ARCA biopharma, Inc.
Form 10-Q
May 15, 2009
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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 MARCH 31, 2009

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

ARCA BIOPHARMA, 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)**
8001 Arista Place, Suite 200 Broomfield, CO	**80021**
(Address of Principal Executive Offices)	**(Zip Code)**

(720) 940-2200

(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 has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ¨ No ¨

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

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

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 May 8, 2009: 7,570,103

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ARCA BIOPHARMA, INC.

FORM 10-Q

FOR THE QUARTER ENDED MARCH 31, 2009

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PART I. FINANCIAL INFORMATION

ITEM 1. CONSOLIDATED FINANCIAL STATEMENTS (unaudited)

ARCA BIOPHARMA, INC.

(a development stage enterprise)

CONSOLIDATED BALANCE SHEETS

(unaudited)

	March 31, 2009	December 31, 2008
	(in thousands, except share and per share amounts)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 25,920	$ 7,740
Marketable securities	9,368	
Deferred transaction costs		1,668
Other current assets	1,656	270
Total current assets	36,944	9,678
Restricted cash	6,000	
Property and equipment, net	1,628	1,303
In-process research and development	6,000	
Other assets	1,178	98
Total assets	$ 51,750	$ 11,079
LIABILITIES AND STOCKHOLDERS EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 1,296	$ 804
Accrued compensation and employee benefits	3,296	1,071
Accrued expenses and other liabilities	2,589	1,549
Bank note payable, current portion	1,979	3,948
Convertible notes payable		8,351
Deferred rent, current portion	124	107
Accrued facility exit costs, current portion	5,482	
Total current liabilities	14,766	15,830
Bank note payable, net of current portion	1,493	
Deferred rent, net of current portion	402	430
Accrued facility exit costs, net of current portion	6,758	
Deferred tax liability	2,281	
Other long-term liabilities	727	132
Total liabilities	26,427	16,392

Commitments and contingencies		
Preferred Stock:		
Redeemable, convertible preferred stock, $0.001 par value		
Series A, 9,222,257 shares authorized; 0 and 9,222,257 shares issued and outstanding at March 31, 2009 and December 31, 2008, respectively; liquidation preference of $15 million at December 31, 2008		14,958
Series B, 6,511,961 shares authorized; 0 and 6,455,579 shares issued and outstanding at March 31, 2009 and December 31, 2008, respectively; liquidation preference of $18 million at December 31, 2008		17,907
Stockholders equity (deficit):		
Common stock, $0.001 par value; 100 million and 40 million shares authorized at March 31, 2009 and December 31, 2008, respectively; 7,569,903 and 954,420 shares issued and outstanding at March 31, 2009 and December 31, 2008, respectively	8	1
Additional paid-in capital	56,167	2,573
Unrealized loss on marketable securities	(33)	
Deficit accumulated during the development stage	(30,819)	(40,752)
Total stockholders equity (deficit)	25,323	(38,178)
Total liabilities and stockholders equity (deficit)	$ 51,750	$ 11,079

See accompanying notes to consolidated financial statements.

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ARCA BIOPHARMA, INC.

(a development stage enterprise)

CONSOLIDATED STATEMENTS OF OPERATIONS

(unaudited)

	Three Months Ended March 31,		Period from December 17, 2001 (date of inception) to March 31,
	2009	2008	2009
	(in thousands, except share and per share amounts)		
Costs and expenses:			
Research and development	$ 4,592	$ 2,361	$ 30,746
Sales, general and administrative	5,324	1,634	20,725
Merger transaction costs	5,470		5,470
Total costs and expenses	15,386	3,995	56,941
Loss from operations	(15,386)	(3,995)	(56,941)
Gain on bargain purchase	25,282		25,282
Interest and other income	101	124	1,145
Interest and other expense	(64)	(5)	(305)
Net income (loss)	$ 9,933	$ (3,876)	$ (30,819)
Less: Accretion of redeemable convertible preferred stock	(135)	(14)	(245)
Less: Deemed preferred stock dividend for additional common shares issuable under anti-dilution provision	(781)		(781)
Net income (loss) attributable to common stockholders	$ 9,017	$ (3,890)	$ (31,845)
Net income (loss) attributable to common stockholders per share:			
Basic	$ 1.61	$ (5.67)	
Diluted	$ 1.41	$ (5.67)	
Weighted average shares outstanding:			
Basic	5,611,586	686,560	
Diluted	7,086,223	686,560	

See accompanying notes to consolidated financial statements.

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ARCA BIOPHARMA, INC.

(a development stage enterprise)

CONSOLIDATED STATEMENTS OF PREFERRED STOCK AND STOCKHOLDERS EQUITY (DEFICIT)

(unaudited)

	Preferred Stock				Stockholders Equity (Deficit)					
	Series A Redeemable Convertible Preferred Stock		Series B Redeemable Convertible Preferred Stock		Common stock		Additional Paid In Capital	Deficit Accumulated During the Development Stage	Other Comprehensive Income (Loss)	Total
	Shares	Amount	Shares	Amount	Shares	Amount				
	(in thousands, except share and per share amounts)									
Balance, December 17, 2001 (date of inception)		$		$		$	$	$	$	$
Issuance of common stock to founders on December 31, 2002, for cash, at $0.06 per share					15,529		1			1
Net loss								(116)		(116)
Balance, December 31, 2003					15,529		1	(116)		(115)
Issuance of common stock on September 30, 2004, for cash, at $0.06 per share					118,319		7			7
Net loss								(511)		(511)
Balance, December 31, 2004					133,848		8	(627)		(619)
Issuance of common stock on January 3, 2005, for cash, at $0.06 per share					17,533		1			1
Issuance of common stock on January 3, 2005, upon conversion of notes payable and related accrued interest at $0.06 per share					17,867		1			1
Issuance of common stock on October 14, 2005, for intellectual property license rights, at $8.14 per share					5,419		44			44
Issuance of common stock on October 14, 2005, upon conversion of notes payable and related accrued interest					186,571		1,354			1,354
Net loss								(1,459)		(1,459)
Balance, December 31, 2005					361,238		1,408	(2,086)		(678)
Issuance of common stock on February 21,					104,229		75			75

2006, for intellectual property license rights, at $0.72 per share								
Issuance of Series A on February 22, 2006, for cash, at $1.6265 per share	5,727,354	9,316						
Issuance of Series A on February 22, 2006, upon conversion of notes payable and related accrued interest, at $1.6265 per share	420,817	684						
Issuance of common stock upon exercise of stock options, for cash					48,111		3	3
Issuance of common stock on February 22, 2006, for intellectual property and product license rights, at $0.72 per share					83,443	1	59	60
Issuance of common stock on June 23, 2006, for intellectual property license rights, at $0.90 per share					15,028		15	15
Issuance of common stock on November 7, 2006, for intellectual property license rights, at $0.90 per share					229			
Issuance of Series A on December 8, 2006, for cash, at $1.6265 per share	3,074,086	5,000						
Series A offering costs		(98)						
Share-based compensation							39	39
Accretion of offering costs of redeemable convertible preferred stock		17					(17)	(17)
Net loss							(5,241)	(5,241)
Balance, December 31, 2006	9,222,257	14,919			612,278	1	1,582	(7,327)	(5,744)
Issuance of Series B convertible redeemable preferred stock, on May 31, 2007 for $2.439 per share			3,688,902	9,000				
Issuance of Series B convertible redeemable preferred stock, on December 28, 2007 for $3.253 per share			2,766,677	9,000				
Series B offering Costs				(147)				
Accretion of Series A offering costs		19					(19)	(19)
Accretion of Series B offering costs				18			(18)	(18)
Issuance of common stock for intellectual property license rights, on January 18, 2007 at $1.68 per share					7,817		13	13
Issuance of common stock for intellectual property license rights,					3,852		7	7

on June 30, 2007 at $1.80 per share									
Issuance of common stock for commercial license rights, on July 19, 2007, vests upon achievement of specified criteria					16,698				
Share-based compensation							50		50
Issuance of shares to executive on February 19, 2007, vesting upon achievement of specified criteria, subject to repurchase					83,490				
Issuance of common stock upon exercise of stock options for cash					13,359		16		16
Net loss								(13,994)	(13,994)
Balance, December 31, 2007	9,222,257	14,938	6,455,579	17,871	737,494	1	1,631	(21,321)	(19,689)
Accretion of Series A offering costs		20					(20)		(20)
Accretion of Series B offering costs				36			(36)		(36)
Share-based compensation							545		545
Estimated fair value of warrants issued in connection with convertible notes payable							399		399
Issuance of common stock upon exercise of stock options, for cash					216,926		54		54
Net loss								(19,431)	(19,431)
Balance, December 31, 2008	9,222,257	14,958	6,455,579	17,907	954,420	1	2,573	(40,752)	(38,178)
Adjustment for fractional shares on common conversion					(39)				
Deemed preferred stock dividend for additional common shares issuable under anti-dilution provision				781			(781)		(781)
Accretion of Series A offering costs		42					(42)		(42)
Accretion of Series B offering costs				93			(93)		(93)
Conversion of preferred stock	(9,222,257)	(15,000)	(6,455,579)	(18,781)	3,042,740	3	33,778		33,781
Restricted stock release from restriction							75		75
Conversion of convertible notes and related accrued interest					872,792	1	8,500		8,501
Conversion of warrants for preferred stock							36		36
Share-based compensation							194		194
Merger / reverse stock split Nuvelo, Inc.					2,686,957	3	11,910		11,913
Adjustment for fractional shares					(609)				

Issuance of common stock upon exercise of stock options for cash		12,778		16			16
Issuance of common stock under employee stock purchase plan and upon vesting of restricted stock units		864		1			1
Comprehensive income (loss):							
Net income					9,933		9,933
Unrealized loss on marketable securities						(33)	(33)
Comprehensive income							9,900
Balance, March 31, 2009	$	7,569,903	$ 8	$ 56,167	$ (30,819)	$ (33)	$ 25,323

See accompanying notes to consolidated financial statements.

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ARCA BIOPHARMA, INC.

(a development stage enterprise)

CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

	Three Months Ended March 31,		Period from December 17, 2001 (date of inception) to March 31,
	2009	2008	2009
Cash flows used in operating activities:			
Net income (loss)	$ 9,933	$ (3,876)	$ (30,819)
Adjustments to reconcile net income (loss) to net cash used in operating activities:			
Gain on bargain purchase	(25,282)		(25,282)
Depreciation and amortization	115	23	455
Non-cash interest expense	28	5	137
Share-based compensation	194	21	865
Issuance of common stock for license rights			214
Interest on notes converted to Series A Preferred Stock			5
Interest on notes converted to common stock			48
Accretion of liabilities	78		78
Loss from disposal of property and equipment			24
Change in operating assets and liabilities (net of amounts acquired):			
Other current assets	2,429	(80)	2,165
Other assets			(75)
Accounts payable	(1,697)	62	(894)
Accrued expenses and other liabilities	(3,250)	(152)	(1,244)
Deferred rent	(10)		527
Net cash used in operating activities	(17,462)	(3,997)	(53,796)
Cash flows provided by (used in) investing activities:			
Cash received from Merger	30,392		30,392
Payment of deferred transaction costs			(1,186)
Purchase of property and equipment	(155)	(132)	(1,826)
Proceeds from sale of marketable securities	5,700		5,700
Proceeds from sale of property and equipment	202		207
Net cash provided by (used in) investing activities	36,139	(132)	33,287
Cash flows (used in) provided by financing activities:			
Proceeds from issuance of convertible notes payable and related warrants for common stock			10,841
Proceeds from issuance of bank note payable			4,000
Proceeds from stock subject to repurchase			38
Proceeds from the issuance of preferred stock			32,316
Preferred stock offering costs			(246)
Proceeds from the issuance of common stock	17	5	99
Repayment of principal on bank note payable	(514)		(514)
Repayment of principal on convertible notes payables			(105)

Net cash (used in) provided by financing activities	(497)	5	46,429
Net increase (decrease) in cash and cash equivalents	18,180	(4,124)	25,920
Cash and cash equivalents, beginning of period	7,740	15,862	
Cash and cash equivalents, end of period	$ 25,920	$ 11,738	$ 25,920
Supplemental cash flow information:			
Interest paid	$ 41	$	$ 51
Supplemental disclosure of noncash investing and financing transactions:			
Accrued interest converted to equity on notes payable	$ 151	$	$ 163

See accompanying notes to consolidated financial statements.

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ARCA BIOPHARMA, INC.

(a development stage enterprise)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

(1) The Company and Summary of Significant Accounting Policies

Description of Business

ARCA biopharma, Inc. (the Company or ARCA), a Delaware corporation, is headquartered in Broomfield, Colorado and is principally focused on developing and commercializing genetically-targeted therapies for heart failure and other cardiovascular diseases. The Company s first drug candidate is Gencaro , a next generation beta-blocker and vasodilator for advanced heart failure and other indications, which the Company believes has the potential to be the first genetically targeted cardiovascular drug. Gencaro was the subject of a Phase III heart failure mortality trial involving more than 2,700 patients and was unique in gathering DNA data on over 1,000 of its participants. The Company has licensed exclusive, worldwide rights to Gencaro. In September 2008, the U.S. Food and Drug Administration (FDA) accepted for filing the Company s New Drug Application (NDA) for Gencaro.

Merger with Nuvelo, Inc.

On January 27, 2009, the Company completed a business combination (the Merger) with ARCA Colorado in accordance with the terms of that Agreement and Plan of Merger and Reorganization, dated September 24, 2008, and amended on October 28, 2008 (as amended, the Merger Agreement), in which a wholly-owned subsidiary of Nuvelo merged with and into ARCA Colorado, with ARCA Colorado continuing after the Merger as the surviving corporation and a wholly-owned subsidiary of Nuvelo. Immediately following the Merger, the Company changed its name from Nuvelo, Inc. to ARCA biopharma, Inc. The business combination is treated as a reverse merger for accounting purposes, and ARCA Colorado is the accounting acquirer, and the entity formerly known as Nuvelo, Inc. is the acquired company (Nuvelo or the acquired company). The results of operations and cash flows for the three months ended March 31, 2009 include the activities of the acquired company since the date of the Merger. Pursuant to the rules and regulations of the Securities and Exchange Commission, the historical financial statements of ARCA Colorado replaced the historical financial statements of the acquired company, and the disclosures in this report relating to the pre-Merger business of the Company, unless noted as being the business of Nuvelo prior to the Merger, pertain to the business of ARCA Colorado prior to the Merger. See Note 2 for further discussion of the Merger.

Merger Exchange Ratio and Reverse Stock Split

In conjunction with and immediately prior to the Merger, Nuvelo effected a 20-for-1 reverse stock split. As a result, and in accordance with the Merger Agreement, each outstanding common share and warrant or option to purchase ARCA Colorado s common stock prior to the Merger was converted into the right to receive or purchase 0.16698070 (the Exchange Ratio) shares of the Company s common stock (see Note 2), which Exchange Ratio incorporates the effect of the reverse stock split. All common shares, options and warrants to purchase common shares and per common share amounts for all periods presented in the accompanying financial statements and notes have been adjusted retroactively to reflect the effect of the Exchange Ratio, except for the par value per share and the number of shares authorized, which are not affected by the Exchange Ratio.

The accompanying financial statements and notes have not been adjusted to retroactively reflect the effect of the Exchange Ratio on preferred shares, warrants to purchase preferred shares, and per preferred share amounts. The ratios used to convert ARCA Colorado s preferred stock and warrants to purchase ARCA Colorado s preferred stock prior to the Merger into the right to receive or purchase shares of the Company s common stock as a result of the Merger is discussed in Note 2.

Development Stage Risks, Liquidity and Going Concern

The Company is in the development stage and devotes substantially all of its efforts towards obtaining regulatory approval, building product commercialization capabilities, and raising capital necessary to fund its operations. As previously disclosed in the Company s Annual Report on Form 10-K, the regulatory approval process for the Gencaro NDA is expensive and time-consuming and subject to the risk that the FDA may

determine that the available clinical data for Gencaro are not sufficiently strong to demonstrate Gencaro s safety and efficacy. Any such determination could prevent or delay regulatory approval and commercialization of Gencaro. As part of the FDA review of the NDA, the Company has had extensive interactions with, and has recently provided substantial supplemental information to the FDA. The submission of this or additional information could result in an extension of the review of the Gencaro NDA beyond the May 31, 2009 PDUFA date.

The Company has not generated revenue to date and is subject to a number of risks similar to those of other development stage companies, including dependence on key individuals, the development of and regulatory approval of commercially viable products, the need to obtain adequate additional financing necessary to fund the development and commercialization of its products, and competition from larger companies. The Company has historically funded its operations through issuances of convertible promissory notes, and shares of its common and preferred stock. As a result of the closing of the Merger, the Company acquired approximately $45 million in cash and short-term investments.

Since ARCA Colorado was founded on December 11, 2001 (Inception), the Company has incurred substantial losses and negative cash flows from operations. For the three months ended March 31, 2009, the Company incurred a loss from operations of $15.4 million and had negative cash flows from operations of $17.5 million.

As previously disclosed in its Annual Report on Form 10-K, the Company s strategy to commercialize Gencaro, if approved, has been to raise sufficient capital to establish internal sales and marketing capabilities as well as its own distribution network for the product, if practicable. As a result of the continuing substantial disruption in the capital markets, the difficulty of raising a significant amount of capital on acceptable terms in light of these disruptions, and consideration of any potential extension of the review of the Gencaro NDA beyond the May 31, 2009 PDUFA date, the Company is currently exploring strategic alternatives for commercializing Gencaro, including a potential strategic combination or a license of the Gencaro commercialization rights. Alternatively, the Company may continue to seek substantial additional funding through public or private debt or equity markets to support the continued development and commercialization of Gencaro. In light of the Company s current strategic direction and capital needs, the Company is actively evaluating restructuring alternatives. The Company believes that, after giving effect to an anticipated restructuring, its current cash, cash equivalents and marketable securities balances will be sufficient to fund operations through at least December 31, 2009 although the Company may seek to raise additional capital to augment its cash position. The Company is unable to assert to that its current cash, cash equivalents and marketable securities are sufficient to fund operations for the next twelve months, and as a result, there is substantial doubt about the Company s ability to continue as a going concern after December 31, 2009.

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The Company s liquidity, and its ability to complete any strategic transaction or to raise additional capital, depends on a number of factors, including, but not limited to, the following:

- timing and outcome of the FDA s response to the Company s NDA for Gencaro which, if approved, would trigger an $8 million milestone payment that would then be due within six months;
- the costs of commercializing the Company s product candidates if regulatory approvals are obtained, including the costs of establishing or contracting for marketing, sales and manufacturing capabilities, and other costs related to the size of the Company s organization, which costs, the Company currently expects to substantially defer pending its review of strategic alternatives;
- general economic and industry conditions affecting the availability and cost of capital;
- the Company s ability to reduce costs associated with its operation;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights; and
- the terms and conditions of the Company s existing collaborative and licensing agreements.

Should strategic alternatives or additional capital not be available to the Company in the near term, or not be available on acceptable terms, the Company may further delay or reduce operational activities to conserve its cash resources. The accompanying financial statements have been prepared with the assumption that the Company is a going concern and will be able to realize its assets and discharge its liabilities in the normal course of business and do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the inability of the Company to continue as a going concern.

Basis of Presentation

The Company has generated no revenue to date and its activities have consisted of seeking regulatory approval, product commercialization, and raising capital. Accordingly, the Company is considered to be in the development stage at March 31, 2009, as defined in Statement of Financial Accounting Standards (SFAS) No. 7, *Accounting and Reporting by Development Stage Enterprises*.

