NUVELO INC
Form 10-Q
November 05, 2008
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

x **QUARTERLY REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2008

OR

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

Commission File Number 000-22873

NUVELO, INC.

(Exact Name of Registrant as Specified in Its Charter)

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

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

(Address of Principal Executive Offices, including Zip Code)

650-517-8000

(Registrant s Telephone Number, including Area Code)

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

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

Large accelerated filer ¨	Accelerated filer x	Non-accelerated filer ¨ (Do not check if a smaller reporting company)	Smaller Reporting Company ¨

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

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

Class	**Number of Shares Outstanding**
Common Stock $0.001 par value	On October 31, 2008: 53,663,805

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FORM 10-Q

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PART I. FINANCIAL INFORMATION

ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

NUVELO, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(unaudited)

	September 30, 2008	December 31, 2007
	(In thousands)	
ASSETS		
Cash and cash equivalents	$ 35,168	$ 32,061
Marketable securities	23,964	65,506
Collaboration receivables	835	588
Other current assets	950	1,831
Total current assets	60,917	99,986
Restricted cash	6,000	6,000
Property and equipment, net	7,383	8,906
Goodwill		4,671
Other assets	1,099	1,120
Total assets	$ 75,399	$ 120,683
LIABILITIES AND STOCKHOLDERS EQUITY		
Accounts payable	$ 2,642	$ 2,307
Accrued compensation and employee benefits	1,191	2,350
Accrued clinical trial and drug manufacturing costs	1,463	3,232
Current portion of deferred revenue	250	250
Current portion of deferred rent	1,444	1,400
Current portion of accrued facility exit costs	6,816	7,389
Other current liabilities	539	1,259
Total current liabilities	14,345	18,187
Non-current portion of deferred revenue	875	16,063
Non-current portion of deferred rent	4,514	5,597
Non-current portion of accrued facility exit costs	10,105	13,098
Other liabilities	845	79
Total liabilities	30,684	53,024
Stockholders equity:		
Preferred stock		
Common stock	53	53
Additional paid-in capital	542,422	538,070
Accumulated other comprehensive income (loss)	(90)	49
Accumulated deficit	(497,670)	(470,513)
Total stockholders equity	44,715	67,659

Total liabilities and stockholders equity	$ 75,399	$ 120,683

See accompanying notes to condensed consolidated financial statements.

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NUVELO, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
	(In thousands, except per share data)			
Contract revenues	$ 63	$ 63	$ 15,188	$ 46,798
Operating expenses:				
Research and development	5,407	9,494	24,555	33,452
General and administrative	3,698	4,204	11,359	16,843
Restructuring		2,336	2,470	2,336
Facility exit charge			1,472	
Impairment of goodwill			4,671	
Total operating expenses	9,105	16,034	44,527	52,631
Operating loss	(9,042)	(15,971)	(29,339)	(5,833)
Interest income, net	524	1,613	2,182	5,168
Net loss	$ (8,518)	$ (14,358)	$ (27,157)	$ (665)
Basic and diluted net loss per share	$ (0.16)	$ (0.27)	$ (0.51)	$ (0.01)
Weighted average shares used in computing basic and diluted net loss per share	53,616	53,361	53,536	53,310

See accompanying notes to condensed consolidated financial statements.

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NUVELO, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(unaudited)

	Nine Months Ended September 30,	
	2008	2007
	(In thousands)	
Cash flows from operating activities:		
Net loss	$ (27,157)	$ (665)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,739	1,766
Stock-based compensation expense	4,171	7,876
Non-cash facility exit charge and accretion expense	2,622	1,485
Impairment of assets	4,671	1,117
Changes in operating assets and liabilities:		
Collaboration receivables	(247)	8,129
Other current assets	881	2,175
Other assets	21	290
Accounts payable	335	(4,545)
Accrued compensation and employee benefits	(1,159)	(523)
Accrued clinical trial and drug manufacturing costs	(1,769)	(10,423)
Other current liabilities	35	(269)
Deferred revenue	(15,188)	(31,798)
Deferred rent	(1,039)	(996)
Accrued facility exit costs	(6,188)	(6,011)
Accrued interest		82
Other non-current liabilities	45	
Net cash used in operating activities	(38,227)	(32,310)
Cash flows from investing activities:		
Maturities of marketable securities	86,013	119,578
Purchases of marketable securities	(44,610)	(92,912)
Purchases of property and equipment	(216)	(353)
Increase in restricted cash		(6,000)
Net cash provided by investing activities	41,187	20,313
Cash flows from financing activities:		
Proceeds from issuance of common stock under employee stock purchase plan	181	377
Payments on bank loans and capital lease obligations	(34)	(1,524)
Payments on related party line of credit		(2,063)
Net cash provided by (used in) financing activities	147	(3,210)
Net increase (decrease) in cash and cash equivalents	3,107	(15,207)
Cash and cash equivalents at beginning of period	32,061	60,335
Cash and cash equivalents at end of period	$ 35,168	$ 45,128

See accompanying notes to condensed consolidated financial statements.

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NUVELO, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

September 30, 2008

(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, 2007 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 other current liabilities in the condensed consolidated balance sheets and 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, 2007.

The unaudited condensed consolidated financial statements include the accounts of Nuvelo, Inc. and its subsidiaries. All inter-company transactions and accounts have been eliminated on consolidation.

Nuvelo is a biopharmaceutical company engaged in the discovery, development and commercialization of novel drugs for acute cardiovascular disease, cancer and other debilitating medical conditions.

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.

Fair Value Disclosures

On January 1, 2008, the Company adopted FASB Statement of Financial Accounting Standards No. 157, *Fair Value Measurements* (SFAS 157). SFAS 157 establishes a common definition for fair value to be applied to U.S. GAAP requiring use of fair value, establishes a framework for measuring fair value, and expands disclosure about such fair value measurements. In February 2008, the FASB issued FASB Staff Position No. FAS 157-2, *Effective Date of FASB Statement No. 157* (FSP 157-2), which delays the effective date of SFAS 157 for all nonfinancial assets and nonfinancial liabilities, except items that are recognized or disclosed at fair value on a recurring basis (at least annually), until fiscal years beginning after November 15, 2008. The implementation of SFAS 157 for financial assets and financial liabilities did not have a material impact on our consolidated financial position and results of operations. The Company is currently assessing the impact of adopting SFAS 157 for nonfinancial assets and nonfinancial liabilities on its financial position and results of operations.

SFAS 157 defines fair value as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date (exit price). SFAS 157 classifies the inputs used to measure fair value into the following hierarchy:

Level 1 Unadjusted quoted prices in active markets for identical assets or liabilities

Level 2 Unadjusted quoted prices in active markets for similar assets or liabilities; unadjusted quoted prices for identical or similar assets or liabilities in markets that are not active; or inputs other than quotes prices that are observable for the asset or liability

Level 3 Unobservable inputs for the asset or liability

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The following table represents the Company s fair value hierarchy for its financial assets (cash equivalents and marketable securities) measured at fair value on a recurring basis as of September 30, 2008 (in thousands):

	Level 1	Level 2	Level 3	Total
Money market funds	$ 30,286	$	$	$ 30,286
Corporate debt securities		27,953		27,953
Total	$ 30,286	$ 27,953	$	$ 58,239

Money market funds, which are expected to maintain a net asset value of $1 per share, are categorized in Level 1 of the fair value hierarchy. Corporate debt securities are categorized in Level 2 of the fair value hierarchy. The fair value of these securities is generally based on pricing models which take into consideration market prices of identical or similar securities from multiple sources and the securities accreted balance on the reporting day.

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 allows entities to voluntarily choose, at specified election dates, to measure many financial instruments and certain other items at fair value that are not currently required to be measured at fair value. The effective date for the Company is January 1, 2008. To date, the Company has not elected this fair value option for any assets or liabilities.

2. Proposed Merger with ARCA biopharma, Inc.

On September 24, 2008, Nuvelo entered into an Agreement and Plan of Merger and Reorganization (the Merger Agreement) with ARCA biopharma, Inc., a private Delaware corporation (ARCA), and Dawn Acquisition Sub, Inc., a Delaware corporation and wholly owned subsidiary of Nuvelo (Merger Sub), amended October 28, 2008, pursuant to which, on the terms and subject to the conditions set forth in the Merger Agreement, Merger Sub will be merged with and into ARCA, with ARCA surviving the merger (the Merger) as a wholly-owned subsidiary of Nuvelo. Upon the terms and subject to the conditions set forth in the Merger Agreement, Nuvelo will issue, and holders of ARCA capital stock will receive, shares of common stock of Nuvelo, such that following the consummation of the transactions contemplated by the Merger Agreement, current stockholders of Nuvelo are expected to own approximately 33% of the common stock of the combined company and current ARCA stockholders, together with holders of ARCA options and warrants assumed by Nuvelo, are expected to own or have the right to acquire approximately 67% of the common stock of the combined company, after giving effect to the issuance of shares pursuant to ARCA s outstanding options and warrants primarily on a treasury-method basis, and without giving effect to any shares issuable pursuant to Nuvelo s outstanding options and warrants. The Merger is intended to qualify for federal income tax purposes as a tax-free reorganization under the provisions of Section 368(a) of the U.S. Internal Revenue Code of 1986, as amended.

Consummation of the Merger is subject to closing conditions, including among other things, (i) declaration of effectiveness by the Securities and Exchange Commission of the registration statement on Form S-4 with respect to the registration of the shares of Nuvelo common stock to be issued in the Merger, filed on October 30, 2008; (ii) approval and adoption of the Merger Agreement and Merger by the requisite vote of the stockholders of ARCA; (iii) approval of the issuance of shares of Nuvelo common stock in connection with the Merger by the requisite vote of Nuvelo stockholders; and (iv) conditional approval for the listing of Nuvelo common stock to be issued in the Merger on any of the Nasdaq Global Select Market, Nasdaq Global Market or Nasdaq Capital Market. In order to comply with Nasdaq listing requirements, Nuvelo intends to seek stockholder approval to effect a reverse stock split of its common stock in conjunction with the closing of this transaction.

The Merger will be treated by Nuvelo as a reverse merger and will be accounted for as a business combination using the purchase method of accounting in accordance with GAAP. For accounting purposes, ARCA is considered to be acquiring Nuvelo in the Merger, as the existing stockholders of ARCA will have a controlling interest in the combined company and ARCA s management will be the management of the combined company. The transaction will be accounted for under the purchase method of accounting in accordance with Statement of Financial Accounting Standards, or SFAS, No. 141, *Business Combinations*, assuming the Merger will close on or prior to December 31, 2008. However, if the Merger were to be consummated in 2009, SFAS 141R would apply and would materially change the accounting treatment.

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The Merger Agreement contains certain termination rights for both Nuvelo and ARCA, and further provides that, upon termination of the Merger Agreement under specified circumstances, ARCA may be required to pay Nuvelo a termination fee of approximately $1.9 million and Nuvelo may be required to pay ARCA a termination fee of approximately $0.9 million.

3. Net Loss Per Share

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

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

	September 30,	
	2008	2007
Stock options and restricted stock units	5,608	7,572
Warrants	850	850
Total	6,458	8,422

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 September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
Net loss, as reported	$ (8,518)	$ (14,358)	$ (27,157)	$ (665)
Change in unrealized gain (loss) on available-for-sale securities	(102)	16	(139)	1
Change in unrealized gain (loss) on hedging instruments				(6)
Comprehensive loss	$ (8,620)	$ (14,342)	$ (27,296)	$ (670)

5. Stock-based Compensation

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
Research and development	$ 153	$ 783	$ 512	$ 2,924
General and administrative	805	1,170	2,422	4,023
Restructuring		926	1,237	926
Total	$ 958	$ 2,879	$ 4,171	$ 7,873

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 and, as a result, a full valuation allowance is applied to this deferred tax asset.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
Expected term		4.80 years	4.63 years	4.94 years
Expected volatility		0.92	0.95	0.88
Risk-free interest rate		4.50%	2.78%	4.66%
Expected dividend yield				
Weighted-average grant date fair value per share	$	1.64	$ 1.08	$ 2.48

No options were granted to employees in the three months ended September 30, 2008. In the nine months ended September 30, 2008, the Company granted employees options to purchase 1,285,800 shares of its common stock. In the three and nine months ended September 30, 2007, the Company granted employees options to purchase 51,200 and 1,567,750 shares of common stock, respectively.

The Company terminated two executives in connection with its reduction in force announced in March 2008 (see Note 6, Restructuring). The two former executives were entitled to a 12-month acceleration in vesting of their options at the time of their termination. For the nine months ended September 30, 2008, the Company recorded $1.2 million of stock-based compensation expense as a result of this acceleration in vesting of these options and classified this expense as part of restructuring expense.

6. Restructuring

On March 17, 2008, the Company announced its decision to discontinue alfimeprase clinical development and restructure to make additional resources available for its other research and development programs. In connection with the restructuring, the Company reduced its workforce by approximately 19 percent and recorded a restructuring expense of $2.5 million, including $1.3 million of termination benefits and $1.2 million of non-cash stock-based compensation expense, for the nine months ended September 30, 2008. As of September 30, 2008, $0.4 million of termination benefits remained unpaid and were classified under accrued compensation and employee benefits in the condensed consolidated balance sheet.

In connection with the restructuring announced in August 2007, the Company recorded a restructuring expense of $2.3 million, including $1.4 million of termination benefits and $0.9 million of non-cash stock-based compensation expense, for the nine months ended September 30, 2007. Of the $1.4 million termination benefits, $1.0 million was paid in 2007 and the balance was paid in the nine months ended September 30, 2008.

7. Facility Exit Costs

The Company 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 Company exited the Sunnyvale facility and accrued $26.6 million to reflect the estimated present value of future lease-related payments less estimated net income from sublease rental. The future lease-related payments are scheduled to be made periodically until the lease expires.

The balance of accrued facility exit costs represents the fair value of the lease liability based on assumptions regarding the vacancy period, sublease terms, and the probability of subleasing this space. The estimates and assumptions are re-evaluated each quarter and are based upon current market data, including vacancy rates and lease activities for similar facilities within the area. As of March 31, 2008, the Company determined that the likelihood of subleasing the Sunnyvale facility during the remainder of the lease term has become remote and, therefore, recorded a $1.5 million charge to reflect such change in the sublease assumption. The charge increased the net loss per share by $0.03 for the nine months ended September 30, 2008.

