
Cash flows from financing activities:		
Payments on bank loans and capital lease obligations	(395)	(395)
Payments on related party line of credit	(688)	(688)
Proceeds from issuance of common stock from public offerings, net		112,010
Proceeds from issuance of common stock upon exercise of options, warrants and under employee stock purchase plan	166	1,389
Net cash provided by (used in) financing activities	(917)	112,316
Net increase in cash and cash equivalents	6,520	128,246
Cash and cash equivalents at beginning of period	60,335	37,764
Cash and cash equivalents at end of period	\$ 66,855	\$ 166,010

Edgar Filing: NUVELO INC - Form 10-Q

See accompanying notes to condensed consolidated financial statements.

Table of Contents

NUVELO, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

March 31, 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, including collaboration receivables in the condensed consolidated statements of cash flows. 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 engaged in the discovery, development and commercialization of novel acute cardiovascular and cancer therapies. The Company's development pipeline includes three acute cardiovascular programs, alfineprase, rNAPc2 and NU172, as well as two main oncology programs, rNAPc2 and NU206. In December 2006, as a result of the failure of the first trial in each of the two Phase 3 programs for alfineprase to meet their primary endpoints, the Company suspended enrollment in the second trial in each of these programs, pending further analyses and discussions with outside experts, data safety monitoring boards and regulatory agencies, as well as with the Company's partner for this program, Bayer HealthCare AG (Bayer).

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.

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.

Significant Accounting Policies

With the exception noted below, during the three months ended March 31, 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

Edgar Filing: NUVELO INC - Form 10-Q

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.

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 common stock equivalents 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:

	March 31,	
	2007	2006
Options	8,922,615	6,923,510
Warrants	1,095,614	1,786,685
Restricted stock units	154,500	
Total	10,172,729	8,710,195

3. Stock-based Compensation

Stock-based compensation expense related to employee stock options, restricted stock units and employee stock purchase plan purchase rights was \$2.2 million and \$3.1 million for the three months ended March 31, 2007 and 2006, of which \$1.0 million and \$1.3 million was recorded to research and development expense and \$1.2 million and \$1.8 million was recorded to general and administrative expense, respectively. 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 March 31,	
	2007	2006
Expected term	4.95 years	5.41 years
Expected volatility	0.87	0.73
Risk-free interest rate	4.65%	4.55%
Expected dividend yield		
Weighted-average grant date fair value per share	\$ 2.48	\$ 10.05

The Company granted options to purchase 1,318,350 and 153,000 shares of common stock with total estimated fair values of \$3.3 million and \$1.5 million in the three months ended March 31, 2007 and 2006, respectively, including grants to non-employees. Of the options granted in the three months ended March 31, 2007, options for the purchase of 1,307,750 shares vest ratably over a period of three years from the date of grant. There were no options exercised in the three months ended March 31, 2007.

The Company granted 183,000 restricted stock units during the three months ended March 31, 2007, of which 28,500 were forfeited during the quarter, with all such units having a grant date fair value of \$3.54. The fair values of employee restricted stock units granted under the Company's stock incentive plans are 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 three months ended March 31, 2007. The unamortized compensation expense related to unvested restricted stock units as of March 31, 2007, excluding estimated forfeitures, was \$0.6 million. The weighted average period over which compensation expense related to these restricted stock units is expected to be recognized is 2.84 years.

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, subject to stockholder approval.

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	
	March 31,	
	2007	2006
Net loss, as reported	\$ (15,349)	\$ (19,651)
Change in unrealized gain (loss) on hedging instruments	(5)	45
Change in unrealized gain (loss) on available-for-sale securities	(8)	27
Comprehensive loss	\$ (15,362)	\$ (19,579)

5. Facility Exit Costs

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 will be made periodically until the lease expires.

The balance of accrued facility exit costs represent 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

Edgar Filing: NUVELO INC - Form 10-Q

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 three months ended March 31, 2007 (in thousands):

Balance as of December 31, 2006	\$ 26,616
Amounts paid during the period	(1,968)
Non-cash accretion	526
Balance as of March 31, 2007	\$ 25,174

The \$526,000 of non-cash accretion is included in general and administrative expenses for the three months ended March 31, 2007.

6. Borrowing Arrangements

In August 2004, the Company entered into a Loan and Security Agreement (Loan Agreement) with Silicon Valley Bank (SVB) that originally provided a \$6.0 million term loan facility and a \$4.0 million revolving credit line, and grants SVB a security interest over certain of the Company's assets, excluding intellectual property. The Loan Agreement contains certain covenants and reporting requirements with which the Company was in compliance as of March 31, 2007. Proceeds may be used solely for working capital or other general business needs.

In December 2004, the Company completed a \$2.6 million initial draw-down and in March 2005 completed a \$1.5 million second draw-down from the term loan facility. On June 30, 2005, the remaining \$1.9 million of the facility expired unused. The \$2.6 million draw-down is being repaid in 30 equal monthly installments, plus accrued interest of 6.43% per annum, ending on October 1, 2007. The \$1.5 million draw-down is being repaid in 36 equal monthly installments, plus accrued interest of 6.78% per annum, ending on March 1, 2008.

