ARCA biopharma, Inc.
Form 10-Q
August 15, 2011
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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 JUNE 30, 2011

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 x 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 August 11, 2011: 10,516,333

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ARCA BIOPHARMA, INC.

FORM 10-Q

FOR THE QUARTER ENDED JUNE 30, 2010

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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)

	June 30, 2011	December 31, 2010
	(in thousands, except share and per share amounts)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 7,463	$ 7,025
Other current assets	364	137
Total current assets	7,827	7,162
Property and equipment, net	490	690
Other assets	264	304
Total assets	$ 8,581	$ 8,156
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 517	$ 388
Accrued compensation and employee benefits	115	175
Accrued expenses and other liabilities	339	506
Deferred rent, current portion	33	121
Total current liabilities	1,004	1,190
Deferred rent, net of current portion	32	195
Total liabilities	1,036	1,385
Commitments and contingencies		
Preferred Stock:		
Preferred stock, $0.001 par value; 5 million shares authorized; none issued and outstanding as of June 30, 2011 and December 31, 2010		
Stockholders equity:		
Common stock, $0.001 par value; 100 million shares authorized; 10,515,707 and 8,834,535 shares issued and outstanding at June 30, 2011 and December 31, 2010, respectively	11	9
Additional paid-in capital	67,756	65,072
Deficit accumulated during the development stage	(60,222)	(58,310)
Total stockholders equity	7,545	6,771

Total liabilities and stockholders equity	$ 8,581	$ 8,156

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 June 30,		Six Months Ended June 30,		Period from December 17, 2001 (date of inception) to June 30, 2011
	2011	2010	2011	2010	
	(in thousands, except share and per share amounts)				
Costs and expenses:					
Research and development	$ 497	$ 700	$ 1,187	$ 1,520	$ 40,457
Selling, general and administrative	1,207	1,569	2,719	3,197	37,029
Merger transaction costs					5,470
Restructuring expense, net					2,413
Loss on impairment of in-process research and development					6,000
Total costs and expenses	1,704	2,269	3,906	4,717	91,369
Loss from operations	(1,704)	(2,269)	(3,906)	(4,717)	(91,369)
Gain on bargain purchase					25,282
Gain on assignment of patent rights	2,000		2,000		2,000
Interest and other income		1	1	2	2,025
Interest and other expense	(2)	(2)	(7)	(4)	(441)
Income (loss) before income taxes	294	(2,270)	(1,912)	(4,719)	(62,503)
Benefit from income taxes					2,281
Net income (loss)	$ 294	$ (2,270)	$ (1,912)	$ (4,719)	$ (60,222)
Less: Accretion of redeemable convertible preferred stock					(245)
Less: Deemed preferred stock dividend for additional common shares issuable under anti-dilution provisions					(781)
Net income (loss) available to common stockholders	$ 294	$ (2,270)	$ (1,912)	$ (4,719)	$ (61,248)
Net loss available to common stockholders per share:					
Basic	$ 0.03	$ (0.26)	$ (0.20)	$ (0.58)	
Diluted	$ 0.03	$ (0.26)	$ (0.20)	$ (0.58)	

Weighted average shares outstanding:				
Basic	10,129,328	8,732,837	9,477,206	8,189,663
Diluted	10,250,178	8,732,837	9,477,206	8,189,663

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

Series B offering Costs				(147)					
Accretion of Series A offering costs		19					(19)		(19)
Accretion of Series B offering costs				18			(18)		(18)
Issuance of common stock for intellectual property license rights, on January 18, 2007 at $1.68 per share					7,817		13		13
Issuance of common stock for intellectual property license rights, 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)
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				781			(781)		(781)