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The following table summarizes the activity related to facility exit costs liabilities for the nine months ended September 30, 2008 (in thousands):

Balance as of December 31, 2007	$ 20,487
Amounts paid during the period	(6,188)
Non-cash accretion	1,150
Change in fair value due to change in sublease assumption	1,472
Balance as of September 30, 2008	$ 16,921

The non-cash accretion, which was included in general and administrative expenses, was $0.4 million and $1.2 million for the three and nine months ended September 30, 2008, and $0.5 million and $1.5 million for the three and nine months ended September 30, 2007, respectively.

The Company has also recorded a $0.8 million facility restoration obligation related to the Sunnyvale facility. The Company currently expects to complete the facility restoration in 2011. Accordingly, this obligation was classified as other long-term liabilities as of September 30, 2008.

8. Goodwill

The Company tests goodwill for impairment using a fair value approach at the reporting unit level on an annual basis or when events indicate that the carrying value of the asset may be impaired in accordance with Statement of Financial Accounting Standards No. 142, *Goodwill and other Intangible Assets*, (SFAS 142). Consistent with the determination that the Company has only one reporting segment, it has determined that there is only one reporting unit and, therefore, goodwill is tested at the entity level. The Company has elected October 31st as its measurement date. The Company completed its last annual goodwill tests as of October 31, 2007, and no impairments were recognized.

SFAS 142 requires a two-step test for goodwill impairment. In the first step, the Company compares the fair value of the Company to its carrying value. The Company generally bases its fair value on its market capitalization, which is based on quoted market prices of its common stock, taking into account other factors that may affect the fair value of the Company as a whole. If the fair value of the Company exceeds the carrying value of its net assets, goodwill is not impaired and the Company is not required to proceed to the second step of the impairment test.

In the first quarter of 2008, the Company performed a goodwill impairment test due to the significant decline of its stock price subsequent to the alfimeprase announcement on March 17, 2008 (see Note 6, Restructuring). Significant judgment is required to evaluate the fair value of a company, as quoted market prices of a company s common stock and consequently market capitalization may experience significant fluctuations in reaction to disclosures of new information about the company. Based on the upward trend in the price of the Company s common stock following the initial decrease after the announcement and through the filing of the Form 10-Q for the first quarter of 2008, management concluded that the market capitalization following the initial market reaction to the announcement did not provide a good indication of the Company s fair value. Accordingly, management concluded that the carrying value of the net assets at that time did not exceed the Company s fair value and consequently, goodwill was not impaired at March 31, 2008.

In the second quarter of 2008, the Company performed an additional goodwill impairment test as the upward trend in the market price of the Company s common stock did not continue and the Company s market capitalization remained lower than its carrying value. Since the carrying value exceeded the fair value, at June 30, 2008, the Company performed the second step in order to determine the implied fair value of the Company s goodwill and compare it to the carrying value of goodwill. The activities in the second step included valuing the tangible and intangible assets and liabilities of the Company based on their fair value and determining the implied goodwill based upon the difference between the fair value of the reporting unit and the net fair values of identified tangible and intangible assets and liabilities. Based on the results of the second step of calculating the implied goodwill, the Company recorded an impairment charge of the full balance of goodwill totaling $4.7 million.

9. Agreements with Bayer

In June 2007, the Company and Bayer Healthcare AG (Bayer) terminated their January 2006 license and collaboration agreement for the development and commercialization of alfimeprase. As part of the termination agreement with Bayer, the Company agreed to waive Bayer s obligation to provide Nuvelo 12 months notice of termination in consideration of Bayer s agreement to pay Nuvelo a lump sum of $15.0 million. Nuvelo also granted Bayer the option to reacquire rights to alfimeprase upon the initiation of a pivotal stroke trial or upon Nuvelo s public announcement that it is discontinuing further development of alfimeprase in the stroke indication. The notice period during which Bayer could exercise the option would begin upon the Company making certain information available to Bayer and last for 30 days after delivery of the

information.

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The Company announced its decision to discontinue alfimeprase clinical development on March 17, 2008 and provided the information to Bayer as required by the termination agreement in April 2008. The $15.0 million termination payment, which had been recorded as deferred revenue, was recognized as revenue in May 2008 upon the expiration of the notice period.

10. Segment Information

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

11. Nasdaq Listing Requirement

On May 1, 2008, the Company received a notice from The Nasdaq Stock Market indicating that, for 30 consecutive business days, the bid price for the Company s common stock had closed below the minimum $1.00 per share requirement for continued inclusion on the Nasdaq Global Market. The Company was given 180 calendar days, or until October 28, 2008, to regain compliance with this listing requirement, which would be accomplished if the bid price of the Company s common stock closed at $1.00 per share or more for a minimum of 10 consecutive business days. The notice from Nasdaq also indicated that, if the Company does not regain compliance by October 28, 2008, Nasdaq will provide a staff determination letter notifying the Company that its common stock will be delisted, after which Nuvelo may appeal the staff determination to the Nasdaq Listing Qualifications Panel. On October 16, 2008, Nasdaq advised the Company that it had suspended until January 19, 2009 the enforcement of the rules requiring a minimum $1.00 closing bid price for all Nasdaq listed companies.

Following the end of this suspension period and the 12 days balance of the Company s initial 180 days compliance period, the Company expects to receive a staff determination letter if it has not regained compliance by that time. Upon receipt of the determination letter, the Company intends to submit a request to appeal the determination and present a plan for compliance at an oral hearing with Nasdaq in Washington, D.C. The request for appeal will automatically stay the determination until the appeal is heard and a Nasdaq panel rules on whether to grant conditional listing for up to 180 days following the staff determination in order for the Company to complete its plan of compliance. There can be no assurance that the appeal will be successful or on the timeline presented above or that the plan of compliance and the Company will be able to satisfy the requirements for maintaining a Nasdaq Global Market listing.

If the Company does not regain compliance with this listing requirement by the new deadline imposed by Nasdaq, but meets the initial inclusion criteria for the Nasdaq Capital Market (except for the bid price requirement), the Company may apply to transfer the listing of its common stock to this market. If accepted by the Nasdaq Capital Market, the Company will be provided with an additional 180-day period to demonstrate compliance. If the Company is not eligible for an additional compliance period at that time, Nasdaq will provide written notification that the Company s securities will be delisted. Upon such notice, the Company may appeal the determination to the Nasdaq Listing Qualifications Panel. There can be no assurance that the Company s common stock would be eligible for transfer to the Nasdaq Capital Market, or, if the Company appeals Nasdaq staff s determination, that such appeal would be successful.

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

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

Overview

We are a biopharmaceutical company dedicated to improving the lives of patients through the discovery, development and commercialization of novel drugs for acute cardiovascular disease, cancer and other debilitating medical conditions. Our development pipeline includes NU172, a direct thrombin inhibitor that has completed Phase 1 development for use as a short-acting anticoagulant during medical or surgical procedures, and Phase 1 clinical candidate NU206, a recombinant, secreted protein for the potential treatment of gastrointestinal, or GI, diseases, including cancer therapy induced mucositis and inflammatory bowel disease, in addition to bone disease and wound healing. In addition, we have research programs in leukemia therapeutic antibodies and Wnt signaling pathway therapeutics.

Proposed Merger with ARCA biopharma, Inc.

On September 24, 2008, Nuvelo entered into an Agreement and Plan of Merger and Reorganization, or the Merger Agreement, with ARCA biopharma, Inc., a privately-held biopharmaceutical company, or ARCA, and Dawn Acquisition Sub, Inc., a wholly owned subsidiary of Nuvelo, or Merger Sub, amended October 28, 2008, pursuant to which Merger Sub will be merged with and into ARCA, with ARCA surviving the merger, or the Merger, as a wholly-owned subsidiary of Nuvelo. Under the Merger Agreement, Nuvelo will issue, and holders of ARCA capital stock will receive, shares of common stock of Nuvelo, such that following the consummation of the transactions contemplated by the Merger Agreement, current stockholders of Nuvelo are expected to own approximately 33% of the common stock of the combined company and current ARCA stockholders, together with holders of ARCA options and warrants assumed by Nuvelo, are expected to own or have the right to acquire approximately 67% of the common stock of the combined company, after giving effect to the issuance of shares pursuant to ARCA s outstanding options and warrants primarily on a treasury-method basis, and without giving effect to any shares issuable pursuant to Nuvelo s outstanding options and warrants. The Merger is intended to qualify for federal income tax purposes as a tax-free reorganization under the provisions of Section 368(a) of the U.S. Internal Revenue Code of 1986, as amended.

Consummation of the Merger is subject to closing conditions, including among other things, (i) declaration of effectiveness by the SEC of the registration statement on Form S-4 with respect to the registration of the shares of Nuvelo common stock to be issued in the Merger, filed on October 30, 2008; (ii) approval and adoption of the Merger Agreement and Merger by the requisite vote of the stockholders of ARCA; (iii) approval of the issuance of shares of Nuvelo common stock in connection with the Merger by the requisite vote of Nuvelo stockholders; and (iv) conditional approval for the listing of Nuvelo common stock to be issued in the Merger on any of the Nasdaq Global Select Market, Nasdaq Global Market or Nasdaq Capital Market. In order to comply with Nasdaq listing requirements, Nuvelo intends to seek stockholder approval to effect a reverse stock split of its common stock in conjunction with the closing of this transaction.

The Merger will be treated by Nuvelo as a reverse merger and will be accounted for as a business combination using the purchase method of accounting in accordance with GAAP. For accounting purposes, ARCA is considered to be acquiring Nuvelo in the Merger, as the existing stockholders of ARCA will have a controlling interest in the combined company and ARCA s management will be the management of the combined company. The transaction will be accounted for under the purchase method of accounting in accordance with Statement of Financial Accounting Standards, or SFAS, No. 141, *Business Combinations*, assuming the Merger will close on or prior to December 31, 2008. However, if the Merger were to be consummated in 2009, SFAS 141R would apply and would materially change the accounting treatment.

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The Merger Agreement contains certain termination rights for both Nuvelo and ARCA, and further provides that, upon termination of the Merger Agreement under specified circumstances, ARCA may be required to pay Nuvelo a termination fee of approximately $1.9 million and Nuvelo may be required to pay ARCA a termination fee of approximately $0.9 million.

Product Pipeline

NU172

NU172 is a short-acting aptamer, a single-stranded nucleic acid that forms a well-defined three-dimensional shape conceptually similar to an antibody. NU172 was designed to directly inhibit thrombin s ability to stimulate blood clot formation in the setting of medical or surgical procedures where human blood is exposed to foreign materials. Specifically, NU172 is being studied as a potential short-acting anticoagulant for use during procedures such as coronary artery bypass graft, or CABG, surgery, kidney dialysis and a variety of vascular surgical and coronary interventions. Approximately 450,000 CABG procedures and 50 million dialysis procedures are performed annually in the U.S. In these procedures, heparin is often paired with its antidote protamine as the anticoagulation effect of heparin needs to be reversed once the procedure has been completed. Data from the Phase 1 trial and preclinical studies suggest that NU172 has the potential to produce rapid and predictable onset and offset of anticoagulation, work in stagnant blood, avoid thrombocytopenia, and has the potential for non-renal clearance. These studies also suggest that NU172 may have a short half-life in patients, giving it the potential to be rapidly reversed without the need for an antidote.

In August 2008, we completed the Phase 1b proof-of-concept trial, demonstrating that NU172 rapidly produced and maintained anticoagulation with a rapid return toward baseline after the infusion ended. The single-center, Phase 1b trial examined the safety, tolerability and pharmacokinetics of intravenous bolus plus infusion dosing of NU172 in 24 healthy male volunteers. Volunteers were given a 2 mg/kg bolus dose followed by escalating infusion doses of NU172 for four hours. In all four cohorts, NU172 produced dose-dependent increases in anticoagulation, measured by activated clotting time (ACT), prothrombin time (PT) and activated partial thromboplastin time (aPTT). The highest infusion dose rate tested, 6.0 mg/kg/hr, resulted in an average ACT per subject ranging from 373 to 414 seconds and an increase of approximately three times baseline. Average PT values per subject ranged from 56 to 92 seconds and had an increase of approximately five times baseline. Average aPTT values per subject ranged from 130 to 178 seconds and had an increase of approximately five times baseline. All measurements were maintained stably throughout the four-hour infusion. Once the infusion ended, the ACT and other coagulation parameters showed a rapid return toward baseline, consistent with the short plasma half-life of NU172 observed in the Phase 1a trial. In addition, NU172 was well-tolerated with no serious adverse events.

We anticipate initiating a Phase 2 study evaluating NU172 in CABG patients in the fourth quarter of 2008 or first quarter of 2009.

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. In February 2008, we paid Archemix a $1.0 million milestone fee in connection with the dosing of the first patient in the Phase 1 trial for NU172. If we enroll the first patient in a Phase 2 trial of NU172, which we anticipate may occur before the second quarter of 2009, we are obligated to pay Archemix a $3.0 million milestone fee.

NU206

NU206 (R-spondin1) is a recombinant, secreted protein that acts as a key regulator of the Wnt pathway, a critical pathway that stimulates cell growth and differentiation during homeostasis and pathogenesis in specific tissues including the GI epithelium and bone. NU206 s function is to antagonize an inhibitor of the Wnt pathway, DKK1, thereby turning on the pathway. Preclinical studies suggest it can promote growth and repair in animal models of radiation or cancer chemotherapy induced GI injury, inflammatory bowel disease, bone disease and wound healing. In animal models of GI disease, the effect of NU206 was transient and reversible in normal tissue. Once administration of NU206 is stopped, the epithelium of the intestine reverts to its normal state and does not continue to proliferate.

We initiated a Phase 1 single ascending dose trial in healthy volunteers in July 2008 and expect data from the trial in the second half of 2008. We also plan to initiate a Phase 1b multiple ascending dose trial in healthy volunteers in the fourth quarter of 2008 or first quarter of 2009. We are currently evaluating partnership and out-licensing opportunities for NU206.

In March 2005, we entered into a collaboration agreement with the Kirin Pharma Company, Limited for the development and commercialization of NU206. Under this agreement, all operating expenses and any profits related to the development and commercialization of NU206 are being shared 60 percent by us and 40 percent by Kirin.

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Research Programs

In addition to our clinical and development-stage drug candidates, we have research programs in leukemia therapeutic antibodies and Wnt signaling pathway therapeutics. We are currently evaluating partnership and out-licensing opportunities for both of our research programs.