In July 2005, the Loan Agreement was amended to increase the revolving credit line facility from \$4.0 million to \$8.0 million and extend the facility through August 29, 2006, and in August 2006, the Loan Agreement was amended to extend the revolving credit line facility through August 28, 2007. As of March 31, 2007, the Company has yet to draw down any of the funds available under this facility. Of the \$8.0 million total line, \$6.0 million is currently being reserved to collateralize a letter of credit issued to The Irvine Company related to the lease for the facility at 985 Almanor Avenue in Sunnyvale, California, and of the remaining \$2.0 million, a portion is being reserved as collateral for foreign exchange hedging contracts with SVB, and a portion is available for working capital and other general business needs. Any borrowings under this line shall bear interest at SVB's prime rate, being 8.25% as of March 31, 2007, and would cause replacement collateral to be required for the items above.

Table of Contents**7. Common Stock**

In August 2005, the Company entered into a Committed Equity Financing Facility (CEFF) with Kingsbridge Capital Ltd. (Kingsbridge), under which Kingsbridge has committed to purchase up to \$75.0 million of the Company's common stock within a three-year period, subject to certain conditions and limitations. As part of the arrangement, the Company issued a warrant to Kingsbridge to purchase 350,000 shares of the Company's common stock at a price of approximately \$12.07 per share, which is exercisable beginning six months after the date of grant and for a period of five years thereafter. 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 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, being \$5.94 per share, 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 \$2.9 million for the three months ended March 31, 2006. 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.

8. Collaborative Agreements***Bayer***

In January 2006, the Company entered into a license and collaboration agreement with Bayer for the development and commercialization of alfineprase internationally. Under this agreement, Bayer has the right to commercialize alfineprase in all territories outside the United States and, if commercialized, will pay tiered royalties on net sales of alfineprase, if any, ranging from a minimum of 15 percent to a maximum of 37.5 percent. Nuvelo retains all commercialization rights and profits from any alfineprase sales in the United States. The Company received an up-front cash payment from Bayer of \$50.0 million upon entry into the agreement and is eligible to receive up to an additional \$335.0 million in milestone payments, including \$165.0 million in development milestones and \$170.0 million in sales and commercialization milestones over the course of the agreement. The \$50.0 million up-front cash payment was deferred upon receipt and is being recognized as revenue on a straight-line basis over the performance period under the agreement, estimated to be through September 2020. Under the terms of the agreement, Bayer has the right to terminate the collaboration at its option upon 12 month's notice. Nuvelo is responsible for 60 percent of any costs for alfineprase global development programs, and Bayer is 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. Each party solely bears the expense of any country-specific alfineprase clinical trials conducted to support product approval solely in its territory, which in Nuvelo's case is limited to the United States. Nuvelo will continue to bear sole responsibility for milestone payments and royalties owed to Amgen Inc. under the license agreement entered into with them in October 2004.

Edgar Filing: NUVELO INC - Form 10-Q

In December 2006, all clinical trials for alfimeprase were suspended pending further analyses and discussions with outside experts, data safety monitoring boards and regulatory agencies, as well as with Bayer. For the three months ended March 31, 2007 and 2006, \$3.0 million and \$5.5 million, respectively, was billed to Bayer for Nuvelo's alfimeprase-related global development spending as a result of this cost-sharing arrangement. These amounts have been recorded as an offset to research and development expense in the statement of operations.

Dendreon

In February 2004, Nuvelo entered into a licensing agreement in accordance with which it obtained exclusive worldwide rights to all indications of rNAPc2 and all other rNAPc molecules owned by Dendreon Corporation. Under the terms of the agreement, the Company paid Dendreon an upfront fee of \$4.0 million (\$0.5 million in cash and \$3.5 million in Nuvelo common stock), which was recorded as a research and development expense. Future milestone payments to Dendreon could reach as much as \$23.5 million if all development and commercialization milestones are achieved. If rNAPc2 is commercialized, Nuvelo will also be responsible for paying royalties to Dendreon depending on sales of rNAPc2.

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. In addition, Nuvelo is obligated to purchase Archemix common stock having a value equal to the lesser of \$10.0 million or 15 percent of the shares issued by Archemix in a qualified public offering of Archemix stock occurring within five years of the effective date of the collaboration agreement. At the initiation of the first Phase 3 study for any licensed compound, Archemix has the option to elect to participate in profits from sales of the compound by funding its *pro rata* share of prior and future product development and commercialization expenses, in lieu of receiving milestone payments and royalties with respect to that compound.

Table of Contents***Pharmaceutical Division of Kirin Brewery Company, Ltd.***

In March 2005, Nuvelo entered into a collaboration agreement with the Pharmaceutical Division of Kirin Brewery Company, Ltd. (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.

9. Transactions with Related Parties

Dr. Rathmann, a former member of the Company's Board of Directors and current chairman emeritus, provided a \$20.0 million line of credit to the Company in August 2001, of which \$11.0 million was drawn down, with the remaining \$9.0 million having expired unused. The related promissory note bears interest at the prime rate plus 1%. In November 2003, the Company began repaying the outstanding balance over 48 months with equal monthly principal payments of \$0.2 million. Accrued interest will be paid with the final payment in October 2007, unless both are repaid before then. As of March 31, 2007, the remaining principal and accrued interest to date totaled \$3.8 million, and the interest rate on the note on this date was 9.25%. The outstanding principal and interest under the note may be repaid at any time in cash, or upon mutual agreement, by conversion into shares of the Company's common stock at a price based upon the average price of Nuvelo's common stock over a 20-day period ending two days prior to the conversion or, if in connection with an equity financing, at the offering price. As of March 31, 2007, 1,189,402 shares would be issuable to fully repay the principal and interest outstanding upon conversion.