Accounting Estimates in the Preparation of Financial Statements

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. The Company bases estimates on various assumptions that are believed to be reasonable under the circumstances. The Company believes significant judgment was involved in estimating the fair value of assets acquired and liabilities assumed in the Merger, including in-process research and development, facility exit costs, clinical trial accruals, and in estimating other accrued liabilities, stock-based compensation, and income taxes. Management is continually evaluating and updating these estimates, and it is possible that these estimates will change in the future or that actual results may differ from these estimates.

Cash Equivalents and Marketable Securities

Cash equivalents consist of money market funds and debt securities with maturities of 90 days or less at the time of purchase. The Company considers its investments in marketable debt securities, which consist of U.S. Treasury, U.S. government agency, corporate debt and asset-backed securities, as available for use in current operations. Accordingly, the Company classifies these investments as short-term. The Company invests its excess cash in securities with strong ratings and has established guidelines relative to diversification and maturity with the objective of maintaining safety of principal and liquidity.

The Company classifies all cash equivalents and marketable securities as available-for-sale securities, as defined by Statement of Financial Accounting Standards No. 115, *Accounting for Certain Investments in Debt and Equity Securities,* and records investments at fair value. Unrealized holding gains and losses on available-for-sale securities, net of any tax effect, are excluded from earnings and are reported in accumulated other comprehensive income (loss), a separate component of stockholders equity, until realized. The specific identification method is utilized to calculate the cost to determine realized gains and losses from the sale of available-for-sale securities. Realized gains and losses are included in interest income in the statements of operations.

Concentrations of Credit Risk

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash and cash equivalents, marketable securities and other receivables. The Company has no off-balance-sheet concentrations of credit risk, such as foreign exchange contracts, option contracts, or foreign currency hedging arrangements. The Company maintains cash and cash equivalent balances in the form of bank demand deposits, money market fund accounts and debt securities with financial institutions that management believes are creditworthy. Such balances may at times exceed the insured amount.

Fair Value of Financial Instruments

On January 1, 2008, the Company adopted SFAS No. 157, *Fair Value Measurements,* or SFAS No. 157. SFAS No. 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,* or FSP 157-2, which delays the effective date for SFAS No. 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 No. 157 for financial assets and financial liabilities and FSP 157-2 for nonfinancial assets and nonfinancial liabilities did not have a material impact on the Company s financial position and results of operations.

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SFAS No. 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 No. 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

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 March 31, 2009 (in thousands):

	Level 1	Level 2	Level 3	Total
Money market fund	$ 25,209	$	$	$ 25,209
Corporate debt securities		9,368		9,368
Total	$ 25,209	$ 9,368	$	$ 34,577

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

Statement of Financial Accounting Standards No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities,* 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. To date, the Company has not elected this fair value option for any assets or liabilities.

Restricted Cash

Restricted cash represents a certificate of deposit used to collateralize a letter of credit as required by the lease agreement assumed in the Merger for the acquired company s facility in Sunnyvale, California. See Note 6, Facility Exit Costs, for discussion of the related lease commitment, and Note 8, Commitments and Contingencies, for discussion of the letter of credit arrangement.

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation and amortization. Cost includes expenditures for equipment, leasehold improvements, replacements, and renewals. Maintenance and repairs are charged to expense as incurred. When assets are sold, retired, or otherwise disposed of, the cost and accumulated depreciation are removed from the accounts and any resulting gain or loss is reflected in operations. The cost of property and equipment is depreciated using the straight-line method over the estimated useful lives of the related assets. Leasehold improvements are amortized over the shorter of the life of the lease or the estimated useful life of the assets. Property and equipment acquired in the Merger were recorded at the estimated fair value as of the date of the Merger, and are subsequently depreciated using the straight-line method over the estimated useful lives of the related assets.

Long-Lived Assets and Impairments

The Company reviews long-lived assets whenever events or changes in circumstances indicate that the carrying value of such assets may not be recoverable. Management believes that there is no indication that an impairment of its long-lived assets has occurred from Inception through

March 31, 2009. As a development stage company, the Company has not generated positive cash flows from operations, and such cash flows may not materialize for a significant period in the future, if ever. Additionally, the Company may make changes to its business plan that would result in changes to expected cash flows from long-lived assets. As a result, it is reasonably possible that future evaluations of long-lived assets may result in impairment.

Accrued Expenses

As part of the process of preparing its financial statements, the Company is required to estimate accrued expenses. This process involves identifying services that third parties have performed on the Company s behalf and estimating the level of service performed and the associated cost incurred for these services as of the balance sheet date. Examples of estimated accrued expenses include contract service fees, such as fees payable to contract manufacturers in connection with the production of materials related to the Company s drug product, and professional service fees, such as attorneys, consultants, and clinical research organizations. The Company develops estimates of liabilities using its judgment based upon the facts and circumstances known at the time.

Segments

The Company operates in one segment. Management uses one measure of profitability and does not segment its business for internal reporting.

Research and Development

Research and development costs are expensed as incurred. These consist primarily of salaries, contract services, and supplies.

Costs related to clinical trial and drug manufacturing activities are based upon estimates of the services received and related expenses incurred by contract research organizations (CROs), clinical study sites, drug manufacturers, collaboration partners, laboratories, consultants, or otherwise. Related contracts vary significantly in length, and could be for a fixed amount, a variable amount based on actual costs incurred, capped at a certain limit, or for a combination of these elements. Activity levels are monitored through communications with the CROs and other vendors, including detailed invoices and task completion review, analysis of expenses against budgeted amounts, and pre-approval of any changes in scope of the services to be performed. Certain significant vendors may also provide an estimate of costs incurred but not invoiced on a periodic basis. Expenses related to the CROs and clinical studies are primarily based on progress made against specified milestones or targets in each period.

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Stock-Based Compensation

Effective January 1, 2006, the Company adopted SFAS No. 123(R), *Share-Based Payment*, using the prospective method of transition. Under that transition method, compensation cost recognized in each subsequent period includes: (a) compensation costs for current period vesting of all share-based payments granted prior to January 1, 2006, based on the intrinsic value method prescribed by APB Opinion No. 25, and (b) compensation cost for current period vesting of all share-based payments granted or modified subsequent to January 1, 2006, based on the grant date fair value estimated in accordance with the provisions of SFAS No. 123(R). The Company recognizes compensation costs for its share-based awards on a straight-line basis over the requisite service period for the entire award.

From Inception through December 31, 2005, the Company accounted for issuances of stock-based compensation under the intrinsic-value-based method of accounting prescribed by Accounting Principles Board, or APB, Opinion No. 25, *Accounting for Stock Issued to Employees*, and related interpretations, including FASB Interpretation No. 44, *Accounting for Certain Transactions involving Stock Compensation an Interpretation of APB Opinion No. 25*. Under this method, compensation expense is generally recorded on the date of grant only if the estimated fair value of the underlying stock exceeds the exercise price.

Exit and Disposal Activities

As a result of the Merger, the Company assumed a facility lease agreement for a facility which the acquired company had previously exited. The fair value of the obligation related to such lease was estimated as of the date of the Merger using a discounted cash flow model which considered the estimated future cash flows under the lease and an estimate of sublease rental income and other lease operating expenses. The estimated fair value of the liability was recorded as accrued facility exit costs on the consolidated balance sheet. The accretion of the liability due to the passage of time is recorded as a general and administrative expense.

Income Taxes

The current provision for income taxes represents actual or estimated amounts payable or refundable on tax returns filed or to be filed each year. Deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in the period that includes the enactment date. The overall change in deferred tax assets and liabilities for the period measures the deferred tax expense or benefit for the period. The measurement of deferred tax assets may be reduced by a valuation allowance based on judgmental assessment of available evidence if deemed more likely than not that some or all of the deferred tax assets will not be realized. The Company has recorded a valuation allowance against its deferred tax assets, as management has concluded that it is more likely than not that the net deferred tax asset will not be realized through future taxable income, based primarily on the Company s history of operating losses. As a result of the Merger, a change of ownership of Nuvelo per IRC Section 382 has occurred, and accordingly, the Company s ability to utilize Nuvelo s historical net operating loss carryforwards has been substantially reduced.

Earnings (Loss) Per Share

The Company calculates net earnings (loss) per share in accordance with SFAS No. 128, *Earnings Per Share*. Basic net earnings (loss) per share was determined by dividing net earnings (loss) attributable to common stockholders by the weighted average common shares outstanding during the period, excluding common stock subject to vesting provisions. Diluted net earnings (loss) per share is computed by dividing the net earnings (loss) attributable to common stockholders by the weighted average number of common shares outstanding during the period increased to include, if dilutive, the number of additional common shares that would have been outstanding if the potential common shares had been issued. The Company s potentially dilutive shares include redeemable convertible preferred stock, convertible notes payable, options and warrants.

A reconciliation of numerator and denominator used in the calculation of basic and diluted net earnings (loss) per share follows:

(In thousands, except shares and per share data)	Three Months Ended March 31, 2009	2008
BASIC		
Net income (loss)	$ 9,933	$ (3,876)
Less: Accretion of redeemable convertible preferred stock	(135)	(14)
	(781)	

Deemed preferred stock dividend for additional common shares issuable under anti-dilution provision		
Net income (loss) available to common shareholders	$ 9,017	$ (3,890)
Weighted average shares of common stock outstanding	5,653,331	786,748
Less: Weighted-average shares of unvested common stock	(41,745)	(100,188)
Total weighted-average shares used in computing net income (loss) per share attributed to common stockholders	5,611,586	686,560
Basic earnings (loss) per share	$ 1.61	$ (5.67)
DILUTED		
Net income (loss)	$ 9,933	$ (3,876)
Add: Interest on convertible notes payable	33	
Less: Accretion of redeemable convertible preferred stock		(14)
Net income (loss) available to common shareholders	$ 9,966	$ (3,890)
Weighted average shares outstanding	5,611,586	686,560
Dilutive impact of stock plans	343,483	
Dilutive impact of convertible securities	1,131,154	
Dilutive shares outstanding	7,086,223	686,560
Diluted earnings (loss) per share	$ 1.41	$ (5.67)

Potentially dilutive securities representing 0.7 million and 3.1 million weighted average shares of common stock were excluded for the three months ended March 31, 2009 and 2008, respectively, because including them would have an anti-dilutive effect on net earnings (loss) attributable to common stockholders per share.

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Recent Accounting Pronouncements

Effective January 1, 2008, the Company adopted SFAS No. 157. In February 2008, the FASB issued FASB Staff Position No. 157-2, which provided a one year deferral of the effective date of SFAS No. 157 for nonfinancial assets and nonfinancial liabilities, except those that are recognized or disclosed in the financial statements at fair value at least annually. SFAS No. 157 defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles and expands disclosures about fair value measurements. SFAS No. 157 applies under other accounting pronouncements that require or permit fair value measurements and does not require any new fair value measurements. The standard describes a fair value hierarchy based on three levels of inputs, the first two of which are considered observable and the last unobservable, that may be used to measure fair value. The adoption of SFAS No. 157 had no material impact on the Company s consolidated financial statements. The Company adopted the provisions of SFAS No. 157 with respect to non-financial assets and liabilities effective January 1, 2009. Such adoption did not have a material impact on the Company s consolidated financial statements.

In December 2007, the FASB issued SFAS No. 141(R), *Business Combinations,* and SFAS No. 160, *Accounting and Reporting of Noncontrolling interest in Consolidated Financial Statements, an amendment of ARB No. 51*. These new standards have significantly changed the financial accounting and reporting of business combination transactions and noncontrolling (or minority) interests in consolidated financial statements. SFAS No. 141(R) requires the acquirer of a business to recognize and measure the identifiable assets acquired, the liabilities assumed, and any non-controlling interest in the acquiree at fair value on the acquisition date. SFAS No. 141(R) also requires that transactions costs related to the business combination be expensed as incurred and that changes in accounting for business combination related deferred tax asset valuation allowances and income tax uncertainties after the measurement period be recognized as current period income tax expense. SFAS No. 141(R) applies prospectively to business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2008. The Company applied the provisions of SFAS No. 141(R) to the Merger transaction as discussed in Note 2. Costs incurred during 2008 associated with the Merger were recorded as deferred transaction costs at December 31, 2008. On January 1, 2009, as part of the Company s adoption of SFAS No. 141(R), the balance of deferred transaction costs was expensed.

In December 2007, the FASB ratified the consensus reached by the Emerging Issues Task Force (EITF) on EITF Issue 07-1, *Accounting for Collaborative Arrangements* (EITF 07-1). EITF 07-1 requires collaborators to present the results of activities for which they act as the principal on a gross basis and report any payments received from (made to) other collaborators based on other applicable GAAP or, in the absence of other applicable GAAP, based on analogy to authoritative accounting literature or a reasonable, rational, and consistently applied accounting policy election. The effective date for the Company was January 1, 2009. The adoption of EITF 07-1 had no impact on the Company s financial statements.

In June 2008, the FASB ratified the consensus reached on EITF Issue No. 07-05, *Determining Whether an Instrument (or Embedded Feature) Is Indexed to an Entity s Own Stock* (EITF No. 07-05). EITF No. 07-05 clarifies the determination of whether an instrument (or an embedded feature) is indexed to an entity s own stock, which would qualify as a scope exception under SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities*. EITF No. 07-05 is effective for financial statements issued for fiscal years beginning after December 15, 2008. Early adoption for an existing instrument is not permitted. The adoption of EITF 07-5 had no impact on the Company s financial statements.

(2) Merger with Nuvelo, Inc. on January 27, 2009

On January 27, 2009, the Company completed the Merger contemplated by the Merger Agreement. Pursuant to the Merger Agreement, a wholly-owned subsidiary of Nuvelo merged with and into ARCA Colorado, with ARCA Colorado continuing after the Merger as the surviving corporation and a wholly-owned subsidiary of Nuvelo. Immediately following the Merger, the Company changed its name from Nuvelo, Inc. to ARCA biopharma, Inc., and its common stock began trading on the Nasdaq Global Market under the symbol ABIO on January 28, 2009.

The Merger is treated as a reverse merger and accounted for as a business combination using the acquisition method of accounting in accordance with SFAS No. 141(R). For accounting purposes, ARCA Colorado is considered to have acquired Nuvelo in the Merger, as the stockholders of ARCA Colorado prior to the Merger now have a controlling interest in the combined company and the Company s management is the former management of ARCA Colorado. Under the acquisition method of accounting, the assets acquired and liabilities assumed of Nuvelo are recorded as of the acquisition date, at their respective fair values. The results of operations and cash flows for the three months ended March 31, 2009 include the activities of the acquired company since the date of the Merger.

Immediately prior to the Merger, each share of ARCA Colorado s Series A preferred stock automatically converted into 1 share of ARCA Colorado s common stock; each share and warrant to purchase ARCA Colorado s Series B-1 preferred stock automatically converted into 1.219875 shares or warrants to purchase, as applicable, of ARCA Colorado s common stock; each share and warrant to purchase ARCA

Colorado s Series B-2 preferred stock automatically converted into 1.6265 shares or warrants to purchase, as applicable, of ARCA Colorado s common stock. In connection with the Merger, each share of ARCA Colorado s common stock was converted into the right to receive 0.16698070 shares of the Company s common stock.

Each option and warrant to purchase shares of ARCA Colorado s common stock outstanding at the effective time of the Merger was assumed by the Company at the effective time of the Merger. Each such option or warrant became an option or warrant, as applicable, to acquire that number of shares of the Company s common stock equal to the product obtained by multiplying the number of shares of ARCA Colorado s common stock subject to such option or warrant by 0.16698070, rounded down to the nearest whole share of the Company s common stock. Following the Merger, each such option or warrant has an exercise price per share of the Company s common stock equal to the quotient obtained by dividing the per share purchase price of ARCA Colorado s common stock subject to such option or warrant by 0.16698070, rounded up to the nearest whole cent.

Immediately following the Merger, ARCA Colorado s former stockholders, together with the former holders of ARCA Colorado s options and warrants owned or had the right to acquire upon the exercise of outstanding options and warrants approximately 67% of the common stock of the Company and Nuvelo stockholders prior to the Merger owned approximately 33% of the common stock of the Company. 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.

Prior to the completion of the Merger, Nuvelo was developing drugs for acute cardiovascular disease, gastro-intestinal, or GI, diseases and other debilitating medical conditions. Its development pipeline included NU172, a direct thrombin inhibitor that has completed Phase I development for use as a short-acting anticoagulant during medical or surgical procedures, and Phase I clinical candidate NU206, a recombinant, secreted protein for the potential treatment of GI, diseases, including inflammatory bowel disease, mucositis and bone disease. In the first quarter of 2008, Nuvelo discontinued the clinical development of its only clinical-stage product candidate, alfimeprase. ARCA Colorado merged with Nuvelo primarily to increase its cash resources in the short-term while enhancing its access to capital necessary to commercialize its late stage product candidate, Gencaro, and to build its product development pipeline.

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The estimated total acquisition consideration to acquire Nuvelo is based on the market capitalization of Nuvelo as of January 27, 2009, and the estimated fair values of its vested stock options and warrants outstanding on that date, as this was deemed the most reliable measure of the consideration effectively transferred to acquire Nuvelo on that date, and is as follows (in thousands):

Market capitalization of Nuvelo common stock	$ 11,824
Estimated fair value of options and warrants assumed	88
Total acquisition consideration	$ 11,912

The Company considered alternative approaches to measure the acquisition consideration, such as basing the acquisition consideration on the fair value of Nuvelo s net assets, or based on ARCA Colorado s fair value rather than the fair value of Nuvelo s common stock on the consummation date. The Company believes the most reliable measurement of consideration is based on the market capitalization of Nuvelo and the fair values of its vested stock options and warrants as of the date of the Merger, as it is the most objectively verifiable value.

Under the acquisition method of accounting, in accordance with SFAS No. 141(R), the total acquisition consideration is allocated to the assets acquired and liabilities assumed based on their estimated fair values as of the date of the Merger. The Company has not finalized the acquisition consideration allocation as of the date of this report. The preliminary allocation, based on the estimated fair values of the assets acquired and liabilities assumed as of the date of the Merger, is as follows (in thousands):

Estimated purchase price allocation:	
Cash and cash equivalents	$ 30,392
Marketable securities	15,106
Collaboration receivable	626
Other current assets	1,247
Restricted cash	6,000
Property and equipment	489
In-process research and development	6,000
Other non-current assets	1,084
Accounts payable	(2,189)
Accrued employee liabilities	(3,579)
Other current liabilities	(1,406)
Accrued facility exit costs	(13,278)
Other liabilities	(74)
Deferred tax liability	(2,281)
Unfavorable lease obligation	(943)
Gain on bargain purchase	(25,282)
Total acquisition consideration	$ 11,912

Cash and cash equivalents, marketable securities and other tangible assets and liabilities: The tangible assets and liabilities were valued at their respective carrying amounts by Nuvelo, except for adjustments to certain property and equipment, deferred revenue, deferred rent, facility exit costs and other liabilities, necessary to state such amounts at their estimated fair values at the acquisition date. See Note 6, Facility Exit Costs, for discussion of the accrued facility exit costs, and Note 8, Commitments and Contingencies, for discussion of the unfavorable lease liability.