Leukemia Therapeutic Antibody Program

We have monoclonal antibody (mAbs) candidates discovered by our leukemia therapeutic antibody program. We are completing preclinical studies with a series of chimeric mAbs to select drug candidates for the potential treatment of chronic lymphocytic leukemia and acute mylogenous leukemia.

Wnt Therapeutics Program

The Wnt signaling pathway is critical for regulating cell growth and differentiation during homeostasis and pathogenesis. We have developed a comprehensive approach to target key receptors and secreted proteins that modulate the Wnt pathway. In addition, we have produced mAbs and secreted recombinant proteins with biological activity in cellular assays and animal disease models. Potential indications include: inflammatory bowel disease, peptic ulcers, mucositis, wound healing, and cancer, as well as bone disorders and osteolytic lesions caused by osteoarthritis and multiple myeloma. Our lead candidate in this program is NU206, a Wnt regulator also known as R-Spondin1, which we are developing in collaboration with Kirin.

Results of Operations

Contract Revenues

Contract revenues were $0.1 million and $15.2 million for the three and nine months ended September 30, 2008, compared with $0.1 million and $46.8 million in the corresponding periods of 2007.

In the nine months ended September 30, 2008, we recorded as revenue $15.0 million that was received from Bayer HealthCare AG (Bayer) in connection with the termination of our collaboration agreement in June 2007. Following our decision to discontinue further clinical development of alfimeprase, the $15.0 million, which had been recorded as deferred revenue, was recognized as revenue in May 2008 upon the expiration of the notice period, as defined in the termination agreement with Bayer.

In the nine months ended September 30, 2007, we recorded as revenue $45.8 million of the $50.0 million up-front license fee received from Bayer in January 2006 as a result of the termination of our collaboration agreement in June 2007. The up-front license fee had been recorded as deferred revenue upon receipt and was being recognized on a straight-line basis over the performance period under the agreement, originally estimated to be through September 2020.

We expect the quarterly amortization of existing deferred revenue for the remainder of 2008 to be $63,000 due to the ongoing revenue recognition from an up-front license fee received from Kirin under our NU206 collaboration agreement. We currently do not have any other sources of revenue. In the future, we may not be able to 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, or R&D, expenses primarily consist of clinical trial and drug manufacturing costs, personnel costs, including related stock-based compensation expense, license, collaboration and royalty fees and allocated facilities expenses.

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

Program	Since Inception	Nine Months Ended September 30, 2008	2007
		(In millions)	
Alfimeprase	$ 124.2	$ 4.8	$ 5.4
NU172	17.6	4.5	7.1
NU206	13.7	4.1	2.9

R&D expenses were $5.4 million for the three months ended September 30, 2008, compared with $9.5 million for the corresponding period in 2007, net of cost sharing credits billable to collaboration partners of $0.8 million and $0.3 million, respectively. The decrease of $4.1 million in 2008 was primarily attributed to the following: a $1.6 million decrease in NU172-related expenses, a $1.0 million decrease in alfimeprase-related expenses, a $0.8 million decrease in expenses related to rNAPc2 due to the suspension of development in 2007, and a $0.6 million decrease in employees stock-based compensation expense.

R&D expenses were $24.6 million for the nine months ended September 30, 2008, compared with $33.5 million for the corresponding period in 2007, net of cost sharing credits billable to collaboration partners of $2.8 million and $4.9 million, respectively. The decrease of $8.9 million in 2008 was primarily attributed to the following: a $3.7 million decrease in expenses related to rNAPc2 due to the suspension of development in 2007, a $2.6 million decrease in NU172-related expenses, a $0.6 million decrease in alfimeprase-related expenses, and a $2.4 million decrease in employees stock-based compensation expense, partially offset by a $1.2 million increase in NU206-related expenses.

The decrease in NU172-related expenses in 2008 was primarily due to decreased expenditures in manufacturing and toxicology studies, partially offset by increases in clinical trial and collaboration expenses as a result of the initiation of the Phase 1a and Phase 1b trials. The increase in NU206-related expenses in 2008 was primarily due to increased expenditures in manufacturing, process development, toxicology studies and clinical trials.

In addition to the development programs discussed above, we have research programs, including leukemia therapeutic antibodies and Wnt therapeutics. For the three and nine months ended September 30, 2008, research expenses totaled $1.4 million and $5.0 million, compared with $1.4 million and $4.6 million for the corresponding periods in 2007, respectively.

We expect that total R&D expenses in the fourth quarter of 2008 would be comparable with or higher than that in the third quarter of 2008, largely dependent on the timing of when the Phase 2 trial for NU172 and the Phase 1b trial for NU206 will be initiated.

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 maintenance of existing collaboration agreements with cost-sharing arrangements, 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.

General and Administrative Expenses

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

G&A expenses were $3.7 million for the three months ended September 30, 2008, compared with $4.2 million for the corresponding period in 2007. The decrease of $0.5 million in 2008 was primarily related to a $0.7 million decrease in personnel-related expenses as a result of a reduction in headcount, partially offset by an increase in consulting and professional fees of $0.4 million related to merger related expenses.

G&A expenses were $11.4 million for the nine months ended September 30, 2008, compared with $16.8 million in the corresponding period of 2007. The decrease of $5.4 million in 2008 was primarily related to a $3.9 million decrease in personnel-related expenses as a result of a reduction in headcount and a $1.1 million charge related to the impairment of software implementation costs recorded in the 2007 period.

We expect G&A expenses in the fourth quarter of 2008 to be consistent with or higher than that in the third quarter of 2008 primarily due to merger related expenses.

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Restructuring

On March 17, 2008, we announced that data from our alfimeprase Phase 2 program in catheter occlusion (CO), known as SONOMA-3, did not show sufficient improvement in catheter opening at the higher dose and concentration evaluated in the study to meet the desired target product profile. As a result, we ended further clinical development of alfimeprase, including the programs in CO and acute ischemic stroke, and restructured the company to make additional resources available for our other research and development programs. In connection with the restructuring, we reduced our workforce by approximately 19 percent and recorded a restructuring expense of $2.5 million, including $1.3 million of termination benefits and $1.2 million of non-cash stock-based compensation expense for the nine months ended September 30, 2008.

On August 1, 2007, we announced a reduction in our workforce by approximately 30 percent to realign our organization to focus on core development programs that we believe would produce nearest-term proof-of-concept data. In addition, we announced the decision to suspend development of rNAPc2 in all indications including cancer and acute coronary syndromes. As a result, we recorded a restructuring expense of $2.3 million for the three and nine months ended September 30, 2007, including $1.4 million of termination benefits and $0.9 million of non-cash stock-based compensation expense.

Facility Exit Charge

In December 2006, we exited the Sunnyvale facility and recorded a liability for the remaining lease obligations, less estimated sublease income, for the remainder of the lease term. For the nine months ended September 30, 2008, we recorded a $1.5 million charge reflecting the change in our sublease assumption, as we determined that the likelihood of subleasing the Sunnyvale facility has become remote. We will continue to pursue sublease opportunities and make necessary adjustments to the liability if and when we enter into a sublease agreement in the future.

Impairment of Goodwill

In the first quarter of 2008, we performed a goodwill impairment test due to the significant decline of our stock price subsequent to the March 17, 2008 alfimeprase announcement discussed above. As a result of the impairment test, we determined that goodwill was not impaired as management concluded that the market capitalization following the initial market reaction to the announcement did not provide a good indication of the Company s fair value based on the upward trend in the price of the Company s common stock following the initial decrease after the announcement and through the filing of the Form 10-Q for the first quarter of 2008.

In the second quarter of 2008, we performed an additional goodwill impairment test as the upward trend in the market price of the Company s common stock did not continue and the our market capitalization remained lower than our carrying value. As a result of this impairment test, we determined that goodwill was impaired as of June 30, 2008. Accordingly, we recorded an impairment charge of the full balance of goodwill totaling $4.7 million in the second quarter of 2008 (also see Note 8 to the Condensed Consolidated Financial Statements).

Interest Income, Net

Interest income, net, was $0.5 million and $2.2 million for the three and nine months ended September 30, 2008, compared with $1.6 million and $5.2 million in the corresponding periods of 2007. The decrease was primarily due to declining balances in cash, cash equivalents and marketable securities and a substantial reduction in the yield on cash equivalents and marketable securities.

Liquidity and Capital Resources

Cash and Cash Equivalents, Marketable Securities and Restricted Cash

	September 30, 2008	December 31, 2007
	(In thousands)	
Cash and cash equivalents	$ 35,168	$ 32,061
Marketable securities	23,964	65,506
Restricted cash	6,000	6,000
	$ 65,132	$ 103,567

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As of September 30, 2008, we had total cash and cash equivalents, marketable securities and restricted cash of $65.1 million, as compared with $103.6 million as of December 31, 2007. The decrease of $38.5 million resulted primarily from operating expenditures during the period.

As of September 30, 2008, all of our 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 corporate debt, U.S. government agency and asset-backed securities. We make our investments in accordance with our investment policy. The primary objectives of our investment policy are liquidity and safety of principal.

Cash Flows from Operating, Investing and Financing Activities

	Nine Months Ended September 30,	
	2008	2007
	(In thousands)	
Net cash provided by (used in):		
Operating activities	$ (38,227)	$ (32,310)
Investing activities	41,187	20,313
Financing activities	147	(3,210)
Net increase (decrease) in cash and cash equivalents	$ 3,107	$ (15,207)

Net cash used in operating activities was $38.2 million in the nine months ended September 30, 2008, compared with $32.3 million in the corresponding period of 2007. The increase of $5.9 million in net cash used in operating activities was primarily due to the receipt of $15 million from Bayer in the 2007 period in connection with the termination of the collaboration agreement, partially offset by an overall reduction in R&D and G&A expenses in the 2008 period.

Net cash provided by investing activities was $41.2 million in the nine months ended September 30, 2008, compared with $20.3 million in the corresponding period of 2007. The increase of $20.9 million was primarily due to a decrease in purchases of marketable securities.

Net cash provided by financing activities was $0.1 million in the nine months ended September 30, 2008, compared with net cash used in financing activities of $3.2 million in the corresponding period of 2007. The change was primarily related to the payment in full of bank loans and related party line of credit in 2007.

Sources and Uses of Capital

Our primary sources of liquidity to date have been financing activities and collaboration receipts. In order to complete development of our current product pipeline, we will need to raise funds through additional public and/or private offerings and collaboration activities in the future. 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.

In August 2005, we entered into a Committed Equity Financing Facility (CEFF) with Kingsbridge Capital Ltd. (Kingsbridge), under which Kingsbridge committed to purchase up to a total of $75.0 million of our common stock, not to exceed 8,075,000 shares, within a three-year period, subject to certain conditions and limitations. Under the CEFF, we sold 1,839,400 shares for gross proceeds of $14.4 million in the fourth quarter of 2005, and a further 568,247 shares for gross proceeds of $10.0 million in October 2006. There has been no further sale of shares to Kingsbridge since October 2006. The CEFF expired in October 2008.

In July 2006, we entered into a collaboration agreement with Archemix. Under the agreement, Archemix is responsible for the discovery of short-acting aptamers targeting the coagulation cascade for use in acute cardiovascular procedures, and we are responsible for development and worldwide commercialization of these product candidates. If we enroll the first patient in a Phase 2 trial of NU172, which we anticipate may occur before the second quarter of 2009, a $3.0 million milestone fee is payable to Archemix. In addition, we are obligated to purchase Archemix common stock having a value equal to the lesser of $10.0 million or 15 percent of the total gross proceeds raised by Archemix in a qualified public offering of Archemix stock occurring within five years of the effective date of the collaboration agreement.

We have a $6.0 million letter of credit issued to the landlord of our Sunnyvale facility as required by the lease agreement of this facility, and the letter of credit is being collateralized by a certificate of deposit of the same amount, which is recorded as restricted cash.

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Our future capital requirements and the adequacy of available funds will depend on many factors, including those set forth under Part II, Item 1A. Risk Factors. We may not be able to secure additional financing to meet our funding requirements on acceptable terms, if at all. If we raise additional funds by issuing equity securities, substantial dilution to our existing stockholders may result. If we are unable to obtain additional funds, we will have to reduce our operating costs and delay our research and development programs. We believe that we have adequate balance in cash, cash equivalents and marketable securities 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, 2007.

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 credit 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, 2007.

ITEM 4. CONTROLS AND PROCEDURES

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

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

We continue to review and improve the design and effectiveness of our internal controls over financial reporting in order to remain in compliance with Section 404 of the Sarbanes-Oxley Act of 2002. There has been no change in our internal controls during our fiscal quarter ended September 30, 2008 that has materially affected, or is reasonably likely to materially affect, our internal controls over financial reporting.

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PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

On 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 granted our motion to transfer the cases to the Northern District of California in July 2007. Plaintiffs have filed motions for consolidation, lead plaintiff and lead plaintiff s counsel in the Northern District of California. Plaintiffs filed their consolidated complaint in the Northern District of California on November 9, 2007. We filed a motion to dismiss plaintiffs consolidated complaint on December 21, 2007. Plaintiffs filed an opposition to our motion to dismiss on February 4, 2008. On June 12, 2008, the Court held a hearing on the motion to dismiss. The motion to dismiss the consolidated complaint is still pending. We currently cannot determine the impact that this litigation will have on our business, results of operations or financial condition.

On March 19, 2007, we received a summons related to a derivative suit that had been filed in the Superior Court for California, San Mateo County, by an alleged individual stockholder of Nuvelo, purportedly on behalf of Nuvelo against certain of Nuvelo s current and former officers and directors. The complaint alleges among other claims, that the defendants breached their fiduciary duties to Nuvelo by issuing or failing to prevent the issuance of purportedly false and misleading statements between January 5, 2006 and December 11, 2006 relating to the clinical trial results of alfimeprase, which we announced on December 11, 2006, and that certain defendants benefited from these actions. On April 18, 2007, we filed a demurrer to the complaint on the ground that plaintiff was not excused from issuing a demand to the board prior to filing the lawsuit. Plaintiffs filed oppositions to our demurrer, and we have subsequently filed replies to Plaintiffs oppositions. The Court heard this motion on July 30, 2007, and granted our demurrer, but also granted plaintiffs the opportunity to file an amended complaint. Plaintiffs filed an amended complaint on October 15, 2007. We filed our reply to their amended complaint on December 6, 2007. The Court heard the motion on December 17, 2007. On January 2, 2008, the Superior Court for California, San Mateo County, entered final judgment dismissing in its entirety, with prejudice, the second amended consolidated derivative complaint.