10. Segment Information

The Company is engaged in the discovery, development and commercialization of novel acute cardiovascular and cancer therapies. The Company has only one reportable segment and, therefore, all segment-related financial information required by Statement of Financial Accounting Standards No. 131, *Disclosures About Segments of an Enterprise and Related Information*, is included in the condensed consolidated financial statements. The reportable segment reflects the Company's structure, reporting responsibilities to the chief executive officer and the nature of the products under development.

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 and cancer therapy. Our development pipeline includes several acute cardiovascular and oncology programs. The cardiovascular portfolio includes three programs: alfineprase, a direct acting fibrinolytic for the potential treatment of thrombotic-related disorders; rNAPc2, an anticoagulant that inhibits the factor VIIa and tissue factor protease complex; and preclinical candidate NU172, a direct thrombin inhibitor for use as a short-acting anticoagulant during medical procedures. The oncology portfolio includes two main programs: preclinical candidate NU206 for the potential treatment of chemotherapy/radiation therapy-induced mucositis and inflammatory bowel disease; and rNAPc2, which is in Phase 2 development for potential use as a cancer therapy. In addition, we expect to leverage our expertise in secreted proteins and antibody discovery to expand our pipeline and create additional partnering and licensing opportunities.

Alfimeprase

Alfimeprase is a recombinant direct-acting fibrinolytic (rDAF), or blood clot dissolver, that is intended to directly degrade fibrin when delivered through a catheter at the site of a blood clot. We have two Phase 3 programs for alfimeprase, one in patients with acute peripheral arterial occlusion (PAO), known as NAPA, and one in patients with central venous catheter occlusion (CO), known as SONOMA. In December 2006, we completed the first trial in each of these Phase 3 programs. These trials did not meet their primary endpoints, and we suspended the second Phase 3 trials in these programs pending further analyses and discussions with outside experts, data safety monitoring boards and regulatory agencies, as well as with our partner, Bayer HealthCare AG (Bayer). After these discussions are completed, we will determine the appropriate course of action regarding the potential future development of alfimeprase. Planned Phase 2 trials in acute ischemic stroke and deep venous thrombosis (DVT) are also on hold until further analyses and discussions of the Phase 3 acute PAO and CO data have been completed. We expect to provide guidance on the future direction of alfimeprase in the first half of 2007.

Under our license and collaboration agreement with Bayer, we are responsible for 60 percent of any costs for alfimeprase global development programs, and Bayer is 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. Each party solely bears the expense of any country-specific alfimeprase clinical trials conducted to support product approval solely in its territory, which in our case is limited to the United States. For the first quarter 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 has been recorded as an offset to research and development expense in the statement of operations. This amount is significantly lower as compared to the \$8.6 million billed in the fourth quarter of 2006 as a result of the suspension of active alfimeprase development in December 2006. We expect the second quarter 2007 reimbursement to also be lower than in prior quarters since development remains suspended pending a review of the data and a decision on the future development of the drug.

rNAPc2

Recombinant nematode anticoagulant protein c2 (rNAPc2) is a recombinant protein fashioned after one originally isolated from the saliva of the dog hookworm. rNAPc2 is currently being evaluated for the potential treatment of acute coronary syndromes (ACS) and a variety of cancers including metastatic colorectal cancer (mCRC). The potential anticoagulant effect of rNAPc2 results from its ability to block the factor VIIa/tissue factor protease complex, which is the initial step of coagulation or blood clot formation. In June 2006, we completed our Phase 2 clinical trial in ACS, known as the ANTHEM (Anticoagulation with rNAPc2 To Help Eliminate MACE)/TIMI 32 trial, and have since presented results at various medical conferences.

In addition, rNAPc2 interferes with the tissue factor/factor VIIa protease complex. This complex has been shown to play a role in activating the cellular signaling events leading to metastasis and angiogenesis in a variety of cancers. We began a Phase 2 trial of rNAPc2 for the second-line treatment of patients with mCRC in December 2006. This proof of concept study will enroll up to 100 mCRC patients, who will be given escalating doses (2.5 mcg/kg, 5 mcg/kg and 10 mcg/kg) twice weekly. Efficacy endpoints will include progression-free, metastasis-free and overall survival.

Table of Contents

In March 2007, we were granted two separate fast track designations by the U.S. Food and Drug Administration (FDA) for rNAPc2. The first fast track designation is for first-line treatment of mCRC to improve progression-free survival and overall survival when added to Avastin(R)-containing 5- fluorouracil (5-FU)-based chemotherapy regimens. The other is for second-line treatment of mCRC to improve progression-free survival and overall survival when added to 5-FU-based chemotherapy regimens.

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 and short bowel syndrome. We expect to initiate a Phase 1 trial with NU206 in the first half of 2007.

We are developing NU206 in collaboration with the Pharmaceutical Division of Kirin Brewery Company, Ltd. (Kirin). Given that we expect to enter clinical trials in 2007, we anticipate that our expenses for this program, and the proportion of our operating expenses associated with this program, will increase in 2007 over those in 2006.