anti-dilution provision								
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 with Nuvelo, Inc.					2,686,957	3	11,910	11,913
Adjustment for fractional shares					(609)			
Share-based compensation							845	845
Issuance of common stock upon exercise of stock options for cash					63,123		114	114
Issuance of common stock under employee stock purchase plan and upon vesting of restricted stock units					1,064		2	2
Estimated fair value of warrants issued in connection with lease termination							377	377
Net loss								(9,138) (9,138)
Balance, December 31, 2009					7,620,448	8	57,294	(49,890) 7,412
Issuance of common stock for cash, net of offering costs					1,164,600	1	7,181	7,182
Issuance of common stock upon exercise of stock options for cash					49,487		139	139
Share-based compensation							458	458
Net loss								(8,420) (8,420)
Balance, December 31, 2010					**8,834,535**	**9**	**65,072**	**(58,310) 6,771**
Issuance of common stock for cash, net of offering costs					1,681,172	2	2,531	2,533
Share-based compensation							153	153
Net loss								(1,912) (1,912)
Balance, June 30, 2011	**$**		**$**		**10,515,707**	**$ 11**	**$ 67,756**	**$ (60,222) $ 7,545**

See accompanying notes to consolidated financial statements.

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ARCA BIOPHARMA, INC.

(a development stage enterprise)

CONSOLIDATED STATEMENTS OF CASH FLOWS

(unaudited)

	Six Months Ended June 30,		Period from December 17, 2001 (date of inception) to June 30, 2011
	2011	2010	
		(in thousands)	
Cash flows used in operating activities:			
Net loss	$ (1,912)	$ (4,719)	$ (60,222)
Adjustments to reconcile net loss to net cash used in operating activities:			
Gain on bargain purchase			(25,282)
Gain on patent rights assignment	(2,000)		(2,000)
Depreciation and amortization	195	171	1,330
Non-cash interest expense			211
Share-based compensation	153	224	2,127
Issuance of warrants for lease termination			377
Accretion of liabilities			152
Impairment of property and equipment			125
Impairment of in-process research and development			6,000
Write-off of deferred tax liability			(2,281)
Gain on marketable securities available for sale			(263)
(Gain) loss from disposal of property and equipment	5	(4)	72
Other, net			267
Change in operating assets and liabilities (net of amounts acquired):			
Other current assets	(81)	(12)	2,447
Other assets	40		7,206
Accounts payable	129	(254)	(1,673)
Accrued expenses and other liabilities	(325)	(521)	(19,089)
Deferred rent	(251)	(55)	65
Net cash used in operating activities	(4,047)	(5,170)	(90,431)
Cash flows (used in) provided by investing activities:			
Cash received from Merger			30,392
Payment of deferred transaction costs			(1,186)
Purchase of property and equipment	(1)	(2)	(1,861)
Proceeds from sale of marketable securities			15,369
Proceeds from sale of property and equipment	1	6	334
Proceeds from assignment of patent rights	2,000		2,000
Net cash (used in) provided by investing activities	2,000	4	45,048
Cash flows (used in) provided by financing activities:			
Proceeds from issuance of convertible notes payable and related warrants for common stock			10,841
Proceeds from issuance of bank note payable			4,000
Proceeds from stock subject to repurchase			38
Proceeds from the issuance of preferred stock			32,316

Preferred stock offering costs			(246)
Proceeds from the issuance of common stock	3,000	7,658	10,855
Payment of offering costs	(467)	(338)	(805)
Repayment of principal on bank note payable			(4,000)
Repayment of principal on convertible notes payables			(105)
Repayment of principal on vendor finance agreement	(48)		(48)
Net cash (used in) provided by financing activities	2,485	7,320	52,846
Net (decrease) increase in cash and cash equivalents	438	2,154	7,463
Cash and cash equivalents, beginning of period	7,025	7,763	
Cash and cash equivalents, end of period	$ 7,463	$ 9,917	$ 7,463
Supplemental cash flow information:			
Interest paid	$ 2	$ 4	$ 109
Supplemental disclosure of noncash investing and financing transactions:			
Accrued interest on notes payable converted to equity	$	$	$ 163
Warrant issued in connection with credit facility	$	$	$ 111
Accrued deferred transaction costs	$	$	$ 482
Vendor finance agreement	$ 147	$	$ 147

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, Development Stage, and Basis of Presentation

Description of Business

ARCA biopharma, Inc., or the Company or ARCA, a Delaware corporation, is headquartered in Broomfield, Colorado and is principally focused on developing genetically-targeted therapies for cardiovascular diseases. The Company s lead product candidate, Gencaro™ (bucindolol hydrochloride), a pharmacologically unique beta-blocker and mild vasodilator, is being developed for the treatment of chronic heart failure, or HF, and the prevention of atrial fibrillation, or AF in patients with HF. The Company has identified common genetic variations in the cardiovascular system that it believes interact with Gencaro s pharmacology and may predict patient response. The Company has collaborated with LabCorp to develop the Gencaro Test, a companion test for the genetic markers that identify these common genetic variations.