In-process research and development: In-process research and development (IPR&D) represents projects under development by Nuvelo at the date of the Merger that had not yet been completed and had not achieved regulatory approval. It is estimated that approximately $6.0 million of the acquisition consideration represents purchased IPR&D primarily related to projects associated with the Nuvelo NU172 program. The fair value of IPR&D was determined using an income approach, as well as discussions with Nuvelo s management and a review of certain program-related documents and forecasts of future cash flows. The income approach, a valuation method that establishes the business value based on a stream of future economic benefits, such as net cash flows, discounted to their present value, included probability adjustments to projected expenses and revenue in order to reflect the expected probabilities of incurring development cost prior to commercialization and the probability of achieving commercial revenue due to drug discovery and regulatory risks. An appropriately risk-adjusted discount rate was

utilized to discount the probability adjusted net cash flows to their present value, to reflect the time value of money and risks of commercialization, sales, and competition, which are risk elements explicitly not addressed in the probability adjustments. The Company will continue to periodically reassess the value of purchased IPR&D, and in connection with those periodic reassessments, may determine that its valuation should change, even materially, based on, among other factors, changes in management s views regarding anticipated future economic benefits of the IPR&D. IPR&D is considered an indefinite-lived intangible asset. Depending upon the results of the research and development projects, the value of the IPR&D will either be amortized beginning upon successful completion of the project or impaired if the project fails or is abandoned. The Company has recorded a deferred tax liability of $2.3 million related to the IPR&D asset.

Pre-acquisition contingencies: The Company retains the obligations under Nuvelo s employment agreements and compensation plans, pursuant to which Nuvelo employees are entitled to termination benefits upon change of control and involuntary termination. Such plans were established prior to merger negotiations with ARCA Colorado, and were not entered into to benefit ARCA Colorado. These plans create a contingent liability for the Company as of the acquisition date, which is estimated for employees expected to be involuntary terminated at $1.7 million and is included in the consideration allocation above under the caption Accrued employee liabilities . The Company has not currently identified any other pre-acquisition contingencies where an acquisition-date liability is probable and the amount of the liability can be reasonably estimated. If information becomes available to the Company prior to the end of the measurement period, which would indicate that a liability is probable and the amount can be reasonably estimated, such items will be included in the acquisition consideration allocation.

Gain on bargain purchase: In accordance with SFAS No. 141(R), any excess of fair value of acquired net assets over the acquisition consideration results in a gain on bargain purchase. Prior to recording a gain, the acquiring entity must reassess whether all acquired assets and assumed liabilities have been identified and recognized and perform re-measurements to verify that the consideration paid, assets acquired, and liabilities assumed have been properly valued. The Company underwent such a reassessment, and as a result, has recorded a gain on bargain purchase of $25.3 million. If new information is obtained about facts and circumstances that existed as of the acquisition date that, if known, would have affected the measurement of the amounts recognized for assets acquired and liabilities assumed, the Company will retrospectively adjust the amounts recognized as of the acquisition date. The final acquisition consideration and allocation thereof may change significantly from these estimates.

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The acquisition consideration allocation indicates that the Merger resulted in a gain on bargain purchase of $25.3 million. In accordance with the acquisition method of accounting, any resulting gain on bargain purchase must be recognized in earnings on the acquisition date. This gain is largely determined by the trading price of Nuvelo s common stock on Nasdaq prior to the Merger. The Company believes that the gain on bargain purchase resulted from various factors that may have impacted the trading price of Nuvelo s common stock, including, without limitation, the significant declines in the securities markets during the fourth quarter of 2008; uncertainty concerning the combined entities ability to obtain regulatory approval of the Gencaro NDA; timing and conditions of an approval, its ability to successfully commercialize Gencaro, if approved, and to raise additional capital to support the commercialization of Gencaro and to fund other business objectives; uncertainty regarding the combined entities ability to successfully integrate the business operations of Nuvelo; and uncertainty regarding the combined entities ability to further identify, develop and achieve commercial success for products and technologies; all of which may have impacted Nuvelo s market capitalization at the time the Merger was consummated.

Merger transaction costs: The Company has incurred merger transaction costs of $5.5 million, including financial advisory, legal, accounting and due diligence costs, which are recorded as merger transaction expenses on the consolidated statement of operations. Through December 31, 2008, the Company had incurred $1.7 million of merger transaction expenses, which were recorded as deferred transaction costs on the consolidated balance sheet at that date. On January 1, 2009, as part of the adoption of SFAS No. 141(R), the balance of deferred transaction costs was expensed to merger transaction expenses on the consolidated statement of operations.

In connection with the Merger, a substantial majority of Nuvelo s employees were involuntarily terminated, subsequent to transition periods of up to 12 weeks from the date of the Merger. Pursuant to pre-existing employment agreements and compensation plans, termination benefits of $3.1 million had been accrued as of the date of the Merger. In addition to the termination benefits pursuant to the assumed Nuvelo compensation plans, the Company has offered retention bonuses to employees on transition plans totaling $290,000, which are being expensed as incurred over the transition period.

The following table provides supplemental pro forma financial information for the three months ended March 31, 2009 and 2008 as if the acquisition had occurred as of the beginning of each year presented. For each period presented, the unaudited pro forma results exclude the nonrecurring charges for the merger transaction costs and the gain on bargain purchase. The unaudited pro forma results do not reflect any operating efficiencies or potential cost savings that may result from the consolidation of the operations of ARCA Colorado and Nuvelo. Accordingly, these unaudited pro forma results are presented for illustrative purposes and are not intended to represent or be indicative of the actual results of operations of the combined company that would have been achieved had the acquisition occurred at the beginning of each period presented, nor are they intended to represent or be indicative of future results of operations.

	Three Months Ended, March 31,	
(in thousands, except per share data)	**2009**	**2008**
Revenue	$	$
Net loss	$ (15,866)	$ (22,291)
Net loss per share, basic and diluted	$ (2.10)	$ (3.48)

(3) Financial Instruments

Available-for-sale Investments

The cost and fair value of the Company s available-for-sale investments as of March 31, 2009 and December 31, 2008 were as follows (in thousands):

	March 31, 2009			
	Amortized Cost	**Gross Unrealized Gains**	**Gross Unrealized Losses**	**Estimated Fair Value**
Money market fund	$ 25,209	$	$	$ 25,209
Corporate debt securities	9,401		(33)	9,368

	$ 34,610	$	$ (33)	$ 34,577

Reported as:

Cash equivalents	$ 25,209
Marketable securities	9,368
	$ 34,577

	December 31, 2008			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Money market fund	$ 7,671	$	$	$ 7,671(a)

(a) Reported as cash equivalents

The contract maturity of all of the Company s available-for-sale investments is less than one year.

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The following is a summary of available-for-sale investments with unrealized losses and their related fair value by the period of time each investment has been in an unrealized loss position (in thousands):

	March 31, 2009		December 31, 2008	
	Unrealized Losses	Estimated Fair Value	Unrealized Losses	Estimated Fair Value
Unrealized loss position for less than one year	$ (33)	$ 7,368	$	$

Due to the short maturities of investments, the type and quality of security held, the relatively small size of unrealized losses compared to fair value, and the short duration of such unrealized losses, the Company believes these unrealized losses to be temporary in nature.

Fair Value of Other Financial Instruments

The carrying amount of other financial instruments, including cash and accounts payable, approximated fair value due to their short maturities, and the carrying amount of the Company s bank note approximates the fair value, as the applicable interest rate approximated market rate. As of March 31, 2009 and December 31, 2008, the Company did not have any other debt or foreign exchange forward contracts outstanding.

(4) Property and Equipment

Property and equipment consist of the following:

	Estimated Life	March 31, 2009	December 31, 2008
		(in thousands)	
Computer equipment	3 years	$ 333	$ 218
Lab equipment	5 years	286	85
Furniture and fixtures	5 years	509	415
Computer software	3 years	177	149
Leasehold improvements	Lesser of useful life or life of the lease	741	739
		2,046	1,606
Less accumulated depreciation and amortization		(418)	(303)
		$ 1,628	$ 1,303

For the three months ended March 31, 2009 and March 31, 2008, and for the period from Inception through March 31, 2009, depreciation and amortization expense was $115,000, $23,000 and $455,000, respectively.

(5) Comprehensive Income (Loss)

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

	Three Months Ended March 31,	
	2009	2008
Net income (loss), as reported	$ 9,933	$ (3,876)

Change in unrealized loss on available-for-sale securities	(33)	
Comprehensive income (loss)	$ 9,900	$ (3,876)

(6) Facility Exit Costs

As a result of the Merger, the Company assumed an operating lease for a 139,000-square-foot facility in Sunnyvale, California (the Sunnyvale facility), which had previously been exited by the acquired company. The term of the lease for the facility expires on May 31, 2011. The Company recorded a facility exit liability of $13.3 million as of the acquisition date to reflect the estimated fair value of this liability using a discounted cash flow method. As of March 31, 2009, estimated future lease-related payments totaling $15.0 million are scheduled to be made periodically until the lease expires. The Company also assumed a sublease agreement related to this facility, pursuant to which estimated sublease income of $2.5 million is expected to be received over the sublease term from March 1, 2009 through May 31, 2011.

The following table summarizes the activities related to accrued facility exit costs for the three months ended March 31, 2009 (in thousands):

Fair value of facility exit cost liability assumed:	$ 13,278
Amounts paid during the period	(1,198)
Amounts received during the period	42
Non-cash accretion, net	118
Balance as of March 31, 2009	$ 12,240

The non-cash accretion expense of $118,000 for the three months ended March 31, 2009 was included in general and administrative expenses.

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(7) Convertible Promissory Notes

In October 2008, the Company entered into convertible promissory notes with certain of ARCA Colorado s existing investors. The principal amount of the convertible notes was $8.4 million and the notes bore interest at 6% per annum. The entire principal and accrued interest on the notes was due on March 31, 2009. In January 2009, upon closing of the Merger, the principal balance of $8.4 million and the accrued interest of $151,000 were converted into common stock at a rate consistent with the Series B-2 Preferred Stock into 872,792 shares of common stock. In connection with the issuance of the notes, the Company issued warrants, with an estimated fair value of $399,000, to the noteholders which allows them to purchase 179,659 shares of common stock at an exercise price of $9.7406 per share.

(8) Commitments and Contingencies

In addition to the legal matters discussed in Note 12, the Company has or is subject to the following commitments and contingencies:

(a) Employment Agreements

The Company maintains employment agreements with several key executive employees. The agreements may be terminated at any time by the Company with or without cause upon written notice to the employee, and entitle the employee to wages in lieu of notice for periods not exceeding one calendar year from date of termination without cause or by the employee for good reason. Certain of these agreements also provide for payments to be made under certain conditions related to a change in control of the Company.

(b) Operating Leases

As a result of the Merger, the Company assumed two facility operating leases, including the lease of the Sunnyvale facility. The term of the lease for the Sunnyvale facility expires on May 31, 2011. The Company recorded a facility exit liability of $13.3 million as of the acquisition date to reflect the estimated fair value of this liability using a discounted cash flow method. The Sunnyvale facility lease requires a letter of credit issued to the facility s landlord in the amount of $6.0 million. The letter of credit is being collateralized by a certificate of deposit of the same amount, which is recorded as restricted cash in the accompanying consolidated balance sheet. The Company also assumed a sublease agreement related to this facility, which requires the subtenant to pay a monthly base rent of $57,000, except during the first four months of the term, and a substantial majority of the facility operating expenses charged by the facility s landlord. The term of the sublease commenced on March 1, 2009 and ends on May 31, 2011.

The second facility operating lease assumed in the Merger is a seven-year agreement for approximately 69,000 square feet of space in San Carlos, California. The lease term commenced on September 1, 2005, and contains an option to cancel after five years upon payment of certain amounts specified in the lease, and two options to extend the lease for five additional years, each at 95% of the then-current fair market rental rate (but not less than the existing rental rate). Nuvelo used this facility for its headquarters prior to the Merger. The Company also assumed a sublease agreement related to this facility for approximately 6,800 square feet of the space. The term of the sublease, which started in February 2008 and expires in January 2011, can be extended by the subtenant for three additional periods of one year each, subject to certain conditions contained in the sublease agreement. The Company is seeking to sublease the entire facility. As of the acquisition date, the Company determined that the net terms of the lease and sublease were unfavorable compared with the market terms of leases for similar facilities, and as result recorded a liability representing the estimated the fair value of such unfavorable terms. The Company estimated the fair value of the unfavorable lease liability to be $943,000 as of the acquisition date using a discounted cash flow model comparing the contractual lease payments and receipts to an estimated market rate for such receipts. The unfavorable lease liability is classified on the accompanying consolidated balance sheet as accrued expenses and other liabilities for the current portion and as other long-term liabilities for the non-current portion. The Company will amortize this liability to operating expense on a straight-line basis over the term of the lease and sublease.

On February 8, 2008 the Company entered into a lease agreement for approximately 15,000 square feet of newly constructed office facilities in Broomfield, Colorado, which serves as the Company s primary business offices. The Company relocated to the new facility upon its completion in July 2008. The lease has a term of 5 years with rights to extend the term for two additional three year periods. Per the lease agreement, base rent is subject to annual increases of approximately three percent per year. The rent expense for the lease is being recognized on a straight-line basis over the lease term. Tenant improvement reimbursements from the landlord totaled $593,000 which were recorded as deferred rent and are amortized as reductions to rent expense over the lease term.

Below is a summary of the future minimum lease payments committed under the two leases assumed in the Merger and the Company s facility in Broomfield, Colorado (in thousands):

Remainder of 2009	$ 6,458
2010	8,865
2011	5,223
2012	1,790
2013	128
Total future minimum rental payments	22,464
Less: aggregate future minimum rentals under subleases	(1,769)
	$ 20,695

(c) CardioDx, Inc.

In June 2006, the Company entered into a license agreement with CardioDx, Inc. The license gives the Company a nonexclusive, royalty bearing license for diagnostic rights to key genetic markers that are relevant for prescribing Gencaro. The term of the agreement extends to the latest expiring patent underlying the diagnostic rights. The license permits the Company to sublicense its rights under certain conditions, and in February 2007, the Company sublicensed its rights and transferred its royalty and other fee obligations to Laboratory Corporation of America.

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(d) Laboratory Corporation of America

In February 2007, the Company entered into a commercialization and licensing agreement with Laboratory Corporation of America, or LabCorp, to develop, make, market and sell diagnostic tests in connection with the medical prescription of the Company s lead compound, Gencaro. Under the agreement the Company granted to LabCorp an exclusive license to its diagnostic rights under the CardioDx agreement and the Company s diagnostic rights associated with Gencaro. The license agreement has a term of 10 years. The sublicense transferred the royalty and all other fee obligations of the Company arising out of the sale of diagnostic tests by LabCorp. Royalty payments will be made directly to CardioDx by LabCorp. If LabCorp does not fulfill its royalty payment and other fee obligations, the Company is responsible for the payments. In addition, the Company granted to LabCorp 16,698 shares of common stock. The shares are subject to a restricted stock agreement in which shares vest upon the attainment of certain regulatory approval and drug product sales milestones.

(e) Cardiovascular Pharmacology and Engineering Consultants, LLC, or CPEC

Under the terms of its strategic license agreement with CPEC, a licensing subsidiary of Indevus Pharmaceuticals Inc. (a wholly owned subsidiary of Endo Pharmaceuticals as of March 23, 2009), holding ownership rights to certain clinical trial data of Gencaro, the Company will incur milestone and royalty obligations upon the occurrence of certain events. In August 2008, the Company paid CPEC a milestone payment of $500,000 based on the July 31, 2008 submission of its NDA with the FDA. If the FDA grants marketing approval for Gencaro, the Company will owe CPEC another milestone payment of $8.0 million, which is due within six months after FDA approval. The Company s royalty obligation ranges from 7.5% to 20% of revenue from the related product based on achievement of specified product sales levels.

(9) Bank Note Payable

In July 2007 the Company obtained a credit facility of $4.0 million from Silicon Valley Bank (SVB), or the Credit Facility, to be used solely for working capital and to fund general business requirements. In August 2008, the Company borrowed the full $4.0 million available under the growth capital facility. In January 2009, the Credit Facility was amended to mature on March 23, 2009. Pending the execution and delivery of definitive documentation to amend the Credit Facility and extend the maturity date until December 1, 2010, SVB agreed to extend the maturity date of the Credit Facility until April 6, 2009 and subsequently to April 17, 2009.

On April 10, 2009, the Company and SVB agreed to amend the Credit Facility pursuant to which the maturity on the Credit Facility was extended until December 1, 2010. In addition, the principal amount outstanding under the Credit Facility will bear interest at a rate of 4.25% per annum, unless the Company and its subsidiaries fail to maintain the lesser of $10 million or 100% of all of their invested cash balances in designated accounts with SVB, in which event, the interest rate will be permanently increased to a rate equal to SVB s prime rate plus 2.0%, which shall be fixed as of the date such accounts fall below the thresholds. Monthly principal and interest payments are due on the Credit Facility through the maturity date of December 1, 2010.

The agreement contains customary affirmative and negative covenants including, without limitation, (i) covenants requiring the Company to comply with applicable laws, provide to SVB copies of the Company s financial statements, maintain appropriate levels of insurance, protect, defend and maintain the validity and enforceability of the Company s material intellectual property, and (ii) covenants restricting the Company s ability to dispose of all or substantially all of its assets, engage in other lines of business, change its senior management, enter into transactions constituting a change of control, assume additional indebtedness, incur liens on its assets, among other covenants. The Company s obligations under the Credit Facility are secured by a majority of the Company s assets.

The Company agreed to pledge to SVB restricted certificates of deposit (CD s) issued by SVB, with the aggregate amount of the pledged CD s varying from time to time depending on the aggregate amount of unrestricted cash maintained by the Company with SVB. So long as the Company and its subsidiaries maintain at least $20 million in cash at SVB, no pledged CD is required. So long as the Company and its subsidiaries maintain less than $20 million but at least $15 million in cash at SVB, the Company is required to pledge CD s to SVB in an aggregate amount equal to 33 1/3% of the then outstanding principal amount of the Credit Facility. So long as the Company and its subsidiaries maintain less than $15 million but at least $10 million in cash at SVB, it is required to pledge CD s to SVB in an aggregate amount equal to 66 2/3% of the then outstanding principal amount of the Credit Facility. Finally, for so long as the Company and its subsidiaries maintain less than $10 million in cash at SVB, the Company is required to pledge CD s to SVB equal to 100% of the then outstanding principal amount of the Credit Facility.

As of March 31, 2009, the Company had $3.5 million outstanding under the Credit Facility, which has been recorded as bank note payable on the consolidated balance sheet. No additional borrowings may be made under the facility. Following is a summary of the payments under the Credit Facility (in thousands):

Remainder of 2009	$ 1,564
2010	2,085
	3,649
Less: Interest payments	132
Unamortized debt discount	45
	$ 3,472

(10) Collaborative Agreements

The following collaborative agreements have been assumed as a result of the Merger:

Archemix

In July 2006, Nuvelo entered into a collaboration agreement with Archemix Corporation. Under the agreement, Archemix is responsible for the discovery of short-acting aptamers targeting the coagulation cascade for use in acute cardiovascular procedures, and the Company is responsible for development and worldwide commercialization of these product candidates. In August 2006, Nuvelo made an upfront license fee payment to Archemix of $4.0 million, and pursuant to the terms of the agreement committed to funding at least $5.25 million of Archemix s research over the first three years of the agreement. Archemix may receive payments totaling up to $35.0 million per development compound on the achievement of specified development and regulatory milestones, along with potential royalty payments based on sales of licensed compounds. In February 2008, Nuvelo paid Archemix a $1.0 million milestone fee that was accrued upon dosing of the first patient in the Phase I trial for NU172. If the Company enrolls the first patient in a Phase II trial of NU172, which is not expected to occur in 2009, the Company is obligated to pay Archemix a $3.0 million milestone fee. At the initiation of the first Phase III 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. In addition, the Company is obligated to purchase Archemix common stock having a value equal to the lesser of $10.0 million or 15% of the shares issued by Archemix in a qualified initial public offering of Archemix stock occurring within five years of the effective date of the 2006 collaboration agreement.