On or about December 6, 2001, Variagenics, Inc. was sued in a complaint filed in the United States District Court for the Southern District of New York naming it and certain of its officers and underwriters as defendants. The complaint purportedly is filed on behalf of persons purchasing Variagenics stock between July 21, 2000 and December 6, 2000, and alleges violations of Sections 11, 12(a)(2) and 15 of the Securities Act of 1933, as amended and Section 10(b) of the Securities Exchange Act of 1934, as amended, and Rule 10b-5 promulgated thereunder. The complaint alleges that, in connection with Variagenics July 21, 2000 initial public offering, or IPO, the defendants failed to disclose additional and excessive commissions purportedly solicited by and paid to the underwriter defendants in exchange for allocating shares of Variagenics stock to preferred customers and alleged agreements among the underwriter defendants and preferred customers tying the allocation of IPO shares to agreements to make additional aftermarket purchases at predetermined prices. Plaintiffs claim that the failure to disclose these alleged arrangements made Variagenics registration statement on Form S-1 filed with the SEC in July 2000 and the prospectus, a part of the registration statement, materially false and misleading. Plaintiffs seek unspecified damages. On or about April 19, 2002, an amended complaint was filed which makes essentially the same allegations. On or about July 15, 2002, Variagenics and the individuals filed a motion to dismiss. We are involved in this litigation as a result of our merger with Variagenics in January 2003. On July 16, 2003, Nuvelo s Board of Directors approved a settlement proposal initiated by the plaintiffs. However, because of a recent court ruling, the settlement class, as defined in the settlement papers, is no longer feasible. While a new complaint has not been filed against us, there are several focus cases against other issuers in which new complaints have been filed. Defendant issuers in the focus cases filed motions to dismiss the new complaints. On March 26, 2008, the District Court issued an order granting in part and denying in part the focus issuers motions to dismiss. The focus issuers had been advised that plaintiffs intended to file new complaints against us, but none have been filed yet. We believe that any attorneys fees, loss or settlement payment with respect to this suit will be paid by our insurance provider. However, it is possible that we could be forced to incur material expenses in the litigation if the parties cannot achieve a settlement, and, in the event of an adverse outcome, our business could be harmed.

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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, 2007 are marked with an asterisk(*).

Risks Related to the Proposed Merger

If the combined company is not able to successfully develop and commercialize ARCA s lead product candidate, Gencaro, or another product candidate, it may not be able to continue its business operations.*

ARCA and Nuvelo currently have no products that have received regulatory approval for commercial sale. The process to develop, obtain regulatory approval for and commercialize potential product candidates is long, complex and costly. Following the merger, Gencaro, which is currently the subject of an NDA awaiting FDA approval, will be the combined company s only product candidate at a late stage of clinical development. As a result, the combined company s business is expected to be substantially dependent on its ability to obtain regulatory approval for and successfully commercialize Gencaro in a timely manner.

In addition to Gencaro, the combined company will have two product candidates in clinical trials, NU172 and NU206. These product candidates must be rigorously tested in clinical trials, and be shown to be safe and effective, before the FDA or other regulatory authorities outside the U.S. will consider them for approval. Failure to demonstrate that one or more of the combined company s product candidates is safe and effective, or significant delays in demonstrating such safety and efficacy, could diminish the benefits of the merger. Failure to obtain marketing approval of one or more of the combined company s product candidates from appropriate regulatory authorities, or significant delays in obtaining such approval, could diminish the benefits of the merger. If approved for sale, the combined company s product candidates must be successfully commercialized. Failure to successfully commercialize one or more of the combined company s product candidates could diminish the benefits of the merger, and, in particular, if the NDA for Gencaro is not approved, or is substantially delayed, or if the combined company is unable to successfully commercialize Gencaro, it may not be able to earn sufficient revenues to continue its business.

If the combined company fails to obtain additional financing, it may be unable to fund its operations and commercialize its product candidates.*

The combined company expects that the cash used in its operations will increase for the next several years, and that it will spend substantial amounts to complete the development, regulatory approval and commercialization of Gencaro and other product candidates and to license or acquire other product candidates. ARCA believes that, if the merger is completed, existing cash and cash equivalents will be sufficient to meet the combined company s projected operating requirements through 2009.

The combined company s future funding requirements will depend on many factors, including:

- whether or when Gencaro is approved for sale;
- whether or when Gencaro s companion product, the Gencaro companion genetic test, is approved for sale;
- the costs of establishing sales, marketing and distribution capabilities;
- the terms and timing of any collaborative, licensing and other arrangements that it has or may establish;
- cash requirements of any future acquisitions of product candidates;
- the scope, results and timing of preclinical studies and clinical trials and other development activities;

the effects of competing clinical, technological and market developments; and

the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights.

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Even if the combined company receives FDA approval to commercialize Gencaro, it cannot predict the amount of revenue it will generate from sales of Gencaro. Until the combined company can generate a sufficient amount of product revenue, it expects to finance future cash needs through public or private securities offerings or debt financings. To the extent that additional funds are raised by issuing equity securities, the combined company s stockholders may experience dilution.

If additional debt financing is raised in the future, the combined company may be required to grant any lenders a security interest in all or a portion of its assets and issue warrants to acquire its equity securities, resulting in dilution to its stockholders. In addition, any such debt financing may involve restrictive covenants, including limitations on the combined company s ability to incur additional debt, limitations on its ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact its ability to conduct its business.

The combined company may also be required to:

- seek collaborators for its product candidates at an earlier stage than otherwise would be desirable and on terms that are less favorable than might otherwise be available; and

- relinquish, license or otherwise dispose of rights to technologies, product candidates or products that it would otherwise seek to develop or commercialize itself.

Future additional funding may not be available on acceptable terms, or at all. If the combined company is unable to raise additional capital when required or on acceptable terms, then the combined company may have to significantly delay, scale back or discontinue the development or commercialization of one or more of its product candidates.

The combined company will be relying upon a third party to obtain marketing clearance or approval of the companion test. There is no guarantee that the FDA will grant timely clearance or approval of the companion test, if at all, and failure to obtain such timely clearance or approval would adversely affect the combined company s ability to market Gencaro.*

The drug label being sought for Gencaro would identify the patient receptor genotypes with a likelihood of enhanced efficacy, as well as those with a likelihood of a standard beta-blocker response and the smaller unfavorable subgroup with a low probability of benefit. Accordingly, the combined company believes it will be critical to the successful commercialization of Gencaro to develop a companion genetic test, or the Gencaro Test, that is simple to administer, useful and widely available.

The Gencaro Test is subject to regulation by the FDA and by comparable agencies in various foreign countries. The process of complying with the requirements of the FDA and comparable agencies is costly, time consuming and burdensome.

ARCA is relying on a third party to determine the appropriate regulatory pathway for the Gencaro Test and to obtain marketing clearance or approval from the FDA. Based on FDA guidance, it is anticipated that the Gencaro Test will be the subject of a PMA regulatory submission although the FDA may later decide that the Gencaro Test should be evaluated for clearance under the FDA s 510(k) notification process. ARCA does not believe that any further clinical trials will be required for the Gencaro Test PMA, though there is no guarantee that FDA will not require additional clinical data.

Despite the time and expense expended, regulatory clearance or approval is never guaranteed. If regulatory clearance or approval is delayed, or FDA approval of the Gencaro Test is not obtained at all or in parallel with the approval of Gencaro, or if the Gencaro Test cannot be successfully commercialized or commercialized in a manner that effectively supports the combined company s commercial efforts, or if the information concerning the differential response to Gencaro resulting from certain genetic variation is not included in the approval label for Gencaro, ARCA s commercial launch may be significantly affected. In such cases, the combined company could be forced to identify a new third-party test provider and obtain regulatory approval for that provider s genetic test, which could substantially delay and negatively affect the commercial prospects for Gencaro.

If Gencaro is approved, the FDA may require that the companion genetic test be administered to all patients before they receive Gencaro, which could limit its potential market.*

Gencaro is a pharmacologically unique beta-blocker and mild vasodilator for heart failure that is more effective in certain patient populations but less effective in other patient populations than other beta-blockers currently being marketed, or

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potentially not effective at all. Based on certain genetic markers, ARCA believes that it can be determined whether Gencaro will be more effective or less effective for potential patients. ARCA has a contractual relationship with a third party to develop, obtain regulatory approval of and commercialize a genetic test to detect these genetic variations in patients.

Because Gencaro may not be effective in some patient populations, and these populations can be identified using the Gencaro Test, the FDA may require that the Gencaro Test be administered to all patients before they receive Gencaro. The FDA could also prohibit prescribing Gencaro to that patient population that is not positively affected by Gencaro. As a result, the market for Gencaro could be restricted, and the combined company s business could be harmed.

Future sales of Gencaro may suffer if its marketplace acceptance is negatively affected by the companion genetic test.*

The companion genetic test for Gencaro is an important component of the commercial strategy for Gencaro. ARCA believes that the genetic test helps predict response to Gencaro, and that this aspect of the drug is important to its ability to compete effectively with current therapies. The companion genetic test adds an additional step in the prescribing process, an additional cost for the patient, the risk that the test results may not be rapidly available and the possibility that it may not be available at all hospitals and medical centers. Any one of these factors could affect prescriber behavior, which in turn may substantially impede market acceptance of the genetic test, which could cause significant harm to Gencaro s ability to compete, and in turn harm the combined company s business.

If Nuvelo and ARCA are not successful in integrating their organizations, the combined company may not be able to operate efficiently after the merger or to realize any benefits from the merger.*

Achieving the benefits of the merger will depend in part on the successful integration of Nuvelo s and ARCA s technical and business operations and personnel in a timely and efficient manner. The integration process requires coordination of the personnel of both companies, involves the integration of systems, applications, policies, procedures, business processes and operations and is a complex, costly and time-consuming process. The difficulties of combining the operations of the companies 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 combined company s liquid capital and other assets efficiently to develop the business of the combined company;
- appropriately managing the liabilities of the combined company;
- diverting management s attention from ongoing business concerns; and
- coordinating geographically separate organizations.

Neither Nuvelo nor ARCA can assure you that they will receive any benefits of this or any other merger or acquisitions, or that any of the difficulties described above will not adversely affect the combined company. The integration process may be difficult and unpredictable because of possible conflicts and differing opinions on business, scientific and regulatory matters. If Nuvelo and ARCA cannot successfully integrate their technical and business operations and personnel, the combined company may not realize the expected benefits of the merger.

Nuvelo and ARCA expect to incur significant costs integrating the companies into a single business.*

Nuvelo and ARCA expect to incur significant costs integrating their technical and business operations and personnel, which may include costs for employee redeployment, relocation or severance, conversion of information systems, reorganization of facilities, disposition of excess facilities and relocation or disposition of excess equipment. The benefits of the merger may not be sufficient to justify these integration costs.

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Integrating Nuvelo and ARCA may divert the attention of the combined company s management away from its operations.*

The successful integration of Nuvelo s and ARCA s technical and business operations and personnel may place a significant burden on the combined company s management and internal resources. The diversion of management s attention and any difficulties encountered in the transition and integration process could result in delays in clinical trial and product development programs of the combined company and could otherwise harm the combined company s business, financial condition and operating results.

Nasdaq will consider the anticipated merger a reverse merger and therefore will require the combined company to submit a new listing application, which will require certain actions on the combined company s part and may not be successful, which would result in you having difficulty converting your investment into cash effectively.*

Nasdaq will consider the proposed merger as a reverse merger and will require the combined company to submit a new listing application. Nasdaq may not approve the combined company s new listing application. If this occurs and the merger is still consummated, you may have difficulty converting your investments into cash effectively.

Additionally, as part of the new listing application, the combined company will be required to submit, among other things, a plan for the combined company to conduct a reverse stock split. A reverse stock split would increase the per share trading price by a yet undetermined multiple. The change in share price may affect the volatility and liquidity of the combined company s stock, as well as the marketplace s perception of the stock. As a result, the relative price of the combined company s stock may decline and/or fluctuate more than in the past, and you may have trouble converting your investments in the combined company into cash effectively.

Failure to complete the merger could adversely affect Nuvelo s stock price and Nuvelo s future business and operations.*

The merger is subject to the satisfaction of closing conditions, including approval by Nuvelo and ARCA stockholders, and neither Nuvelo nor ARCA can assure you that the merger will be approved. In the event that the merger is not consummated, Nuvelo and ARCA may be subject to many significant costs, including legal, accounting and advisory fees related to the merger, which must be paid even if the merger is not completed, and the payment of a termination fee under certain circumstances. If the merger is not consummated, the market price of Nuvelo common stock could decline as a result.

Completion of the merger may result in dilution of future earnings per share to the stockholders of Nuvelo.*

The completion of the merger may result in greater net losses or a weaker financial condition compared to that which would have been achieved by either Nuvelo or ARCA on a stand-alone basis. The merger could fail to produce the benefits that the companies anticipate, or could have other adverse effects that the companies currently do not foresee. In addition, some of the desired outcomes of the merger, such as the achievement of operating synergies, may not be realized. In this event, the merger could result in greater losses as compared to the losses that would have been incurred by Nuvelo on a stand alone basis if the merger had not occurred.

The costs associated with the merger are difficult to estimate, may be higher than expected and may harm the financial results of the combined company.*

Nuvelo and ARCA estimate that they will incur aggregate direct transaction costs of approximately $7.2 million associated with the merger, and additional costs associated with the consolidation and integration of operations, which cannot be estimated accurately at this time. If the total costs of the merger exceed Nuvelo s and ARCA s estimates or the benefits of the merger do not exceed the total costs of the merger, the financial results of the combined company could be adversely affected.

Nuvelo and ARCA executive officers and directors may have interests that are different from, or in addition to, those of Nuvelo and ARCA stockholders generally.*

The executive officers and directors of Nuvelo and ARCA may have interests in the merger that are different from, or are in addition to, those of Nuvelo and ARCA stockholders generally. These interests include ownership through affiliated entities of Nuvelo common stock, certain ARCA directors being appointed to and replacing certain Nuvelo directors from the Nuvelo board of directors immediately after the effective time of the merger, certain Nuvelo executive officers receiving change in control payments in connection with merger and the adoption of new employment agreements for certain ARCA executives in connection with the merger and/or the provision and continuation of indemnification and insurance arrangements for current directors of ARCA following consummation of the merger.

