ARCA biopharma, Inc.
Form 10-Q
November 16, 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 SEPTEMBER 30, 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 November 11, 2009: 7,612,370**

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ARCA BIOPHARMA, INC.

FORM 10-Q

FOR THE QUARTER ENDED SEPTEMBER 30, 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)

	September 30, 2009	December 31, 2008
	(in thousands, except share and per share amounts)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 10,642	$ 7,740
Deferred transaction costs		1,668
Other current assets	805	270
Total current assets	11,447	9,678
Property and equipment, net	1,145	1,303
In-process research and development	6,000	
Other assets	83	98
Total assets	$ 18,675	$ 11,079
LIABILITIES AND STOCKHOLDERS EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 658	$ 804
Accrued compensation and employee benefits	862	1,071
Accrued expenses and other liabilities	835	1,549
Bank note payable		3,948
Convertible notes payable		8,351
Deferred rent, current portion	112	107
Total current liabilities	2,467	15,830
Deferred rent, net of current portion	345	430
Deferred tax liability	2,281	
Other long-term liabilities	62	132
Total liabilities	5,155	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 September 30, 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 September 30, 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 September 30, 2009 and December 31, 2008, respectively; 7,604,976 and 954,420 shares issued and outstanding at September 30, 2009 and December 31, 2008, respectively	8	1
Additional paid-in capital	57,216	2,573
Deficit accumulated during the development stage	(43,704)	(40,752)
Total stockholders equity (deficit)	13,520	(38,178)
Total liabilities and stockholders equity (deficit)	$ 18,675	$ 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 September 30,		Nine Months Ended September 30,		Period from December 17, 2001 (date of inception) to September 30, 2009
	2009	2008	2009	2008	
	(in thousands, except share and per share amounts)				
Costs and expenses:					
Research and development	$ 1,112	$ 3,767	$ 9,209	$ 8,363	$ 35,363
Selling, general and administrative	2,007	2,658	11,192	6,037	26,593
Merger transaction costs			5,470		5,470
Restructuring expense, net	1,131		2,396		2,396
Total costs and expenses	4,250	6,425	28,267	14,400	69,822
Loss from operations	(4,250)	(6,425)	(28,267)	(14,400)	(69,822)
Gain on bargain purchase			25,282		25,282
Interest and other income	13	31	217	204	1,261
Interest and other expense	(71)	(21)	(184)	(60)	(425)
Net loss	$ (4,308)	$ (6,415)	$ (2,952)	$ (14,256)	$ (43,704)
Less: Accretion of redeemable convertible preferred stock		(13)	(135)	(42)	(245)
Less: Deemed preferred stock dividend for additional common shares issuable under anti-dilution provisions			(781)		(781)
Net loss attributable to common stockholders	$ (4,308)	$ (6,428)	$ (3,868)	$ (14,298)	$ (44,730)
Net loss attributable to common stockholders per share:					
Basic and diluted	$ (0.57)	$ (8.52)	$ (0.56)	$ (19.72)	
Weighted average shares outstanding:					
Basic and diluted	7,576,234	754,253	6,921,996	725,121	

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	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, 2006, for intellectual property license rights, at $0.72 per share					104,229		75		75
Issuance of Series A on February 22, 2006, for cash, at $1.6265 per share	5,727,354	9,316							
	420,817	684							

Issuance of Series A on February 22, 2006, upon conversion of notes payable and related accrued interest, at $1.6265 per share									
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, on June 30, 2007 at $1.80 per share					3,852		7		7
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)

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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	Total
	Shares	Amount	Shares	Amount	Shares	Amount			
	(in thousands, except share and per share amounts)								
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
Merger / reverse stock split Nuvelo, Inc.					2,686,957	3	11,910		11,913
Adjustment for fractional shares					(609)				
Share-based compensation							786		786
Issuance of common stock upon exercise of stock options for cash					47,651		95		95
Issuance of common stock under employee stock purchase plan					1,064		2		2

and upon vesting of restricted stock units						
Estimated fair value of warrants issued in connection with lease termination				377		377
Net loss					(2,952)	(2,952)
Balance, September 30, 2009	**$**	**$ 7,604,976**	**$ 8**	**$ 57,216**	**$ (43,704)**	**$ 13,520**

See accompanying notes to consolidated financial statements.

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ARCA BIOPHARMA, INC.

(a development stage enterprise)

CONSOLIDATED STATEMENTS OF CASH FLOWS

(unaudited)

	Nine Months Ended September 30,		Period from December 17, 2001 (date of inception) to September 30, 2009
	2009	2008	
	(in thousands)		
Cash flows used in operating activities:			
Net loss	$ (2,952)	$ (14,256)	$ (43,704)
Adjustments to reconcile net loss to net cash used in operating activities:			
Gain on bargain purchase	(25,282)		(25,282)
Depreciation and amortization	366	132	706
Non-cash interest expense	102	12	211
Share-based compensation	786	121	1,457
Issuance of warrants for lease termination	377		377
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	152		152
Impairment of property and equipment	125		125
Loss from disposal of property and equipment	31	24	55
Change in operating assets and liabilities (net of amounts acquired):			
Other current assets	2,549	(96)	2,285
Other assets	7,063		6,988
Accounts payable	(2,335)	(16)	(1,532)
Accrued expenses and other liabilities	(19,719)	863	(17,713)
Deferred rent	(79)	562	458
Net cash used in operating activities	(38,816)	(12,654)	(75,150)
Cash flows provided by (used in) investing activities:			
Cash received from Merger	30,392		30,392
Payment of deferred transaction costs		(564)	(1,186)
Purchase of property and equipment	(185)	(1,243)	(1,856)
Proceeds from sale of marketable securities	15,106		15,106
Proceeds from sale of property and equipment	310	5	315
Net cash provided by (used in) investing activities	45,623	(1,802)	42,771
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	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	95	51	177
Repayment of principal on bank note payable	(4,000)		(4,000)
Repayment of principal on convertible notes payables			(105)
Net cash (used in) provided by financing activities	(3,905)	4,051	43,021
Net increase (decrease) in cash and cash equivalents	2,902	(10,405)	10,642
Cash and cash equivalents, beginning of period	7,740	15,862	
Cash and cash equivalents, end of period	$ 10,642	$ 5,457	$ 10,642
Supplemental cash flow information:			
Interest paid	$ 97	$ 7	$ 107
Supplemental disclosure of noncash investing and financing transactions:			
Accrued interest on notes payable converted to equity	$ 151	$	$ 163
Warrant issued in connection with credit facility	$	$ 62	$ 111

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 genetically-targeted therapies for heart failure and other cardiovascular diseases. The Company s lead product candidate is Gencaro ™ (bucindolol hydrochloride), a pharmacologically unique beta-blocker and mild vasodilator for chronic heart failure, or HF. Bucindolol was the subject of a Phase 3 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. On May 29, 2009, the FDA issued a Complete Response Letter to the Company which stated that the FDA could not approve the Gencaro NDA in its current form and specified additional actions and information required by the FDA for approval of the NDA. The Company is in the process of reviewing the Complete Response Letter with the FDA, including the necessary actions required to address the issues identified in the Complete Response Letter. As a result of these discussions, the Company expects that it will be required to conduct a new multi-year active comparator superiority trial involving approximately 3,000 patients in a genotype-defined heart failure population to address the efficacy concerns raised in the Complete Response Letter. Therefore, FDA approval of Gencaro, if it occurs, will be substantially delayed.

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 nine months ended September 30, 2009 include the activities of the acquired company since the date of the Merger. Pursuant to the rules and regulations of the United States Securities and Exchange Commission (the SEC), 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.

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ARCA BIOPHARMA, INC.

(a development stage enterprise)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Unaudited)

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, exploring strategic alternatives for further developing and commercializing Gencaro, if approved, and raising capital necessary to fund its operations. 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 raise 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 $45.5 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 nine months ended September 30, 2009, the Company incurred a loss from operations of $28.3 million and had negative cash flows from operations of $38.8 million.

In September 2008, the FDA accepted for filing the Company s NDA for Gencaro. On May 29, 2009, the FDA issued a Complete Response Letter to the Company which stated that the FDA could not approve the Gencaro NDA in its current form and specified additional actions and information required by the FDA for approval of the NDA. The Company is in the process of reviewing the Complete Response Letter with the FDA, including the necessary actions required to address the issues identified in the Complete Response Letter. Based on recent discussions with the FDA, the Company expects a new multi-year active comparator superiority trial involving approximately 3,000 patients in a genotype-defined heart failure population will be required to support the Company s application for regulatory approval. The Company expects that it may be able to present additional clinical data to support the approval of Gencaro based on the achievement of a predefined result on an interim analysis in this clinical trial. The Company intends to seek the use of the FDA s Special Protocol Assessment, or SPA, process to establish the design of the clinical trial, including trial size, clinical endpoints and/or data analyses that are acceptable to the FDA.

In light of the expected multi-year delay in obtaining FDA approval for Gencaro, if at all, the substantial additional costs associated with the development of Gencaro, including the costs associated with the expected additional clinical trial, the substantial cost of commercializing Gencaro if it is approved, and the need to raise a significant amount of capital on acceptable terms to finance the proposed clinical trial and the Company s ongoing operations, the Company has reduced its operating expenses, suspended its development activities for programs other than Gencaro, and is evaluating strategic alternatives. The Company will need to complete a strategic transaction, such as a strategic combination or license of Gencaro commercialization rights, or raise substantial additional funding through public or private debt or equity markets to support the continued clinical development of Gencaro, including the expected additional clinical trial. Even if the Company is able to fund continued development and Gencaro is approved, the Company expects it will need to complete a strategic transaction or raise substantial additional funding through public or private debt or equity markets to successfully commercialize Gencaro.