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Kirin

In March 2005, Nuvelo entered into a collaboration agreement with Kyowa Hakko Kirin Company, Limited for the development and commercialization of NU206. In accordance with the terms of this agreement, Nuvelo received a $2.0 million upfront cash payment from Kirin in April 2005. Nuvelo agreed to lead worldwide development, manufacturing and commercialization of the compound. All operating expenses and any profits related to the development and commercialization of NU206 are being shared 60% by the Company and 40% by Kirin. If this agreement is terminated, or Kirin or the Company elects under certain circumstances to no longer actively participate in the collaboration, the relationship with respect to NU206 will convert from an expense and profit-sharing structure to a royalty-based structure.

(11) Preferred Stock

(a) Series A Redeemable Convertible Preferred Stock

In February 2006, the Company issued 6,148,171 shares of Series A Redeemable Convertible Preferred Stock, or Series A Preferred Stock, at a price of $1.6265 per share. In December 2006, the Company issued an additional 3,074,086 shares of Series A Preferred Stock at a price of $1.6265 per share. Each share was initially convertible into one share of common stock. Each holder of Series A Preferred Stock was entitled to receive, if and when declared, payment of an equivalent per-share dividend based on the number of common shares into which each share of Series A Preferred Stock was convertible, as of the date of declaration. The rate of conversion of Series A Preferred Stock into common stock was required to be adjusted in the event the Company issued dilutive shares of common stock according to a formula defined in the Company s Restated Certificate of Incorporation. Holders of Series A Preferred Stock were entitled to vote as though the Series A Preferred Stock were converted into common stock.

(b) Series B Redeemable Convertible Preferred Stock

In May 2007, the Company issued 3,688,902 shares of Series B Redeemable Convertible Preferred Stock, or Series B-1 Preferred Stock, at a price of $2.439 per share. In December 2007, the Company issued 2,766,677 shares of Series B-2 Redeemable Convertible Preferred Stock, or Series B-2 Preferred Stock, at a price of $3.253 per share. Each share of Series B-1 Preferred Stock and Series B-2 Preferred Stock was initially convertible into one share of ARCA Colorado common stock. Each holder of Series B-1 Preferred Stock and Series B-2 Preferred Stock was entitled to receive, if and when declared, payment of an equivalent per-share dividend based on the number of shares of ARCA Colorado common stock into which each share of Series B-1 Preferred Stock and Series B-2 Preferred Stock was convertible, as of the date of declaration. The rate of conversion of Series B-1 Preferred Stock and Series B-2 Preferred Stock into ARCA Colorado common stock was required to be adjusted in the event the Company issues dilutive shares of ARCA Colorado common stock according to a formula defined in the Company Restated Certificate of Incorporation. Holders of Series B-1 Preferred Stock and Series B-2 Preferred Stock were entitled to vote as though the Series B-1 Preferred Stock and Series B-2 Preferred Stock were converted into ARCA Colorado common stock.

(c) Conversion of Preferred Stock

As a result of the Merger on January 27, 2009:

each share of Series A Preferred Stock automatically converted into one share of ARCA Colorado s common stock;

each share of Series B-1 Preferred Stock automatically converted into 1.219875 shares of ARCA Colorado s common stock;

each share of Series B-2 Preferred Stock automatically converted into 1.6265 shares of ARCA Colorado s common stock; and

each share of ARCA Colorado s common stock, including each share issued upon conversion of the Series A Preferred Stock, Series B-1 Preferred Stock and Series B-2 Preferred Stock, was converted into the right to receive 0.16698070 shares of common stock of the Company.

In aggregate the 15,677,836 shares of Preferred Stock outstanding at the time of the Merger were converted into 3,042,740 shares of the common stock of the Company. In January 2009, the Company recorded a $781,000 charge against net income (loss) attributable to common shareholders related to the additional common shares issuable to holders of Series B-1 Preferred Stock and Series B-2 Preferred Stock as a result of Series B-1 Preferred Stock and Series B-2 Preferred Stock anti-dilution provisions in effect at the consummation of the Merger.

(d) Warrants for Series B Redeemable Preferred Stock

In July 2007, the Company issued warrants to purchase 31,790 shares of Series B-1 Preferred Stock to SVB in connection with the Credit Facility. The warrants had an exercise price of $2.439 per share, a 10 year life, and were fully vested and exercisable at the time of grant. As a result of the Merger, these warrants were converted into warrants to purchase 6,475 shares of common stock at an exercise price of $14.61 per share. In August 2008, the Company issued 24,592 warrants for its Series B-2 Preferred Stock to SVB in connection with a borrowing under the Credit Facility. The warrants had an exercise price of $3.253 per share, a 10-year life, and were fully vested and exercisable at the time of grant. As a result of the Merger, such warrants were converted into warrants to purchase 6,679 shares of common stock at an exercise price of $19.48 per share. The estimated fair value of the warrants at the time of issuance was accounted for as a debt discount within long-term liabilities, and will be reflected as additional interest expense over the term of the Credit Facility.

(12) Legal Matters

On February 9, 2007, Nuvelo 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 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 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.

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On December 4, 2008, the Court issued an order dismissing plaintiff s complaint, and granting leave to amend. On January 23, 2009, plaintiffs filed an amended complaint, alleging similar claims. On March 24, 2009, defendants filed a motion to dismiss the amended complaint. Based on the Court s December 4, 2008 order, and plaintiff s amended complaint, the Company believes that any attorneys fees, loss or settlement payment with respect to this suit will be paid by its insurance provider. However, it is possible that the Company could be forced to incur material expenses in the litigation if the case is not finally dismissed, or if the parties cannot achieve a settlement, and, in the event of an adverse outcome, the Company s business could be harmed.

In addition, 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. The Company is involved in this litigation as a result of Nuvelo s 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 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. The Company believes that any attorneys fees, loss or settlement payment with respect to this suit will be paid by its insurance provider. However, it is possible that the Company 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, the Company s business could be harmed.

(13) Stock-based Compensation

In conjunction with the Merger, the Company discontinued grants under its 2004 Stock Option Plan, or the Plan, effective January 27, 2009. As of March 31, 2009, options to purchase 702,258 shares with a weighted-average exercise price of $2.51 per share were outstanding under the Plan. Options and awards outstanding under this plan will continue to vest according to the original terms of each grant. No new awards will be granted under the Plan.

As a result of the Merger, the Company assumed Nuvelo s 2004 Equity Incentive Plan, or the Equity Plan. Under the Equity Plan grants of stock options (including indexed options), stock appreciation rights, restricted stock purchase rights, restricted stock bonuses, restricted stock units, performance shares, performance units and deferred stock units are authorized. Awards may be granted to employees, directors and consultants of the Company, except for incentive stock options, which may be granted only to employees. Subsequent to the Merger, the Company intends to grant stock-based compensation awards under the Equity Plan. As of January 27, 2009, options to purchase 235,807 shares with a weighted-average exercise price of $161.53 per share, and 699 restricted stock units were outstanding under the Equity Plan, of which 218,830 options and no restricted stock units were fully vested.

Pursuant to Nuvelo s severance plans, generally upon a change in control and involuntary termination of employment, outstanding stock options and stock awards held by a non-executive employee became fully vested. The Merger qualified as a change in control as defined under the severance plan. Involuntarily terminated employees held options to purchase 112,550 shares with a weighted-average exercise price of $144.63 per share and 699 restricted stock units, the unvested portion of which awards was accelerated upon the holder s termination date. These awards will generally remain outstanding and exercisable for 90 days subsequent to the holder s termination date. Due to the exercise prices of such awards significantly exceeding the market value of the Company s stock, and the relatively short period to the cancellation date, the fair value assigned to the unvested awards as of the acquisition date was minimal. Awards outstanding with Nuvelo s chief executive officer were subject to acceleration upon change in control. Options outstanding with this former executive total 106,247 and will remain outstanding under the original terms of each award, as this executive continues to serve on the board of directors of the Company. Awards outstanding representing options to purchase 17,010 shares with a weighted-average exercise price of $117.71 per share to employees and consultants who are not being involuntarily terminated will continue to vest according to the original terms of the grant. Due to the exercise prices of such awards significantly exceeding the market value of the Company s stock, the fair value assigned to the unvested awards as of the acquisition date was minimal.

The Company granted options to purchase 278,153 and 134,169 shares of common stock in the three months ended March 31, 2009 and March 31, 2008, respectively. Generally, stock options become exercisable at a rate of 25% per year for a period of four years from the date of grant and have a maximum term of 10 years. The fair values of employee stock options granted in the three months ended March 31, 2009 and March 31, 2008 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 value per share:

	Three Months Ended March 31,	
	2009	2008
Expected term	6.4 years	6.1 years
Expected volatility	77%	62%
Risk-free interest rate	1.86%	3.00%
Expected dividend yield	0%	0%
Weighted-average grant date fair value per share	$ 3.83	$ 0.19

In November 2006, the Company entered into a restricted stock agreement with its President and CEO for 83,490 shares, whereby the President and CEO could purchase the shares at their estimated fair value of $0.90 per share. The Company retained certain repurchase rights (allowing the Company to repurchase the shares at the price paid by this individual) on 41,745 shares that would have lapsed on the date that the trading value of Company s common stock, listed on a national exchange, resulted in market capitalization of the Company, as reported by such exchange over the immediately preceding ten business days, of at least $250.0 million, or a corporate transaction resulted in consideration paid by the acquirer of at least $250.0 million. Repurchase rights on the remaining 41,745 shares would have lapsed on the same terms as the first 41,745 if the two conditions above were met with values of at least $500.0 million. In February 2007, the Company amended the purchase terms of the restricted stock agreement to provide that the purchase price for 41,745 shares was deemed to be satisfied in consideration for services rendered to the Company, with an estimated fair value of $37,250. The estimated fair value of the services was expensed, and the total consideration received of $75,000 was reflected as a long-term liability. In October 2008, the restricted stock agreement was amended to provide that the Company s repurchase rights would lapse with respect to all 83,490 shares upon close of the Merger. As a result of such amendment, the Company estimated the fair value of the modification to be $438,000 of which $88,000 was recognized as share-based compensation expense in the three months ended March 31, 2009.

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For the three months ended March 31, 2009 and 2008 and for the period from Inception through March 31, 2009, the Company recognized the following non-cash, share-based compensation expense (in thousands):

	March 31,		Period from December 17, 2001 (date of inception) to March 31, 2009
	2009	2008	
Research and Development	$ 22	$ 6	$ 159
General and Administrative	172	15	706
Total	$ 194	$ 21	$ 865

(14) Income Taxes

SFAS No. 109 requires that a valuation allowance should be provided if it is more likely than not that some or all of the Company s deferred tax assets will not be realized. The Company s ability to realize the benefit of its deferred tax assets will depend on the generation of future taxable income. Due to the uncertainty of future profitable operations and taxable income, the Company has recorded a full valuation allowance against its net deferred tax assets.

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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, including statements about the timing and outcome of regulatory reviews and approvals, anticipated expenditures relating to seeking regulatory approval and the potential commercialization of Gencaro, expectations with respect to the commercialization of Gencaro, if approved, ARCA s plans with respect to obtaining additional capital or consummating a strategic transaction, and ARCA s ability to continue to operate as a going concern and its future capital requirements. 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, including our Annual Report on form 10-K for the year ended December 31, 2008. Actual results and performance could also differ materially from time to time from those projected in our filings with the SEC.

Overview

ARCA is a biopharmaceutical company whose principal focus is developing genetically-targeted therapies for heart failure and other cardiovascular diseases.

ARCA s lead product candidate is Gencaro™ (bucindolol hydrochloride), a pharmacologically unique beta-blocker and mild vasodilator, which is under review by the U.S. Food and Drug Administration, or FDA, for chronic heart failure, or HF. Gencaro is an oral tablet formulation, dosed twice daily. ARCA has identified common genetic variations, or genetic markers, that it believes predicts patient response to Gencaro. Subject to approval by the FDA, ARCA, through its collaboration with Laboratory Corporation of America, or LabCorp, anticipates introducing a test for these genetic markers with the market launch of Gencaro, potentially making Gencaro the first genetically-personalized cardiovascular drug. When prescribed using the test for these markers, ARCA believes that Gencaro can become an important new therapy for many HF patients, with the potential for positive clinical outcomes in a defined genetic subpopulation, and good tolerability. Gencaro was the subject of a major North America based heart failure Phase III trial, known as BEST, which ARCA believes will provide the primary basis for the FDA s determination on the approvability of Gencaro in the U.S. In September 2008, the FDA formally accepted for filing ARCA s New Drug Application, or NDA, for Gencaro as a potential treatment for HF. In accordance with the Prescription Drug User Fee Act, or PDUFA, the FDA s goal is to complete its review of the Gencaro NDA by May 31, 2009.

As previously noted in ARCA S Annual Report on Form 10-K, the regulatory approval process for the Gencaro NDA is expensive and time-consuming and subject to the risk that the FDA may determine that the available clinical data for Gencaro are not sufficiently strong to demonstrate Gencaro s safety and efficacy. Any such determination could prevent or delay regulatory approval and commercialization of Gencaro. As part of the FDA review of the NDA, ARCA has had extensive interactions with, and has recently provided substantial supplemental information to the FDA. The submission of this or additional information could result in an extension of the review of the Gencaro NDA beyond the May 31, 2009 PDUFA date.

Chronic heart failure is one of the largest health care problems in the United States and the rest of the world. Beta-blockers are part of the current standard of care for HF, and are considered to be among the most effective drug classes for the disease. However, a significant percentage of eligible patients in the United States is not being treated, or does not tolerate or respond well to those beta-blockers currently approved for the treatment of HF. ARCA believes that new therapies for which patient response can be predicted before a drug is prescribed can help improve the current standard of practice in the treatment of HF.

ARCA has collaborated with LabCorp to develop the Gencaro Test, a companion test for the genetic markers that predict clinical response to Gencaro. The proposed use of the Gencaro Test, if approved by the FDA, will be to enable a physician to determine, prior to therapy, whether a patient is likely to have a good response to Gencaro. LabCorp has developed the Gencaro Test to be administered using a blood test or a cheek swab, and to provide prompt results to the treating physician. The Gencaro Test was submitted through the Premarket Approval, or PMA, process in January 2009, and an FDA decision on approval of the blood test method, based on FDA guidance, is expected in conjunction with the FDA decision on Gencaro.

ARCA currently holds worldwide rights to Gencaro. As previously disclosed in its Annual Report on Form 10-K, ARCA s strategy to commercialize Gencaro, if approved, has been to raise sufficient capital to establish internal sales and marketing capabilities as well as its own distribution network for the product, if practicable. As a result of the continuing substantial disruption in the capital markets, the difficulty of raising a significant amount of capital on acceptable terms in light of these disruptions, and consideration of any potential extension of the review of the Gencaro NDA beyond the May 31, 2009 PDUFA date, ARCA is currently exploring strategic alternatives for commercializing Gencaro, including a potential strategic combination or a license of the Gencaro commercialization rights. Alternatively, ARCA may continue to

seek substantial additional funding through public or private debt or equity markets to support the continued development of and commercialization of Gencaro. In light of ARCA s current strategic direction and capital needs, ARCA is actively evaluating restructuring alternatives.

If approved, ARCA believes that Gencaro will have market exclusivity under federal and international laws following commercial launch, and will also potentially have protection under patent applications, which ARCA believes would substantially extend market exclusivity. ARCA also believes there is potential to pursue several significant follow-on indications for Gencaro, including various forms of cardiac arrhythmias.

ARCA believes that its expertise in cardiovascular pathophysiology and genetics, and its clinical and commercial experience, will also enable it to identify and develop other cardiovascular therapies, with an emphasis on those that may be personalized using genetic markers.

Results of Operations

Research and Development Expenses

Research and development, or R&D, expenses were $4.6 million for the three months ended March 31, 2009 as compared to $2.4 million for the corresponding period in 2008, an increase of $2.2 million. Approximately $1.8 million of the cost increase is attributed to increased medical affairs, regulatory, and clinical activities in anticipation of the potential commercialization of Gencaro and in support of our NDA. These increases were offset by a decrease of approximately $700,000 in contract manufacturing costs for the comparable period. ARCA also incurred approximately $1.0 million of clinical development and manufacturing process development costs for projects acquired through the Merger with Nuvelo, specifically NU172 and NU206. These expenses consist primarily of personnel costs related to former Nuvelo employees on transition plans, pre-clinical studies initiated during the quarter, as well as costs for collaborative development arrangements. Employees on transition plans were employed for periods up to twelve weeks after the Merger to facilitate the transition of the business to ARCA. These increased expenditures were partially offset by decreased costs related to ARCA s regulatory activities.

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Research and development expenses for the remainder of 2009 are expected to vary depending primarily on the timing and outcome of the FDA s review of the NDA for Gencaro and ARCA s evaluation of strategic alternatives. For the remainder of 2009, ARCA intends to limit its development activities and expenditures to ARCA s contractual requirements for product candidates other than Gencaro pending the FDA decision on approvability of Gencaro. Research and development expenses for the remainder of 2009 are expected to include the following:

- Consulting and advisory service costs in support of the NDA for Gencaro; and
- Continuation of the manufacturing and process control projects for tableting and packaging of Gencaro to support Gencaro s anticipated commercial launch timeline, if approved by the FDA.

Selling, General and Administrative Expenses

Selling, general and administrative expenses, or SG&A, primarily consist of personnel costs, consulting and professional fees, insurance, facilities and depreciation expenses, and various other administrative costs. Direct costs paid to third parties related to the Merger transaction were classified as merger transaction costs on the consolidated statement of operations as discussed below, and therefore are excluded from SG&A.

ARCA s SG&A expenses were $5.3 million for the three months ended March 31, 2009, as compared to $1.6 million for the corresponding period in 2008. The increase in these expenses of nearly $3.7 million is attributable to integration activities related to the Merger, increased costs related to public-company reporting requirements, as well as investment in commercial infrastructure. The significant components of the increase in SG&A expenses include:

- Approximately $700,000 of increased commercial and marketing costs, largely due to increased personnel, marketing program expense, consulting, and market research costs in preparation for the potential commercial launch of Gencaro.
- Approximately $1.3 million of increased G&A personnel costs, of which approximately $650,000 are costs related to former Nuvelo employees on transitional employment plans, generally for up to twelve weeks following the Merger, to facilitate the integration of the business activities into ARCA. The remainder of the increase in G&A personnel costs is due to increased headcount from the comparable prior period.
- Approximately $701,000 of increased costs primarily related to legal, auditing, and tax compliance, consulting, and insurance incurred primarily to complete post-Merger transitions, corporate governance, transitional SEC filings, and NASDAQ fees associated with being a public company.
- Approximately $541,000 of increased facilities costs related to facilities assumed in the Merger. The majority of these costs are attributable to the former Nuvelo headquarters.