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The combined company will need to significantly increase the size of its organization and may experience difficulties in managing its growth.*

ARCA and Nuvelo are small companies. As of September 30, 2008, ARCA has approximately 44 full-time employees and Nuvelo has approximately 51 employees. The merger will make certain positions redundant; such redundancies will result in terminations. While the merger will create redundancies and result in terminations, the combined company expects that it will need to substantially increase and modify its operations in the future to conduct clinical trials for any future product candidates and commercialize Gencaro and any other future product candidates that the combined company acquires or develops. Future growth will impose significant added responsibilities on members of management, including the need to identify, recruit, maintain and integrate additional employees. The combined company s future financial performance and its ability to commercialize its product candidates and to compete effectively will depend, in part, on its ability to manage any future growth effectively. To that end, the combined company must be able to:

- manage its clinical trials effectively;
- integrate current and additional management, administrative, financial and sales and marketing personnel;
- hire new personnel necessary to effectively commercialize product candidates it licenses;
- develop its administrative, accounting and management information systems and controls; and
- hire and train additional qualified personnel.

Material weaknesses may exist when the combined company reports on the effectiveness of its internal control over financial reporting for purposes of its reporting requirements.*

Prior to the filing of the registration statement in connection with the merger, ARCA was not subject to the Sarbanes-Oxley Act of 2002. Therefore, ARCA s management and independent registered public accounting firm did not perform an evaluation of ARCA s internal control over financial reporting as of December 31, 2007 in accordance with the provisions of the Sarbanes-Oxley Act. Material weaknesses may exist when the combined company reports on the effectiveness of its internal control over financial reporting for purposes of its reporting requirements under the Exchange Act or Section 404 of the Sarbanes-Oxley Act after the merger. The existence of one or more material weaknesses would preclude a conclusion that the combined company maintains effective internal control over financial reporting. Such a conclusion would be required to be disclosed in the combined company s future Annual Reports on Form 10-K and could impact the accuracy and timing of its financial reporting and the reliability of its internal control over financial reporting, which could harm the combined company s reputation and cause the market price of its common stock to drop.

The combined company s stock price is expected to be volatile, and the market price of its common stock may drop following the merger.*

The market price of the combined company s common stock could be subject to significant fluctuations following the merger. Market prices for securities of early-stage pharmaceutical, biotechnology and other life sciences companies have historically been particularly volatile. Some of the factors that may cause the market price of the combined company s common stock to fluctuate include:

- the regulatory status of Gencaro, and whether and when it is approved for sale, if at all;
- the results of the combined company s current and any future clinical trials and NDAs of its current and future product candidates;

the entry into, or termination of, key agreements, including key strategic alliance agreements;

the results and timing of regulatory reviews relating to the approval of the combined company s product candidates;

failure of any of the combined company s product candidates, if approved, to achieve commercial success;

general and industry-specific economic conditions that may affect the combined company s research and development expenditures;

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- the results of clinical trials conducted by others on drugs that would compete with the combined company s product candidates;
- issues in manufacturing the combined company s product candidates or any approved products;
- the initiation of, material developments in or the conclusion of litigation to enforce or defend any of the combined company s intellectual property rights;
- the loss of key employees;
- the introduction of technological innovations or new commercial products by competitors of the combined company;
- changes in estimates or recommendations by securities analysts, if any, who cover the combined company s common stock;
- future sales of the combined company s common stock;
- changes in the structure of health care payment systems; and
- period-to-period fluctuations in the combined company s financial results.

Moreover, the stock markets in general have experienced substantial volatility that has often been unrelated to the operating performance of individual companies. These broad market fluctuations may also adversely affect the trading price of the combined company s common stock.

In the past, following periods of volatility in the market price of a company s securities, stockholders have often instituted class action securities litigation against those companies. Such litigation, if instituted, could result in substantial costs and diversion of management attention and resources, which could significantly harm the combined company s profitability and reputation.

Nuvelo and ARCA do not expect the combined company to pay cash dividends, and accordingly, stockholders must rely on stock appreciation for any return on their investment in the combined company.*

Nuvelo and ARCA anticipate that the combined company will retain its earnings, if any, for future growth and therefore does not anticipate paying cash dividends in the future. As a result, only appreciation of the price of the combined company s common stock will provide a return to stockholders. Investors seeking cash dividends should not invest in the combined company s common stock.

Anti-takeover provisions in the combined company s charter and bylaws may prevent or frustrate attempts by stockholders to change the board of directors or current management and could make a third-party acquisition of the combined company difficult.*

The combined company s certificate of incorporation and bylaws, as amended, will contain provisions that may discourage, delay or prevent a merger, acquisition or other change in control that stockholders may consider favorable, including transactions in which stockholders might otherwise receive a premium for their shares. These provisions could limit the price that investors might be willing to pay in the future for shares of the combined company s common stock.

Nuvelo and ARCA may not be able to complete the merger or may elect to pursue a different strategic transaction, which may not occur on commercially reasonably terms or at all.*

Neither Nuvelo nor ARCA can assure you that they will close the pending merger in a timely manner or at all. The merger agreement is subject to many closing conditions and termination rights. If Nuvelo and ARCA do not close the pending merger, Nuvelo s and ARCA s board of

directors may elect to attempt to complete a different strategic transaction. Attempting to complete a different strategic transaction would prove to be costly and time consuming, and neither Nuvelo nor ARCA can make any assurances that a future strategic transaction will occur on commercially reasonable terms or at all.

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Risks Related to Nuvelo s Business

Nuvelo may not be able to develop and commercialize any of Nuvelo s product candidates successfully.*

Nuvelo has two product candidates in clinical development, and does not know whether it will be able to develop them successfully. In January 2008, Nuvelo announced its enrollment of the first patient in a single-center, Phase 1 trial to determine the safety, tolerability and pharmacokinetics of escalating bolus doses of NU172. In April 2008, Nuvelo announced positive results from this Phase 1 trial. In August 2008, Nuvelo completed a Phase 1b proof-of-concept trial, in which NU172 rapidly produced and maintained anticoagulation with a rapid return toward baseline after the infusion ended. Nuvelo anticipates initiating a Phase 2 study evaluating NU172 in coronary artery bypass graft, or CABG, patients in the fourth quarter of 2008 or first quarter of 2009. Nuvelo cannot predict whether the results of the anticipated Phase 2 study will be consistent with the results of the earlier studies. Nuvelo cannot predict whether it will be able to initiate and complete the Phase 2 study, or whether it will be successful. Nuvelo has only tested NU172 in healthy, normal volunteers, and does not know how active it will be, or how well it will be tolerated, in patients undergoing medical or surgical procedures.

Nuvelo initiated a Phase 1 single ascending dose healthy volunteer trial for NU206 in Australia in July 2008 and expects top-line data from this trial in the fourth quarter of 2008. Nuvelo cannot predict whether Nuvelo will be able to successfully complete the Phase 1 trial for NU206 in healthy volunteers. Currently, Nuvelo does not have approval from the FDA to study NU206 in healthy volunteers. Nuvelo does not know how active NU206 will be in humans, or how well NU206 will be tolerated.

Nuvelo has had material clinical development failures in the past and may again in the future. In 2006, Nuvelo s clinical-stage product candidate, alfimeprase, did not meet its primary endpoint in the first of two planned Phase 3 trials for the treatment of acute peripheral arterial occlusion, or PAO, and in the first of two planned Phase 3 trials for the treatment of catheter occlusion, or CO. All clinical trials for alfimeprase were suspended in December 2006. Nuvelo subsequently reported its decision to close the suspended PAO trial. In the second quarter of 2007, Nuvelo reported its decision to pursue alfimeprase for the treatment of CO in a Phase 2 trial using a single, higher and more concentrated dose of alfimeprase and reported Nuvelo s decision to pursue alfimeprase for the treatment of acute ischemic stroke in a Phase 2 clinical trial. On March 17, 2008, Nuvelo announced that the data from its alfimeprase Phase 2 trial in CO did not show sufficient improvement in catheter opening at the higher dose and concentration evaluated in the study to meet the desired target product profile. As a result, Nuvelo ended further clinical development of alfimeprase, including the programs in CO and acute ischemic stroke.

In August 2007, Nuvelo announced the suspension of its clinical development of Nuvelo s product candidate, rNAPc2, for the treatment of metastatic colorectal cancer and acute coronary syndromes.

Other than Nuvelo s NU172 and NU206 product development programs, all of Nuvelo s potential products and programs, including its research programs in leukemia therapeutic antibodies and Wnt signaling pathway therapeutics, 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 Nuvelo is unable to successfully develop and commercialize its products, Nuvelo s business, results of operations and financial condition will be affected in a materially adverse manner.

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

Nuvelo s business strategy requires it to manage its operations to provide for the continued research and development of its product candidates. Nuvelo s strategy also calls for it to manage relationships with collaborators and other third parties, while simultaneously managing the expenses generated by these activities. In August 2007, Nuvelo announced a reduction of approximately 30% of its workforce, across its research, clinical development and administrative functions. This reduction in force was a part of Nuvelo s efforts to reduce its operating expenses through prioritization of Nuvelo s development portfolio and streamlining Nuvelo s infrastructure. As a result of the reduction in force, Nuvelo recorded a restructuring charge of approximately $2.3 million in the third quarter of 2007. On March 17, 2008, Nuvelo announced the decision to discontinue alfimeprase clinical development and restructure to make additional resources available for its other research and development programs. As a result of the reduction in force, Nuvelo recorded a restructuring expense of $2.5 million in the first quarter of 2008.

Nuvelo continues to believe that strict cost containment in the near term is essential if its current funds are to be sufficient to allow it to continue its currently planned operations. If Nuvelo is unable to effectively manage its current operations, it may not be able to implement its business strategy and its financial condition and results of operations will be adversely affected. If Nuvelo is unable to effectively manage its expenses, Nuvelo may find it necessary to reduce its expenses through another reduction in its workforce, which could adversely affect Nuvelo s operations.

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If Nuvelo encounters difficulties enrolling patients in its clinical trials, its trials could be delayed or otherwise adversely affected.

Clinical trials for Nuvelo s product candidates require that Nuvelo identify and enroll a large number of patients with the disorder or condition under investigation. Nuvelo may not be able to enroll a sufficient number of patients to complete its 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, including the off-label use of therapies approved for related indications;
- efforts to facilitate timely enrollment in clinical trials;
- the success of Nuvelo s 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 Nuvelo has difficulty enrolling a sufficient number of patients to conduct its clinical trials as planned, Nuvelo may need to delay or terminate ongoing or planned clinical trials, either of which would have a negative effect on its business. Delays in enrolling patients in Nuvelo s clinical trials would also adversely affect its ability to generate product, milestone and royalty revenues, and could impose significant additional costs on Nuvelo or on its collaborators.

Nuvelo s clinical trials for its product candidates may not yield results that will enable Nuvelo to further develop its products and obtain the regulatory approvals necessary to sell them.*

Nuvelo, and its collaborators, will only receive regulatory approval for its product candidates if Nuvelo can demonstrate in carefully designed and conducted clinical trials that the product candidate is safe and effective. Nuvelo does not know whether its 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. Nuvelo has spent, and expects to continue to spend, significant amounts of time and money in the clinical development of its product candidates. It will take Nuvelo several years to complete its testing, and failure can occur at any stage of testing. The results Nuvelo obtains in preclinical testing and early clinical trials may not be predictive of results that are obtained in later studies. Nuvelo may suffer significant setbacks in advanced clinical trials, even after promising results in earlier studies.

For example, in December 2006, Nuvelo announced that alfimeprase did not meet its primary endpoint in the first of two planned Phase 3 trials for the treatment of acute PAO and in the first of two planned Phase 3 trials for the treatment of CO. In the second quarter of 2007, Nuvelo reported its decision to close the suspended PAO trial. In March 2008, Nuvelo announced that the data from its alfimeprase Phase 2 program in CO did not show sufficient improvement in catheter opening at the higher dose and concentration evaluated in the study to meet the desired target product profile. As a result, Nuvelo ended further clinical development of alfimeprase, including the programs in CO and acute ischemic stroke. Based on results at any stage of clinical trials, Nuvelo may decide to repeat or redesign a trial or discontinue development of one or more of Nuvelo s product candidates. If Nuvelo fails to adequately demonstrate the safety and efficacy of its products under development, Nuvelo will not be able to obtain the required regulatory approvals to commercialize Nuvelo s product candidates, and its business, results of operations and financial condition would be materially adversely affected.

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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 U.S. and in foreign countries, including those for informed consent and good clinical practices. Nuvelo may not be able to comply with these requirements and the FDA, a similar foreign authority, an IRB, or Nuvelo may suspend or terminate clinical trials at any time.

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

If clinical trials for a product candidate are unsuccessful, Nuvelo will be unable to commercialize the product candidate. If one or more of Nuvelo s clinical trials are delayed, it will be unable to meet its anticipated development timelines. Either circumstance could cause the market price of Nuvelo s common stock to decline. For example, in December 2006, after Nuvelo announced that alfimeprase did not meet its primary endpoint in Phase 3 trials for the treatment of PAO and a Phase 3 trial for CO, the closing price of Nuvelo s common stock was $4.05 on the day of the announcement, as compared with $19.55 on the trading day prior to the announcement. Similarly, when Nuvelo announced it was terminating all clinical development of alfimeprase in March 2008, the closing price of Nuvelo s common stock was $0.73 the day after the announcement, as compared with $1.36 prior to the announcement.

If Nuvelo fails to maintain existing licenses, or fails to develop new collaborations, its business will be harmed.*

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

- a significant amount of Nuvelo s management team s time and effort;
- effective allocation of Nuvelo and third-party resources to multiple projects;
- agreements with third parties as to ownership of proprietary rights and development plans, including clinical trials or regulatory approval strategy; and
- the recruitment and retention of management, scientific and other personnel.

In March 2005, Nuvelo entered into a collaboration agreement with the Kirin Pharma Company, Limited for the development and commercialization of NU206. Nuvelo initiated a Phase 1 single ascending dose healthy volunteer trial for NU206 in Australia in July 2008, and expects top-line data expected from this trial in the fourth quarter of 2008. All operating expenses and any 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 Nuvelo 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. If the agreement is terminated by Kirin, Nuvelo will be responsible for all costs and expenses associated with Nuvelo s research and development of NU206.