The Company believes that its cash and cash equivalents balance as of September 30, 2009 will be sufficient to fund its operations, at its current cost structure, through at least March 31, 2010. The Company is unable to assert that its current cash and cash equivalents are sufficient to fund operations significantly beyond that date, and as a result, there is substantial doubt about the Company s ability to continue as a going concern. The accompanying consolidated financial statements have been prepared with the assumption that the Company will continue as 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. As a result of the significant additional required development of Gencaro, including the additional clinical trial, the Company may not be able to raise sufficient capital on acceptable terms, or at all, to continue development of Gencaro or to continue operations and may not be able to execute any strategic transaction.

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ARCA BIOPHARMA, INC.

(a development stage enterprise)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Unaudited)

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

- results of discussions with the FDA regarding the requirements for approval of the Gencaro NDA, particularly, the requirements for a new clinical trial and the costs and timing of such a trial;
- the market price of the Company s stock and the availability and cost of additional equity capital from existing and potential new investors;
- general economic and industry conditions affecting the availability and cost of capital;
- the Company s ability to control costs associated with its operations;
- the costs of filing, prosecuting, defending and enforcing patent claims and other intellectual property rights; and
- the terms and conditions of the Company s existing collaborative and licensing agreements.

The sale of additional equity or convertible debt securities would likely result in substantial additional dilution to the Company s stockholders. If the Company raises additional funds through the incurrence of indebtedness, the obligations related to such indebtedness would be senior to rights of holders of the Company s capital stock and could contain covenants that would restrict the Company s operations. The Company also cannot predict what consideration might be available, if any, to the Company or its stockholders, in connection with any strategic transaction. 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 be unable to realize value from its assets and discharge its liabilities in the normal course of business which may, among other alternatives, cause the Company to further delay, substantially reduce or discontinue operational activities to conserve its cash resources.

Basis of Presentation

The Company has generated no revenue to date and its activities have consisted of seeking regulatory approval, preparing for commercialization, and raising capital. Accordingly, the Company is considered to be in the development stage at September 30, 2009.

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

Cash equivalents generally consist of money market funds and debt securities with maturities of 90 days or less at the time of purchase. 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 as available-for-sale 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.

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ARCA BIOPHARMA, INC.

(a development stage enterprise)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Unaudited)

Concentrations of Credit Risk

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash and cash equivalents 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.

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. 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. It is reasonably possible that future evaluations of long-lived assets, including changes from the Company s current expected use of long-lived assets, may result in material impairments.

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

The Company 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 the Company in determining the estimated fair value of this asset 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:

- projected development costs, timing of such costs, and outcomes of clinical trials,
- 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 annual test for impairment will be performed in the fourth quarter. 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 estimated 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.

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

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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 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.

Stock-Based Compensation

The Company s stock-based compensation cost recognized includes: (a) compensation costs for current period vesting of all share-based awards granted prior to January 1, 2006, based on the intrinsic value method, and (b) compensation cost for current period vesting of all share-based awards granted or modified subsequent to January 1, 2006, based on the estimated grant date fair value. 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. 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.

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 occurred, and accordingly, the Company s ability to utilize Nuvelo s pre-Merger net operating loss carryforwards has been substantially reduced.

Earnings (Loss) Per Share

The Company calculates basic earnings per share by dividing (loss) earnings attributable to common stockholders by the weighted average common shares outstanding during the period, excluding common stock subject to vesting provisions. Diluted earnings per share is computed by dividing (loss) earnings 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 and convertible notes payable outstanding prior to the Merger and options and warrants.

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

(In thousands, except shares and per share data)	Three Months Ended September 30, 2009	Three Months Ended September 30, 2008	Nine Months Ended September 30, 2009	Nine Months Ended September 30, 2008
Net loss	$ (4,308)	$ (6,415)	$ (2,952)	$ (14,256)
Less: Accretion of redeemable convertible preferred stock		(13)	(135)	(42)
Deemed preferred stock dividend for additional common shares issuable under anti-dilution provision			(781)	
Net loss available to common shareholders	$ (4,308)	$ (6,428)	$ (3,868)	$ (14,298)
Weighted average shares of common stock outstanding	7,592,932	854,441	6,946,951	825,309
Less: Weighted-average shares of unvested common stock	(16,698)	(100,188)	(24,955)	(100,188)
Total weighted-average shares used in computing net loss per share attributed to common stockholders	7,576,234	754,253	6,921,996	725,121
Basic and diluted loss per share	$ (0.57)	$ (8.52)	$ (0.56)	$ (19.72)

Potentially dilutive securities representing 1.3 million and 3.2 million weighted average shares of common stock were excluded for the three months ended September 30, 2009 and 2008, respectively, and 1.6 million and 3.2 million for the nine months ended September 30, 2009 and 2008, respectively, because including them would have an anti-dilutive effect on net loss attributable to common stockholders per share.

Accounting Standards Updates

In June 2009, the Financial Accounting Standards Board (FASB) issued its final Statement of Financial Accounting Standard (SFAS). SFAS No. 168, *The FASB Accounting Standards Codification and the Hierarchy of Generally Accepted Accounting Principles a replacement of FASB Statement No. 162*, made the FASB Accounting Standards Codification (the Codification or ASC) the single source of U.S. Generally Accepted Accounting Principles (U.S. GAAP) used by nongovernmental entities in the preparation of financial statements, except for rules and interpretive releases of the SEC under authority of federal securities laws, which are sources of authoritative accounting guidance for SEC registrants. The Codification is meant to simplify user access to all authoritative accounting guidance by reorganizing U.S. GAAP pronouncements into accounting topics within a consistent structure. The Codification supersedes all existing non-SEC accounting and reporting standards and was effective for the company beginning July 1, 2009. Following SFAS No. 168, the Board will not issue new standards in the form of Statements, FASB Staff Positions, or Emerging Issues Task Force Abstracts; instead, it will issue Accounting Standards Updates. The FASB will not consider Accounting Standards Updates as authoritative in their own right. These updates will serve only to update the Codification, provide background information about the guidance, and provide the bases for conclusions on the change(s) in the Codification. References made to FASB guidance throughout this document have been updated for the Codification.

Effective April 1, 2009, the Company adopted the provisions of FASB ASC Topic 855, *Subsequent Events* (ASC 855). Prior to ASC 855, the authoritative guidance for subsequent events was previously addressed only in U.S. auditing standards. ASC 855 establishes general standards of accounting for and disclosure of events that occur after the balance sheet date but before financial statements are issued or are available to be issued and requires the Company to disclose the date through which it has evaluated subsequent events and whether that was the date the

financial statements were issued or available to be issued. ASC 855 does not apply to subsequent events or transactions that are within the scope of other applicable U.S. GAAP that provide different guidance on the accounting treatment for subsequent events or transactions. The adoption of ASC 855 did not have a material impact on the consolidated financial statements.

The Company adopted the provisions of FASB ASC Topic 820, *Fair Value Measurements and Disclosures* (ASC 820), with respect to non-financial assets and non-financial liabilities effective January 1, 2009. ASC 820 defines fair value, establishes a framework for measuring fair value and expands disclosures about fair value measurements. The adoption of these provisions did not have a material impact on the Company s consolidated financial statements.

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Effective January 1, 2009 the Company adopted the provisions of FASB ASC Topic 805, *Business Combinations* (ASC 805) and FASB ASC 810-10-65-1, *Noncontrolling Interests in Consolidated Financial Statements - an amendment of ARB No. 51*. These new provisions have significantly changed the financial accounting and reporting of business combination transactions and noncontrolling (or minority) interests in consolidated financial statements. ASC 805 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. ASC 805 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. ASC 805 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 ASC 805 to the Merger. 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 ASC 805, the balance of deferred transaction costs was expensed.

Effective January 1, 2009, the Company adopted the provisions of FASB ASC Subtopic 808-10, *Collaborative Agreements* (ASC 808-10). ASC 808-10 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 U.S. GAAP or, in the absence of other applicable U.S. GAAP, based on analogy to authoritative accounting literature or a reasonable, rational, and consistently applied accounting policy election. The adoption of ASC 808-10 had no impact on the Company s financial statements.

Effective January 1, 2009, the Company adopted the provisions of FASB ASC Subtopic 815-40, *Contracts in Entity s own Equity* (ASC 815-40). ASC 815-40 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 ASC Topic 815, *Derivatives and Hedging*. The adoption of ASC 815-40 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 ASC 805. 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 nine months ended September 30, 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, 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, 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.

At the effective time of the Merger, each option and warrant to purchase shares of ARCA Colorado s common stock outstanding was assumed by the Company. 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.

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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 acting thrombin inhibitor that has completed Phase 1 development for use as a short-acting anticoagulant during medical or surgical procedures, and Phase 1 clinical candidate NU206, a recombinant, secreted protein for the potential treatment of 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.

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 ASC 805, 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):

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

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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.

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. A 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 was 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 was probable and the amount of the liability could be reasonably estimated. As a result of the Merger, the Company also became party to the legal matters described in Note 11, for which an acquisition-date liability was not considered probable. If information becomes available to the Company prior to the end of the measurement period related to these contingencies, or others not yet identified by the Company, which would indicate that a liability was probable and the amount could have been reasonably estimated as of the acquisition date, such items will be included in the acquisition consideration allocation.

Gain on bargain purchase: In accordance with ASC 805, 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.

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 was 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.

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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 ASC 805, 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 were expensed as incurred over the transition period.

The following table provides supplemental pro forma financial information for the three and nine months ended September 30, 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, September 30,		Nine Months Ended, September 30,	
(in thousands, except per share data)	**2009**	**2008**	**2009**	**2008**
Revenue	$	$	$	$ 15,000
Net loss	(4,308)	(15,017)	(28,751)	(36,758)
Net loss per share, basic and diluted	$ (0.57)	$ (2.32)	$ (3.80)	$ (5.70)

(3) Financial Instruments

Fair value is defined 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). Inputs used to measure fair value are classified 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) measured at fair value on a recurring basis as of September 30, 2009 (in thousands):

	Level 1	Level 2	Level 3	Total
Money market fund	$ 10,295	$	$	$ 10,295

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The cost and fair value of the Company s available-for-sale investments as of September 30, 2009 and December 31, 2008 were as follows (in thousands):

	September 30, 2009			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Money market fund	$ 10,295			$ 10,295(a)

	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.