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 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 \$0.9 million in the three months ended March 31, 2007, compared to \$1.1 million in the corresponding period of 2006. Both periods include \$0.8 million from the recognition of revenue from the \$50.0 million up-front license fee received from Bayer in January 2006. The up-front license fee was recorded as deferred revenue upon receipt and is being recognized on a straight-line basis over the performance period under the agreement, estimated to be through September 2020, when the last significant alfineprase-related patent expires.

We expect the amortization of existing deferred revenue to be consistent in the remainder of 2007 due to the ongoing revenue recognition from up-front license fees. 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.

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, as these are not tracked by individual program):

Program	Since Inception	Three Months Ended March 31,	
		2007	2006
Alfimeprase	\$ 53.4	\$ 3.9	\$ 4.9
rNAPc2	9.6	1.6	1.0
NU206	4.0	0.7	0.7
NU172	7.0	1.9	

R&D expenses were \$12.7 million for the first quarter of 2007 compared to \$12.1 million for the corresponding period of 2006, net of cost sharing credits billable to collaboration partners of \$3.3 million and \$7.0 million, respectively. The increase of \$0.6 million in 2007 was primarily due to an increase in spending of \$1.9 million related to NU172, partially offset by a \$1.0 million reduction in spending on alfimeprase.

R&D expenses for 2007 related to alfimeprase are dependent on the future course of action regarding development of this drug candidate, which is expected to be determined in the first half of 2007. We expect to continue to invest in rNAPc2, 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, charges or credits for warrant revaluations, professional fees, insurance, facilities and depreciation expenses, and various other administrative costs.

Table of Contents

G&A expenses were \$5.4 million in the three months ended March 31, 2007, compared to \$10.2 million in the corresponding period of 2006. The decrease of \$4.8 million was primarily due to a non-cash charge of \$2.9 million in the 2006 period for the quarterly revaluation of a warrant issued in connection with the committed equity financing facility, and reductions of \$0.7 million in occupancy costs as a result of the exit charges accrued in December 2006 related to the facility in Sunnyvale, California, \$0.6 million in stock-based compensation expense and \$0.5 million in commercialization-related expenses for alfineprase.

Interest Income (Expense), Net

We had net interest income of \$1.8 million in the three months ended March 31, 2007, compared to \$1.6 million in the corresponding period of 2006. The increase was primarily due to 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 March 31, 2007, our accumulated deficit was \$473.6 million. During the three months ended March 31, 2007, we incurred a net loss of \$15.3 million, compared to \$19.7 million in the corresponding period of 2006. The decrease resulted primarily from the reduction in G&A 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, cash equivalents and short-term investment balances as of the dates indicated were as follows:

	March 31, 2007	December 31, 2006
	(In thousands)	
Cash and cash equivalents	\$ 66,855	\$ 60,335
Short-term investments	67,951	92,791
Cash, cash equivalents and short-term investments	\$ 134,806	\$ 153,126

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

	Three Months Ended March 31,	
	2007	2006
	(In thousands)	
Net cash provided by (used in):		
Operating activities	\$ (17,177)	\$ 18,092
Investing activities	24,614	(2,162)
Financing activities	(917)	112,316
Net increase in cash and cash equivalents	\$ 6,520	\$ 128,246

Cash, Cash Equivalents and Short-term Investments

As of March 31, 2007, we had total cash, cash equivalents and short-term investments of \$134.8 million, as compared to \$153.1 million as of December 31, 2006. The decrease of \$18.3 million resulted primarily from operating expenditures during the period.

Edgar Filing: NUVELO INC - Form 10-Q

As of March 31, 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.

Cash Provided by (Used in) Operating Activities

Net cash used in operating activities was \$17.2 million in the three months ended March 31, 2007, compared to \$18.1 million provided by operating activities in the corresponding period of 2006. The change of \$35.3 million was primarily due to the \$50.0 million up-front license fee received from Bayer in the 2006 period, partially offset by a \$10.7 million increase in cash provided as a result of changes in collaboration receivables between the periods.

Operating cash usage in 2007 is partly dependent on the future course of action regarding alfineprase development, which is expected to be determined in the first half of 2007.

Cash Provided by (Used in) Investing Activities

Net cash provided by investing activities was \$24.6 million in the three months ended March 31, 2007, compared to \$2.2 million used in investing activities in the corresponding period of 2006. The change of \$26.8 million was primarily due to increased maturities of short-term investments.

Cash Provided by (Used in) Financing Activities

Net cash used in financing activities was \$0.9 million in the three months ended March 31, 2007, compared to \$112.3 million provided by financing activities in the corresponding period of 2006. The change of \$113.2 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.

Table of Contents

In August 2005, we entered into a Committed Equity Financing Facility (CEFF) with Kingsbridge Capital Ltd. (Kingsbridge), under which Kingsbridge has committed to purchase up to a total of \$75.0 million of our common stock, 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 7 to the Condensed Consolidated Financial Statements elsewhere in this filing).

We have a Loan and Security Agreement in place with Silicon Valley Bank (SVB) under which we have a fully-utilized term loan facility of \$4.1 million and an \$8.0 million revolving credit line facility which expires on August 28, 2007. The term loan facility was utilized in two draw-downs, the first being for \$2.6 million, which is being repaid in 30 equal monthly installments, plus accrued interest of 6.43% per annum, through October 1, 2007; the second draw-down of \$1.5 million is being repaid in 36 equal monthly installments, plus accrued interest of 6.78% per annum, through March 1, 2008. We have yet to draw down any of the funds available under the \$8.0 million revolving credit line, although \$6.0 million of this amount is currently being reserved to collateralize a letter of credit issued to The Irvine Company related to the lease for the facility at 985 Almanor Avenue in Sunnyvale, California, and of the remaining \$2.0 million, a portion is being reserved as collateral for foreign exchange hedging contracts with SVB and a portion is available for working capital and other general business needs. Any borrowings under this line shall bear interest at SVB's prime rate and would cause replacement collateral to be required for the items above.