On July 31, 2006, Nuvelo 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 Nuvelo is responsible for development and worldwide commercialization of these product candidates. Under the agreement, Nuvelo made an upfront license fee payment to Archemix of $4.0 million. Nuvelo is also funding at least $5.25 million of Archemix s research in the area of short-acting aptamer discovery over the first six years of the agreement. In addition, Nuvelo may have to make payments to Archemix totaling up to $35.0 million per development compound on the achievement of specified development and regulatory milestones, along with potential royalty payments based on sales of licensed compounds. In August 2008, Nuvelo completed a Phase 1b proof-of-concept trial, in which NU172 rapidly produced and maintained anticoagulation with a rapid return toward baseline after the infusion ended. Nuvelo anticipates initiating a Phase 2 study evaluating NU172 in CABG patients in the fourth quarter of 2008 or first quarter of 2009. If and when Nuvelo enrolls the first patient in a Phase 2 study of NU172, a $3.0 million milestone fee becomes payable to Archemix. 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. Nuvelo also is obligated to purchase Archemix common stock having a value equal to the lesser of $10.0 million or 15 percent of the total gross proceeds raised by Archemix in a qualified public offering of Archemix stock occurring within five years of the effective date of the new collaboration agreement.

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Due to the factors discussed above and other possible disagreements with current or potential collaborative partners, Nuvelo may be delayed or prevented from developing or commercializing NU172, NU206 or other preclinical product candidates, or Nuvelo may become involved in litigation or arbitration with its partners, which would be time-consuming or expensive and could have a material adverse effect on Nuvelo s stock price. Nuvelo s relationships with its collaboration partners also may be materially adversely affected by any failure to successfully enroll or complete any of its planned trials of its product candidates. Nuvelo s efforts to manage simultaneously a number of collaboration arrangements may not be successful, and its failure to manage effectively such collaborations would significantly harm its business, financial condition and results of operations.

In addition to Nuvelo s existing collaborations, Nuvelo may enter into new collaborative arrangements whereby Nuvelo would share costs of identifying, developing and marketing product candidates. Nuvelo cannot assure you that it will be able to negotiate new collaboration arrangements of this type on acceptable terms, or at all.

Nuvelo heavily depends on third parties for manufacturing and a variety of other functions, including clinical trials management. Nuvelo s current and future arrangements with its manufacturers and other third parties may not provide it with the benefits Nuvelo expects.*

Nuvelo does not have the resources, facilities or experience to manufacture its product candidates on its own. Nuvelo relies on third parties, such as contract research and manufacturing organizations, to manufacture its product candidates for clinical trials, and, if Nuvelo s product candidates are approved, in quantities for commercial sales. Nuvelo currently relies on a number of sole-source service providers and suppliers to manufacture bulk drug substance, fill and finish its product candidates and label and package them. Nuvelo does not have long-term supply agreements with these third-party manufacturers. Nuvelo 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 Nuvelo s product candidates.

Since a Phase 2 study of NU172 is to be initiated, and NU206 is in Phase 1 clinical trials, Nuvelo is dependent upon third-party contract manufacturers to develop the necessary production processes and produce the volume of cGMP-grade material needed to complete such trials. Nuvelo has entered into and intends 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 product candidates and (iii) fill and finish and label and package Nuvelo s material. Nuvelo cannot be certain that it will be able to complete these tasks on a timely basis or that it 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 Nuvelo s filing for an IND or impede Nuvelo s progress through the clinical trial phase. Any significant delay or interruption would have a material adverse effect on Nuvelo s ability to file an IND with the FDA and/or proceed with the clinical trial phase for any of its product candidates.

Moreover, contract manufacturers that Nuvelo may use must continually adhere to cGMP enforced by the FDA through a facilities inspection program. If one of Nuvelo s contract manufacturers fails to maintain compliance, the production of Nuvelo s 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 Nuvelo s product candidates.

Nuvelo also currently relies upon third parties to perform administrative functions and functions related to the research, development, preclinical testing and clinical trials of its product candidates. Nuvelo s reliance on third-party contract research organizations and consultants that manage and monitor its clinical trials may result in delays in completing, or in failing to complete, Nuvelo s clinical trials if they fail to perform with the speed and competency Nuvelo expects. Nuvelo s reliance on third-party contract research organizations to conduct research and testing, including GLP, and toxicology studies necessary to gather the data necessary to file INDs with the FDA for any of Nuvelo s product candidates may result in delays in Nuvelo s regulatory filings if the third parties 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 Nuvelo s clinical programs may be delayed and Nuvelo s research and development costs may increase, which may in turn have a material adverse affect on Nuvelo s business.

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Nuvelo s 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, Nuvelo s product 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 Nuvelo or the supplier or manufacturer), resulting in delayed clinical studies, regulatory submissions and commercialization of Nuvelo s product candidates;
- failure to identify acceptable manufacturers or other suppliers or enter into favorable long-term agreements with them;
- ineffective clinical trials management or monitoring resulting in delays in or interruptions to Nuvelo s clinical trials;
- delays in, or failures to achieve, scale-up to commercial quantities of Nuvelo s product candidates resulting in delayed regulatory submissions and commercialization of Nuvelo s product candidates;
- Nuvelo s inability to effectively control the resources devoted by Nuvelo s partners to its programs or products;
- disagreements with third parties that could disrupt Nuvelo s operation or delay or terminate the research, development or manufacturing of product candidates, or result in litigation or arbitration;
- inadequate contractual protection or difficulty in enforcing the contracts if one of Nuvelo s partners fails to perform;
- failure of these third parties to comply with regulatory requirements;
- conflicts of interest between third parties work for Nuvelo 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 Nuvelo s product candidates.

Given these risks, Nuvelo s current and future arrangements with third parties may not be successful. If these efforts fail, Nuvelo 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 Nuvelo s product development or commercialization.

Nuvelo is dependent on key personnel, and it must attract and retain qualified employees, collaborators and consultants.*

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

Nuvelo s success will depend on Nuvelo s ability to attract and retain qualified employees to help develop its potential products and execute its research and development strategy. Nuvelo has programs in place to retain personnel, including programs to create a positive work environment

and competitive compensation packages. Because competition for employees in Nuvelo s field is intense, however, Nuvelo may be unable to retain its existing personnel or attract qualified individuals to fill open positions. In addition, in August 2007 and again in March 2008 Nuvelo reduced its workforce as part of its efforts to reduce operating expenses through prioritization of its development portfolio and streamlining its infrastructure. These reductions in Nuvelo s workforce, together with its evaluation of strategic alternatives, may impair its ability to recruit and retain qualified employees and to effectively complete administrative and development functions. If Nuvelo needs to rehire terminated individuals or hire individuals with similar skills, it may be unable to do so. Nuvelo s 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 Nuvelo s internal research efforts. Competition for collaborators is intense. Nuvelo also relies on services provided by outside consultants. Attracting and retaining qualified outside consultants is competitive, and, generally, outside consultants can terminate their relationship with Nuvelo at will. If Nuvelo does not retain qualified personnel, outside consultants and scientific collaborators, or if it experiences turnover or difficulties recruiting new employees or outside consultants, Nuvelo s research and development programs could be delayed, and it could experience difficulties in generating sufficient revenue to maintain its business.

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Nuvelo may not achieve its projected development goals in the time frames it announces and expects.

Nuvelo sets goals for, and makes public statements regarding, the timing of certain accomplishments, such as the commencement and completion of clinical trials and the disclosure of trial results, which Nuvelo sometimes refers 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 Nuvelo s 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 Nuvelo s products. There can be no assurance that Nuvelo s clinical trials will be completed, or that it will make regulatory submissions or receive regulatory approvals as planned. If Nuvelo fails to achieve one or more of these milestones as planned, its business will be materially adversely affected, and the price of Nuvelo s shares will decline.

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

Several of Nuvelo s drug development programs are currently in the research stage or in preclinical development, including Nuvelo s research programs in leukemia therapeutic antibodies and Wnt signaling pathway therapeutics. Although Nuvelo s clinical development-stage product candidates have shown favorable results in preclinical studies, these results may not be replicated in Nuvelo s clinical trials with humans. Before Nuvelo makes any products available to the public from its research and development programs, Nuvelo or its 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 Nuvelo s research does advance, Nuvelo will need to engage in certain additional preclinical development efforts to determine whether a product is sufficiently safe and effective to enter clinical trials. Nuvelo has 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 Nuvelo s research and preclinical studies are predictive of the results that Nuvelo may see in its clinical trials with humans or that they are predictive of whether any resulting products will be safe and effective in humans.

FDA and international regulatory approval of Nuvelo s products is uncertain.

The research, testing, manufacturing and marketing of drug products such as those proposed to be developed by Nuvelo or its 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, Nuvelo or its 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, Nuvelo must show that the manufacturing facilities used to produce the products are in compliance with current cGMP and that the process for manufacturing the product has been validated in accordance with the requirements of the FDA and comparable agencies in other countries.

The process of obtaining FDA and other required regulatory approvals and clearances typically takes several years and will require Nuvelo 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 product candidate, the disease or condition that the product candidate is in development for, and the regulations applicable to that particular product candidate. The FDA or comparable international regulatory authorities can delay, limit or deny approval of a product candidate for many reasons, including:

- a product 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 Nuvelo and Nuvelo s collaboration partners interpret them;
- the FDA or comparable international regulatory authorities may not approve Nuvelo s manufacturing processes or facilities or the processes or facilities of Nuvelo s collaboration partners; or
- the FDA or comparable international regulatory officials may change their approval polices or adopt new regulations.

In addition, in order to market any products outside of the U.S., Nuvelo and its collaborators must establish and comply with numerous and varying regulatory requirements of other jurisdictions, including the European Medicines Evaluation

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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 U.S. 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 U.S.

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

- warning letters;
- fines;
- civil penalties;
- injunctions;
- recall or seizure of products;
- total or partial suspension of production;
- refusal of the government to grant approvals; or
- withdrawal of approvals and criminal prosecution.

Any delay or failure by Nuvelo, or its collaboration partners, to obtain regulatory approvals for Nuvelo s product candidates:

- would adversely affect Nuvelo s ability to generate product, milestone and royalty revenues;
- could impose significant additional costs on Nuvelo or its collaboration partners;
- could diminish competitive advantages that Nuvelo may attain;
- would adversely affect the marketing of Nuvelo s products; and
- could cause the price of Nuvelo s shares to decline.

Even if Nuvelo receives regulatory approval for its product candidates, the FDA or international regulatory authorities may impose limitations on the indicated uses for which Nuvelo s products may be marketed and subsequently withdraw approval or take other actions against Nuvelo, or its products, that are adverse to Nuvelo s 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.

Nuvelo has not yet commercialized any of its product candidates; Nuvelo s ability to commercialize products is unproven.

Nuvelo has not yet commercialized any of its in-licensed therapeutic product candidates. Nuvelo s 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;

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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 Nuvelo from marketing a product.

Any regulatory approvals that Nuvelo or its collaboration partners receive for Nuvelo s 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, Nuvelo, its collaborators and its 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 Nuvelo does not develop a commercially viable product, then Nuvelo will suffer significant harm to its 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 the commercial launch of the product in the approved indication or indications, and to effectively market, distribute and sell the product for use in the approved indication or indications. In addition, the marketing, distribution, sale and reimbursement of pharmaceutical products is heavily regulated, and Nuvelo must comply with all such applicable laws and regulations, or incur costs, fees, fines and other liabilities associated with non-compliance. If Nuvelo s or a collaboration partner s commercial launch of a product approved for commercial sale were to be unsuccessful, or if Nuvelo or a collaboration partner were to fail in Nuvelo s or their efforts to properly market, distribute or sell any product approved for sale, Nuvelo s business, financial condition and operating results would suffer significant harm.

Even if approved, Nuvelo s products may not be accepted in the marketplace, and Nuvelo may not be able to generate significant revenue, if any.

Even if they are approved for marketing, Nuvelo s 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 Nuvelo, alone or in conjunction with 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;

Nuvelo s products potential advantages over alternative treatment methods;

marketing, sales and distribution support of Nuvelo s 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 Nuvelo alone, or in conjunction with Nuvelo s collaboration partners, develops. In practice, competitors may be more effective in marketing their drugs. The lack of such market acceptance would significantly harm Nuvelo s business, financial condition and results of operations. Even if Nuvelo s 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 Nuvelo s business, or may not provide an acceptable return on Nuvelo s investment in the development of these products. As a result, the commercialization of any of Nuvelo s product candidates could fail even if Nuvelo receives marketing approval from the FDA or similar foreign authorities, and acceptance by the medical and patient communities.

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Nuvelo faces intense competition.*

The biopharmaceutical industry is intensely competitive, which is accentuated by the rapid pace of technological development. Nuvelo s products, if successfully developed, will compete with a number of traditional drugs and therapies and with new products currently under development. Nuvelo also expects to face increased competition in the future as new companies enter Nuvelo s markets. Research and discoveries by others may result in breakthroughs that render Nuvelo s potential products obsolete even before they begin to generate any revenue. The competitors for Nuvelo s 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 Nuvelo has. Nuvelo s lead clinical-stage product candidate, NU172, is an anticoagulant that has the potential for predictable anticoagulant effects and rapid self-reversal. If approved, it could face competition from other drugs or devices that are used to anticoagulate a patient in the setting of medical or surgical procedures where human blood is exposed to foreign materials such as coronary artery bypass graft surgery, kidney dialysis and a variety of vascular surgical and coronary interventions. Competition differs depending on the indication and includes, for example, heparin and its antidote, protamine, as well as Angiomax® bivalirudin, an approved product of The Medicines Company. Nuvelo s second product candidate, NU206, if approved for the treatment of mucositis, could face competition from drugs such as palifermin, an approved Amgen product.

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

Many of the companies developing competing products have greater expertise than Nuvelo or its 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 Nuvelo in recruiting and retaining qualified scientific and management personnel as well as in acquiring technologies complementary to Nuvelo s programs. Nuvelo may face competition with respect to:

- product efficacy and safety;
- the timing and scope of regulatory approvals;
- availability of resources;
- reimbursement coverage; and
- price and patent position, including the potentially dominant patent positions of others.

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

Nuvelo is subject to the risk of natural disasters.

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

Risks Related to Nuvelo s Capital Structure and Financial Results and Stock Price Volatility

Nuvelo will need to raise additional capital, and such capital may be unavailable to Nuvelo when it needs it or not available on acceptable terms.