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. As of September 30, 2009, the Company did not have any debt outstanding. As of December 31, 2008, the fair value of the Company s bank note approximated the carrying amount, as the applicable interest rate approximated market rate. As of December 31, 2008, the fair value of the Company s convertible notes also approximated the carrying amount, due to the then recent negotiation of the convertible notes and the short-term nature.

(4) Property and Equipment

Property and equipment consist of the following (in thousands):

	Estimated Life	September 30, 2009	December 31, 2008
Computer equipment	3 years	$ 271	$ 218
Lab equipment	5 years	142	85
Furniture and fixtures	5 years	447	415
Computer software	3 years	187	149
Leasehold improvements	Lesser of useful life or life of the lease	744	739
		1,791	1,606

Less accumulated depreciation and amortization	(646)	(303)
	$ 1,145	$ 1,303

For the nine months ended September 30, 2009 and 2008, and for the period from Inception through September 30, 2009, depreciation and amortization expense was $366,000, $132,000 and $706,000, respectively.

For the three and nine months ended September 30, 2009, the Company recorded impairment charges of $42,000 and $125,000, respectively, based upon management s determination of excess carrying value of certain computer and office equipment over the fair value less cost to sell. In conjunction with the lease termination and exit of the San Carlos facility in September 2009, the remaining office equipment was determined to be impaired resulting in a $42,000 charge. In the second quarter of 2009, as a result of the reduction in force, management reviewed excess computer and office equipment for impairment and recognized a charge of $83,000. The impairment charges are classified as restructuring expense in the consolidated statement of operations.

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(5) Restructuring

Reduction in Force

In the second quarter of 2009, the Company implemented a restructuring plan under which it terminated 44 employees from its research and development and selling, general and administrative functions. The Company implemented the restructuring plan in connection with its strategy to seek alternatives for commercializing Gencaro and to lower operating expenses to preserve the Company s capital resources. The Company honored the Nuvelo, Inc. Change in Control Severance Benefit Plan for legacy Nuvelo employees affected; honored the employment agreement of one affected employee; and for the balance of affected employees, offered cash severance, acceleration of vesting on outstanding options representing the number of options that would have vested in one year had such employees continued to provide service to the Company, and an extension of the post-termination exercise period of the outstanding stock options to approximately one year. No employees were asked to perform service beyond a minimum retention period.

As a result of the restructuring plan, the Company recorded a restructuring charge of $1.2 million for personnel-related termination costs in the second quarter of 2009, of which $795,000 relates to severance amounts to be paid in cash and $387,000 relates to the acceleration of vesting on outstanding stock options (see Note 12, Stock-based Compensation). In the third quarter of 2009, the Company reduced the restructuring charge by $120,000 due to a change in estimate of severance costs. The Company expects to complete all payments associated with this restructuring plan by the end of 2009.

The following table summarizes activity in the severance accrual for the nine months ended September 30, 2009 (in thousands):

Severance costs expected to be paid in cash, accrued through September 30, 2009	$ 795
Cash payments	(567)
Other adjustments	(120)
Severance accrual at September 30, 2009	$ 108

The severance accrual is classified as accrued compensation and employee benefits on the consolidated balance sheet.

As a result of the reduction in force, management reviewed excess computer and office equipment for impairment. The Company recorded an impairment charge of $83,000, based on the excess of the carrying value over the fair value less cost to sell. The impairment charge is classified as restructuring expense in the consolidated statement of operations.

Lease Termination Sunnyvale facility

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 was set to expire 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.

In August 2009, the Company and landlord for the Sunnyvale Facility entered into a Lease Surrender and Termination Agreement (the Sunnyvale Termination Agreement) providing for the early termination of the lease agreement associated with the Sunnyvale Facility. Under the terms and conditions of the Sunnyvale Termination Agreement, the lease was terminated effective July 31, 2009 in consideration of a

termination payment by the Company to the landlord consisting of: (i) retention by the landlord of a security deposit in the amount of $543,000; (ii) the draw down by the landlord of full amount of the letter of credit in the amount of $6.0 million previously issued to secure tenant obligations under the lease; and (iii) an additional cash payment of $2.0 million. The letter of credit was collateralized by a certificate of deposit of the same amount, which was recorded as restricted cash in the consolidated balance sheet. As a result of the early termination of the lease agreement, the Company wrote-off the accrued facility exit cost balance of $11.0 million and recognized a gain of $2.4 million, which is included within restructuring expense in the consolidated statement of operations.

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(Unaudited)

The following table summarizes the activities related to accrued facility exit costs for the nine months ended September 30, 2009 (in thousands):

Fair value of facility exit cost liability assumed in the Merger:	$ 13,278
Amounts paid prior to termination	(2,860)
Amounts received prior to termination	268
Non-cash accretion, net	306
Extinguishment upon lease termination	(10,992)
Balance as of September 30, 2009	$

The non-cash accretion expense of $306,000 for the nine months ended September 30, 2009 was included in general and administrative expenses.

Lease Termination San Carlos facility

As a result of the Merger, the Company also assumed a seven-year lease agreement for approximately 69,000 square feet of space in San Carlos, California (the San Carlos Facility). The lease term commenced on September 1, 2005, and contained 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 sublease agreement dated January 2008 and expiring 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 had continued to use this facility for certain laboratory and general business purposes. As of the date of the Merger, 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 a result recorded a liability representing the estimated 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 payment and receipts. The unfavorable lease liability was 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 and was being amortized to operating expense on a straight-line basis over the term of the lease and sublease.

In September 2009, the Company and the landlord of the San Carlos Facility and BioMed Realty, L.P. (BioMed) entered into a Lease Termination and Warrant Purchase Agreement (the San Carlos Termination Agreement) providing for the early termination of the lease agreement dated January 11, 2005, as amended, and the issuance of a warrant to BioMed to purchase shares of common stock of the Company. Under the terms and conditions of the San Carlos Termination Agreement, the lease was terminated effective September 18, 2009 in consideration of a termination payment by the Company to the landlord consisting of: (i) a cash payment of $3.4 million; (ii) retention by the landlord of a security deposit in the amount of $490,000; (iii) issuance to BioMed of a warrant to purchase 130,890 shares of common stock of the Company at an exercise price of $3.82 per share, the closing price for the Company s common stock on the Nasdaq Global Market on the date the San Carlos Termination Agreement was executed; and (iv) the assignment to the landlord of the sublease described above. The Company estimated the fair value of the warrants using the Black-Scholes model to be $377,000. In connection with the San Carlos Termination Agreement and the exiting of the San Carlos Facility, the Company also wrote-off the unfavorable lease liability and deferred rent balances of $848,000 and accrued transaction costs of $100,000, and as a result recognized a restructuring charge of $3.7 million. Additionally, an asset impairment charge was recorded in third quarter of 2009 for $42,000 representing the excess carrying value over fair value less cost to sell relating to the remaining office equipment at the San Carlos Facility. The impairment charge is classified as restructuring expense in the consolidated statement of operations.

(6) 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.

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The entire principal and accrued interest on the notes were scheduled to be 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.

(7) 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 Credit Facility. The principal amount outstanding under the Credit Facility bore interest at a rate of 4.25% per annum, unless the Company and its subsidiaries failed 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 would have been permanently increased to a rate equal to SVB s prime rate plus 2.0%, which would be fixed as of the date such accounts fall below the thresholds. Monthly principal and interest payments were due on the Credit Facility through the maturity date of December 1, 2010. The Company s obligations under the Credit Facility were secured by a majority of the Company s assets. The Company also 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.

On July 10, 2009, subsequent to the scheduled July 1, 2009 payment, the Company repaid all amounts due under the Credit Facility, which totaled $2.9 million of outstanding principal and interest.

(8) Commitments and Contingencies

In addition to the legal matters discussed in Note 11, the Company has or is subject to the following commitments and contingencies:

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.

Operating Leases

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 Company s facility in Broomfield, Colorado as of September 30, 2009 (in thousands):

Remainder of 2009	$ 58
2010	237
2011	244
2012	251
2013	127
Total future minimum rental payments	$ 917

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CardioDx, Inc.

In June 2006, the Company entered into a license agreement with CardioDx, Inc (CardioDx). 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.

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. LabCorp has the right to cancel the agreement and give the rights to the diagnostic back to the Company. 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.

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), 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 also has the obligation to make milestone payments of up to $5.0 million in the aggregate upon regulatory marketing approval in Europe and Japan. The Company s royalty obligation ranges from 12.5% to 25% of revenue from the related product based on achievement of specified product sales levels, including a 5% royalty that CPEC is obligated to pay under its original license agreement for Gencaro. The Company has the right to buy down the royalties to a range of 12.5% to 17% by making a payment to CPEC within six months of regulatory approval.

(9) Collaborative Agreements

The following collaborative agreement has 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. This funding commitment has been satisfied. 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 1 trial for NU172. If the Company enrolls the first patient in a Phase 2 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 3 study for any licensed compound, Archemix has the option to elect to participate in profits from sales of the compound by funding its pro rata share of prior and future product development and commercialization expenses, in lieu of receiving milestone payments and royalties with respect to that compound. 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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(10) 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

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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. See Note 7, Bank Note Payable, for discussion of the repayment of the Credit Facility.

(11) 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.

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. On July 15, 2009, the Court held a hearing on the motion to dismiss. On August 17, 2009, the Court granted in part and denied in part defendants motion. The Company filed its answer to plaintiff s complaint on October 1, 2009. Based on 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 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. The Company is involved in this litigation as a result of Nuvelo s merger with Variagenics in January 2003. On April 1, 2009 the parties entered into a settlement agreement. On October 5, 2009, the Court approved the settlement agreement. The Company s share of the settlement is approximately $385,000. Although the settlement has been approved, it has been appealed by members of the class. The Company 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 the Company could be forced to incur material expenses in the litigation if the parties cannot complete a settlement, and, in the event of an adverse outcome, the Company s business could be harmed.