In light of ARCA s current strategic direction and capital needs, ARCA is actively evaluating restructuring alternatives. For the second half of 2009, ARCA s SG&A expenses are expected to decrease compared to the first half as a result of the anticipated restructuring and ARCA s decision to seek strategic alternatives for commercializing Gencaro, if approved.

ARCA anticipates that any restructuring actions are likely to result in a material charge in the second quarter of 2009.

Merger Transaction Costs

During the three months ended March 31, 2009, ARCA expensed nearly $5.5 million in transaction costs related to the Merger. These costs are comprised of financial advisory fees paid upon completion of the Merger and legal fees incurred in the first quarter of 2009 totaling approximately $3.8 million. Prior to December 31, 2008 ARCA had incurred merger transaction expenses, including legal, accounting and due

diligence costs of approximately $1.7 million. These costs were recorded on ARCA s consolidated balance sheet as deferred transaction costs on December 31, 2008. On January 1, 2009, as part of ARCA s adoption of SFAS No. 141(R), these deferred transaction costs were expensed. There were no such comparative expenses in the first quarter of 2008.

Gain on Bargain Purchase

In accordance with SFAS No. 141(R), any excess of fair value of acquired net assets over the acquisition consideration results in a gain on bargain purchase, and as a result, ARCA recorded a gain on bargain purchase of $25.3 million in connection with the Merger. This gain is largely determined by the trading price of Nuvelo s common stock on Nasdaq prior to the Merger, which ARCA believes is the most reliable measure of the consideration effectively transferred to effect the acquisition of Nuvelo. ARCA believes the gain on bargain purchase resulted from various factors that may have impacted the trading price of Nuvelo s common stock, including, without limitation, the significant declines in the securities markets during the fourth quarter of 2008; uncertainty concerning the combined entities ability to obtain regulatory approval of the Gencaro NDA, ability to successfully commercialize Gencaro, if approved, and to raise additional capital to support the commercialization of Gencaro and to fund other business objectives; uncertainty regarding the combined entities ability to successfully integrate the business operations of Nuvelo; and uncertainty regarding the combined entities ability to further identify, develop and achieve commercial success for products and technologies; all of which may have impacted Nuvelo s market capitalization at the time the Merger was consummated. There was no such comparative gain in the first quarter of 2008.

Interest and Other Income

Interest and other income was $101,000 in the first quarter of 2009, as compared to $124,000 in the first quarter of 2008. The decrease in interest and other income in the 2009 period was primarily due to a reduction in the yield on cash equivalents and marketable securities.

Interest and Other Expense

Interest and other expense was $64,000 in the first quarter of 2009, as compared to $5,000 in the first quarter of 2008. The increase in interest and other expense in the 2009 period was primarily due to interest on the bank note payable and convertible notes payable.

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Liquidity and Capital Resources

Cash and Cash Equivalents and Marketable Securities

	March 31, 2009	December 31, 2008
	(in thousands)	
Cash and cash equivalents	$ 25,920	$ 7,740
Marketable securities	9,368	
	$ 35,288	$ 7,740

As of March 31, 2009, ARCA had total cash and cash equivalents and marketable securities $35.3 million, as compared to $7.7 million as of December 31, 2008. The increase of $27.5 million is comprised primarily of $45.5 million acquired in the Merger, offset by cash used for operating activities during the period, including merger transaction costs paid of $4.3 million.

As of March 31, 2009, all of ARCA s investments in marketable securities were 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.* They were recorded at their fair value and primarily consisted of corporate debt securities. ARCA has made its investments in accordance with its investment policy, the primary objectives of which are liquidity and safety of principal.

Cash Flows from Operating, Investing and Financing Activities

	Three Months Ended March 31, 2009	2008
	(in thousands)	
Net cash (used in) provided by:		
Operating activities	$ (17,462)	$ (3,997)
Investing activities	36,139	(132)
Financing activities	(497)	5
Net increase (decrease) in cash and cash equivalents	$ 18,180	$ (4,124)

The increase in net cash used in operating activities for the three months ended March 31, 2009 as compared with the three months ended March 31, 2008 was primarily due to increases in R&D and SG&A expenses as discussed above, and $4.3 million of merger transaction costs paid.

The increase in net cash provided by or used in investing activities for the three months ended March 31, 2009 as compared with the three months ended March 31, 2008 was primarily due to $30.4 million of cash received from the Merger and $5.7 million of proceeds from the sale of marketable securities.

The increase in net cash used in or provided by financing activities for the three months ended March 31, 2009 as compared with the three months ended March 31, 2008 was primarily due to payments on the bank note in the 2009 period.

Sources and Uses of Capital

ARCA s primary source of liquidity to date has been capital raised from financing activities and the Merger. ARCA s 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.

Under the license agreement for the worldwide rights to Gencaro, ARCA is obligated under the CPEC license to make an $8.0 million milestone payment within 180 days after receiving approval from the FDA. ARCA also has the obligation under the CPEC license to make milestone payments of up to $5.0 million in the aggregate upon regulatory marketing approval in Europe and Japan.

Under the collaboration agreement with Archemix, Archemix is responsible for the discovery of short-acting aptamers targeting the coagulation cascade for use in acute cardiovascular procedures, and ARCA is responsible for development and worldwide commercialization of these product candidates. If the first patient is enrolled in a Phase II trial of NU172, which is currently not expected to occur in 2009, a $3.0 million milestone fee is payable to Archemix. In addition, ARCA 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 initial public offering of Archemix stock occurring within five years of the effective date of the 2006 collaboration agreement.

As previously disclosed in its Annual Report on Form 10-K, ARCA s strategy to commercialize Gencaro, if approved, has been to raise sufficient capital to establish internal sales and marketing capabilities as well as its own distribution network for the product, if practicable. As a result of the continuing substantial disruption in the capital markets, the difficulty of raising a significant amount of capital on acceptable terms in light of these disruptions, and consideration of any potential extension of the review of the Gencaro NDA beyond the May 31, 2009 PDUFA date, ARCA is currently exploring strategic alternatives for commercializing Gencaro, including a potential strategic combination or a license of the Gencaro commercialization rights. Alternatively ARCA may continue to seek substantial additional funding through public or private debt or equity markets to support the continued development of and commercialization of Gencaro. In light of ARCA s current strategic direction and capital needs, ARCA is actively evaluating restructuring alternatives. ARCA believes that, after giving effect to an anticipated restructuring, its current cash, cash equivalents and marketable securities balances will be sufficient to fund operations until at least December 31, 2009 although ARCA may seek to raise additional capital to augment its cash position. ARCA is unable to assert that its current cash, cash equivalents and marketable securities are sufficient to fund operations for the next twelve months, and as a result, there is substantial doubt about ARCA s ability to continue as a going concern beyond December 31, 2009. The financial statements contained in this report have been prepared with the assumption that ARCA is a going concern and will be able to realize its assets and discharge its liabilities in the normal course of business and do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the inability of ARCA to continue as a going concern.

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ARCA s liquidity, and its ability to complete any strategic transaction or to raise additional capital, depends on a number of factors, including, but not limited to, the following:

- timing and outcome of the FDA s response to ARCA s NDA for Gencaro which, if approved, would trigger an $8 million milestone payment that would then be due within six months;
- the costs of commercializing ARCA s product candidates if regulatory approvals are obtained, including the costs of establishing or contracting for marketing, sales and manufacturing capabilities, and other costs related to the size of its organization, which costs ARCA currently expects to substantially defer pending its review of strategic alternatives;
- general economic and industry conditions affecting the availability and cost of capital;
- ARCA s ability to reduce costs associated with its operations;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights; and
- the terms and conditions of ARCA s existing collaborative and licensing agreements.

The sale of additional equity or convertible debt securities would likely result in substantial additional dilution to ARCA s stockholders. If ARCA raises additional funds through the incurrence of additional indebtedness, the obligations related to such indebtedness would be senior to rights of holders of ARCA s capital stock and could contain covenants that would restrict ARCA s operations.

Critical Accounting Policies and Estimates

A critical accounting policy is one that is both important to the portrayal of ARCA s financial condition and results of operation and requires management s most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain. ARCA s significant accounting policies are described in Note 1 of Notes to the Consolidated Financial Statements included within Item 1 in this report. In addition to the accounting policies described in Note 1, the following is also applicable:

Valuation & Impairment Review of Acquired In-process Research and Development

ARCA acquired a significant in-process research and development (IPR&D) asset through the Merger primarily related to NU172. A valuation firm was engaged to assist ARCA in determining the estimated fair values of these assets as of the acquisition date. Discounted cash flow models are typically used in these valuations, and the models require the use of significant estimates and assumptions including but not limited to:

- projecting regulatory approvals,
- estimating future cash flows from product sales resulting from completed products and in-process projects, and
- developing appropriate discount rates and probability rates by project.

The IPR&D asset is considered an indefinite-lived intangible asset and is not subject to amortization. IPR&D must be tested for impairment annually or more frequently if events or changes in circumstances indicate that the asset might be impaired. The impairment test consists of a

comparison of the fair value of the IPR&D with its carrying amount. If the carrying amount of the IPR&D exceeds its fair value, an impairment loss must be recognized in an amount equal to that excess. After an impairment loss is recognized, the adjusted carrying amount of the IPR&D will be its new accounting basis. Subsequent reversal of a previously recognized impairment loss is prohibited. The initial determination and subsequent evaluation for impairment, of the IPR&D asset requires management to make significant judgments and estimates.

Off-Balance Sheet Arrangements

ARCA has 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, ARCA enters into contractual arrangements under which ARCA 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. ARCA has entered into indemnity agreements with each of its directors, officers and certain employees. Such indemnity agreements contain provisions, which are in some respects broader than the specific indemnification provisions contained in Delaware law. ARCA also maintains 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

Not applicable.

ITEM 4. CONTROLS AND PROCEDURES

ARCA maintains disclosure controls and procedures that are designed to ensure that information required to be disclosed in the reports that it files 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 ARCA s 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.

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

ARCA s internal control over financial reporting was materially affected as a result of the Merger on January 27, 2009 as described in Note 2 of Notes to the Consolidated Financial Statements included within Item 1 in this report. As ARCA Colorado was a private company, it was not subject to Section 404 of the Sarbanes-Oxley Act of 2002 which requires companies to include in their annual report an assessment of internal controls over financial reporting and, if applicable, the related auditor attestation report. During 2009, ARCA plans to dedicate internal resources and engage outside consultants to implement a work plan such that it may complete an evaluation of ARCA s internal control over financial reporting as of December 31, 2009 and include an internal control assessment and the related auditor attestation report in ARCA s 2009 Form 10-K.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

On February 9, 2007, Nuvelo 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 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 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.

On December 4, 2008, the Court issued an order dismissing plaintiff s complaint, and granting leave to amend. On January 23, 2009, plaintiffs filed an amended complaint, alleging similar claims. On March 24, 2009, defendants filed a motion to dismiss the amended complaint. Based on the Court s December 4, 2008 order, and plaintiff s amended complaint, the Company believes that any attorneys fees, loss or settlement payment with respect to this suit will be paid by its insurance provider. However, it is possible that the Company could be forced to incur material expenses in the litigation if the case is not finally dismissed, or if the parties cannot achieve a settlement, and, in the event of an adverse outcome, the Company s business could be harmed.

In addition, 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. The Company is involved in this litigation as a result of Nuvelo s 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 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. The Company believes that any attorneys fees, loss or settlement payment with respect to this suit will be paid by its insurance provider. However, it is possible that the

Company 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, the Company s business could be harmed.

ITEM 1A. RISK FACTORS

An investment in ARCA s securities involves certain risks, including those set forth below and elsewhere in this report. In addition to the risks set forth below and elsewhere in this report, other risks and uncertainties not known to ARCA, that are beyond its control or that ARCA deems to be immaterial may also materially adversely affect ARCA s business operations. You should carefully consider the risks described below as well as other information and data included in this report.

Those risks described below that reflect substantive changes from the risks described under Part I, Item 1A Risk Factors included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2008, as filed with the Securities and Exchange Commission on March 27, 2009 have been marked with an (*).

Risks Related to ARCA s Financial Condition

In light of the continuing substantial disruption in the capital markets, the difficulty of raising a significant amount of capital on acceptable terms in light of these disruptions, and consideration of any potential extension of the review of the Gencaro NDA beyond the May 31, 2009 PDUFA date, ARCA is evaluating strategic alternatives. If ARCA can not complete a strategic transaction, or alternatively, raise additional funds through the public or private debt and equity markets, it will not be able to commercialize Gencaro, even if approved, and may not be able to continue operations.

As previously disclosed in its Annual Report on Form 10-K, ARCA s strategy to commercialize Gencaro, if approved, has been to raise sufficient capital to establish internal sales and marketing capabilities as well as its own distribution network for the product, if practicable. As a result of the continuing substantial disruption in the capital markets, the difficulty of raising a significant amount of capital on acceptable terms in light of these disruptions, and consideration of any potential extension of the review of the Gencaro NDA beyond the May 31, 2009 PDUFA date, ARCA is currently exploring strategic alternatives for commercializing Gencaro, including a potential strategic combination or a license of the Gencaro commercialization rights. Alternatively ARCA may continue to seek substantial additional funding through public or private debt or equity markets. If ARCA is unable to complete a strategic transaction or to obtain substantial additional funding through the public or private debt and equity markets it will be unable to complete development of or commercialize Gencaro and may not be able to continue as a going concern beyond December 31, 2009.

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ARCA s liquidity, and its ability to complete any strategic transaction or to raise additional capital, depends on a number of factors, including, but not limited to, the following:

- timing and outcomes of regulatory approvals, in particular the approval of ARCA s NDA for Gencaro by the FDA;
- the costs of commercializing products, particularly Gencaro, if and when regulatory approvals are obtained, including the costs of establishing or contracting for marketing, sales and manufacturing capabilities, and other costs related to increasing the size of ARCA s organization;
- general economic and industry conditions affecting the availability and cost of capital;
- ARCA s ability to reduce costs associated with its operations;
- the costs of filing, prosecuting, defending and enforcing any intellectual property rights related to Gencaro, including patents and patent applications; and
- the terms and conditions of ARCA s existing collaborative and licensing agreements.

ARCA cannot predict what consideration might be available, if any, to ARCA or its stockholders, in connection with any strategic transaction. Given the current state of the capital markets, the substantial capital needed to commercialize Gencaro if approved, and ARCA s current market capitalization, any sale of additional equity or convertible debt securities as an alternative to a strategic transaction would likely result in substantial additional dilution to ARCA s stockholders. If ARCA were able to raise additional funds through the incurrence of additional indebtedness, the obligations related to such indebtedness would be senior to rights of holders of ARCA capital stock and could contain covenants that would restrict ARCA s operations. Any required additional funds may not be available on reasonable terms, if at all.

In light of ARCA s capital needs and current resources, there is substantial doubt about its ability to continue as a going concern beyond December 31, 2009.

If ARCA is unable to complete a strategic transaction or, alternatively, raise sufficient additional capital, ARCA may be unable to realize value from its assets and discharge its liabilities in the normal course of business. These uncertainties raise substantial doubt about ARCA s ability to continue as a going concern beyond December 31, 2009. The financial statements contained in this report have been prepared with the assumption that ARCA is a going concern and will be able to realize its assets and discharge its liabilities in the normal course of business and do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the inability of ARCA to continue as a going concern beyond December 31, 2009. If ARCA becomes unable to continue as a going concern, it may have to liquidate its assets, and might realize significantly less than the values at which they are carried on ARCA s financial statements, and stockholders may lose all or part of their investment in ARCA common stock.

ARCA s existing indebtedness could adversely affect its financial condition, prevent it from fulfilling its financial obligations and limit its ability to complete a strategic transaction or obtain additional capital.

ARCA is obligated as a party under a Loan and Security Agreement dated July 17, 2007, as amended, with Silicon Valley Bank, or SVB, under which SVB provided a growth capital facility of up to $4.0 million, to be used solely for working capital and to fund ARCA s general business requirements. The growth capital facility matures on December 1, 2010. The principal amount outstanding under the growth capital facility bears interest at a rate of 4.25% per annum, unless ARCA and its subsidiaries fail to maintain the lesser of $10 million or 100% of all of their invested cash balances in designated accounts with SVB, in which event, the interest rate will be permanently increased to a rate equal to the SVB s prime rate plus 2.0%, which shall be fixed as of the date such accounts fall below the thresholds. ARCA and its subsidiaries also agreed to pledge to SVB restricted certificates of deposit, or CD s issued by SVB, with the aggregate amount of the pledged CD s varying from time to time depending on the aggregate amount of unrestricted cash maintained by ARCA and its subsidiaries with SVB. As of April 30, 2009, approximately $3.3 million aggregate principal amount was outstanding under the SVB credit facility. No additional drawings are permitted

under the credit facility. The credit facility is not subject to any prepayment penalties.

The agreement contains customary affirmative and negative covenants including, without limitation, (i) covenants requiring ARCA to comply with applicable laws, provide to SVB copies of ARCA s financial statements, maintain appropriate levels of insurance, protect, defend and maintain the validity and enforceability of ARCA s material intellectual property, and (ii) covenants restricting ARCA s ability to dispose of all or substantially all of its assets, engage in other lines of business, change its senior management, enter into transactions constituting a change of control, assume additional indebtedness, incur liens on its assets, among other covenants. ARCA Colorado s obligations under the credit facilities are secured by a majority of ARCA Colorado s assets.

This indebtedness could have important consequences to you. For example, it could:

- make it more difficult to satisfy financial obligations to third parties other than SVB;
- increase vulnerability to adverse economic and industry conditions;
- require ARCA to dedicate a substantial portion of its cash to debt service, thereby reducing the availability of ARCA s cash to fund working capital, capital expenditures, research and development efforts and other general corporate purposes;
- limit ARCA s flexibility in planning for, or reacting to, changes in our business and the industry in which it operates;
- place ARCA at a competitive disadvantage compared to our competitors that have less or no debt;
- limit ARCA s ability to borrow additional funds; and
- limit ARCA s ability to make future acquisitions.

Continued disruption in financial markets has and may continue to affect ARCA s ability to access sufficient funding.

The global financial crisis and the broad domestic economic downturn have disrupted credit and equity markets globally, which has reduced the availability, and increased the costs of investment capital and credit. A continuation or worsening of these conditions may make it difficult or impossible for ARCA to refinance its indebtedness and access adequate funding to raise additional capital if needed, and may otherwise have a material adverse effect on ARCA s liquidity and capital resources.

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ARCA may be limited in its ability to access sufficient funding through a private equity or convertible debt offering.

Nasdaq rules impose restrictions on ARCA s ability to raise funds through a private offering of ARCA s common stock, convertible debt or similar instruments without obtaining stockholder approval. Under Nasdaq rules, an offering of more than 20% of ARCA s total shares outstanding for less than the greater of book or market value requires stockholder approval unless the offering qualifies as a public offering for purposes of the Nasdaq rules. As of March 31, 2009, ARCA had 7,569,903 shares of common stock outstanding, 20% of which is approximately 1,514,000 shares. To the extent ARCA seeks to raise funds through a private offering of stock, convertible debt or similar instruments, it would be limited in how much funding it could raise privately without requiring a stockholder vote.

Risks Related to ARCA s Business

If ARCA is not able to obtain FDA approval and successfully develop and provide for the commercialization of Gencaro in a timely manner, it may not be able to continue its business operations.