Dr. Rathmann, a former member of our Board of Directors and current chairman emeritus, provided us with a \$20.0 million line of credit in August 2001, of which \$11.0 million was drawn down, with the remaining \$9.0 million having expired unused. The related promissory note bears interest at the prime rate plus 1%. In November 2003, we began repaying the outstanding balance over 48 months with equal principal payments of \$0.2 million. Accrued interest will be paid with the final payment in October 2007, unless both are repaid before then. As of March 31, 2007, the remaining principal and accrued interest to date totaled \$3.8 million, and the interest rate on the note on this date was 9.25%. The outstanding principal and interest under the note may be repaid at any time in cash or, upon mutual agreement, by conversion into shares of our common stock at a price based upon the average price of our common stock over a 20-day period ending two days prior to the conversion or, if in connection with an equity financing, at the offering price. As of March 31, 2007, 1,189,402 shares would be issuable to fully repay the principal and interest outstanding upon conversion.

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 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.

Table of Contents

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.

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.

Edgar Filing: NUVELO INC - Form 10-Q

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 March 31, 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. Three 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, three 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 will rule on the motions to transfer the cases before it decides the motions for consolidation, lead plaintiff and lead plaintiff's counsel. 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. The Court is currently scheduled to hear this motion on May 24, 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. The final terms of the settlement are still being negotiated. We believe that any loss or settlement amount will not be material to our financial position or results of operations, and that any settlement payment and attorneys' fees accrued with respect to the suit will be paid by our insurance provider. However, it is possible that the parties may not reach agreement on the final settlement documents or that the Federal District Court may not approve the settlement in whole or part. We could be forced to incur material expenses in the litigation if the parties do not reach agreement of the final settlement documents, and in the event there is an adverse outcome, our business could be harmed. 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.

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(*).

RISKS RELATED TO OUR BUSINESS

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

We currently have two clinical-stage drug candidates. The first 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 are currently suspended pending further analyses and discussions with outside experts, data safety monitoring boards and regulatory agencies, as well as with our partner, Bayer. After these discussions are completed, we will determine the appropriate course of action regarding the potential future development of alfimeprase. We may be unable to resume development of alfimeprase, and if so, our business, results of operations and financial condition will be affected in a materially adverse manner. We are currently enrolling patients in a Phase 2 trial of our second drug candidate, rNAPc2, for the treatment of metastatic colorectal cancer. If we are unable to further develop rNAPc2 for any reason, our business, results of operations and financial condition may be affected in a materially adverse manner. 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.

If we fail to maintain existing licenses and collaborations, such as our collaboration with Bayer, 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.

Table of Contents

In January 2006, we entered into a license and collaboration agreement with Bayer for the development and commercialization of alfimeprase internationally. In December 2006, all clinical trials for alfimeprase were suspended pending further analyses and discussions with outside experts, data safety monitoring boards and regulatory agencies, as well as with Bayer. Under this agreement with Bayer, Bayer has the right to commercialize alfimeprase in all territories outside the United States and, if commercialized, will pay us tiered royalties on net sales of alfimeprase, if any ranging from a minimum of 15 percent to a maximum of 37.5 percent. We retain all commercialization rights and profits from alfimeprase sales in the United States, if any. We received an up-front cash payment from Bayer of \$50.0 million upon entry into the agreement and are eligible to receive up to an additional \$335.0 million in milestone payments, including \$165.0 million in development milestones and \$170.0 million in sales and commercialization milestones over the course of the agreement. We currently cannot predict if or when any of these milestones will be achieved. Under the terms of the agreement, Bayer has the right to terminate the collaboration at its option upon 12 months notice. We are responsible for 60 percent of any costs for US development programs associated with alfimeprase and solely bear the expense of any country-specific alfimeprase clinical trials conducted by us where the country-specific clinical trials are not part of the agreed global development program.

The suspension of our clinical trials for alfimeprase may negatively impact our collaboration with Bayer. If we fail to maintain a successful collaboration with Bayer, Bayer could terminate our agreement, which would have a material, adverse effect on our business. Termination of our collaboration with Bayer could force us to expend additional amounts to develop alfimeprase, if further development is possible, and to obtain regulatory approval. Additionally, termination of the collaboration could delay any potential commercial launch of alfimeprase and our ability to pursue development of alfimeprase in other indications.

In October 2004, we obtained worldwide rights to develop and commercialize alfimeprase from Amgen in exchange for payment to Amgen of future development milestones and royalties. Future milestone payments under the license agreement could total as much as \$35.0 million. Under our agreement with Bayer, we retain sole responsibility for making these payments to Amgen.

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

In March 2005, we entered into a collaboration agreement with the Pharmaceutical Division of Kirin for the development and commercialization of NU206. All operating expenses and profits related to the development and commercialization of NU206 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.