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(12) Stock-based Compensation

Related to the Merger

In conjunction with the Merger, the Company discontinued grants under its 2004 Stock Option Plan effective January 27, 2009. As of September 30, 2009, options to purchase 564,997 shares with a weighted-average exercise price of $2.39 per share were outstanding under this 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 this 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. As of January 27, 2009, the date the Merger was consummated, 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. Subsequent to the Merger, the Company has granted stock-based compensation awards under the Equity Plan.

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. Employees involuntarily terminated in connection with the Merger 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. As of January 27, 2009, 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. As of January 27, 2009, 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 were not involuntarily terminated in connection with the Merger continued 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.

Stock Option Modification

As discussed above in Note 5, the restructuring plan implemented by the Company in the second quarter modified certain outstanding unvested stock options held by the affected employees. Outstanding stock options held by affected employees not formerly employed by Nuvelo were modified such that vesting was accelerated on outstanding options representing the number of options that would have vested in one year had such employees continued to provide service to the Company, and the post-termination exercise period of the outstanding stock options was extended to approximately one year. The Company accelerated the vesting on 55,441 stock options.

The Company estimated the fair value of the modified awards using the Black-Scholes model with the following inputs: 1 year expected term; 94% volatility, 0.52% risk-free interest rate, and 0% dividend yield. As a result, the Company recorded a net charge of $381,000 for the option acceleration.

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Summary of Option Activity and Expense

The Company granted options to purchase 1,670 and 491,974 shares of common stock in the three and nine months ended September 30, 2009, 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 and nine months ended September 30, 2009 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 September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
Expected term	6.4 years	6.0 years	6.4 years	6.0 years
Expected volatility	82%	62%	79%	62%
Risk-free interest rate	3.10%	3.31%	1.32%	3.15%
Expected dividend yield	0%	0%	0%	0%
Weighted-average grant date fair value per share	$ 2.65	$ 0.27	$ 3.21	$ 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 first quarter of 2009.

For the three and nine months ended September 30, 2009 and 2008 and for the period from Inception through September 30, 2009, the Company recognized the following non-cash, share-based compensation expense (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,		Period from December 17, 2001 (date of inception) to September 30,
	2009	2008	2009	2008	2009
Research and Development	$ 34	$ 60	$ 82	$ 72	$ 219
Selling, General and Administrative	78	20	317	49	851
Restructuring Expense			387		387

Total	$ 112	$ 80	$ 786	$ 121	$ 1,457

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(13) Income Taxes

In accordance with U.S. GAAP, 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.

(14) Subsequent Events

The Company has evaluated subsequent events for recognition or disclosure through the time of filing these consolidated financial statements on Form 10-Q with the SEC on November 16, 2009, and has not identified any such events.

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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 being developed for the treatment of chronic heart failure. Gencaro is an oral tablet formulation, dosed twice daily. ARCA currently holds worldwide rights to Gencaro.

Chronic heart failure, or HF, 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 with, 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 identified common genetic variations in the cardiac nervous system that it believes interact with Gencaro s pharmacology and may predict patient response. ARCA has collaborated with LabCorp to develop the Gencaro Test, a companion test for the genetic markers that may predict clinical response to Gencaro. LabCorp has developed the Gencaro Test to be run using a blood sample to provide prompt results to the treating physician. The Gencaro Test was submitted through the Premarket Approval, or PMA, process in January 2009.

Bucindolol was the subject of a major North America based heart failure Phase 3 trial, known as the BEST trial. In September 2008, the U.S. Food and Drug Administration (FDA) formally accepted for filing ARCA s New Drug Application (NDA) for Gencaro as a potential treatment for HF, based on the BEST trial. On May 29, 2009, the FDA issued a Complete Response Letter to ARCA which stated that it could not approve the Gencaro NDA in its current form and specified additional actions and information required by the FDA for approval of the NDA. In the Complete Response Letter, the FDA raised clinical effectiveness issues, asserting that the BEST trial does not adequately demonstrate efficacy of Gencaro in reducing all-cause mortality in patients with heart failure. The Complete Response Letter states that in order to obtain approval of Gencaro, among other things, ARCA must conduct an additional clinical efficacy trial of Gencaro in patients with heart failure.

ARCA is in the process of reviewing the Complete Response Letter with the FDA, including the necessary actions required to address the issues identified in the Complete Response Letter. As a result of these discussions, ARCA expects that it will be required to conduct a new multi-year active comparator superiority trial involving approximately 3,000 patients in a genotype-defined heart failure population to address the efficacy concerns raised in the Complete Response Letter. ARCA expects that it may be able to present additional clinical data to support the approval of Gencaro based on the achievement of a predefined result on an interim analysis in this clinical trial. ARCA intends to seek the use of the FDA s Special Protocol Assessment, or SPA, process to establish the design of the clinical trial, including trial size, clinical endpoints and/or data analyses that are acceptable to the FDA. As a result, FDA approval of Gencaro, if it occurs, will be substantially delayed.

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In addition to requiring an additional efficacy trial of Gencaro, the Complete Response Letter also required additional actions and raised additional issues. The Complete Response Letter states that ARCA must conduct additional clinical pharmacology studies to address drug-drug interaction and pharmacokinetic issues, and additional non-clinical studies to further characterize Gencaro metabolites. The Complete Response Letter also raised concerns regarding the integrity of the BEST data based on the FDA s audit of certain clinical sites involved in the BEST trial. ARCA is currently in discussions with the FDA regarding these additional actions and issues.

In light of the expected multi-year delay in obtaining FDA approval for Gencaro, if at all, the substantial additional costs associated with the development of Gencaro, including the costs associated with the expected additional clinical trial, the substantial cost of commercializing Gencaro if it is approved, and the need to raise a significant amount of capital on acceptable terms to finance the proposed clinical trial and ARCA s ongoing operations, ARCA has reduced its operating expenses, suspended its development activities for programs other than Gencaro, and is evaluating strategic alternatives. ARCA will need to complete a strategic transaction, such as a strategic combination or license of Gencaro commercialization rights, or raise substantial additional funding through public or private debt or equity markets to support the continued clinical development of Gencaro, including the expected additional clinical trial. Even if ARCA is able to fund continued development and Gencaro is approved, ARCA expects it will need to complete a strategic transaction or raise substantial additional funding through public or private debt or equity markets to successfully commercialize Gencaro.

If approved, ARCA believes that Gencaro will have market exclusivity under federal law 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.

Results of Operations

Research and Development Expenses

ARCA s research and development, or R&D, expenses were $1.1 million for the three months ended September 30, 2009 as compared to $3.8 million for the corresponding period of 2008, a decrease of $2.7 million. Substantially all of the costs for the 2009 quarter related to development of Gencaro. Costs for personnel, license fees, manufacturing, and clinical study projects decreased compared to the 2008 period. Personnel costs decreased approximately $750,000 due to the company s change in strategy and related restructuring implemented in the second quarter of 2009. Licensing fees decreased $500,000 because in third quarter of 2008, ARCA paid a milestone license fee for Gencaro of $500,000 in conjunction with its NDA submission. There was no similar fee during the comparable 2009 period. Manufacturing process development work decreased $525,000 for the 2009 quarter compared to 2008. In 2008 ARCA had significant projects underway in this area to support the NDA and prepare for commercialization. There were no projects of similar scale during the three months ended September 30, 2009. Clinical and regulatory project costs decreased approximately $710,000 compared to the same period in 2008. In 2008 ARCA had Phase I clinical studies underway and was preparing clinical sites for possible FDA inspection. The studies have been completed with no similar costs in the three months ended September 30, 2009, and clinical site audit preparation also decreased significantly in this period.

ARCA s R&D expenses were $9.2 million for the nine months ended September 30, 2009 as compared to $8.4 million for the corresponding period of 2008, an increase of approximately $850,000. For the nine months ended September 30, 2009, clinical study costs increased approximately $2.2 million for clinical development projects initiated by Nuvelo on the NU 172 and NU 206 compounds obtained in the Merger. These expenses consist primarily of pre-clinical studies ongoing during the nine month period, costs related to collaborative development arrangements assumed in the Merger, and personnel costs of former Nuvelo employees on transition plans. Employees on transition plans were employed for periods up to twelve weeks after the Merger to facilitate the transition of the business to ARCA. For the nine months ended September 30, 2009, ARCA s development expense under the collaboration agreement with Archemix totaled approximately $875,000. The obligation to fund such development expenses under the collaboration agreement concluded early in the third quarter of 2009. R&D costs associated with our development of Gencaro have decreased approximately $1.3 million in the nine months ended September 30, 2009 period compared to the same period of 2008. The decrease was primarily attributable to decreased spending on manufacturing and process control projects. During 2008 there were significant manufacturing process development projects in support of the NDA filing and in anticipation of commercial launch. There were no projects of similar scale during the nine months ended September 30, 2009.

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Research and development expenses for the remainder of 2009 are expected to vary depending primarily on the results of discussions with the FDA regarding the FDA s requirements for approval of the Gencaro NDA. For the remainder of 2009, ARCA expects its R&D activities and expenditures for product candidates other than Gencaro to be minimal. R&D expenses for the remainder of 2009 are expected to primarily include the following:

- consulting and advisory service costs in support of the NDA for Gencaro;
- continuation of manufacturing and process control projects for tableting and packaging of Gencaro for stability analysis in support of the NDA; and
- preparations and design of clinical work and other costs necessary to address the issues raised in the FDA s Complete Response Letter.

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, and costs of our restructuring plan implemented in the second quarter of 2009 are classified as restructuring expense on the consolidated statement of operations, and therefore are excluded from SG&A. Merger transaction costs and restructuring expenses are discussed below.

ARCA s SG&A expenses were $2.0 million for the three months ended September 30, 2009, as compared to $2.7 million for the corresponding period in 2008, a decrease of approximately $650,000. ARCA s SG&A expenses were $11.2 million for the nine months ended September 30, 2009, as compared to $6.0 million for the corresponding period of 2008, an increase of approximately $5.2 million.