ARCA currently has 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. The Gencaro NDA is currently under FDA review. Gencaro is ARCA s only product candidate at a late stage of clinical development. As a result, ARCA s business, including its ability to successfully complete any potential strategic transaction to enable commercialization of Gencaro, is substantially dependent on its ability to obtain regulatory approval for Gencaro in a timely manner. As part of the FDA review of the NDA, ARCA has had extensive interactions with, and has recently provided substantial supplemental information to the FDA. The submission of this or additional information could result in an extension of the review of the Gencaro NDA beyond the May 31, 2009 PDUFA date.

Failure to demonstrate that a product candidate, particularly Gencaro, is safe and effective, or significant delays in demonstrating such safety and efficacy, would adversely affect ARCA s business. Failure to obtain marketing approval of a product candidate, particularly Gencaro, from appropriate regulatory authorities, or significant delays in obtaining such approval, would also adversely affect ARCA s business and could, among other things, preclude ARCA from completing a strategic transaction or obtaining additional financing necessary to continue as a going concern.

Even if approved for sale, a product candidate must be successfully commercialized to generate value. ARCA does not currently have the capital resources to commercialize Gencaro and, as a result, will need to complete a strategic transaction, or, alternatively, raise substantially additional funds to enable commercialization of Gencaro. Failure to successfully provide for the commercialization of Gencaro, if it is approved, in a timely manner, would damage ARCA s business and may prevent ARCA from continuing as a going concern.

Transitioning from a developmental stage company will require successful completion of a number of steps, many of which are outside of ARCA s control and, consequently, ARCA can provide no assurance of its successful and timely transition from a developmental stage company.

ARCA is a development stage biopharmaceutical company with a limited operating history. To date ARCA has not generated any product revenue and has historically funded its operations through investment capital. ARCA s future growth depends on its ability to emerge from the developmental stage and successfully commercialize or provide for the commercialization of Gencaro and its other product candidates, which in turn, will depend, among other things, on ARCA s ability to:

- develop and obtain regulatory approval for Gencaro or other product candidates;
- successfully partner a companion genetic test with the commercial launch of Gencaro;
- enter into a strategic transaction enabling the commercialization of Gencaro, or alternatively, raise significant additional capital and build an internal specialty sales and marketing capability;

pursue additional indications for Gencaro and develop other product candidates, including other cardiovascular therapies;

obtain commercial quantities of Gencaro or other product candidates at acceptable cost levels; and

successfully conduct and complete clinical trials for Gencaro and other product candidates.

Any one of these factors or other factors discussed in this report could affect ARCA s ability to successfully commercialize Gencaro and other product candidates, which could impact ARCA s ability to earn sufficient revenues to transition from a developmental stage company and continue its business.

If ARCA is required to establish a direct sales force in the U.S. and unable to do so, its business may be harmed.

ARCA currently intends to pursue a strategic alternative for the commercialization of Gencaro, if it is approved, and has suspended its efforts to build internal sales, marketing and distribution capabilities. If ARCA elects to rely on third parties to sell Gencaro and any other products, then it may receive less revenue than if it sold such products directly. In addition, ARCA may have little or no control over the sales efforts of those third parties.

If ARCA is unable to complete a strategic transaction, it would be unable to commercialize Gencaro or any other product candidate without substantial additional capital. Even if such capital were secured, ARCA would be required to build internal sales, marketing and distribution capabilities to market Gencaro in the U.S. While certain ARCA employees have experience in establishing and managing a sales force, these employees have no such experience since being with ARCA.

In the event ARCA is unable to sell Gencaro and other selected product candidates, either directly or through third parties via a strategic transaction, the commercialization of Gencaro may be delayed indefinitely and ARCA may be unable to continue as a going concern.

ARCA is relying upon LabCorp to obtain marketing clearance or approval of the companion Gencaro Test. There is no guarantee that the FDA will grant timely clearance or approval of the Gencaro Test, if at all, and failure to obtain such timely clearance or approval would adversely affect ARCA s ability to market Gencaro.

The drug label being sought for Gencaro would identify the patient receptor genotypes with a potential for 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, ARCA 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 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.

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Under ARCA s agreement with LabCorp, LabCorp is responsible for determining the appropriate regulatory pathway for the Gencaro Test and obtaining market clearance or approval from the FDA. Based on FDA guidance, LabCorp has submitted a PMA regulatory submission, which the FDA formally accepted in January 2009. The FDA may decide that the Gencaro Test should be evaluated for clearance under the FDA s 510(k) notification process. LabCorp and ARCA do 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 if LabCorp is unable to obtain FDA approval of the Gencaro Test at all or in parallel with the approval of Gencaro, or is unable to commercialize the test successfully and in a manner that effectively supports the commercial efforts for Gencaro, or if the information concerning the differential response to Gencaro resulting from certain genetic variation is not included in the approval label for Gencaro, the commercial launch of Gencaro may be significantly and adversely affected. In such cases, ARCA 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 and ARCA s ability to continue as a going concern.

Future sales of Gencaro may suffer if its marketplace acceptance is negatively affected by the Gencaro Test.

The Gencaro Test is an important component of the commercial strategy for Gencaro. ARCA believes that the Gencaro Test helps predict patient response to Gencaro, and that this aspect of the drug is important to its ability to compete effectively with current therapies. The Gencaro Test adds an additional step in the prescribing process, an additional cost for the patient and payors, the risk that the test results may not be rapidly available and the possibility that it may not be available at all to hospitals and medical centers. Although ARCA anticipates that Gencaro will be the first genetically-targeted cardiovascular drug, Gencaro will be one of a number of successful drugs in the beta-blocker class currently on the market. Prescribers may be more familiar with these other beta-blockers, and may be resistant to prescribing Gencaro as an HF therapy without efforts on ARCA s part to educate prescribers. Any one of these factors could affect prescriber behavior, which in turn may substantially impede market acceptance of the Gencaro Test, which could cause significant harm to Gencaro s ability to compete, and in turn harm ARCA s business.

Unless ARCA is able to generate sufficient product revenue, ARCA will continue to incur losses from operations and may not achieve or maintain profitability.

ARCA s historical losses, among other things, have had and will continue to have an adverse effect on ARCA s stockholders equity and working capital. Even if ARCA receives regulatory approval for any of its product candidates, including Gencaro, sales of such products may not generate sufficient revenue for it to achieve or maintain profitability. As a result, it expects to continue to incur significant and increasing operating losses for the foreseeable future. Because of the numerous risks and uncertainties associated with developing therapeutic drugs, ARCA may experience larger than expected future losses and may never reach profitability.

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

The success of ARCA s business is highly dependent on the principal members of ARCA s scientific and management staff, including its Chairman of the Board, Michael R. Bristow, and its President and Chief Executive Officer, Richard, B. Brewer. The loss of the services of any such individual might seriously harm ARCA s product development efforts. Recruiting and training personnel with the requisite skills is challenging and extremely competitive.

****ARCA s product candidates are subject to extensive regulation, which can be costly and time-consuming, and unsuccessful or delayed regulatory approvals could increase ARCA s future development costs or impair ARCA s future revenue.***

The preclinical and clinical development, testing, manufacture, safety, efficacy, labeling, storage, recordkeeping, advertising, promotion, sale, and marketing, and distribution of ARCA s product candidates are subject to extensive regulation by the FDA and other regulatory authorities in the United States and elsewhere. These regulations also vary in important, meaningful ways from country to country. ARCA is not permitted to market a potential drug in the United States until ARCA receives approval of an NDA from the FDA. ARCA has not received an NDA approval from the FDA for any of its product candidates. There can be no guarantees with respect to ARCA s product candidates that clinical studies will adequately support an NDA, that the products will receive necessary regulatory approvals, or that they will prove to be commercially successful.

To receive regulatory approval for the commercial sale of any product candidates, ARCA must demonstrate safety and efficacy in humans to the satisfaction of regulatory authorities through preclinical studies and adequate and well-controlled clinical trials of the product candidates. This process is expensive and can take many years, and failure can occur at any stage of the testing. ARCA s failure to adequately demonstrate the safety and efficacy of its product candidates will prevent regulatory approval and commercialization of such products. With respect to Gencaro, the FDA could determine that the preclinical studies and clinical trials conducted Gencaro were inadequate, and such a determination would

prevent regulatory approval and commercialization of Gencaro. For instance, ARCA filed an NDA for Gencaro in July 2008, based primarily on a single Phase III trial. The FDA guidelines generally suggest that sponsors conduct two adequate and well-controlled studies to demonstrate the safety and efficacy of a product candidate such as Gencaro in support of FDA approval. FDA interpretation of the statutory requirements also states that a single study may be sufficient to support approval if the FDA determines that, based on relevant science and other confirmatory evidence, there is strong evidence to establish the safety and efficacy of the drug candidate using a single adequate and well-controlled study. If the FDA determines that the clinical data for Gencaro are not sufficiently strong to demonstrate Gencaro s safety and efficacy for chronic heart failure, then Gencaro may not be approved by the FDA for ARCA s proposed indications, may be approved for a more limited indication, or the FDA may require ARCA to conduct additional studies before approving Gencaro for chronic heart failure. Even if ARCA conducted additional studies and submitted the attendant data, FDA may ultimately decide that the NDA does not satisfy the criteria for approval.

In September 2008, the FDA formally accepted for filing ARCA s NDA, for Gencaro, with the goal of completing its review of the NDA by May 31, 2009. Filing of the NDA indicates that the application is sufficiently complete to allow for FDA to review ARCA s data supporting the safety profile and effectiveness of Gencaro, but does not guarantee approval. As part of the FDA review of the NDA, ARCA has had extensive interactions with, and has recently provided substantial supplemental information to the FDA. The submission of this or additional information could result in an extension of the review of the Gencaro NDA beyond the May 31, 2009 PDUFA date.

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In the event that ARCA or its collaborators conduct preclinical studies that did not comply with Good Laboratory Practices or incorrectly design or carry out human clinical trials or those clinical trials fail to demonstrate clinical significance, ARCA will not likely be able to obtain FDA approval for product development candidates. ARCA s inability to successfully and effectively complete clinical trials for any product candidates on schedule or at all will severely harm ARCA s business. Significant delays in clinical development could materially increase product development costs or allow ARCA s competitors to bring products to market before it does, impairing ARCA s ability to effectively commercialize any future product candidates. ARCA does not know whether planned clinical trials will begin on time, will need to be redesigned or will be completed on schedule, if at all. Clinical trials can be delayed for a variety of reasons, including:

- delays or failures in obtaining regulatory authorization to commence a trial because of safety concerns of regulators relating to ARCA s product candidates or similar product candidates of ARCA s competitors or failure to follow regulatory guidelines;
- delays or failures in obtaining clinical materials and manufacturing sufficient quantities of the product candidate for use in trials;
- delays or failures in reaching agreement on acceptable terms with prospective study sites;
- delays or failures in obtaining approval of ARCA s clinical trial protocol from an institutional review board, or IRB, to conduct a clinical trial at a prospective study site;
- delays in recruiting patients to participate in a clinical trial, which may be due to the size of the patient population, eligibility criteria, protocol design, perceived risks and benefits of the drug, availability of other approved and standard of care therapies, availability of clinical trial sites;
- other clinical trials seeking to enroll subjects with similar profile;
- failure of ARCA s clinical trials and clinical investigators to be in compliance with the FDA s Good Clinical Practices;
- unforeseen safety issues, including negative results from ongoing preclinical studies;
- inability to monitor patients adequately during or after treatment;
- difficulty monitoring multiple study sites; and
- failure of ARCA s third-party contract research organizations, clinical site organizations and other clinical trial managers, to satisfy their contractual duties, comply with regulations or meet expected deadlines.

In addition, any approvals ARCA may obtain may not cover all of the clinical indications for which it seeks approval. In addition, if ARCA chooses to make claims of superiority over currently marketed competitive products, ARCA must substantiate those claims with scientific evidence from prospectively designed head-to-head clinical trials. Also, an approval might contain significant limitations in the form of narrow indications, warnings, precautions or contraindications with respect to conditions of use. If the FDA determines that a risk evaluation and mitigation strategy, or REMS, is necessary to ensure that the benefits of the drug outweigh the risks, ARCA may be required to include as part of the NDA a proposed REMS that may include a package insert directed to patients, a plan for communication with healthcare providers, restrictions on a drug s distribution, or a Medication Guide to provide better information to consumers about the drug s risks and benefits. Finally,

an approval could be conditioned on ARCA s commitment to conduct further clinical trials, which ARCA may not have the resources to conduct or which may negatively impact ARCA s financial situation.

All of ARCA s product candidates are prone to the risks of failure inherent in drug development. The results from preclinical animal testing and early human clinical trials may not be predictive of results obtained in later human clinical trials. Further, although a new product may show promising results in preclinical or early human clinical trials, it may subsequently prove unfeasible or impossible to generate sufficient safety and efficacy data to obtain necessary regulatory approvals. The data obtained from preclinical and clinical studies are susceptible to varying interpretations that may delay, limit or prevent regulatory approval, and the FDA and other regulatory authorities in the United States and elsewhere exercise substantial discretion in the drug approval process. The numbers, size and design of preclinical studies and clinical trials that will be required for FDA or other regulatory approval will vary depending on the product candidate, the disease or condition for which the product candidate is intended to be used and the regulations and guidance documents applicable to any particular product candidate. The FDA or other regulators can delay, limit or deny approval of any product candidate for many reasons, including, but not limited to:

- side effects;
- safety and efficacy;
- defects in the design of clinical trials;
- the fact that the FDA or other regulatory officials may not approve ARCA s or ARCA s third party manufacturer s processes or facilities; or
- the fact that new regulations may be enacted by the FDA or other regulators may change their approval policies or adopt new regulations requiring new or different evidence of safety and efficacy for the intended use of a product candidate.

In light of widely publicized events concerning the safety of certain drug products, regulatory authorities, members of Congress, the Government Accountability Office, medical professionals and the general public have raised concerns about potential drug safety issues. These events have resulted in the withdrawal of certain drug products, revisions to certain drug labeling that further limit use of the drug products and establishment of risk management programs that may, for instance, restrict distribution of drug products. The increased attention to drug safety issues may result in a more cautious approach by the FDA to clinical trials and approval. Data from clinical trials may receive greater scrutiny with respect to safety and the product s risk/benefit profile, which may make the FDA or other regulatory authorities more likely to terminate clinical trials before completion, or require longer or additional clinical trials that may result in substantial additional expense, and a delay or failure in obtaining approval or approval for a more limited indication than originally sought. Aside from issues concerning the quality and sufficiency of submitted preclinical and clinical data, the FDA may be constrained by limited resources from reviewing and determining the approvability of the Gencaro NDA in a timely manner. Indeed, in early 2008, the FDA announced that due to a lack of resources, NDAs may not be reviewed within the performance goals under PDUFA, and from time to time, the FDA has extended the review period for NDAs.

In addition, the manufacture and tableting of Gencaro is done by third party suppliers, who must pass a pre-approval inspection of their facilities before ARCA can obtain marketing approval. The FDA could also request additional information or data, including data from an additional Phase III study, which may extend the review period.

In its NDA, ARCA has requested that the FDA approve Gencaro as a therapy that can be prescribed by physicians for patients with heart failure, and specifically for its effect on certain clinical outcomes for these heart failure patients. ARCA has also requested that certain information be included in the prescribing information distributed with Gencaro that shows the effect of genetic differences in patients on the clinical results for Gencaro. The FDA could approve Gencaro, but without including some or all of the prescribing information that ARCA has requested. For instance, FDA could approve Gencaro without some or all of the pharmacogenetic information in the labeling. This, in turn, could substantially and detrimentally impact ARCA s ability to successfully commercialize Gencaro and effectively protect its intellectual property rights in Gencaro.

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ARCA has no manufacturing capacity which puts it at risk of lengthy and costly delays of bringing its products to market.

ARCA does not currently operate manufacturing facilities for clinical or commercial production of its product candidates, including their active pharmaceutical ingredients, or API. ARCA has no experience in drug formulation or manufacturing, and it lacks the resources and the capabilities to manufacture any of its product candidates on a clinical or commercial scale. ARCA does not intend to develop facilities for the manufacture of product candidates for clinical trials or commercial purposes in the foreseeable future.

ARCA has contracted with Groupe Novasep to manufacture commercial quantities of the API for Gencaro. For drug production, ARCA has contracted with Patheon, Inc. to manufacture the Gencaro tablets. In addition, ARCA is dependent upon other third-party contract manufacturers to develop the necessary production processes and produce the volume of cGMP-grade material needed to conduct any additional study of NU172. These contract manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required to successfully produce, store and distribute ARCA s products. In the event of errors in forecasting production quantities required to meet demand, natural disaster, equipment malfunctions or failures, technology malfunctions, strikes, lock-outs or work stoppages, regional power outages, product tampering, war or terrorist activities, actions of regulatory authorities, business failure, strike or other difficulty, ARCA may be unable to find an alternative third-party manufacturer in a timely manner and the production of its product candidates would be interrupted, resulting in delays and additional costs, which could impact ARCA s ability to commercialize and sell its product candidates.

ARCA or its contract manufacturers may also fail to achieve and maintain required manufacturing standards, which could result in patient injury or death, product recalls or withdrawals, an order by governmental authorities to halt production, delays or failures in product testing or delivery, cost overruns or other problems that could seriously hurt its business. Contract manufacturers also often encounter difficulties involving production yields, quality control and quality assurance, as well as shortages of qualified personnel. In addition, its contract manufacturers are subject to ongoing inspections and regulation by the FDA, the U.S. Drug Enforcement Agency and corresponding state agencies and they may fail to meet these agencies acceptable standards of compliance. If ARCA s contract manufacturers fail to comply with applicable governmental regulations, such as quality control, quality assurance and the maintenance of records and documentation, ARCA may not be able to continue production of the API or finished product. If the safety of any API or product supplied is compromised due to failure to adhere to applicable law or for other reasons, this may jeopardize ARCA s regulatory approval for Gencaro and other product candidates, and ARCA may be held liable for any injuries sustained as a result.

Upon the occurrence of one of the aforementioned events, the ability to switch manufacturers may be difficult for a number of reasons, including:

- the number of potential manufacturers is limited and ARCA may not be able to negotiate agreements with alternative manufacturers on commercially reasonable terms, if at all;
- long lead times are often needed to manufacture drugs;
- the manufacturing process is complex and may require a significant learning curve; and
- the FDA must approve any replacement prior to manufacturing, which requires new testing and compliance inspections.

If ARCA s product candidates receive regulatory approval, ARCA would be subject to ongoing regulatory obligations and restrictions, which may result in significant expenses and limit its ability to develop and commercialize other potential products.

If a product candidate of ARCA is approved by the FDA or by another regulatory authority, ARCA would be held to extensive regulatory requirements over product manufacturing, testing, distribution, labeling, packaging, adverse event reporting and other reporting to regulatory authorities, storage, advertising, marketing, promotion, distribution, and record keeping. Regulatory approvals may also be subject to significant limitations on the indicated uses or marketing of the product candidates. Potentially costly follow-up or post-marketing clinical studies may be required as a condition of approval to further substantiate safety or efficacy, or to investigate specific issues of interest to the regulatory authority. Previously unknown problems with the product candidate, including adverse events of unanticipated severity or frequency, may result in additional regulatory controls or restrictions on the marketing or use of the product or the need for post marketing studies, and could include suspension or withdrawal of the products from the market.