Nuvelo will need to raise significant additional capital to finance the research and clinical development of Nuvelo s product candidates. If future securities offerings are successful, they could dilute Nuvelo s current stockholders equity

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interests and reduce the market price of Nuvelo s common stock. Financing may be unavailable when Nuvelo needs it or may not be available on acceptable terms. The unavailability of financing may require Nuvelo to delay, scale back or eliminate expenditures for the research and development of Nuvelo s potential biopharmaceutical products. Nuvelo may also be required to raise capital by granting rights to third parties to develop and market product candidates that Nuvelo would prefer to develop and market on its own, potentially reducing the ultimate value that Nuvelo could realize from these product candidates.

If Nuvelo is unable to obtain additional financing when it needs it, the capital markets may perceive that Nuvelo is not able to raise the amount of financing it desires, or on the terms that it desires. This perception, if it occurs, may negatively affect the market price of Nuvelo s common stock. If sufficient capital is not available, Nuvelo may be forced to delay, reduce the scope of, eliminate or divest one or more of Nuvelo s research or development programs. As an example, in August 2007, Nuvelo announced that it suspended the clinical development of rNAPc2. Any such action could significantly harm Nuvelo s business, financial condition and results of operations.

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

- any business transactions or arrangements through which the Company acquires or purchases new products, product candidates or other companies;
- Nuvelo s ability to maintain, and the financial commitments involved in, Nuvelo s existing collaborative and licensing arrangements, including Nuvelo s ability to continue to receive cost-sharing reimbursements from Kirin;
- progress in current and anticipated clinical studies of Nuvelo s products, including NU172 and NU206;
- Nuvelo s need to develop, acquire or license new technologies or products;
- future funding commitments to new and existing collaborators, such as Archemix, from which Nuvelo is obligated to purchase Archemix common stock having a value equal to the lesser of $10.0 million or 15% of the total gross proceeds raised by Archemix in a qualified public offering;
- the cost of manufacturing Nuvelo s material for preclinical and clinical purposes;
- Nuvelo s ability to establish new collaborative relationships with other companies to share costs and expertise of identifying, developing and commercializing product candidates;
- the magnitude and scope of Nuvelo s research and development programs, including development of product candidates;
- continued scientific progress in Nuvelo s research and development programs, including progress in Nuvelo s research and preclinical studies;
- the cost involved in maintaining facilities to support research and development of Nuvelo s product candidates;

the cost of prosecuting and enforcing Nuvelo s intellectual property rights;

the time and cost involved in obtaining regulatory approvals;

competing technological and market developments;

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

other factors not within Nuvelo s control.

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As of September 30, 2008, Nuvelo s stock price does not meet the minimum bid price for continued listing on the Nasdaq Global Market. Nuvelo s ability to publicly or privately sell equity securities and the liquidity of Nuvelo s common stock could be adversely affected if Nuvelo is delisted from the Nasdaq Global Market or if Nuvelo is unable to transfer its listing to another stock market.*

Nasdaq Global Market listing standards require that for continued listing, the bid price of Nuvelo s common stock must be a minimum of $1.00 per share. Since Nuvelo announced on March 17, 2008 that it was terminating the development of alfimeprase, the bid price of Nuvelo s common stock has been less than $1.00 each trading day since March 18, 2008. On May 1, 2008, Nuvelo received notice from Nasdaq indicating that, for 30 consecutive business days, the bid price for Nuvelo s common stock had closed below the minimum $1.00 per share requirement for continued inclusion on the Nasdaq Global Market. Nuvelo was given 180 calendar days, or until October 28, 2008, to regain compliance with this listing requirement, which would be accomplished if the bid price of Nuvelo s common stock closed at $1.00 per share or more for a minimum of 10 consecutive business days. As of September 30, 2008, the bid price of Nuvelo s common stock closed at $0.44 per share. The notice from Nasdaq also indicated that, if Nuvelo does not regain compliance by October 28, 2008, Nasdaq will provide a staff determination letter notifying Nuvelo that its common stock will be delisted, after which Nuvelo may appeal the staff determination to the Nasdaq Listing Qualifications Panel. On October 16, 2008, Nasdaq advised Nuvelo that it had suspended until January 19, 2009 the enforcement of the rules requiring a minimum $1.00 closing bid price for all Nasdaq listed companies.

Following the end of this suspension period and the 12 days balance of Nuvelo s initial 180 days compliance period, Nuvelo expects to receive a staff determination letter if it has not regained compliance by that time. Upon receipt of the determination letter, Nuvelo intends to submit a request to appeal the determination and present a plan for compliance at an oral hearing with Nasdaq in Washington, D.C. The request for appeal will automatically stay the determination until the appeal is heard and a Nasdaq panel rules on whether to grant conditional listing for up to 180 days following the staff determination in order for Nuvelo to complete its plan of compliance. There can be no assurance that the appeal will be successful or on the timeline presented above or that the plan of compliance and the combined company will be able to satisfy the requirements for maintaining a Nasdaq Global Market listing.

If Nuvelo does not regain compliance with this listing requirement by the new deadline imposed by Nasdaq, but meets the initial inclusion criteria for the Nasdaq Capital Market (except for the bid price requirement), Nuvelo may apply to transfer the listing of Nuvelo s common stock to this market. If accepted by the Nasdaq Capital Market, Nuvelo will be provided with an additional 180-day period to demonstrate compliance. If Nuvelo is not eligible for an additional compliance period at that time, Nasdaq will provide written notification that Nuvelo s securities will be delisted. Upon such notice, Nuvelo may appeal the determination to the Nasdaq Listing Qualifications Panel. There can be no assurance that Nuvelo s common stock would be eligible for transfer to the Nasdaq Capital Market, or, if Nuvelo appeals Nasdaq staff s determination, that such appeal would be successful.

If Nuvelo s common stock is delisted by Nasdaq, its common stock may be eligible for quotation on the OTC Bulletin Board maintained by Nasdaq, another over-the-counter quotation system, or on the pink sheets. Upon any such delisting, Nuvelo s common stock would become subject to the regulations of the Securities and Exchange Commission relating to the market for penny stocks. A penny stock is any equity security not traded on a national securities exchange that has a market price of less than $5.00 per share. The regulations applicable to penny stocks may severely affect the market liquidity for Nuvelo s common stock and could limit your ability to sell your securities in the secondary market. In such a case, an investor may find it more difficult to dispose of or obtain accurate quotations as to the market value of Nuvelo s common stock, although there can be no assurance that Nuvelo s common stock will be eligible for trading or quotation on any alternative exchanges or markets.

Delisting from Nasdaq could adversely affect Nuvelo s ability to raise additional financing through the public or private sale of equity securities, would significantly affect the ability of investors to trade Nuvelo s securities and would negatively affect the value and liquidity of Nuvelo s common stock. Delisting could also have other negative results, including the potential loss of confidence by employees, the loss of institutional investor interest and fewer business development opportunities.

Nuvelo s stock price has historically been and is likely to remain highly volatile, and an investment in Nuvelo s 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 Nuvelo s common stock and the return on any investment in Nuvelo s common stock.

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Historically, Nuvelo s stock price has been extremely volatile. Between January 1, 2007 and December 31, 2007, the price ranged between a high of $6.63 per share and a low of $1.26 per share. Between January 1, 2008 and September 30, 2008, the price ranged between a high of $1.88 per share and a low of $0.34 per share. In March 2008, Nuvelo announced that the data from Nuvelo s Phase 2 program in catheter occlusion did not show sufficient improvement in catheter opening at the higher dose and concentration evaluated in the study to meet the desired target product profile and that Nuvelo ended further clinical development of alfimeprase. The closing price of Nuvelo s common stock was $0.73 the day after this announcement, as compared with $1.36 prior to this announcement. Significant market price fluctuations of Nuvelo s common stock can be due to a variety of factors, including:

- the depth of demand for Nuvelo s common stock;
- any announcements of or speculation about strategic transactions involving Nuvelo, such as its merging with, being acquired by, or acquiring another entity;
- the experimental nature of, and public concern or expectations with respect to, Nuvelo s product candidates;
- actual or anticipated fluctuations in Nuvelo s operating results;
- sales of Nuvelo s common stock by existing holders, or sales of shares issuable upon exercise of outstanding options and warrants;
- market conditions relating to the biopharmaceutical and pharmaceutical industries;
- any announcements of technological innovations, new commercial products or collaborations, or clinical progress or lack thereof by Nuvelo, its collaborative partners or its competitors;
- announcements concerning regulatory developments or developments with respect to proprietary rights;
- changes in Nuvelo s collaborative arrangements;
- changes in or Nuvelo s failure to meet market or, to the extent securities analysts follow Nuvelo s 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.

Nuvelo has a significant accumulated deficit and anticipates continuing losses.*

Nuvelo has incurred significant net losses, including $130.6 million in 2006, $12.3 million in 2007 and $27.2 million in the nine months ended September 30, 2008. As of September 30, 2008, Nuvelo had an accumulated deficit of $497.7 million and Nuvelo anticipate continuing losses for the foreseeable future.

All of Nuvelo s 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 Nuvelo s drug products will require significant additional research and development, preclinical testing, clinical trials and regulatory approvals.

These activities, together with drug manufacturing, general administrative and other expenses, are expected to result in operating losses for the foreseeable future. To date, Nuvelo has not generated any revenues from product sales. Nuvelo does not expect to achieve significant product sales or royalty revenue from product sales for several years, and it may never do so.

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Nuvelo expects to incur additional operating losses in the future, and these losses may increase significantly as Nuvelo continues preclinical research and clinical trials, applies for regulatory approvals and develops its product candidates. These losses, among other things, have caused and may cause Nuvelo s stockholders equity and working capital to decrease. Nuvelo may not be successful in developing its product candidates and obtaining regulatory approvals. Nuvelo may never generate profits and, as a result, the market price of Nuvelo s common stock could decline.

Moreover, utilization of Nuvelo s net operating loss and research and development credit carryforwards are subject to an annual limitation under the change in ownership provisions of the Internal Revenue Code of 1986 and similar state law provisions, as a result of certain transactions that Nuvelo has entered into prior to 2006. If the proposed merger with ARCA is consummated, a change in ownership of Nuvelo will occur and Nuvelo s ability to utilize these carryforwards will be substantially reduced.

Nuvelo may face fluctuations in operating results.

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

- any business transactions or arrangements through which Nuvelo acquires or purchases new products or product candidates;
- the amount of research and development Nuvelo engage in;
- if Nuvelo is obligated to purchase Archemix common stock having a value equal to the lesser of $10.0 million or 15 percent of the total gross proceeds, in accordance with the collaboration agreement with Archemix;
- the number of product candidates Nuvelo has, their progress in research, preclinical and clinical studies and the costs involved in manufacturing them;
- Nuvelo s ability to maintain existing and enter into new strategic relationships;
- the scope, duration and effectiveness of Nuvelo s licensing and collaborative arrangements;
- Nuvelo s ability to maintain its facilities to support its 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 Nuvelo s;
- changes in government regulation;
- changes in the price of Nuvelo s 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 Nuvelo s competitors.

In addition, as a result of Nuvelo s adoption of SFAS 123(R), Nuvelo 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 Nuvelo uses as a basis for valuing future awards change over time, the magnitude of the expense that Nuvelo must recognize may vary significantly. Any such variance from one period to the next could cause a significant fluctuation in Nuvelo s operating results.

All of Nuvelo s potential products are currently in research, preclinical or clinical development, and revenues from the sales of any products resulting from this research and development may not occur for several years, if at all. Nuvelo has a significant amount of fixed costs such as lease obligations, and certain charges to Nuvelo s statement of operations are dependent on movements in the price of Nuvelo s common stock, which historically has been and is likely to remain highly volatile. As a result, Nuvelo may experience fluctuations in its operating results from quarter to quarter and continue to generate losses. Quarterly comparisons of Nuvelo s financial results may not necessarily be meaningful, and investors should not rely upon such results as an indication of Nuvelo s future performance. In addition, investors may react adversely if Nuvelo s 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 Nuvelo s common stock.

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

Sales in the public market of substantial amounts of Nuvelo s common stock could depress prevailing market prices of its common stock. As of September 30, 2008, Nuvelo had 53,663,805 shares of common stock outstanding. All of these shares are freely transferable without restriction or further registration under the Securities Act, except for shares held by Nuvelo s directors, officers and other affiliates and unregistered shares held by non-affiliates. As of September 30, 2008, Nuvelo s directors, officers and greater than five percent stockholders held approximately 13 percent of the shares of Nuvelo s outstanding common stock. Although Nuvelo does not believe that Nuvelo s 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 Nuvelo s common stock.

As of September 30, 2008, Nuvelo had approximately 12,427,846 shares of Nuvelo s common stock which may be issued under Nuvelo s 2004 Equity Incentive Plan, 2002 Equity Incentive Plan, 1995 Stock Option Plan, Non-Employee Director Stock Option Plan, stock option agreements entered into outside of any of Nuvelo s stock option plans, and Nuvelo s Employee Stock Purchase Plan. Included in these 12,427,846 shares are (i) 5,140,278 shares of Nuvelo s common stock issuable under outstanding options to purchase Nuvelo s common stock under the specified plans, (ii) 440,206 shares of Nuvelo s common stock issuable under stock option agreements entered into outside of any of Nuvelo s stock option plans, (iii) 27,332 shares of Nuvelo s common stock issuable under restricted stock units, (iv) 6,537,957 shares of Nuvelo s common stock reserved for future grants under Nuvelo s 2004 Equity Incentive Plan, and (v) 282,073 shares of Nuvelo s common stock reserved for future issuance under Nuvelo s Employee Stock Purchase Plan. As of September 30, 2008, outstanding options to purchase 4,068,534 shares of common stock were exercisable, and no restricted stock units have been vested. If and when these options are exercised, such shares are available for sale in the open market without further registration under the Securities Act. The existence of these outstanding options and share reserves may negatively affect Nuvelo s 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 Nuvelo s common stock received, may also result in downward pressure on the price of Nuvelo s common stock.

As of September 30, 2008, 850,224 shares of Nuvelo s 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 Nuvelo may issue in the future, are exercised, it could result in additional sales of Nuvelo s common stock in the market, which may have an adverse effect on Nuvelo s stock price.

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

Nuvelo s investments in marketable debt securities are subject to credit risk that may adversely affect their fair value.