Selling and marketing costs decreased approximately $1.1 million in the quarter compared to the comparable 2008 period. The decrease is the result of the change in strategy and restructuring plan implemented during the second quarter of 2009 in which ARCA s commercialization activities for Gencaro were terminated. General and administrative costs increased approximately $330,000 in this period, primarily related to lease obligations assumed in the Merger for Nuvelo facilities. Early termination of these facility leases were negotiated and paid during the quarter as part of the restructuring efforts. The additional costs for early termination of these leases are classified in restructuring expense on the consolidated statement of operations.

The increase in SG&A expenses for the nine months ended September 30, 2009 over the comparable 2008 period is primarily comprised of the following:

- $2.0 million of increased personnel costs, of which $770,000 relate to personnel cost for former Nuvelo employees that had transitional employment plans, generally for up to twelve weeks following the Merger, to facilitate the integration of business activities. The remainder of the increase in personnel costs is due to increased headcount from the comparable 2008 period in preparation for commercialization of Gencaro. The change in strategy and restructuring plan implemented during the second quarter of 2009 eliminated certain SG&A personnel.
- $1.8 million of increased costs related to legal, auditing and tax compliance, and insurance, incurred primarily to complete post-Merger transitions, corporate governance, transitional SEC filings, and Nasdaq fees associated with being a public company.
- $1.6 million of increased facilities expense primarily related to lease agreements assumed in the Merger for Nuvelo facilities. Early termination of these lease obligations were negotiated and paid during the third quarter of 2009 and are more fully described below under the Restructuring Expense caption.

SG&A expenses in the fourth quarter are expected to be comparable to the third quarter of 2009.

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Merger Transaction Costs

During the nine months ended September 30, 2009, ARCA expensed approximately $5.5 million in transaction costs related to the Merger. These costs are comprised primarily 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 ASC 805, these deferred transaction costs were expensed.

Restructuring Expense

In the second quarter of 2009, ARCA implemented a restructuring plan under which it terminated 44 employees from its R&D and SG&A functions. ARCA implemented the restructuring plan in connection with its previously announced strategy to seek strategic alternatives for commercializing Gencaro and to lower operating expenses to preserve capital resources. ARCA honored the Nuvelo, Inc. Change in Control Severance Benefit Plan for legacy Nuvelo employees affected; honored the employment agreement of one affected employee; and for the balance of affected employees, offered cash severance, acceleration of vesting on outstanding options representing the number of options that would have vested in one year had such employees continued to provide service, and an extension of the post-termination exercise period of the outstanding stock options to approximately one year.

As result of the restructuring plan, ARCA recorded a restructuring charge of $1.2 million for personnel-related termination costs in the second quarter of 2009, of which $795,000 relates to severance amounts to be paid in cash and $387,000 relates to the acceleration of vesting on outstanding stock options. In the third quarter of 2009, ARCA reduced the restructuring charge by $120,000 due to a change in estimate of severance costs. ARCA expects to complete all payments associated with these restructuring charges by the end of 2009.

During the third quarter of 2009, ARCA negotiated early terminations of the lease obligations related to the facilities in Sunnyvale, CA and San Carlos, CA, which were assumed in the Merger. The leases were terminated in consideration of payments by ARCA to the landlords consisting of: (i) retention by the landlords of security deposits totaling $1.0 million; (ii) cash payments totaling $5.4 million; (iii) draw down by the landlord of the Sunnyvale facility of the $6.0 million letter of credit previously issued to secure tenant obligations under the lease; and (iv) issuance of warrants to purchase ARCA s common stock with an estimated fair value of $377,000 in accordance with the provisions of the San Carlos facility lease termination. As a result of the early lease terminations, ARCA wrote-off the accrued facility exit cost balance relating to the Sunnyvale facility of $11.0 million and the unfavorable lease liability and deferred rent balances of $848,000 relating to the San Carlos facility, accrued transaction costs of $100,000, and recognized a net charge for terminating the leases of approximately $1.2 million. The $1.2 million net charge is classified as restructuring expense in the consolidated statement of operations.

As part of the restructuring and lease terminations, management reviewed excess computer and office equipment for impairment, and recorded for the three months and nine months ended September 30, 2009, impairment charges of $42,000 and $125,000, respectively, based on the excess of the carrying value over the estimated fair value less estimated costs to sell. The impairment charge is classified as restructuring expense in the consolidated statement of operations.

Gain on Bargain Purchase

In accordance with ASC 805, 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 for the nine months ended September 30, 2009 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.

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Interest and Other Income

Interest and other income was $13,000 in the three months ended September 30, 2009, as compared to $31,000 for the comparable 2008 period. Interest and other income was $217,000 for the nine months ended September 30, 2009, as compared to $204,000 for the comparable 2008 period. During both the three and nine month periods, the ARCA had higher investable balances representing the cash and investments acquired in the Merger. Despite the increase in cash and investments as a result of the Merger, interest and other income decreased for the three months ended September 30, 2009 compared to the same period in 2008 as a result of decreases in investment yields. The slight increase in interest income for the nine month period ended September 30, 2009 compared to the same period in 2008 resulted from the increase in cash and investments as a result of the Merger, offset by the lower investment yields. As ARCA s cash and investments are expected to decline due to requirements to fund future operations, ARCA expects interest income to decrease for the remainder of 2009.

Interest and Other Expense

Interest and other expense was $71,000 for the three months ended September 30, 2009, as compared to $21,000 for the comparable 2008 period. Interest and other expense was $184,000 for the nine months ended September 30, 2009, as compared to $60,000 for the comparable 2008 period. The increases in interest and other expense in the 2009 periods over the 2008 periods were primarily due to interest on the outstanding indebtedness under the Credit Facility and convertible notes. The convertible notes were converted into common stock upon closing of the Merger on January 27, 2009. The outstanding indebtedness under the Credit Facility was repaid in full in July 2009. Interest expense for the remainder of 2009 is expected to be minimal.

Liquidity and Capital Resources

Cash and Cash Equivalents

(in thousands)	September 30, 2009	December 31, 2008
Cash and cash equivalents	$ 10,642	$ 7,740

As of September 30, 2009, ARCA had total cash and cash equivalents of $10.6 million, as compared to $7.7 million as of December 31, 2008. The net increase of $2.9 million is primarily comprised of $45.5 million of cash, cash equivalents and marketable securities acquired in the Merger, offset by $38.8 million of cash used for operating activities and $3.9 million used for financing activities during the period.

Cash Flows from Operating, Investing and Financing Activities

(in thousands)	Nine Months Ended September 30, 2009	2008
Net cash (used in) provided by:		
Operating activities	$ (38,816)	$ (12,654)
Investing activities	45,623	(1,802)
Financing activities	(3,905)	4,051
Net increase (decrease) in cash and cash equivalents	$ 2,902	$ (10,405)

Net cash used in operating activities for the nine months ended September 30, 2009 increased $26.2 million compared with the 2008 period primarily due to increases in R&D and SG&A expenses, as well as $11.4 million of lease termination payments, $4.3 million of merger transaction costs, and $3.7 million of severance costs.

Net cash provided by investing activities for the nine months ended September 30, 2009 increased $47.4 million compared with the 2008 period primarily due to $30.4 million of cash acquired in the Merger and $15.1 million of proceeds from the sale of marketable securities, also acquired in the Merger.

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Net cash used in financing activities for the nine months ended September 30, 2009 primarily represents the repayment of $4.0 million related to the Credit Facility, compared with the 2008 period when $4.0 million was borrowed under the Credit Facility.

Sources and Uses of Capital

ARCA s primary source of liquidity to date has been capital raised from issuances of convertible promissory notes, shares of its common and preferred stock and funds provided by 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.

In light of ARCA s strategic direction and capital needs, ARCA implemented a plan of restructuring in the second quarter of 2009. ARCA implemented the restructuring plan in connection with its previously announced strategy to seek strategic alternatives for commercializing Gencaro and to lower operating expenses to preserve its capital resources.

In the third quarter of 2009, after giving consideration to future financing needs, forecasted cash balances, interest expense, covenants impacting liquidity, and lease payments on excess facilities, ARCA settled the following obligations:

In July 2009, ARCA repaid the balance due under the Credit Facility, consisting of $2.9 million of outstanding principal and interest.

In August 2009, ARCA and the landlord for the facility in Sunnyvale, CA entered into an agreement providing for the early termination of the lease agreement associated with the Sunnyvale facility. The lease was terminated effective July 31, 2009 in consideration of a termination payment to the landlord consisting of: (i) retention by the landlord of a security deposit in the amount of $543,000; (ii) the draw down by the landlord of full amount of the letter of credit in the amount of $6.0 million previously issued to secure tenant obligations under the lease; and (iii) an additional cash payment of $2.0 million. ARCA estimates net cash savings as a result of this lease termination to be approximately $2.6 million.

In September 2009, ARCA and landlord for the facility located in San Carlos, CA entered into an agreement providing for the early termination of the lease agreement dated January 11, 2005, as amended, and the issuance of a warrant to BioMed to purchase shares of common stock of ARCA. The lease was terminated effective September 18, 2009 in consideration of a termination payment to the landlord consisting of: (i) a cash payment of $3.4 million; (ii) retention by the landlord of a security deposit in the amount of $490,000; (iii) issuance to BioMed of a warrant to purchase 130,890 shares of common stock of ARCA at an exercise price of $3.82 per share, the closing price for ARCA s common stock on the Nasdaq Global Market on the date the agreement was executed; and (iv) the assignment to the landlord of a certain sublease dated January 17, 2008 of a portion of the San Carlos facility. ARCA estimates net cash savings as a result of this lease termination to be approximately $2.2 million.

In light of the expected multi-year delay in obtaining FDA approval for Gencaro, if at all, the substantial additional costs associated with the development of Gencaro, including the costs associated with the expected additional clinical trial, the substantial cost of commercializing Gencaro if it is approved, and the need to raise a significant amount of capital on acceptable terms to finance the proposed clinical trial and ARCA s ongoing operations, ARCA has reduced its operating expenses, suspended its development activities for programs other than Gencaro, and is evaluating strategic alternatives. ARCA will need to complete a strategic transaction, such as a strategic combination or license of Gencaro commercialization rights, or raise substantial additional funding through public or private debt or equity markets to support the continued development of Gencaro, including the expected additional clinical trial. Even if ARCA is able to fund continued development and Gencaro is approved, ARCA expects it will need to complete a strategic transaction or raise substantial additional funding through public or private debt or equity markets to successfully commercialize Gencaro.