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 three years of the agreement. In addition, Archemix may receive payments totaling up to \$35.0 million per development compound on the achievement of specified development and regulatory milestones, along with potential royalty payments based on sales of licensed compounds. 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 shares issued by Archemix in a qualified public offering of Archemix stock occurring within five years of the effective date of the new collaboration agreement. At the initiation of the first Phase 3 study for any licensed compound, Archemix has the option to elect to participate in profits from sales of the compound by funding its pro rata share of prior and future product development and commercialization expenses, in lieu of receiving milestone payments and royalties with respect to that compound.

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, rNAPc2, NU206, NU172, or other preclinical product candidates, or we may become involved in litigation or arbitration with these 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.

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. If we are unable to effectively manage our current operations and any growth we may experience, 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 a reduction in our workforce, which could adversely affect our operations. Similarly, if we were to terminate all future development of alfimeprase, expenses related to employees engaged in the development of alfimeprase would no longer be offset by reimbursements from Bayer, and we could find it necessary to reduce our expenses through a reduction in our workforce, which could adversely affect our operations.

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

We, and our collaborators, will only receive regulatory approval for 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 peripheral arterial occlusion and in the first of two planned Phase 3 trials for the treatment of catheter occlusion. Based on results at any stage of clinical trials, we may decide to repeat or redesign a trial or discontinue development of one or more of our drug candidates. If we fail to adequately demonstrate the safety and efficacy of our products under development, we will not be able to obtain the required regulatory approvals to commercialize our drug candidates, and our business, results of operations and financial condition would be materially adversely affected.

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

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 or commercialization 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 acute peripheral arterial occlusion and a Phase 3 trial for 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.

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.

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 Good Manufacturing Practices regulations, or cGMP, and that the process for manufacturing the product has been validated in accordance with the requirements of the FDA and comparable agencies in

other countries.

The process of obtaining FDA and other required regulatory approvals and clearances typically takes several years and will require us to expend substantial capital and resources. Despite the time and expense expended, regulatory approval is never guaranteed. The number of 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.

Edgar Filing: NUVELO INC - Form 10-Q

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;

Table of Contents

finer;

civil penalties;

injunctive;

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.

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

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

Patient enrollment is affected by factors including:

design of the protocol;

the size of the patient population;

eligibility criteria for the study in question;

perceived risks and benefits of the drug under study;

availability of competing therapies;

efforts to facilitate timely enrollment in clinical trials;

the success of our personnel in making the arrangements with potential clinical trial sites necessary for those sites to begin enrolling patients;

patient referral practices of physicians;

availability of clinical trial sites; and

other clinical trials seeking to enroll subjects with similar profiles.

If we have difficulty enrolling a sufficient number of patients to conduct our clinical trials as planned, we may need to delay or terminate ongoing or planned clinical trials, either of which would have a negative effect on our business. Delays in enrolling patients in our clinical trials would also adversely affect our ability to generate product, milestone and royalty revenues, and could impose significant additional costs on us or on our collaborators.

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 suspended trials, near-term trials, additional supplies may be necessary for trials in

Table of Contents

other indications. We do not have an agreement in place for the commercial-scale manufacture of alfimeprase final drug product. We have not yet determined whether we will continue the manufacture of clinical supplies of alfimeprase with our current manufacturer, 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 suspended clinical trials if re-initiated, new 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 and Bayer's efforts to complete any re-initiated clinical trials, or clinical trials in other indications, 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.

With respect to rNAPc2, we received a supply of rNAPc2 from Dendreon, which is being used in our research and development activities and in our currently enrolling Phase 2 trial for the treatment of metastatic colorectal cancer. We are currently engaging third-party manufacturers to produce additional supplies of rNAPc2 for use in future clinical trials and we continue to evaluate the suitability of our original supply of rNAPc2 from Dendreon. Third-party manufacturers may not be able to manufacture the bulk drug substance and final drug product on the timelines, at a cost, in the quantities or with the quality necessary for our ongoing clinical trials or to make this drug commercially viable. Similarly, we may at some point determine that supplies received from Dendreon are no longer suitable for certain research and development activities, which could result in delays in our clinical trials if our third party manufacturers are unable to provide us with the supplies of rNAPc2 we need, when we need them. We also may need to conduct comparative studies or utilize other means to determine bioequivalence between rNAPc2 manufactured by the current manufacturer and the original manufacturer.

If and when any of our other drug candidates, such as NU206 and NU172, enter the clinical trial phase, we will initially depend on third-party contract manufacturers to develop the necessary production processes, and produce the volume of cGMP-grade material needed to complete such trials. We have entered into and intend to enter into 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;

Edgar Filing: NUVELO INC - Form 10-Q

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;

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

We set goals for and make public statements regarding the timing of certain accomplishments, such as the commencement and completion of clinical trials, anticipated regulatory approval dates and time of product launch, which we sometimes refer to as milestones. These milestones may not be achieved, and the actual timing of these events can vary dramatically due to a number of factors such as delays or failures in our clinical trials, disagreements with current or future 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, that we will make regulatory submissions or receive regulatory approvals as planned or that we will be able to launch any of our products in anticipated timeframes. If we fail to achieve one or more of these milestones as planned, our business will be materially adversely affected, and the price of our shares will decline.

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

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

Our success will depend on our ability to attract and retain qualified employees to help develop our potential products and execute our research, development and commercialization strategy. We have programs in place to retain personnel, including programs to create a positive work environment and competitive compensation packages. Because competition for employees in our field is intense, however, we may be unable to retain our existing personnel or attract qualified individuals to fill open positions. 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, development and commercialization programs could be delayed, and we could experience difficulties in generating sufficient revenue to maintain our business.