Furthermore, ARCA s third-party manufacturers and the manufacturing facilities that they use to make ARCA s product candidates are regulated by the FDA. Quality control and manufacturing procedures must continue to conform to cGMP after approval. Drug manufacturers and their subcontractors are required to register their facilities and products manufactured annually with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA, state and/or other foreign authorities. Any subsequent discovery of problems with a product, or a manufacturing or laboratory facility used by ARCA or its collaborators, may result in restrictions on the product, or on the manufacturing or laboratory facility, including a withdrawal of the drug from the market or suspension of manufacturing. Any changes to an approved product, including the way it is manufactured or promoted, often require FDA approval before the product, as modified, can be marketed. ARCA and its third-party manufacturers will also be subject to ongoing FDA requirements for submission of safety and other post-market information.

The marketing and advertising of ARCA s drug products by its collaborators or ARCA will be regulated by the FDA, certain state agencies or foreign regulatory authorities. Violations of these laws and regulations, including promotion of ARCA s products for unapproved uses or failing to disclose risk information, are punishable by criminal and civil sanctions and may result in the issuance of enforcement letters or other enforcement action by the FDA, U.S. Department of Justice, state agencies, or foreign regulatory authorities that could jeopardize ARCA s ability to market the product.

In addition to the FDA, state or foreign regulations, the marketing of ARCA s drug products by ARCA or its collaborators will be regulated by federal, state or foreign laws pertaining to health care fraud and abuse, such as the federal anti-kickback law prohibiting bribes, kickbacks or other remuneration for the order or recommendation of items or services reimbursed by federal health care programs. Many states have similar laws applicable to items or services reimbursed by commercial insurers. Violations of these laws are punishable by criminal and civil sanctions, including, in some instances, imprisonment and exclusion from participation in federal and state health care programs, including the Medicare, Medicaid and Veterans Affairs healthcare programs. Because of the far-reaching nature of these laws, ARCA may be required to discontinue one or more of its practices to be in compliance with these laws. Health care fraud and abuse regulations are complex, and even minor irregularities can potentially give rise to claims that a statute or prohibition has been violated. Any violations of these laws, or any action against ARCA for violations of these laws, even if ARCA successfully defends against it, could have a material adverse effect on ARCA s business, financial condition and results of operations.

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ARCA could also become subject to false claims litigation under federal statutes, which can lead to civil money penalties, restitution, criminal fines and imprisonment, and exclusion from participation in Medicare, Medicaid and other federal and state health care programs. These false claims statutes include the False Claims Act, which allows any person to bring a suit on behalf of the federal government alleging submission of false or fraudulent claims, or causing to present such false or fraudulent claims, under federal programs or contracts claims or other violations of the statute and to share in any amounts paid by the entity to the government in fines or settlement. These suits against pharmaceutical companies have increased significantly in volume and breadth in recent years. Some of these suits have been brought on the basis of certain sales practices promoting drug products for unapproved uses. This new growth in litigation has increased the risk that a pharmaceutical company will have to defend a false claim action, pay fines or restitution, or be excluded from the Medicare, Medicaid, Veterans Affairs and other federal and state healthcare programs as a result of an investigation arising out of such action. ARCA may become subject to such litigation and, if ARCA is not successful in defending against such actions, those actions may have a material adverse effect on its business, financial condition and results of operations. ARCA could also become subject to false claims litigation and consumer protection claims under state statutes, which also could lead to civil monetary penalties, restitution, criminal fines and imprisonment, and exclusion from participation in state health care programs.

Of note, over the past few years there has been an increased focus on the sales and marketing practices of the pharmaceutical industry at both the federal and state level. Additionally, the law or regulatory policies governing pharmaceuticals may change. New statutory requirements may be enacted or additional regulations may be enacted that could prevent or delay regulatory approval of ARCA s product candidates. ARCA cannot predict the likelihood, nature or extent of adverse government regulation that may arise from future legislation or administrative action, either in the U.S. or elsewhere.

If ARCA, its collaborators or its third-party manufacturers fail to comply with applicable continuing regulatory requirements, ARCA s business could be seriously harmed because a regulatory agency may:

- issue untitled or warning letters;
- suspend or withdraw ARCA s regulatory approval for approved products;
- seize or detain products or recommend a product recall of a drug or medical device, or issue a mandatory recall of a medical device;
- refuse to approve pending applications or supplements to approved applications filed by ARCA;
- suspend any of ARCA s ongoing clinical trials;
- impose restrictions on ARCA s operations, including costly new manufacturing requirements, and restrictions on ARCA s sales, marketing and/or distribution of ARCA s products;
- seek an injunction;
- pursue criminal prosecutions;
- close the facilities of ARCA s contract manufacturers; or
- impose civil or criminal penalties.

If LabCorp or certain of its third-party suppliers fail to comply with ongoing FDA or other foreign regulatory authority requirements, or if there are unanticipated problems with the Gencaro Test, these products could be subject to restrictions or withdrawal from the market.

Any medical device for which LabCorp obtains clearance or approval, and the manufacturing processes, reporting requirements, post-approval clinical data and promotional activities for such product, will be subject to continued regulatory review, oversight and periodic inspections by the FDA and other domestic and foreign regulatory bodies. With respect to the Gencaro Test, to the extent applicable, LabCorp and certain of its suppliers will be required to comply with the FDA s Quality System Regulation, or QSR, and International Standards Organization, or ISO, requirements which cover the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage and shipping of any product for which clearance or approval is obtained. Regulatory bodies, such as the FDA, enforce the QSR and other regulations through periodic inspections. The failure by LabCorp, or certain of its third-party manufacturers or suppliers, as the case may be, to comply with applicable statutes and regulations administered by the FDA and other regulatory bodies, or the failure to timely and adequately respond to any adverse inspectional observations or product safety issues, could result in, among other things, enforcement actions. If any of these actions were to occur, it could harm ARCA s reputation and cause product sales and profitability of Gencaro to suffer and may prevent ARCA from generating revenue.

Even if regulatory clearance or approval is granted, such clearance or approval may be subject to limitations on the intended uses for which the product may be marketed and reduce ARCA s potential to successfully commercialize the product and generate revenue from the product.

If LabCorp or certain of its third party suppliers fail to supply the Gencaro Test, the product sales and profitability of Gencaro will suffer.

LabCorp is ARCA s single-source supplier of the Gencaro Test. If LabCorp or its third party suppliers were to cease or interrupt production of or otherwise fail to supply the Gencaro Test, or the materials required to produce it, in a timely manner or at all, ARCA could be unable to obtain a contract manufacturer of companion genetic test for Gencaro for an indeterminate period of time. This could adversely affect ARCA s ability to satisfy demand for Gencaro, which could cause product sales and profitability of Gencaro to suffer and may have an adverse effect on ARCA s financial condition and results of operations.

Medical devices related to Gencaro, such as the Gencaro Test, may in the future be subject to product recalls that could harm ARCA s reputation, business and financial results.

The FDA and similar foreign governmental authorities have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture. In the case of the FDA, the authority to require a mandatory recall must be based on an FDA finding that there is a reasonable probability that the device would cause serious adverse health consequences or death. In addition, foreign governmental bodies have the authority to require the recall of ARCA s products in the event of material deficiencies or defects in design or manufacture. Manufacturers may, under their own initiative, initiate a field correction or removal, known as a recall, for a product if any material deficiency in a device is found. A government-mandated or voluntary recall by ARCA s third-party suppliers, including LabCorp, could occur as a result of component failures, manufacturing errors, design or labeling defects or other deficiencies and issues. Any such recalls would divert managerial and financial resources and may have an adverse effect on ARCA s financial condition and results of operations.

If medical devices related to Gencaro, such as the Gencaro Test, cause or contribute to a death or a serious injury, or malfunction in certain ways, ARCA s third-party suppliers will be subject to medical device reporting regulations, which can result in voluntary corrective actions or agency enforcement actions.

Under the FDA s medical device reporting regulations, medical device manufacturers are required to report to the FDA information that a device has or may have caused or contributed to a death or serious injury or has malfunctioned in a way that would likely cause or contribute to death or serious injury if the malfunction of the device or one of ARCA s similar devices were to recur. If ARCA s third-party suppliers, including LabCorp, fail to report these events to the FDA within the required timeframes, or at all, the FDA could take enforcement action against ARCA s third-party suppliers, including LabCorp. Any such adverse event involving the Gencaro Test also could result in future voluntary corrective actions, such as recalls or customer notifications, or agency action, such as inspection or enforcement action. Any corrective action, whether voluntary or involuntary, taken by ARCA s third-party suppliers, including LabCorp, may significantly affect ARCA s ability to market Gencaro. In such cases, ARCA could be forced to identify a new third-party test provider for the Gencaro Test.

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LabCorp may need to conduct clinical trials to support current or future versions of the Gencaro Test. Delays or failures in any such clinical trials may prevent LabCorp from commercializing any modified or new versions of the Gencaro Test and will adversely affect ARCA s business, operating results and prospects.

Based on discussions with the FDA, ARCA and LabCorp do not believe that clinical data are needed for the Gencaro Test submission. However, the FDA may require clinical data for the Gencaro Test submission and/or future products. Initiating and completing clinical trials necessary to support 510(k)s or PMAs, if required, for current or future products will be time consuming and expensive and the outcome uncertain. Moreover, the results of early clinical trials are not necessarily predictive of future results, and any product ARCA or its third party suppliers, including LabCorp, advance into clinical trials may not have favorable results in later clinical trials.

Conducting successful clinical studies may require the enrollment of large numbers of patients, and suitable patients may be difficult to identify and recruit. Patient enrollment in clinical trials and completion of patient participation and follow-up depends on many factors, including: the size of the patient population; the number of patients to be enrolled; the nature of the trial protocol; the attractiveness of, or the discomforts and risks associated with, the treatments received by enrolled subjects; the availability of appropriate clinical trial investigators, support staff, and proximity of patients to clinical sites; and the patients ability to meet the eligibility and exclusion criteria for participation in the clinical trial and patient compliance. For example, patients may be discouraged from enrolling in clinical trials if the trial protocol requires them to undergo extensive post-treatment procedures or follow-up to assess the safety and effectiveness of ARCA s products or if they determine that the treatments received under the trial protocols are not attractive or involve unacceptable risks or discomforts. In addition, patients participating in clinical trials may die before completion of the trial or suffer adverse medical events unrelated to investigational products.

Development of sufficient and appropriate clinical protocols to demonstrate safety and efficacy are required, and LabCorp, or ARCA may not adequately develop such protocols to support clearance and approval. Significant risk trials will require the submission and approval of an investigational device exemption, or IDE, from the FDA. There is no guarantee that the FDA will approve LabCorp s or ARCA s future IDE submissions. Further, the FDA may require LabCorp or ARCA to submit data on a greater number of patients than originally anticipated and/or for a longer follow-up period or change the data collection requirements or data analysis applicable to ARCA s clinical trials. Delays in patient enrollment or failure of patients to continue to participate in a clinical trial may cause an increase in costs and delays in the approval and attempted commercialization of future products or result in the failure of the clinical trial. In addition, despite considerable time and expense invested in such clinical trials, the FDA may not consider the data to be adequate to demonstrate safety and efficacy. Such increased costs and delays or failures could adversely affect ARCA s third party suppliers , or ARCA s business, operating results and prospects.

Federal regulatory reforms may adversely affect ARCA s or its suppliers ability to sell products profitably.

From time to time, legislation is drafted and introduced in the U.S. Congress that could significantly change the statutory provisions governing the clearance or approval, manufacture and marketing of a medical device. In addition, FDA regulations and guidance are often revised or reinterpreted by the agency in ways that may significantly affect the way that medical devices are marketed and promoted. It is impossible to predict whether legislative changes will be enacted or FDA regulations, guidance or interpretations changed, and what the impact of such changes, if any, may be.

Without limiting the generality of the foregoing, in September 2007, the Food and Drug Administration Amendments Act of 2007, or the Amendments, were enacted. The Amendments require, among other things, that the FDA propose, and ultimately implement, regulations that will require manufacturers to label medical devices with unique identifiers unless a waiver is received from the FDA. Once implemented, compliance with those regulations may require manufacturers to take additional steps in the manufacture and labeling of medical devices. These steps may require additional resources and could be costly. In addition, the Amendments require medical device manufacturers to, among other things, comply with clinical trial registration requirements once clinical trials are initiated.

If approved by the FDA, Gencaro will be entering into a competitive marketplace and may not succeed.

Gencaro is a new type of beta-blocker and vasodilator being developed for heart failure and other indications. While ARCA anticipates that this drug will be the first genetically-targeted cardiovascular drug, Gencaro will be one of a number of successful drugs in the beta-blocker class currently on the market. Currently, there are three branded beta-blockers indicated for chronic heart failure in New York Health Association, or NYHA class II-IV patients: TOPROL-XL (once-a-day formulation), Coreg and Coreg CR (once-a-day). TOPROL-XL and Coreg have generic equivalents commercially available in the U.S. (Metoprolol Succinate and Carvedilol, respectively). The price of the generic forms of these drugs will be less than the anticipated price of Gencaro, if approved. As a result, Gencaro may not be successful in competing against these existing drugs.

Additionally, Forest Laboratories may apply for approval to use Bystolic, a drug currently used to treat high blood pressure, for treatment of heart failure. If approved for treatment of heart failure, Gencaro may not be successful in competing against Bystolic, an already well-known name brand.

ARCA s commercial opportunity may be reduced or eliminated if competitors develop and commercialize products that are safer, more effective, have fewer side effects, are more convenient or are less expensive than Gencaro. If products with any of these properties are developed, or any of the existing products are better marketed, then prescriptions of Gencaro by physicians and patient use of Gencaro could be significantly reduced or rendered obsolete and noncompetitive. Further, public announcements regarding the development of any such competing drugs could adversely affect the market price of ARCA s common stock and the value of its assets.

Future sales of ARCA s products may suffer if they are not accepted in the marketplace by physicians, patients and the medical community.

Gencaro or ARCA s other product candidates may not gain market acceptance among physicians, patients and the medical community. The degree of market acceptance of Gencaro or ARCA s other product candidates will depend on a number of factors, such as its effectiveness and tolerability, as compared with competitive drugs. Also, prevalence and severity of side-effects could negatively affect market acceptance of Gencaro or ARCA s other product candidates. For example, side-effects of Gencaro observed during clinical trials included fatigue, dizziness and slowed heart beat. Failure to achieve market acceptance of Gencaro would significantly harm ARCA s business.

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If ARCA is unable to obtain acceptable prices or adequate reimbursement from third-party payors for Gencaro, or any other product candidates that ARCA may seek to commercialize, then its revenues and prospects for profitability will suffer.

ARCA s or any strategic partner s ability to commercialize Gencaro, or any other product candidates that ARCA may seek to commercialize, is highly dependent on the extent to which coverage and reimbursement for these product candidates will be available from:

- governmental payors, such as Medicare and Medicaid;
- private health insurers, including managed-care organizations; and
- other third-party payors.

Many patients will not be capable of paying for ARCA s potential products themselves and will rely on third-party payors to pay for their medical needs. A primary current trend in the U.S. health care industry is toward cost containment. Large private payors, managed-care organizations, group purchasing organizations and similar organizations are exerting increasing influence on decisions regarding the use of, and reimbursement levels for, particular treatments. Such third-party payors, including Medicare, are challenging the prices charged for medical products and services, and many third-party payors limit reimbursement for newly approved health care products. In particular, third-party payors may limit the reimbursed indications.

Cost-control initiatives could decrease the price ARCA might establish for products, which could result in product revenues lower than anticipated. If the prices for ARCA s product candidates decrease, or if governmental and other third-party payors do not provide adequate coverage and reimbursement levels, then ARCA s revenue and prospects for profitability will suffer.

****ARCA s competitors may be better positioned in the marketplace and thereby may be more successful than ARCA at developing, manufacturing and marketing approved products.***

Many of ARCA s competitors currently have significantly greater financial resources and expertise in conducting clinical trials, obtaining regulatory approvals, managing manufacturing and marketing approved products than ARCA. Other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. In addition, these third parties compete with ARCA in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring therapies and therapy licenses complementary to ARCA s programs or advantageous to its business. ARCA expects that its ability to compete effectively will depend upon its ability to:

- successfully and rapidly complete clinical trials for any future product candidates and obtain all requisite regulatory approvals in a cost-effective manner;
- build an adequate sales and marketing infrastructure, obtain additional funding, or enter into strategic transactions enabling the commercialization of its products;
- develop competitive formulations of its product candidates;
- attract and retain key personnel; and
- identify and obtain other product candidates on commercially reasonable terms.

If ARCA fails to identify and license or acquire other products or product candidates, then it may be unable to expand its business, and the acquisition or licensing of other products or product candidates may put a strain on ARCA s operations and will likely require ARCA to seek additional financing.

One of ARCA s strategies is to license or acquire clinical-stage products or product candidates and further develop them for commercialization. The market for licensing and acquiring products and product candidates is intensely competitive and many of ARCA s competitors may have greater resources than ARCA. If ARCA undertakes any additional acquisitions, whether of product candidates or other biopharmaceutical companies, the process of integrating an acquired product candidate or complementary company into ARCA s business may put a strain on its operations, divert personnel, financial resources and management s attention. If ARCA is not able to reinitiate its research and development efforts and identify and license or acquire other products or product candidates or complete future acquisitions, then it will likely be unable expand its pipeline of product candidates. In addition, any future acquisition would give rise to additional operating costs and will likely require ARCA to seek additional financing. Future acquisitions could result in additional issuances of equity securities that would dilute the ownership of existing stockholders. Future acquisitions could also result in the incurrence of debt, contingent liabilities or the amortization of expenses related to other intangible assets, any of which could adversely affect ARCA s operating results.

Any future product revenues could be reduced by imports from countries where ARCA s product candidates are available at lower prices.

Even if ARCA obtains FDA approval to market Gencaro or other products in the U.S., ARCA s or a strategic partner s sales in the U.S. may be reduced if ARCA s products are imported into the U.S. from lower priced markets, whether legally or illegally. In the U.S., prices for pharmaceuticals are generally higher than in the bordering nations of Canada and Mexico. There have been proposals to legalize the import of pharmaceuticals from outside the U.S. If such legislation were enacted, then ARCA s future revenues could be reduced.

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

Clinical trials for ARCA s product candidates require that ARCA identify and enroll a large number of patients with the disorder or condition under investigation. ARCA 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 ARCA 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.

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If ARCA has difficulty enrolling a sufficient number of patients to conduct its clinical trials as planned, ARCA 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 ARCA s clinical trials would also adversely affect its ability to generate product, milestone and royalty revenues and could impose significant additional costs on ARCA or on its collaborators.

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

ARCA, and its collaborators, will only receive regulatory approval for its product candidates if ARCA can demonstrate in carefully designed and conducted clinical trials that the product candidate is safe and effective. ARCA 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. ARCA has spent, and expects to continue to spend, significant amounts of time and money in the clinical development of its product candidates.

The results ARCA obtains in preclinical testing and early clinical trials may not be predictive of results that are obtained in later studies. ARCA may suffer significant setbacks in advanced clinical trials, even after promising results in earlier studies. Based on results at any stage of clinical trials, ARCA may decide to repeat or redesign a trial or discontinue development of one or more of ARCA s product candidates. If ARCA fails to adequately demonstrate the safety and efficacy of its products under development, ARCA will not be able to obtain the required regulatory approvals to commercialize ARCA s product candidates, and its business, results of operations and financial condition would be materially adversely affected.

Administering ARCA s product candidates to humans may produce undesirable side effects. These side effects could interrupt, delay or halt clinical trials of ARCA 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, ARCA will be unable to commercialize the product candidate. If one or more of ARCA s clinical trials are delayed, it will be unable to meet its anticipated development timelines. Either circumstance could cause the market price of ARCA s common stock to decline.