ARCA believes that its cash and cash equivalents balance as of September 30, 2009 will be sufficient to fund its operations, at its current cost structure, through at least March 31, 2010. ARCA is unable to assert that its current cash and cash equivalents are sufficient to fund operations significantly beyond that date, and as a result, there is substantial doubt about ARCA s ability to continue as a going concern. The consolidated financial statements contained in this report have been prepared with the assumption that ARCA will continue as a going concern and will be able to realize its assets and

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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. ARCA may not be able to raise sufficient capital on acceptable terms or at all to continue development of Gencaro or to continue operations and may not be able to execute any strategic transaction.

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

- results of discussions with the FDA regarding the requirements for approval of the Gencaro NDA, particularly, the requirements for a new clinical trial and the costs and timing of such a trial;
- the market price of ARCA s stock and the availability and cost of additional equity capital from existing and potential new investors;
- general economic and industry conditions affecting the availability and cost of capital;
- ARCA s ability to control 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 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. ARCA also cannot predict what consideration might be available, if any, to ARCA or its stockholders, in connection with any strategic transaction. Should strategic alternatives or additional capital not be available to ARCA in the near term, or not be available on acceptable terms, ARCA may be unable to realize value from its assets and discharge its liabilities in the normal course of business which may, among other alternatives, cause ARCA to further delay, substantially reduce or discontinue operational activities to conserve its cash resources.

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 direct acting thrombin inhibitor that has completed Phase 1 development for use as a short-acting anticoagulant during medical or surgical procedures. A valuation firm was engaged to assist ARCA in determining the estimated fair value of this asset 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:

- projected development costs, timing of such costs, and outcomes of clinical trials,

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 annual test for impairment will be performed in the fourth quarter. The impairment test consists of a

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comparison of the fair value of the IPR&D with its carrying amount. If the carrying amount of the IPR&D exceeds its estimated 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.

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. There have not been any changes in ARCA s internal control over financial reporting during the third quarter of 2009 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. 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 has dedicated internal resources and engaged 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 in ARCA s Form 10-K for the year ended December 31, 2009.

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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. On July 15, 2009, the Court held a hearing on the motion to dismiss. On August 17, 2009, the Court granted in part and denied in part defendants motion. ARCA filed its answer to plaintiff s complaint on October 1, 2009. Based on 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 provider. However, it is possible that ARCA could be forced to incur material expenses in the litigation and, in the event of an adverse outcome, ARCA 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. ARCA is involved in this litigation as a result of Nuvelo s merger with Variagenics in January 2003. On April 1, 2009 the parties entered into a settlement agreement. On October 5, 2009, the Court approved the settlement agreement. ARCA s share of the settlement is approximately $385,000. Although the settlement has been approved, it has been appealed by members of the class. 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 complete a settlement, and, in the event of an adverse outcome, ARCA s business could be harmed.

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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 Business and Financial Condition

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

If ARCA is unable to raise sufficient additional capital or complete a strategic transaction, it may be unable to continue to fund its operations, develop Gencaro or its other product candidates, or 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. The consolidated financial statements contained in this report have been prepared with the assumption that ARCA will continue as 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. 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.

In light of the substantial costs and risks of conducting the expected additional clinical trial, the substantial delay in obtaining FDA approval for Gencaro, if at all, and the need to raise a significant amount of capital on acceptable terms to finance the proposed clinical trial and ARCA s ongoing operations, ARCA has reduced its operating expenses, suspended its development activities for programs other than Gencaro, and is evaluating strategic alternatives. ARCA will need to raise substantial additional funds through the public or private debt and equity markets or, alternatively, complete one or more strategic transactions, to continue development of and, if it is approved, commercialize Gencaro. If ARCA is unable to raise such financing or complete such a transaction, it may not be able to continue operations.

On May 29, 2009, the FDA issued a Complete Response Letter to ARCA which stated that it could not approve the Gencaro NDA in its current form and specified additional actions and information required by the FDA for approval of the NDA. ARCA is in the process of reviewing the Complete Response Letter with the FDA, including the necessary actions required to address the issues identified in the Complete Response Letter, which it expects will include conducting a new multi-year active comparator superiority trial involving approximately 3,000 patients in a genotype-defined heart failure population in addition to other actions. As a result of the issues identified in the Complete Response Letter and subsequent discussions, ARCA believes that FDA approval of Gencaro will occur, if at all, at least several years from now.

In light of the expected multi-year delay in obtaining FDA approval for Gencaro, if at all, the substantial additional costs associated with the development of Gencaro, including the costs associated with the expected additional clinical trial, the substantial cost of commercializing Gencaro if it is approved, and the need to raise a significant amount of capital on acceptable terms to finance the proposed clinical trial and ARCA s ongoing operations, ARCA has reduced its operating expenses, suspended its development activities for programs other than Gencaro, and is evaluating strategic alternatives. ARCA will need to complete a strategic transaction, such as a strategic combination or license of Gencaro commercialization rights, or raise substantial additional funding through public or private debt or equity markets to support the continued development of Gencaro, including the expected additional clinical trial. Even if ARCA is able to fund continued development and Gencaro is approved, ARCA expects it will need to complete a strategic transaction or raise substantial additional funding through public or private debt or equity markets to successfully commercialize Gencaro.

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ARCA believes that its cash and cash equivalents balance as of September 30, 2009 will be sufficient to fund its operations, at its current cost structure, through at least March 31, 2010. ARCA is unable to assert that its current cash and cash equivalents are sufficient to fund operations significantly beyond that date, and as a result, there is substantial doubt about ARCA s ability to continue as a going concern. As a result of the significant additional required development of Gencaro, including the additional clinical trial, ARCA may not be able to raise sufficient capital on acceptable terms, or at all, to continue development of Gencaro or to continue operations and may not be able to execute any strategic transaction.

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

- results of discussions with the FDA regarding the requirements for approval of the Gencaro NDA, particularly, the requirements for a new clinical trial and the costs and timing of such a trial;
- the market price of ARCA s stock and the availability and cost of additional equity capital from existing and potential new investors;
- general economic and industry conditions affecting the availability and cost of capital;
- ARCA s ability to control costs associated with its operations;
- the costs of filing, prosecuting, defending and enforcing 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 dilution to ARCA s stockholders. If ARCA raises additional funds through the incurrence of 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. ARCA also cannot predict what consideration might be available, if any, to ARCA or its stockholders, in connection with any strategic transaction. Should strategic alternatives or additional capital not be available to ARCA in the near term, or not be available on acceptable terms, ARCA may be unable to realize value from its assets and discharge its liabilities in the normal course of business which may, among other alternatives, cause ARCA to further delay, substantially reduce or discontinue operational activities to conserve its cash resources.

If ARCA is not able to successfully develop and obtain FDA approval 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. Gencaro is ARCA s only product candidate at a late stage of clinical development. In September 2008, the FDA accepted for filing the Gencaro NDA. On May 29, 2009, the FDA issued a Complete Response Letter to ARCA, which stated that the FDA could not approve the Gencaro NDA in its current form and specified additional actions and information required by the FDA for approval of the NDA. As a result of issues identified in the Complete Response Letter, FDA approval of Gencaro, if it occurs, is expected to require years of additional clinical development, including a new multi-year active comparator superiority trial involving approximately 3,000 patients in a genotype-defined heart failure population. Clinical trials in heart failure are typically lengthy, complex and expensive and ARCA does not currently have the resources to fund such a trial.

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 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.

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Even if approved for sale, a product candidate must be successfully commercialized to generate value. ARCA does not currently have the capital resources or management expertise to commercialize Gencaro and, as a result, will need to complete a strategic transaction, or, alternatively, raise substantial additional funds to enable commercialization of Gencaro, if it is approved. Failure to successfully provide for the commercialization of Gencaro, if it is approved, would damage ARCA s business.

**** ARCA expects to seek agreement with the FDA as to the use of a special protocol assessment, or SPA, relating to its expected new active comparator superiority trial for Gencaro. ARCA may not be able to obtain approval of an SPA, and even if ARCA does obtain such approval, the use of an SPA does not guarantee any particular outcome from regulatory review of the clinical trial or Gencaro, including any regulatory approval.***

FDA approval of Gencaro, if it occurs, is expected to require years of additional clinical development, including a new multi-year active comparator superiority trial involving approximately 3,000 patients in a genotype-defined heart failure population. Prior to the commencement of this clinical trial, ARCA intends to attempt to reach agreement with the FDA under the special protocol assessment, or SPA, process on the design of such clinical trial. The SPA process allows for FDA evaluation of a clinical trial protocol intended to form the primary basis of an efficacy claim in support of a new drug application, and provides a binding agreement that the design of the clinical trial, including trial size, clinical endpoints and/or data analyses, are acceptable to the FDA. ARCA cannot assure you that it will be able to successfully negotiate an SPA with the FDA regarding this new clinical trial. In addition, an SPA agreement is not a guarantee of approval, and ARCA cannot assure you that the design of, or data collected from, the new Gencaro trial will be adequate to address the concerns raised by the FDA in the Complete Response Letter or obtain the requisite regulatory approvals for Gencaro. Further, an SPA agreement is not binding on the FDA if public health concerns unrecognized at the time the SPA agreement is entered into become evident, other new scientific concerns regarding product safety or efficacy arise, or if ARCA fails to comply with the agreed upon trial protocols. In addition, an SPA agreement may be changed by ARCA or the FDA on written agreement of both parties, and the FDA retains significant latitude and discretion in interpreting the terms of an SPA agreement and the data and results from the new Gencaro trial. As a result, ARCA does not know how the FDA will interpret the parties respective commitments under any SPA agreement, how it will interpret the data and results from the new Gencaro trial, or whether Gencaro will receive any regulatory approvals as a result of any SPA agreement it may enter into with the FDA or the new clinical trial.