The Company has licensed exclusive, worldwide rights to Gencaro and has been granted patents in the U.S. and Europe for methods of treating HF and cardiac arrhythmia patients, which includes AF patients, with bucindolol based on genetic testing, which it believes will provide market exclusivity for Gencaro into at least 2025 in those markets. In addition, the Company believes that if Gencaro is approved, the U.S. Gencaro patent, as well as the patents issued in Europe, will be eligible for patent term extension which, if granted in the U.S., could provide an additional period of market exclusivity in the U.S. of approximately three years, and if granted in Europe could provide an additional five years of market exclusivity.

In September 2008, the U.S. Food and Drug Administration, or FDA, formally accepted for filing the New Drug Application, or NDA, for Gencaro as a potential treatment for HF. In May 2009, the FDA notified the Company through a Complete Response Letter, or CRL, that its NDA for Gencaro was not approvable in its current form, and specified additional actions and information required for approval of the NDA including conducting an additional Phase 3 clinical trial. In May 2010, the Company reached agreement with the FDA on a Special Protocol Assessment, or SPA, for the design of an additional Phase 3 clinical trial to assess the safety and efficacy of Gencaro in approximately 3,200 patients with HF who have the genotype that appears to respond most favorably to Gencaro. The Company believes the SPA agreement would permit this trial, if successful, to serve as the clinical effectiveness basis for the approval of Gencaro in HF. In light of the substantial costs associated with the Phase 3 clinical HF trial, the Company will not initiate the trial until such time as government funding, or a strategic transaction, such as a strategic combination or partnership is secured or the planned AF trial is completed.

The Company is planning to initiate a Phase 3 clinical study of Gencaro in AF patients with HF and left ventricular dysfunction, and believes AF is an attractive indication for Gencaro because data from the BEST trial, the previously conducted Phase 3 HF trial involving Gencaro in 2,708 HF patients, suggest Gencaro may have a potentially significant effect in reducing and/or preventing AF. Based on the BEST trial, the Company believes Gencaro s prevention of AF in HF patients is pharmacogenetically regulated, similar to the effects on HF clinical endpoints, and plans to enroll approximately 300-400 patients with recent onset AF who have the genotype that appears to respond most favorably to Gencaro. The Company anticipates that the trial could begin approximately 6 months after the Company obtains sufficient funding.

To support the continued development of Gencaro, including the additional proposed clinical trials, the Company will need to raise substantial additional funding through public or private debt or equity transactions or a strategic combination or partnership, or government funding.

ARCA also holds exclusive rights to rNAPc2, a potent, long-acting recombinant protein anticoagulant with a unique mechanism of action involving inhibition of tissue factor. Previously, preclinical studies of rNAPc2 demonstrated potential efficacy against two of the most deadly strains of hemorrhagic fever virus, Ebola and Marburg. The Company is currently seeking government or third party funding to further develop rNAPc2 as a potential treatment for viral hemorrhagic fevers and other diseases involving the tissue factor pathway of coagulation. Considering the substantial cost associated with the development of rNAPc2 and ARCA s limited financial resources, further development of rNAPc2 will be dependent upon receipt of government or third party funding, which may not be available.

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, raising capital necessary to fund its operations and Phase 3 AF trial and exploring strategic alternatives for further developing Gencaro. 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 and regulatory approval of commercially viable products, the need to raise

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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 well as through the business combination with Nuvelo, Inc., or Nuvelo.

Since ARCA was founded on December 17, 2001, or Inception, the Company has incurred substantial losses and negative cash flows from operations. Since Inception, the Company incurred a loss from operations of $91.4 million and had negative cash flows from operations of $90.4 million.