Nuvelo maintains a significant portfolio of investments in marketable debt securities, which are recorded at fair value. To minimize Nuvelo s exposure to credit risk, Nuvelo invests in securities with strong credit ratings and has established guidelines relative to diversification and maturity with the objective of maintaining safety of principal and liquidity. Nuvelo does not invest in derivative financial instruments, mortgage-backed securities or auction rate securities, and Nuvelo has not recorded any losses on Nuvelo s securities due to credit or liquidity issues. In 2007 and 2008, rising delinquency and default rates on subprime mortgages and declining home prices had caused a significant decline in the value of residential mortgage-backed securities, which had negatively impacted the entire credit market in the U.S. In recent months, certain other financial instruments had also sustained downgrade in credit ratings and decline in value. Further deterioration in the credit market may have an adverse effect on the fair value of Nuvelo s investment portfolio.

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Nuvelo does not intend to pay cash dividends on its common stock in the foreseeable future.

Nuvelo does not anticipate paying cash dividends on its common stock in the foreseeable future. Any payment of cash dividends will depend upon Nuvelo s financial condition, results of operations, capital requirements and other factors and will be at the discretion of Nuvelo s board of directors. Furthermore, Nuvelo may incur additional indebtedness that may severely restrict or prohibit the payment of dividends.

Nuvelo has implemented anti-takeover provisions that could discourage, prevent or delay a takeover, even if the acquisition would be beneficial to Nuvelo s stockholders.*

Provisions of Nuvelo s certificate of incorporation and bylaws, as well as provisions of Delaware law, could make it more difficult for a third party to acquire Nuvelo, even if doing so would benefit Nuvelo s stockholders. These provisions:

- establish a classified board of directors so that not all members of Nuvelo s 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 Nuvelo s 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 Nuvelo s stockholders; and
- establish advance notice requirements for nominations for election to Nuvelo s board of directors or for proposing matters that can be acted upon at a stockholder meeting.

Specifically, Nuvelo s certificate of incorporation provides that all stockholder action must be effected at a duly called meeting and not by a written consent. The bylaws provide, however, that Nuvelo s stockholders may call a special meeting of stockholders only upon a request of stockholders owning at least 50 percent of Nuvelo s common stock. These provisions of Nuvelo s certificate of incorporation and bylaws could discourage potential acquisition proposals and could delay or prevent a change in control. Nuvelo designed these provisions to reduce Nuvelo s 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 Nuvelo s shares. As a consequence, they also may inhibit fluctuations in the market price of Nuvelo s shares that could result from actual or rumored takeover attempts. Such provisions also may have the effect of preventing changes in Nuvelo s management.

Nuvelo is permitted to issue shares of Nuvelo s preferred stock without stockholder approval upon such terms as Nuvelo s board of directors determines. Therefore, the rights of the holders of Nuvelo s common stock are subject to, and may be adversely affected by, the rights of the holders of Nuvelo s 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 Nuvelo s current stockholders.

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

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

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

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

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

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

Nuvelo has adopted Change in Control and Severance Benefit Plans that could discourage, prevent or delay a takeover, even if the acquisition would be beneficial to Nuvelo s stockholders.*

In December 2004, Nuvelo s board of directors approved an Executive Change in Control and Severance Benefit Plan for Nuvelo s executive officers and other eligible employees, which was amended and restated in August 2007. The purpose of the plan is to provide for the payment of severance benefits and/or change in control benefits to certain of Nuvelo s eligible employees, and the plan supersedes and replaces any change in control and/or severance plans adopted by Nuvelo previously. All of Nuvelo s executive employees at the level of vice president or above have been designated as participants in the plan and Nuvelo s 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 Nuvelo s change in control. If a participant is terminated without cause or constructively terminated one month before or one year after Nuvelo s change in control, he or she will also be entitled to certain cash severance and continued medical benefits. In June 2008, the compensation committee of Nuvelo s board of directors approved a Change in Control Severance Benefit Plan for Nuvelo s employees who are not eligible for benefits under the Executive Change in Control and Severance Benefit Plan, entitling these employees to certain cash severance and continued medical benefits if terminated without cause within one year after Nuvelo s change of control.

The change in control and severance benefits for certain of Nuvelo s employees provided for under these plans are expected to be triggered by the merger with ARCA. If the merger with ARCA is not consummated, these provisions could make it more difficult and expensive, or less desirable, for a third party to acquire Nuvelo, even if doing so would benefit Nuvelo s stockholders.

Risks Related to Nuvelo Intellectual Property and Other Legal Matters

Nuvelo is party to securities litigation, and defending these lawsuits could hurt Nuvelo s business. The volatility of the market price of Nuvelo s 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 Nuvelo, 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 Nuvelo could result in substantial costs and a diversion of management s attention and resources, which could significantly harm Nuvelo s business, financial condition and operating results. For example, in December 2006, after Nuvelo announced that alfimeprase did not meet its primary endpoint in the first of two planned Phase 3 trials for the treatment of acute peripheral arterial occlusion and in the first of two planned Phase 3 trials for the treatment of catheter occlusion, the closing price of one share of Nuvelo s common stock was $4.05 on the day of the announcement, as compared with a closing price of $19.55 on the trading day prior to the announcement. On February 9, 2007, Nuvelo, Inc. and certain of Nuvelo s former and current officers and directors were named as defendants in a purported securities class action lawsuit filed in the U.S. 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 Nuvelo announced on December 11, 2006, and seeks damages on behalf of purchasers of Nuvelo s common stock during the period between January 5, 2006 and December 8, 2006. Specifically, the suit alleges that Nuvelo 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, Nuvelo filed a motion to transfer the four cases to the Northern District of California. The Court granted Nuvelo s motion to transfer the cases to the Northern District of California in July 2007. Plaintiffs have filed motions for consolidation, lead plaintiff and lead plaintiff s counsel in the Northern District of California. Plaintiffs filed their consolidated

complaint in the Northern District of California on November 9, 2007. Nuvelo filed a motion to dismiss plaintiffs consolidated complaint on December 21, 2007. Plaintiffs filed an opposition to Nuvelo s motion to dismiss on February 4, 2008. On June 12, 2008, the Court held a hearing on the motion to dismiss. The motion to dismiss the consolidated complaint is still pending. Nuvelo currently cannot determine the impact that this litigation will have on Nuvelo s business, results of operations or financial condition.

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In addition, Variagenics, with which Nuvelo merged in 2003, 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 Nuvelo s merger with Variagenics, Nuvelo is obligated to continue to defend against this litigation. Nuvelo believes that any attorneys fees, loss or settlement payment with respect to this suit will not be material to Nuvelo s financial position or results of operations, and that any loss, settlement payment or attorneys fees accrued with respect to the suit will be paid by Nuvelo s insurance provider. Because of a recent court ruling, the settlement class, as defined in the settlement papers, is no longer feasible. While a new complaint has not been filed against Nuvelo, there are several focus cases against other issuers in which new complaints have been filed. Defendant issuers in the focus cases filed motions to dismiss the new complaints. On March 26, 2008, the District Court issued an order granting in part and denying in part the focus issuers motions to dismiss. The focus issuers had been advised that plaintiffs intended to file new complaints against Nuvelo, but none have been filed yet. Nuvelo could be forced to incur material expenses in the litigation if the parties cannot achieve a settlement, and in the event there is an adverse outcome, Nuvelo s business could be harmed.

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

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

Nuvelo currently has, or has in-licensed, issued patents and pending patent applications that include claims to Nuvelo s in-licensed clinical products. Nuvelo obtained exclusive worldwide rights to alfimeprase from Amgen in October 2004. Nuvelo obtained exclusive worldwide rights for all indications of rNAPc2 and all of the rNAPc molecules owned by Dendreon in February 2004. The U.S. government may claim a non-exclusive right to use rNAPc2 with respect to the treatment of hemorrhagic fever. Nuvelo also currently has patents that cover some of Nuvelo s technological discoveries and patent applications that Nuvelo expects to protect some of its gene, protein and technological discoveries. Nuvelo will continue to apply for patents for its discoveries. Nuvelo cannot assure you that any of its applications, or its licensors applications, will issue as patents, or that any patent issued or licensed to Nuvelo 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 Nuvelo to generate data, which may involve substantial costs. Nuvelo s pending patent applications may lack priority over others applications or may not result in the issuance of patents. Even if issued, Nuvelo s 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, Nuvelo relies on a combination of trade secrets, copyright and trademark laws, nondisclosure agreements, licenses and other contractual provisions and technical measures to maintain and develop Nuvelo s competitive position with respect to intellectual property. Nevertheless, these measures may not be adequate to safeguard the technology underlying Nuvelo s products. For example, employees, consultants and others who participate in the development of Nuvelo s products may breach their agreements with Nuvelo regarding its intellectual property, and Nuvelo may not have adequate remedies for the breach. Nuvelo s trade secrets could become known through other unforeseen means. Nuvelo depends on its collaborators and other third parties that license intellectual property to Nuvelo to protect its licensed intellectual property. These collaborators and other third parties could fail to take a necessary step to protect Nuvelo s licensed intellectual property, which could seriously harm Nuvelo s intellectual property position.

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

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

If the manufacture, use or sale of Nuvelo s products infringe on the intellectual property rights of others, Nuvelo could face costly litigation, which could cause Nuvelo to pay substantial damages or licensing fees and limit its ability to sell some or all of its 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, U.S. Patent and Trademark Office interference proceedings, and related legal and administrative proceedings in the U.S. 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, Nuvelo s involvement in any litigation, interference or other administrative proceedings could cause Nuvelo to incur substantial expense and could significantly divert the efforts of Nuvelo s technical and management personnel. An adverse determination may subject Nuvelo to the loss of its proprietary position or to significant liabilities, or require Nuvelo 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 Nuvelo from manufacturing and selling its products, if any. These outcomes could materially harm Nuvelo s business, financial condition and results of operations.

Nuvelo s market success depends in part on Nuvelo neither infringing valid, enforceable patents or proprietary rights of third parties, nor breaching any licenses that may relate to Nuvelo s technologies and products. Nuvelo is aware of third-party patents and proprietary rights that may relate to Nuvelo s technology. Nuvelo may be required to obtain licenses to patents or other proprietary rights of others for itself, its collaboration partners and its service providers in order to conduct research, development or commercialization of some or all of Nuvelo s programs. Nuvelo plan to seek licenses, as it deem appropriate, but it is possible that Nuvelo may infringe upon these patents or proprietary rights of third parties. If Nuvelo does not obtain these licenses, it may encounter delays in product market introductions, incur substantial costs while Nuvelo attempts 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 Nuvelo, its collaboration partners or its service providers. Nuvelo may consequently be subjected to substantial damages for past infringement or be required to modify its products if it is ultimately determined that Nuvelo s products infringe a third party s proprietary rights. Further, Nuvelo may be prohibited from selling its products before it obtains a license, which, if available at all, may require Nuvelo to pay substantial royalties, which could adversely impact Nuvelo s product costs and have an impact on its business. Further, if Nuvelo does obtain these licenses, the agreed terms may necessitate reevaluation of the potential commercialization of any one of Nuvelo s 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 Nuvelo could cause Nuvelo s stock price to decline.

Nuvelo faces product liability exposure and potential unavailability of insurance.

Nuvelo risks financial exposure to product liability claims in the event that the use of products developed by Nuvelo, or its collaboration partners, if any, result in personal injury. Nuvelo may experience losses due to product liability claims in the future. Nuvelo has obtained limited product liability insurance coverage. Such coverage, however, may not be adequate or may not continue to be available to Nuvelo in sufficient amounts or at an acceptable cost, or at all. Nuvelo 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 Nuvelo s business, financial condition and results of operations.

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Nuvelo faces 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.

Nuvelo s 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. Nuvelo, its 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. Nuvelo 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 Nuvelo, its collaborators, or service providers fail to comply with applicable laws or regulations, Nuvelo could be required to pay penalties or be held liable for any damages that result, and this liability could exceed Nuvelo s financial resources. Further, future changes to environmental health and safety laws could cause Nuvelo to incur additional expense or restrict its operations. In addition, Nuvelo s collaborators and service providers may be working with hazardous materials, including viruses and hazardous chemicals, in connection with Nuvelo s collaborations. In the event of a lawsuit or investigation, Nuvelo 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 Nuvelo s resources.

Nuvelo also is 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, Nuvelo 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 Nuvelo s products. Nuvelo may be required to incur significant costs to comply with current or future laws or regulations, and Nuvelo 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
2.1	Agreement and Plan of Merger and Reorganization, dated September 24, 2008, by and among Nuvelo, Inc., Dawn Acquisition Sub, Inc. and ARCA biopharma, Inc.(1)
2.2	Amendment No. 1 to Agreement and Plan of Merger and Reorganization, dated October 28, 2008, by and among Nuvelo, Inc., Dawn Acquisition Sub, Inc. and ARCA biopharma, Inc.(6)
3.1	Amended and Restated Certificate of Incorporation of Nuvelo, Inc.(2)

3.2	Amended and Restated By-Laws of Nuvelo, Inc.(3)
4.1	Form of Nuvelo, Inc. Common Stock Certificate.(2)
4.2	Certificate of Designations of Series A Junior Participating Preferred Stock.(2)
4.3	Warrant to purchase 1,491,544 shares (pre-split) of Common Stock of Hyseq, Inc. dated January 8, 2002.(4)
4.4	Warrant to purchase 350,000 shares of Common Stock of Nuvelo, Inc. dated August 4, 2005.(5)
4.5	Registration Rights Agreement by and between Nuvelo, Inc. and Kingsbridge Capital Limited dated August 4, 2005.(5)
4.6	Reference is made to Exhibits 3.1 and 3.2.

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

* Filed herewith.

(1) Previously filed with the SEC as an Exhibit to and incorporated herein by reference from Nuvelo, Inc. s Form 8-K, filed on September 25, 2008, File No. 000-22873.

(2) Previously filed with the SEC as an Exhibit to and incorporated herein by reference from Nuvelo, Inc. s Form 8-K, filed on March 26, 2004, File No. 000-22873.

(3) Previously filed with the SEC as an Exhibit to and incorporated herein by reference from Nuvelo, Inc. s Form 8-K, filed on December 12, 2007, File No. 000-22873.

(4) Previously filed with the SEC as an Exhibit to and incorporated herein by reference from Hyseq, Inc. s Form 10-Q filed on May 15, 2002, File No. 000-22873.

(5) Previously filed with the SEC as an Exhibit to and incorporated herein by reference from Nuvelo, Inc. s Form 8-K, filed on August 5, 2005, File No. 000-22873.

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SIGNATURE

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

Nuvelo, Inc. (Registrant)

By: /s/ Lee Bendekgey
Lee Bendekgey
Senior Vice President and Chief Financial Officer
(Duly Authorized and Principal Financial and Accounting Officer)

Dated: November 5, 2008

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