Based on discussions with the FDA, ARCA expects that an SPA agreement with respect to the new Gencaro trial, if it is reached, may provide for ARCA s presentation of additional clinical data to support the approval of Gencaro based on the achievement of a predefined result on an interim analysis in this clinical trial. ARCA cannot assure you that any SPA agreement for the new Gencaro trial will provide for such interim analysis, or that any such data will be adequate to address the concerns raised by the FDA in the Complete Response Letter or obtain the requisite regulatory approval for Gencaro.

****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, including the anticipated additional clinical trial for Gencaro, 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. ARCA has never conducted a clinical trial and does not currently have sufficient staff with the requisite experience to do so, and ARCA expects therefore that it will have to rely on contract research organizations to conduct its clinical trials. While certain ARCA employees have experience in designing and administering clinical trials, these employees have no such experience since being with ARCA.

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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 expects to rely on contract research organizations to conduct clinical trials, and as a result, will be unable to directly control the timing, conduct and expense of clinical trials.***

ARCA expects that it, or any strategic partners, will rely primarily on third parties to conduct clinical trials, including the clinical trial that it expects will be necessary to respond to the FDA s requirements in the Complete Response Letter. As a result, ARCA will have less control over the conduct of the clinical trials, the timing and completion of the trials, the required reporting of adverse events and the management of data developed through the trials than would be the case if it were relying entirely upon its own staff. Communicating with outside parties can also be challenging, potentially leading to mistakes as well as difficulties in coordinating activities. Outside parties may have staffing difficulties, may undergo changes in priorities or may become financially distressed, adversely affecting their willingness or ability to conduct ARCA s trials. ARCA may experience unexpected cost increases that are beyond its control. Problems with the timeliness or quality of the work of a contract research organization may lead ARCA or any strategic partner to seek to terminate the relationship and use an alternative service provider. However, making this change may be costly and may delay ongoing trials, and contractual restrictions may make such a change difficult or impossible. Additionally, it may be impossible to find a replacement organization that can conduct clinical trials in an acceptable manner and at an acceptable cost.

Even if ARCA does use a contract research organization to conduct clinical trials, ARCA will have to devote substantial resources and rely on the expertise of its employees to manage the work being done by the contract research organization. ARCA has never conducted a clinical trial and does not currently have sufficient staff with the requisite experience to do so. The inability of ARCA s staff to adequately manage any contract research organization that it hires may exacerbate the risks associated with relying on a contract research organization.

****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;

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patient referral practices of physicians;

availability of clinical trial sites; and

other clinical trials seeking to enroll subjects with similar profiles.

If 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 any product, milestone and royalty revenues under collaboration agreements, if any, and could impose significant additional costs on ARCA or on any future collaborators.

ARCA is currently pursuing a strategic transaction, such as a potential combination or license of Gencaro commercialization rights, which may divert attention from the development of Gencaro. The failure to enter into a strategic transaction may materially and adversely affect ARCA s business.

Unless ARCA is able to raise substantial additional funding through other means, ARCA will need to complete a strategic transaction to continue the development of Gencaro. The strategic transactions that ARCA may consider include a potential combination or license of Gencaro commercialization rights. ARCA s board of directors and management team has and will need to devote substantial time and resources to the consideration and implementation of any such strategic transaction. In addition, the continued disruption in the financial markets may lead to an increased number of biotechnology companies that are also seeking to enter into strategic transactions, which may limit ARCA s ability to negotiate favorable terms for any such transaction. Further, ARCA s current employees do not have experience in the strategic transaction process, and its previous efforts to enter into a strategic transaction have not been successful. As a result of these and other factors, there is substantial risk that ARCA may not be able to complete a strategic transaction on favorable terms, or at all. The failure to complete a strategic transaction may materially and adversely affect ARCA s business.

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 September 30, 2009, ARCA had 7,604,976 shares of common stock outstanding, 20% of which is approximately 1,521,000 shares. To the extent ARCA seeks to raise funds through a private offering of stock, convertible debt or similar instruments, it may be limited in how much funding it could raise privately without requiring a stockholder vote.

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. ARCA expects to continue to incur significant and increasing operating losses for the foreseeable future. Even if ARCA ultimately receives regulatory approval for Gencaro or its other product candidates, sales of such products may not generate sufficient revenue for it to achieve or maintain profitability. 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 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 submission of responses to the Complete Response Letter, 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

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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. FDA approval of Gencaro, if it occurs, is expected to require years of additional clinical development, including the completion of a new multi-year active comparator superiority trial involving approximately 3,000 patients in a genotype-defined heart failure population. 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.

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, and subsequent advertising, promotion, sale, marketing, and distribution, if approved, 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 Gencaro or any of its other 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. On May 29, 2009, the FDA issued a Complete Response Letter to ARCA which stated that the FDA could not approve the Gencaro NDA in its current form and specified additional actions and information required by the FDA for approval of the NDA. ARCA is in the process of reviewing the Complete Response Letter with the FDA, including the necessary actions required to address the issues identified in the Complete Response Letter, which it expects will include, among other things, completion of a new multi-year active comparator superiority trial involving approximately 3,000 patients in a genotype-defined heart failure population. As a result of the issues identified in the Complete Response Letter, FDA approval of Gencaro, if it occurs, is expected to require years of additional clinical development. Even if ARCA conducts additional studies and submits the attendant data requested in the Complete Response Letter, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval.

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;

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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 or permit ARCA to make claims of superiority over currently marketed competitive products. 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.

The manufacture and tableting of Gencaro is done by third party suppliers, who must also pass a pre-approval inspection of their facilities before ARCA can obtain marketing approval.

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;

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- 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 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.

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.

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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.

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;

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seek an injunction;

pursue criminal prosecutions;

close the facilities of ARCA s contract manufacturers; or

impose civil or criminal penalties.

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.

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 the 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.

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

Commercialization of Gencaro, particularly the establishment of a sales organization, will require substantial additional capital resources. 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. None of ARCA s current employees have experience in establishing and managing a sales force.

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, if it is approved, may be delayed indefinitely and ARCA may be unable 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

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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, if approved in a timely manner, would 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.

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 board of directors and executive management, including its Chairman of the Board, Richard B. Brewer, and its President and Chief Executive Officer, Michael R. Bristow. The loss of the services of any such individual might seriously harm ARCA s product development, partnering and financing efforts. Recruiting and training personnel with the requisite skills is challenging and ARCA competes for talent with companies that are larger and have more financial resources.

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. 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.

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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, ARCA may be unable to obtain FDA approval for Gencaro or the product sales and profitability of Gencaro may suffer.***

LabCorp is ARCA s single-source supplier of the Gencaro Test and has the right to terminate its agreement with ARCA for any reason. If LabCorp or its third party suppliers were to terminate their agreement with ARCA or 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 complete any additional clinical trials with Gencaro or 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 complete clinical development of Gencaro, including the expected additional clinical trial or to commercialize Gencaro if it is ultimately approved, either of which could 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

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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.

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.

****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:

- conduct an additional clinical trial and develop and obtain regulatory approval for Gencaro or other product candidates;
- successfully partner a companion genetic test with the commercial launch of Gencaro;

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enter into a strategic transaction enabling the continued development and commercialization of Gencaro, or alternatively, raise significant additional capital to enable these activities;

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

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

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.

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, if approved, would 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 has applied 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. 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.

****Health care reform measures could materially and adversely affect ARCA s business.***

In the United States and in foreign jurisdictions there have been, and ARCA expects that there will continue to be, a number of legislative and regulatory proposals aimed at changing the health care system. ARCA is unable to predict what additional legislation or regulation, if any, relating to the health care industry or third-party coverage and reimbursement may be enacted in the future or what effect such legislation or regulation would have on its business. For example, 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 government payors, such as Medicare and Medicaid, private health insurers, including managed care organizations, and other third-party payors, and any change in reimbursement levels from those currently existing could materially and adversely affect ARCA s business. The pendency or approval of such proposals or reforms could result in a decrease in ARCA s stock price or limit its ability to raise capital or to complete a strategic transaction.

****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 product candidates and obtain all requisite regulatory approvals in a cost-effective manner;

build an adequate sales and marketing infrastructure, raise additional funding, or enter into strategic transactions enabling the commercialization of its products;

develop competitive formulations of its product candidates;

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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. For the remainder of 2009, ARCA expects its research and development activities other than those associated with Gencaro will be limited. If ARCA is not able to substantially expand 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.

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 be 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 its 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.

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

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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.

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

Business activity across a wide range of industries and regions has 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 ARCA s workforce;
- increased price competition, which may adversely affect the revenue and gross margins ARCA anticipates from any of its product candidates, once commercialized;
- financial strain on the health care system, which may lead to lower than anticipated sales of ARCA s product candidates, once commercialized;
- the bankruptcy or insolvency of ARCA s 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 ARCA s business, results of operations and financial condition.

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 3 trials for the treatment of acute peripheral arterial occlusion and in the first of two planned Phase 3 trials for the treatment of catheter occlusion, the closing price of one share of Nuvelo s common stock was $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

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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. On July 15, 2009, the Court held a hearing on the motion to dismiss. On August 17, 2009, the Court granted in part and denied in part defendants motion. ARCA filed its answer to plaintiff s complaint on October 1, 2009. Based on 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 provider. However, it is possible that ARCA could be forced to incur material expenses in the litigation 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. On April 1, 2009 the parties entered into a settlement agreement and have filed a motion to approve the settlement with the Court. On October 5, 2009, the Court approved the settlement agreement. ARCA s share of the settlement is approximately $385,000. Although the settlement has been approved, it has been appealed by members of the class. 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 complete a settlement, and, in the event of an adverse outcome, ARCA s business could be harmed.

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

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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 Bristol-Myers Squibb Company (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.