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

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

ARCA would be subject to applicable regulatory approval requirements of the foreign countries in which ARCA markets its products, which are costly and may prevent or delay ARCA from marketing its products in those countries.

In addition to regulatory requirements in the United States, ARCA would subject to the regulatory approval requirements in each foreign country where it markets its products. In addition, ARCA might be required to identify one or more collaborators in these foreign countries to develop, seek approval for and manufacture it products and any companion genetic test for Gencaro. If ARCA determines to pursue regulatory approvals and commercialization of its product candidates internationally, it may not be able to obtain the required foreign regulatory approvals on a timely basis, if at all, and any failure to do so may cause ARCA to incur additional costs or prevent ARCA from marketing its products in foreign countries, which may have a material adverse effect on ARCA s business, financial condition and results of operations.

If ARCA cannot successfully integrate the Nuvelo organization, ARCA 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 ARCA s and Nuvelo s technical and business operations and remaining 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.

ARCA cannot assure you that it will receive any benefits of the Merger or any other merger or acquisitions, or that any of the difficulties described above will not adversely affect ARCA. The integration process may be difficult and unpredictable because of possible conflicts and differing opinions on business, scientific and regulatory matters. If the companies cannot successfully integrate their technical and business operations and personnel, ARCA may not realize the expected benefits of the Merger.

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ARCA expects to incur significant costs integrating the companies into a single business.

ARCA expects to incur significant costs integrating the technical and business operations and personnel of Nuvelo and ARCA, 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.

Integrating the companies may divert the attention of ARCA s management away from its operations.

ARCA s successful integration of Nuvelo s technical and business operations and personnel into its own organization may place a significant burden on ARCA 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 ARCA s clinical trial and product development programs and could otherwise harm ARCA s business, financial condition and operating results.

ARCA has incurred and will continue to incur increased costs as a result of being a public company.

As a public company, ARCA has incurred and will continue to incur significant levels of legal, accounting and other expenses. The Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, and related rules of the SEC and Nasdaq regulate corporate governance practices of public companies and impose significant requirements relating to disclosure controls and procedures and internal control over financial reporting. Compliance with these public company requirements has increased ARCA s costs, required additional resources and made some activities more time consuming. ARCA is required to expend considerable time and resources complying with public company regulations.

Failure to establish and maintain effective internal control over financial reporting could have a material adverse effect on ARCA s business, operating results and stock price.

Maintaining effective internal control over financial reporting is necessary for ARCA to produce reliable financial reports and is important in helping to prevent financial fraud. Prior to the recently completed merger involving Nuvelo, ARCA was not subject to the Sarbanes-Oxley Act. Therefore, ARCA s management only performed an evaluation of Nuvelo s internal control over financial reporting as of December 31, 2008 in accordance with the provisions of the Sarbanes-Oxley Act. Material weaknesses may exist when ARCA 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 for ARCA s fiscal year ending December 31, 2009. The existence of one or more material weaknesses would preclude a conclusion that ARCA maintains effective internal control over financial reporting. Such a conclusion would be required to be disclosed in ARCA 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 ARCA s reputation and cause the market price of its common stock to drop.

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

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

The continued economic downturn could adversely affect our business and operating results.

The U.S. economy was in a recession through much or all of 2008, which has continued and deepened in 2009. As the global financial crisis has broadened and intensified, a severe recession appears likely. Business activity across a wide range of industries and regions is substantially reduced, and many companies are in serious difficulty due to the lack of consumer spending, reduced access to credit, cash flow shortages, deterioration of their businesses, and lack of liquidity in the capital markets. Challenging economic and market conditions may also result in:

reductions to our workforce;

increased price competition, which may adversely affect the revenue and gross margins we anticipate from any of our product candidates, once commercialized;

financial strain on the health care system, which may lead to lower than anticipated sales of our product candidates, once commercialized;

the bankruptcy or insolvency of our collaborators and third party manufacturers; and

difficulties in forecasting, budgeting and planning due to limited visibility into economic conditions.

A prolonged national or regional economic recession, or other events that have produced or could produce major changes economic patterns, such as the housing market crisis, the credit crisis or a terrorist attack, could have a material adverse effect on our business, results of operations and financial condition.

Risks Related to Stock Price Volatility

Ownership of ARCA s common stock is highly concentrated, and it may prevent you and other stockholders from influencing significant corporate decisions and may result in conflicts of interest that could cause ARCA s stock price to decline.

ARCA s executive officers, directors and their affiliates beneficially own approximately 49% of the outstanding common stock of ARCA as of January 27, 2009. Accordingly, these executive officers, directors and their affiliates, acting individually or as a group, have substantial influence over the outcome of a corporate action of ARCA requiring stockholder approval, including the election of directors, any merger, consolidation or sale of all or substantially all of ARCA s assets or any other significant corporate transaction. These stockholders may also delay or prevent a change in control of ARCA, even if such change in control would benefit the other stockholders of ARCA. The significant concentration of stock ownership may adversely affect the value of ARCA s common stock due to investors perception that conflicts of interest may exist or arise.

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ARCA s stock price is expected to be volatile.

ARCA s common stock could be subject to significant fluctuations. 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 ARCA s common stock to fluctuate include:

- the regulatory status of Gencaro and the Gencaro Test, and whether and when they are approved for sale, if at all, and the labeling or other conditions of use imposed by the FDA;
- the ability of ARCA to complete a strategic transaction or to secure substantial additional funding to commercialize Gencaro;
- the results of ARCA s future clinical trials and any future 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 ARCA s product candidates;
- failure of any of ARCA s product candidates, if approved, to achieve commercial success;
- general and industry-specific economic conditions that may affect ARCA s research and development expenditures;
- the results of clinical trials conducted by others on drugs that would compete with ARCA s product candidates;
- issues in manufacturing ARCA s product candidates or any approved products;
- the initiation of material developments in or the conclusion of litigation to enforce or defend any of ARCA s intellectual property rights;
- the loss of key employees;
- the introduction of technological innovations or new commercial products by competitors of ARCA;
- changes in estimates or recommendations by securities analysts, if any, who cover ARCA s common stock;
- future sales of ARCA s common stock;

changes in the structure of health care payment systems; and

period-to-period fluctuations in ARCA 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 ARCA 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 ARCA s profitability and reputation.

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

Sales in the public market of substantial amounts of ARCA s common stock could depress prevailing market prices of its common stock. As of March 31, 2009, ARCA had 7,569,903 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 ARCA s directors, officers and other affiliates and unregistered shares held by non-affiliates. Although ARCA does not believe that its directors, officers and other affiliates 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 ARCA s common stock.

As of March 31, 2009, ARCA had approximately 1.1 million shares of ARCA s common stock which may be issued upon exercise of outstanding stock options. 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 may negatively affect ARCA 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 ARCA s common stock received, may also result in downward pressure on the price of ARCA s common stock.

As of March 31, 2009, approximately 210,000 shares of ARCA s common stock were issuable upon the exercise of outstanding warrants, which were all exercisable as of this date. Once a warrant is exercised, if the shares of ARCA common stock issued upon the exercise of any such warrant are not available for sale in the open market without further registration under the Securities Act, then 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 ARCA may issue in the future, are exercised, it could result in additional sales of ARCA s common stock in the market, which may have an adverse effect on ARCA s stock price.

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

ARCA does not expect to pay cash dividends, and accordingly, stockholders must rely on stock appreciation for any return on their investment.

ARCA anticipates that it 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 its common stock will provide a return to stockholders. Investors seeking cash dividends should not invest in its common stock.

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

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

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

authorize the issuance of up to 5 million additional shares of preferred stock that could be issued by ARCA 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 ARCA s stockholders; and

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

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Specifically, ARCA 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 ARCA s stockholders may call a special meeting of stockholders only upon a request of stockholders owning at least 50% of ARCA s common stock. These provisions of ARCA s certificate of incorporation and bylaws could discourage potential acquisition proposals and could delay or prevent a change in control. ARCA designed these provisions to reduce ARCA 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 ARCA s shares. As a consequence, they also may inhibit fluctuations in the market price of ARCA s shares that could result from actual or rumored takeover attempts. Such provisions also may have the effect of preventing changes in ARCA s management.

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

ARCA 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 10% of its assets with any stockholder, including all affiliates and associates of the stockholder, who owns 15% or more of the corporation s outstanding voting stock, for six years following the date that the stockholder acquired 15% or more of the corporation s stock unless:

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

The provisions of ARCA s governing documents and current Delaware law may, collectively:

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

Risks Related to Intellectual Property and Other Legal Matters

ARCA is party to securities litigation and defending these lawsuits could hurt ARCA s business. The volatility of the market price 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 biotechnology companies, which 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 ARCA could result in substantial costs and a diversion of management s attention and resources, which could significantly harm ARCA 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 III trials for the treatment of acute peripheral arterial occlusion and in the first of two planned Phase III trials for the treatment of catheter occlusion, the closing price of one share of Nuvelo s common stock was $81 (as adjusted for the 20-to-1 reverse stock split) on the day of the announcement, as compared with a closing price of $391 (as adjusted for the 20-to-1 reverse stock split) on the trading day prior to the announcement. On February 9, 2007, Nuvelo 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 alleged violations of the Securities Exchange Act of 1934 related to the clinical trial results of alfimeprase, which Nuvelo announced on December 11, 2006, and sought damages on behalf of purchasers of Nuvelo s common stock during the period between January 5, 2006 and December 8, 2006. Specifically, the suit alleged that Nuvelo misled investors regarding the efficacy of alfimeprase and the drug s likelihood of success. The plaintiff sought 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.

On December 4, 2008, the Court issued an order dismissing plaintiff s complaint, and granting leave to amend. On January 23, 2009, the plaintiffs filed an amended complaint, alleging similar claims. On March 24, 2009, the defendants filed a motion to dismiss the amended complaint. Based on the Court s December 4, 2008 order, and plaintiff s amended complaint, ARCA believes that any attorneys fees, loss or settlement payment with respect to this suit will be paid by its insurance providers. However, it is possible that ARCA could be forced to incur material expenses in the litigation if the case is not finally dismissed, or if the parties cannot achieve a settlement, and, in the event of an adverse outcome, ARCA s business could be harmed.

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, ARCA is obligated to continue to defend against this litigation. ARCA believes that any attorneys fees, loss or settlement payment with respect to this suit will not be material to ARCA 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 ARCA, 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 ARCA, but none have been filed yet. ARCA believes that any attorneys fees, loss or settlement payment with respect to this suit will be paid by Nuvelo s insurance provider. However, it is possible that ARCA 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, ARCA s business could be harmed.

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If product liability lawsuits are successfully brought against ARCA, then ARCA will incur substantial liabilities and may be required to limit commercialization of Gencaro or other product candidates.

ARCA faces product liability exposure related to the testing of its product candidates in human clinical trials, and may face exposure to claims by an even greater number of persons once it begins marketing and distributing its products commercially. If ARCA cannot successfully defend itself against product liability claims, then it will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

decreased demand for its products and product candidates;

injury to its reputation;

withdrawal of clinical trial participants;

costs of related litigation;

substantial monetary awards to patients and others;

loss of revenues; and

the inability to commercialize its products and product candidates.

ARCA has obtained limited product liability insurance coverage. Such coverage, however, may not be adequate or may not continue to be available to ARCA in sufficient amounts or at an acceptable cost, or at all. ARCA may not be able to obtain commercially reasonable product liability insurance for any product approved for marketing.

Defending against claims relating to improper handling, storage or disposal of hazardous chemicals, radioactive or biological materials could be time consuming and expensive.

ARCA s research and development of product candidates may involve the controlled use of hazardous materials, including chemicals, radioactive and biological materials. ARCA cannot eliminate the risk of accidental contamination or discharge and any resultant injury from the materials. Various laws and regulations govern the use, manufacture, storage, handling and disposal of hazardous materials. ARCA may be sued or be required to pay fines for any injury or contamination that results from its use or the use by third parties of these materials. Compliance with environmental laws and regulations may be expensive, and current or future environmental regulations may impair its research, development and production efforts.

The loss of any rights to market key products would significantly impair ARCA s operating results.

ARCA has licensed from CPEC, who has licensed rights in Gencaro from BMS, the exclusive rights to Gencaro for all therapeutic and diagnostic uses in any country until the later of (i) 10 years from the first commercial sale of Gencaro in such country, or (ii) the termination of ARCA s commercial exclusivity in such country. This license includes a sublicense to ARCA from BMS. ARCA is obligated to use commercially reasonable efforts to develop and commercialize Gencaro, including obtaining regulatory approvals. ARCA s ability to develop and commercialize Gencaro is dependent on numerous factors, including some factors that are outside of its control. CPEC has the right to terminate ARCA s license if ARCA materially breaches its obligations under the license agreement and fails to cure any such breach within the terms of the license.

If ARCA s license agreement with CPEC is terminated for reasons related to non-payment of fees, or for any other breach, then ARCA would have no further rights to develop and commercialize Gencaro for any indication. The termination of this license, or of any other agreement which enables ARCA to market a key product or product candidate, could significantly and adversely affect ARCA s business.

Third parties may own or control patents or patent applications that ARCA may be required to license to commercialize its product candidates or that could result in litigation that would be costly and time consuming.

ARCA s or any strategic partner s ability to commercialize Gencaro and other product candidates depends upon its ability to develop, manufacture, market and sell these drugs without infringing the proprietary rights of third parties. A number of pharmaceutical and biotechnology companies, universities and research institutions have or may be granted patents that cover technologies similar to the technologies owned by or licensed to ARCA. ARCA may choose to seek, or be required to seek, licenses under third party patents, which would likely require the payment of license fees or royalties or both. ARCA may also be unaware of existing patents that may be infringed by Gencaro, the genetic testing ARCA intends to use in connection with Gencaro or its other product candidates. Because patent applications can take many years to issue, there may be other currently pending applications that may later result in issued patents that are infringed by Gencaro or ARCA s other product candidates. Moreover, a license may not be available to ARCA on commercially reasonable terms, or at all.

There is a substantial amount of litigation involving patent and other intellectual property rights in the biotechnology and biopharmaceutical industries generally. If a third party claims that ARCA is infringing on its technology, then ARCA s business and results of operations could be harmed by a number of factors, including:

- infringement and other intellectual property claims, even if without merit, are expensive and time-consuming to litigate and can divert management s attention from ARCA s core business;
- monetary damage awards for past infringement can be substantial;
- a court may prohibit ARCA from selling or licensing product candidates unless the patent holder chooses to license the patent to ARCA; and
- if a license is available from a patent holder, ARCA may have to pay substantial royalties.

ARCA may also be forced to bring an infringement action if it believes that a competitor is infringing its protected intellectual property. Any such litigation will be costly, time-consuming and divert management s attention, and the outcome of any such litigation may not be favorable to ARCA.

ARCA s intellectual property rights may not preclude competitors from developing competing products and ARCA s business may suffer.

ARCA s competitive success will depend, in part, on ARCA s ability to obtain and maintain patent protection for its inventions, technologies and discoveries, including intellectual property that ARCA licenses. The patent positions of biotechnology companies involve complex legal and factual questions, and ARCA cannot be certain that ARCA s patents and licenses will successfully preclude others from using ARCA s technology. Although Gencaro has an established patent strategy, 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 ARCA to generate data, which may involve substantial costs. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued. Consequently, ARCA cannot be certain that any of its patent applications will result in the issuance of patents or, if any patents are issued, that they

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will provide significant market protection or will not be circumvented or challenged and found to be unenforceable or invalid. In some cases, patent applications in the U.S. and certain other jurisdictions are maintained in secrecy until patents issue, and since publication of discoveries in the scientific or patent literature often lags behind actual discoveries, ARCA cannot be certain of the priority of inventions covered by pending patent applications. Moreover, ARCA may have to participate in interference proceedings declared by the U.S. Patent and Trademark Office to determine priority of invention or in opposition proceedings in a foreign patent office, any of which could result in substantial cost to ARCA, even if the eventual outcome is favorable. There can be no assurance that a court of competent jurisdiction would hold any patents issued valid. An adverse outcome could subject ARCA to significant liabilities to third parties, require disputed rights to be licensed from third parties or require ARCA to cease using such technology. ARCA could also incur substantial costs in seeking to enforce its proprietary rights against infringement.

While the composition of matter patents on the compound have expired, ARCA holds the intellectual property arising from the discovery of the interaction of Gencaro with the polymorphisms of the $ß_1$ and α_{2c} receptors. ARCA has filed patent applications that claim the use of Gencaro with the diagnosis of a patient s receptor genotype. ARCA s NDA requested a label that will include a claim that efficacy varies based on receptor genotype and a recommendation in the prescribing information that prospective patients be tested for their receptor genotype. Under applicable law, a generic bucindolol label would likely be required to include this recommendation as it pertains directly to the safe or efficacious use of the drug. Such a label could be considered as inducing infringement, carrying the same liability as direct infringement. Even if the patents are granted, the approved label may not contain language covered by the patents, or ARCA may be unsuccessful in enforcing them.

ARCA 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, the patent applications describing ARCA s proprietary methods are filed only in the U.S.

ARCA requires its employees, consultants, business partners and members of its scientific advisory board to execute confidentiality agreements upon the commencement of employment, consulting or business relationships with ARCA. These agreements provide that all confidential information developed or made known during the course of the relationship with ARCA be kept confidential and not disclosed to third parties except in specific circumstances. In the case of employees, the agreements provide that all inventions resulting from work performed for ARCA, utilizing the property or relating to the business of ARCA and conceived or completed by the individual during employment shall be the exclusive property of ARCA to the extent permitted by applicable law.

Third parties may breach these and other agreements with ARCA regarding its intellectual property and ARCA may not have adequate remedies for the breach. Third parties could also fail to take necessary steps to protect ARCA s licensed intellectual property, which could seriously harm ARCA s intellectual property position.

If ARCA is not able to protect its proprietary technology, trade secrets and know-how, then its competitors may develop competing products. Any issued patent may not be sufficient to prevent others from competing with ARCA. Further, ARCA has trade secrets relating to Gencaro, and such trade secrets may become known or independently discovered. ARCA s issued patents and those that may issue in the future, or those licensed to ARCA, may be challenged, opposed, invalidated or circumvented, which could limit ARCA s ability to stop competitors from marketing related products or the term of patent protection that ARCA may have for its product candidates. All of these factors may affect ARCA s competitive position.

If the manufacture, use or sale of ARCA s products infringe on the intellectual property rights of others, ARCA could face costly litigation, which could cause ARCA 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, ARCA s involvement in any litigation, interference or other administrative proceedings could cause ARCA to incur substantial expense and could significantly divert the efforts of ARCA s technical and management personnel. Any public announcements related to litigation or interference proceedings initiated or threatened against ARCA could cause ARCA s stock price to decline. An adverse determination may subject ARCA to the loss of its proprietary position or to significant liabilities, or require ARCA 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 ARCA from manufacturing and selling its products, if any. These outcomes could materially harm ARCA s business, financial condition and results of operations.

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

Information with respect to the meeting of the stockholders of Nuvelo held in January 2009 was included in the Company s Annual Report on Form 10-K, filed on March 27, 2009 and is incorporated herein.

ITEM 5. OTHER INFORMATION

Not applicable.

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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.

ARCA biopharma, Inc. (Registrant)

By: /s/ Kathryn E. Falberg
Kathryn E. Falberg
Chief Financial Officer and Chief Operating Officer

Dated: May 15, 2009

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