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.

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

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

the possibility that a product is toxic, ineffective or unreliable;

failure to obtain regulatory approval for the product;

Edgar Filing: NUVELO INC - Form 10-Q

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. We currently have limited marketing and distribution capability. As the potential commercialization of our products approaches, we intend to hire sales and additional marketing personnel to enable us to participate in the commercialization of our products in the United States. If we are unsuccessful in hiring and retaining sales and marketing personnel with appropriate technical and sales expertise when we need them or in developing an adequate distribution capability to support them, our ability to generate product revenues will be adversely affected.

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.

Table of Contents

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 and is accentuated by the rapid pace of technological development. Our products, if successfully developed, will compete with a number of traditional drugs and therapies and with new products currently under development. We also expect to face increased competition in the future as new companies enter our markets. Research and discoveries by others may result in breakthroughs that render our potential products obsolete even before they begin to generate any revenue. The competitors for our drugs currently in development will vary depending on the particular indication pursued, and may include major pharmaceutical, medical device and biotechnology firms, many of which have substantially greater research and product development capabilities and financial, scientific, marketing and human resources than we have. Our first 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 Meri® Retriever. Our second product candidate, rNAPc2 is an anticoagulant for the potential treatment of acute coronary syndromes (ACS) and is also a potential candidate for the treatment of cancer. If approved for the treatment of ACS, rNAPc2 could face competition from a variety of products, such as enoxaparin from Sanofi-Aventis and fondaparinux from GlaxoSmithKline PLC. If approved for the treatment of colorectal cancer, rNAPc2 could face competition from Genentech's Avastin, ImClone Systems Incorporated's Erbitux, Amgen's Vectibix, as well as numerous other therapeutics for treating cancer.

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.

Edgar Filing: NUVELO INC - Form 10-Q

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.

Edgar Filing: NUVELO INC - Form 10-Q

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

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

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

government health administration authorities;

private health insurers;

health maintenance organizations;

pharmacy benefit management companies; and

other healthcare-related organizations.

Table of Contents

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

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

We had net losses of \$71.6 million in 2005, \$130.6 million in 2006 and \$15.3 million in the three months ended March 31, 2007. As of March 31, 2007, we had an accumulated deficit of \$473.6 million.

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

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

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

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 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. The unavailability of financing may require us to delay, scale back or eliminate expenditures for our research, development and marketing activities necessary to commercialize our potential biopharmaceutical products. We may also be required to raise capital by granting rights to third parties to develop and market drug candidates that we would prefer to develop and market on our own, potentially reducing the ultimate value that we could realize from these drug candidates.

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

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

our ability to maintain, and the financial commitments involved in, our existing collaborative and licensing arrangements, including our ability to continue to receive cost-sharing reimbursements from our collaboration partners;

the status of our collaboration with Bayer, in accordance with the alfimeprase license and collaboration agreement we entered into in January 2006;

progress in current and anticipated clinical studies of our products, including alfimeprase, rNAPc2, NU206 and NU172;

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

future funding commitments to new and existing collaborators;

Table of Contents

the cost of manufacturing our material for preclinical, clinical and commercial 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 common stock to repay our line of credit with Dr. George Rathmann;

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 March 31, 2007, the price ranged between a high of \$4.12 per share and a low of \$3.04 per share. Significant market price fluctuations of our common stock can be due to a variety of factors, including:

Edgar Filing: NUVELO INC - Form 10-Q

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, or upon repayment of our line of credit with Dr. George Rathmann;

market conditions relating to the biopharmaceutical and pharmaceutical industries;

any announcements of technological innovations, new commercial products or collaborations, or clinical progress or lack thereof by us, our collaborative partners or our competitors;

announcements concerning regulatory developments or developments with respect to proprietary rights;

changes in our collaborative arrangements;

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 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;

Table of Contents

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;

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 our two clinical stage drug candidates, 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.

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 alfineprase 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

Edgar Filing: NUVELO INC - Form 10-Q

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. Three 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, three 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 will rule on the motions to transfer the cases before it decides the motions for consolidation, lead plaintiff and lead plaintiff's counsel. We currently cannot determine the impact that this litigation will have on our business, results of operations or financial condition.

Edgar Filing: NUVELO INC - Form 10-Q

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. The Court is currently scheduled to hear this motion on May 24, 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, 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. 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.

Table of Contents**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 March 31, 2007, we had 53,302,460 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 March 31, 2007, our directors, officers and greater than five percent stockholders held approximately 15 percent of the shares of our outstanding common stock. Although we do not believe that our directors, officers and greater than five percent stockholders have any present intentions to dispose of large amounts of any shares of common stock owned by them, there can be no assurance that such intentions will not change in the future. The sale of these additional shares could depress the market price of our common stock.