In light of the substantial additional time and costs associated with the development of Gencaro and the need to raise a significant amount of capital on acceptable terms to finance the additional clinical trial(s) and the Company s ongoing operations, the Company is seeking to raise substantial additional funding through public or private debt or equity transactions or a strategic combination or partnership, or government funding to support the continued development of Gencaro, including any additional clinical trials. In April 2011, the Company raised $2.5 million, net of offering costs, through the sale of our common stock, and may seek additional funding that could allow it to operate while it continues to pursue strategic combination, partnering, additional financing and licensing opportunities. If the Company is delayed in completing or is unable to complete additional funding and/or a strategic transaction, the Company may discontinue its development activities or discontinue its operations.

The Company believes its cash and cash equivalents balance as of June 30, 2011, will be sufficient to fund its operations through March 31, 2012. The Company is unable to assert that its current cash and cash equivalents are sufficient to fund operations beyond that date, and as a result, there is substantial doubt about the Company s ability to continue as a going concern beyond March 31, 2012 These 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. The Company may not be able to raise sufficient capital on acceptable terms, or at all, to continue development of Gencaro or to otherwise continue operations and may not be able to execute any strategic transaction.

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:

- the costs and timing for an additional clinical trial in order to gain possible FDA approval for Gencaro;
- the market price of the Company s stock and the availability and cost of additional equity capital from existing and potential new investors;
- the Company s ability to retain the listing of its common stock on the Nasdaq Capital Market;
- general economic and industry conditions affecting the availability and cost of capital;
- potential receipt of government or third party funding to further develop Gencaro or rNAPc2;
- the Company 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 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 accompanying unaudited consolidated financial statements of the Company were prepared in accordance with generally accepted accounting principles for interim financial information and instructions to Form 10-Q and Rule 10-01 of Regulation S-X. Accordingly, these financial statements do not include all of the information and footnotes required by accounting principles generally accepted in the United States of America for complete financial statements. In the opinion of management, these financial statements include all normal and recurring adjustments considered necessary for a fair presentation of these interim consolidated financial statements. The

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results of operations for the three months and six months ended June 30, 2011 are not necessarily indicative of results expected for the full year ending December 31, 2011. These unaudited consolidated financial statements should be read in conjunction with the audited consolidated financial statements and footnotes thereto for the year ended December 31, 2010 included in the Company s Annual Report on Form 10-K filed with the Securities and Exchange Commission. Amounts presented are rounded to the nearest thousand, where indicated, except per share data and par values.

Concentrations of Credit Risk

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

Accrued Expenses

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

(2) Earnings (Loss) Per Share

The Company calculates basic earnings per share by dividing (loss) earnings available 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 available 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.

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 June 30, 2011	Three Months Ended June 30, 2010	Six Months Ended June 30, 2011	Six Months Ended June 30, 2010
Net income (loss) available to common shareholders	$ 294	$ (2,270)	$ (1,912)	$ (4,719)
Weighted average shares of common stock outstanding	10,146,026	8,749,535	9,493,904	8,206,361
Less: Weighted-average shares of unvested common stock	(16,698)	(16,698)	(16,698)	(16,698)
Total weighted-average shares used in computing net income (loss) per share attributed to common stockholders	10,129,328	8,732,837	9,477,206	8,189,663
Basic earnings (loss) per share	$ 0.03	$ (0.26)	$ (0.20)	$ (0.58)
DILUTED				
Net income (loss)	$ 294	$ (2,270)	$ (1,912)	$ (4,719)
Net income (loss) available to common shareholders	$ 294	$ (2,270)	$ (1,912)	$ (4,719)
Weighted average shares outstanding	10,129,328	8,732,837	9,477,206	8,189,663

Dilutive impact of stock plans	120,850			
Dilutive shares outstanding	10,250,178	8,732,837	9,477,206	8,189,663
Diluted earnings (loss) per share	$ 0.03	$ (0.26)	$ (0.20)	$ (0.58)

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Potentially dilutive securities representing 1.9 million and 1.3 million weighted average shares of common stock were excluded for the three months ended June 30, 2011 and 2010, respectively, and 1.7 million and 1.3 million for the six months ended June 30, 2011 and 2010, respectively, because including them would have an anti-dilutive effect on net earnings (loss) per share.