Certain intellectual property licensed by ARCA, including the diagnostic rights to key genetic markers used in development of the Gencaro Test licensed from CardioDx, Inc. and sublicensed by ARCA to LabCorp, are the subject of additional licensing arrangements to which the party that has licensed rights to ARCA is subject. If such parties were to breach the terms of such licenses or such licenses were otherwise to terminate, ARCA s and its partners rights to use such technology and develop and commercialize their products such as the Gencaro Test may terminate and ARCA s business would be materially harmed.

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.

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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 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. Regardless of merit, the listing of potential patents in the FDA Orange Book for Gencaro may be challenged as being improperly listed. ARCA may have to defend against such claims and possible associated antitrust issues. 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 a $_{2c}$ 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. If the label with the genotype information for Gencaro is not approved, or if generic labels are not required to copy the approved label, competitors could have an easier path to introduce bioequivalent products and ARCA s business may suffer. 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.

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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. Litigation may even be necessary to defend disputes of inventorship or ownership of proprietary rights. The defense and prosecution of intellectual property lawsuits, U.S. Patent and Trademark Office interference proceedings, and related legal and administrative proceedings (e.g., a reexamination) 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. Adverse outcomes in patent litigation may potentially subject ARCA to antitrust litigation which, regardless of the outcome, would adversely affect ARCA s business. 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.

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 owned approximately 38% of the outstanding common stock of ARCA as of September 30, 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.

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 secure substantial additional funding or complete a strategic transaction or to complete development of and commercialize Gencaro;

the results of ARCA s future clinical trials and any future NDAs of its current and future product candidates;

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- 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 September 30, 2009, ARCA had 7,604,976 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 September 30, 2009, there were approximately 1.0 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.

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As of September 30, 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 occur, they would dilute ARCA s current stockholders equity interests and could 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.

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 outstanding 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.

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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 three 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.

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ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS
Not applicable.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES
Not applicable.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS
Not applicable.

ITEM 5. OTHER INFORMATION
Amendment and Restatement of Bylaws

On November 13, 2009, ARCA s board of directors adopted an amendment and restatement of ARCA s bylaws in order to, among other things, (i) allow for certain notices to be provided by electronic transmission, (ii) conform certain provisions regarding stockholder written consents, (iii) amend provisions related to officer compensation in order to allow such compensation to be fixed by a committee of the board of directors or an officer designated by ARCA s board of directors, and (iv) eliminate a requirement that ARCA s board of directors approve any loan. In lieu of a filing under Item 5.03 of Form 8-K, ARCA is making this filing under Item 5 of this Quarterly Report on Form 10-Q.

The above description of the amendments to the bylaws is qualified in its entirety by reference to the complete text of the bylaws, as amended and restated, a copy of which is attached hereto as Exhibit 3.2 to this Quarterly Report of Form 10-Q and is incorporated herein by reference.

Amendment and Restatement of Code of Business Conduct and Ethics

On November 13, 2009, ARCA s board of directors adopted an amended and restated Code of Business Conduct and Ethics (the Ethics Code), which applies to all of ARCA s directors, officers and employees and supersedes and replaces ARCA s prior Code of Business Conduct and Ethics in its entirety. The new Ethics Code was enacted, among other reasons, to (i) reflect the Company s new name, (ii) add certain introductory comments to the Ethics Code, (iii) conform certain references to how violations of the Ethics Code will be addressed to the procedures in ARCA s Complaint and Investigation Policy and Procedures, (iv) add certain provisions relating to the protection of ARCA s intellectual property and confidential information, (v) amend certain policies regarding the acceptable value of gifts, (vi) recommend that employees take questions or concerns regarding the applicability of the Ethics Code to ARCA s Compliance Officer, in addition to that employee s supervisor, and (vii) change certain provisions regarding communications related to investigational drugs. In lieu of a filing under Item 5.05 of Form 8-K, ARCA is making this filing under Item 5 of this Quarterly Report on Form 10-Q. None of the amendments constitute a waiver of any provision of the Ethics Code on behalf of ARCA s Chief Executive Officer, Chief Financial Officer, or Controller.

The foregoing summary of the amendments to the Ethics Code is subject to and qualified in its entirety by reference to the full text of the Ethics Code, as amended and restated, a copy of which is attached hereto as Exhibit 14.1 to this Quarterly Report on Form 10-Q and is incorporated herein by reference.

The Ethics Code is also located on ARCA s website at www.arcabiopharma.com in the section titled Investors, under the subsection titled Corporate Governance. If ARCA makes any further substantive amendments to the Ethics Code or grants any waiver from a provision of the Ethics Code to any executive officer or director, ARCA will promptly disclose the nature of the amendment or waiver on its website and file any Current Report on Form 8-K required by applicable law or Nasdaq listing standards. The information contained on or accessible through ARCA s internet website shall not be deemed to be part of this Quarterly Report on Form 10-Q.

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ITEM 6. EXHIBITS

The following documents are filed as part of this quarterly report on Form 10-Q. The Company will furnish a copy of any exhibit listed to requesting stockholders upon payment of the Company s reasonable expenses in furnishing those materials.

Exhibit Number	Description
2.1	Agreement and Plan of Merger and Reorganization, dated as of September 24, 2008, among Nuvelo, Inc., Dawn Acquisition Sub, Inc. and ARCA biopharma, Inc.(1)
2.2	Amendment No. 1 to Agreement and Plan of Merger and Reorganization dated October 28, 2008, by and among Nuvelo, Inc., Dawn Acquisition Sub, Inc. and ARCA biopharma, Inc.(2)
3.1	Amended and Restated Certificate of Incorporation of the Registrant, as amended.(3)
3.2*	Second Amended and Restated Bylaws of the Registrant.
4.1	Form of Common Stock Certificate.(4)
4.2	Warrant to Purchase Stock Agreement, dated July 17, 2007, by and between ARCA Discovery, Inc. and Silicon Valley Bank.(3)
4.3	Amendment No. 1 to Warrant to Purchase Stock Agreement, dated February 19, 2009, by and between ARCA biopharma, Inc. and SVB Financial Group.(3)
4.4	Warrant to Purchase Stock Agreement, dated August 19, 2008, by and between ARCA biopharma, Inc. and Silicon Valley Bank.(3)
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4.6	Warrant to Purchase Stock Agreement, dated October 10, 2008, by and between ARCA biopharma, Inc. and Boulder Ventures IV, L.P.(3)
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4.10	Warrant to Purchase Stock Agreement, dated October 10, 2008, by and between ARCA biopharma, Inc. and InterWest Partners IX, LP.(3)
4.11	Amendment No. 1 to Warrant to Purchase Stock Agreement, dated February 19, 2009, by and between ARCA biopharma, Inc. and InterWest Partners IX, LP.(3)
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4.16	Warrant to Purchase Stock Agreement, dated October 10, 2008, by and between ARCA biopharma, Inc. and Skyline Venture Partners Qualified Purchaser Fund IV, L.P.(3)
4.17	Amendment No. 1 to Warrant to Purchase Stock Agreement, dated February 19, 2009, by and between ARCA biopharma, Inc. and Skyline Venture Partners Qualified Purchaser Fund IV, L.P.(3)

10.1*	Lease Surrender and Termination Agreement, dated August 5, 2009, by and between ARCA biopharma, Inc. and The Irvine Company LLC.

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10.2	Lease Termination and Warrant Purchase Agreement, dated September 18, 2009, by and between ARCA biopharma, Inc., BMR-201 Industrial Road LLC and BioMed Realty, L.P.(5)
14.1*	Code of Business Conduct and Ethics.
31.1*	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. sec. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

* Filed herewith.

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

(2) Previously filed with the SEC as an Exhibit to and incorporated herein by reference from Nuvelo, Inc. s Form 8-K, filed October 29, 2008, File No. 000-22873.

(3) Previously filed with the SEC as an Exhibit to and incorporated herein by reference from ARCA biopharma, Inc. s Form 10-K, filed on March 27, 2009, File No. 000-22873.

(4) Previously filed with the SEC as an Exhibit to and incorporated herein by reference from ARCA biopharma, Inc. s Form 8-K, filed on January 28, 2009, File No. 000-22873.

(5) Previously filed with the SEC as an Exhibit to and incorporated herein by reference from ARCA biopharma Inc. s Form 8-K, filed September 24, 2009, File No. 000-22873.

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SIGNATURE

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

ARCA biopharma, Inc. (Registrant)

By: /s/ KATHRYN E. FALBERG
Kathryn E. Falberg
Chief Financial Officer and Chief Operating Officer
Dated: November 16, 2009

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4.16	Warrant to Purchase Stock Agreement, dated October 10, 2008, by and between ARCA biopharma, Inc. and Skyline Venture Partners Qualified Purchaser Fund IV, L.P.(3)
4.17	

Amendment No. 1 to Warrant to Purchase Stock Agreement, dated February 19, 2009, by and between ARCA biopharma, Inc. and Skyline Venture Partners Qualified Purchaser Fund IV, L.P.(3)

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10.1*	Lease Surrender and Termination Agreement, dated August 5, 2009, by and between ARCA biopharma, Inc. and The Irvine Company LLC.
10.2	Lease Termination and Warrant Purchase Agreement, dated September 18, 2009, by and between ARCA biopharma, Inc., BMR-201 Industrial Road LLC and BioMed Realty, L.P.(5)
14.1*	Code of Business Conduct and Ethics.
31.1*	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. sec. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

* Filed herewith.

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

(2) Previously filed with the SEC as an Exhibit to and incorporated herein by reference from Nuvelo, Inc. s Form 8-K, filed October 29, 2008, File No. 000-22873.

(3) Previously filed with the SEC as an Exhibit to and incorporated herein by reference from ARCA biopharma, Inc. s Form 10-K, filed on March 27, 2009, File No. 000-22873.

(4) Previously filed with the SEC as an Exhibit to and incorporated herein by reference from ARCA biopharma, Inc. s Form 8-K, filed on January 28, 2009, File No. 000-22873.

(5) Previously filed with the SEC as an Exhibit to and incorporated herein by reference from ARCA biopharma Inc. s Form 8-K, filed September 24, 2009, File No. 000-22873.