Under registration statements on Form S-8 under the Securities Act, as of March 31, 2007, we have also registered approximately 10,634,078 shares of our common stock which may be issued under our 2004 Equity Incentive Plan, 2002 Equity Incentive Plan, 1995 Stock Option Plan, Non-Employee Director Stock Option Plan, Scientific Advisory Board/Consultants Stock Option Plan, stock option agreements entered into outside of any of our stock option plans, and our Employee Stock Purchase Plan. Included in the 10,634,078 shares, as of March 31, 2007, are (i) 8,149,076 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) 154,500 shares of our common stock outstanding under restricted stock units, (iv) 1,431,868 shares of our common stock reserved for future grants under our 2004 Equity Incentive Plan, and (v) 125,095 shares of our common stock reserved for future issuance under our Employee Stock Purchase Plan. As of March 31, 2007, outstanding options were exercisable for 3,958,126 shares of common stock. 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 March 31, 2007, 1,095,614 shares of our common stock were issuable upon the exercise of outstanding warrants, which were all exercisable as of this date. Once a warrant is exercised, the holder can arrange for the resale of shares either by invoking any applicable registration rights, causing the shares to be registered under the Securities Act and thus freely transferable, or by relying on an exemption to the Securities Act. If these registration rights, or similar registration rights that may apply to securities we may issue in the future, are exercised, it could result in additional sales of our common stock in the market, which may have an adverse effect on our stock price.

As of March 31, 2007, \$3.8 million of our common stock was issuable, upon mutual agreement, to convert the remaining amount due on the promissory note under our line of credit with Dr. George Rathmann, including accrued interest, at a conversion price equal to the average price of our common stock over a 20-day period, ending two days prior to conversion, or, if in connection with an equity financing, at the offering price. If we agree to repay this note with our common stock, whether pursuant to acceleration of the note or otherwise, the resale of shares of our common stock received by Dr. Rathmann may also result in significant downward pressure on the market price of our common stock.

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. 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.

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.

Edgar Filing: NUVELO INC - Form 10-Q

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. 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. 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. Kingsbridge will not be 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.

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. Under our August 31, 2004 Loan and Security Agreement with Silicon Valley Bank, as amended, we cannot pay dividends without Silicon Valley Bank's prior written consent, except for dividends paid in shares of our capital stock. Furthermore, we may incur additional indebtedness that may severely restrict or prohibit the payment of dividends.

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

Table of Contents

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

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

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

establish a classified board of directors so that not all members of our board may be elected at one time;

authorize the issuance of up to 5,000,000 shares of preferred stock that could be issued by our board of directors to increase the number of outstanding shares and hinder a takeover attempt;

limit who may call a special meeting of stockholders;

prohibit stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders; and

establish advance notice requirements for nominations for election to our board of directors or for proposing matters that can be acted upon at a stockholder meeting.

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

Edgar Filing: NUVELO INC - Form 10-Q

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

the board of directors approved the transaction where the stockholder acquired 15 percent or more of the corporation's stock;

after the transaction in which the stockholder acquired 15 percent or more of the corporation's stock, the stockholder owned at least 85 percent of the corporation's outstanding voting stock, excluding shares owned by directors, officers and employee stock plans in which employee participants do not have the right to determine confidentially whether shares held under the plan will be tendered in a tender or exchange offer; or

on or after this date, the merger or sale is approved by the board of directors and the holders of at least two-thirds of the outstanding voting stock that is not owned by the stockholder.

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

lengthen the time required for a person or entity to acquire control of us through a proxy contest for the election of a majority of our board of directors;

discourage bids for our common stock at a premium over market price; and

generally deter efforts to obtain control of us.

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

In December 2004, our board of directors approved an Executive Change in Control and Severance Benefit Plan for our executive officers and other eligible employees, which was amended and restated in May 2005. The purpose of the plan is to provide for the payment of severance benefits and/or change in control benefits to certain of our eligible employees, and the plan supersedes and replaces any change in control and/or severance plans adopted by us previously. All of our executive employees at the level of Vice President or above have been designated as participants in the plan and our board of directors may designate other eligible individuals as participants. The plan provides that, upon a change in control of the company as defined under the plan, all Nuvelo stock options and stock awards held by a plan participant will become fully vested. Such shares held by a plan participant will also become fully vested if the participant is terminated without cause, or constructively terminated, within one month preceding our change in control. If a participant is terminated without cause or constructively terminated one month before or one year

Table of Contents

after our change in control, he or she will also be entitled to certain cash severance and continued medical benefits. The change in control and severance benefits for certain of our employees provided for under this plan could make it more difficult and expensive, or less desirable, for a third party to acquire us, even if doing so would benefit our stockholders.

RISKS RELATED TO INTELLECTUAL PROPERTY AND OTHER LEGAL MATTERS

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

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

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

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

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

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

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

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

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

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

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

We face product liability exposure and potential unavailability of insurance.

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

Table of Contents

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.

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 Number	Description
---------------------------	--------------------

Edgar Filing: NUVELO INC - Form 10-Q

- 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.
- 10.60* Bonuses for Named Executive Officers Awarded January 29, 2007.
- 31.1* Certificate of Chief Executive Officer pursuant to Rule 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 31.2* Certificate of Chief Financial Officer pursuant to Rule 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 32.1* Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. sec. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

Table of Contents

* Filed herewith.

§ Confidential treatment requested.

- (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.

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

Dated: May 10, 2007

Table of Contents**EXHIBIT INDEX**

Exhibit Number	Description
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.
10.60*	Bonuses for Named Executive Officers Awarded January 29, 2007.
31.1*	Certificate of Chief Executive Officer pursuant to Rule 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certificate of Chief Financial Officer pursuant to Rule 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. sec. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

* Filed herewith.

§ Confidential treatment requested.

- (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.

Edgar Filing: NUVELO INC - Form 10-Q

- (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.