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

On January 27, 2009, ARCA Colorado, Inc. (ARCA Colorado) completed the Merger with Nuvelo in accordance with the terms of 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., and its common stock began trading on the Nasdaq Global Market under the symbol ABIO on January 28, 2009. On March 7, 2011, the listing of the Company s common stock was transferred from the Nasdaq Global Market to the Nasdaq Capital Market.

The Merger was 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 was considered to have acquired Nuvelo in the Merger, as the stockholders of ARCA Colorado prior to the Merger had a controlling interest in the combined company and the Company s management is the former management of ARCA Colorado. The results of operations and cash flows include the activities of Nuvelo since the date of the Merger. Pursuant to the rules and regulations of the United States Securities and Exchange Commission, or the SEC, the historical financial statements of ARCA Colorado replaced the historical financial statements of Nuvelo, 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.

The estimated total acquisition consideration of $11.9 million to acquire Nuvelo was 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. The Company estimated the net assets acquired in the Merger to be $37.2 million, including $45.5 million of cash, cash equivalents and marketable securities. In accordance with ASC 805, any excess of fair value of net assets acquired in a business combination over the acquisition consideration results in a gain on bargain purchase, and as a result, the Company recorded a gain on bargain purchase of $25.3 million.

(4) Fair Value Disclosures

As of June 30, 2011, the Company had $7.5 million of cash equivalents consisting of money market funds with maturities of 90 days or less. The Company has the ability to liquidate these investments without restriction. The Company determines fair value for these money market funds and equity securities with Level 1 inputs through quoted market prices. There were no transfers of assets between fair value hierarchy levels during the three-month or six-month periods ended June 30, 2011.

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 quoted prices that are observable for the asset or liability

Level 3 Unobservable inputs for the asset or liability

Fair Value of Other Financial Instruments

The carrying amount of other financial instruments, including cash, accounts payable, and short-term notes payable approximated fair value due to their short maturities.

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(5) Property and Equipment

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

	Estimated Life	June 30, 2011	December 31, 2010
Computer equipment	3 years	$ 189	$ 206
Lab equipment	5 years	142	142
Furniture and fixtures	5 years	393	398
Computer software	3 years	176	176
Leasehold improvements	Lesser of useful life or life of the lease	746	744
		1,646	1,666
Less accumulated depreciation and amortization		(1,156)	(976)
		$ 490	$ 690

As more fully described in *Note 6 Operating Leases*, the Company amended its office lease during the quarter ended June 30, 2011. The lease amendment resulted in a change in the estimated useful lives for existing leasehold improvements and certain furniture and fixtures, effectively shortening the estimated lives significantly. The affected assets will be amortized over approximately four months in accordance with the Company s anticipated office move. The accounting impact of this change in estimate was immaterial for the six months ended June 30, 2011.

For the six months ended June 30, 2011 and June 30, 2010, and for the period from Inception through June 30, 2011, depreciation and amortization expense was $195,000, $171,000, and $1.3 million respectively.

During the quarter and six months ended June 30, 2011, the Company entered into an agreement in which it assigned certain patent rights to a large pharmaceutical company. In exchange for the patent rights, the Company received a $2.0 million cash payment during the quarter.

(6) Commitments and Contingencies

In addition to the legal matters discussed in Note 9, 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, 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. On June 14, 2011, the Company entered into a first amendment (the Amendment) to the lease agreement. Under the terms of the Amendment, the Company and its landlord have mutually agreed for the Company to relocate from its current office suite of approximately 15,000 square feet, to another suite within the same building, comprising approximately 4,500 square feet. The office location will continue to serve as the Company s primary business office. The Amendment also modifies the annual per square foot rate of rent and allows the Company to terminate with three months notice. As part of the agreement, the Company made a one-time payment to the landlord of $200,000, which the landlord has agreed to use for the landlord s improvements in the new leased premises. The original five year term of the Lease remains unchanged.

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Under the original lease, the Company received tenant improvement reimbursements from the landlord totaling $593,000 which were recorded as deferred rent and were amortized as reductions to rent expense. The $200,000 payment made to the landlord in conjunction with the Amendment is recorded against the existing deferred rent. The net deferred rent balance is being amortized as reductions to rent expense over the remaining term of the lease. The unamortized deferred rent balance as of June 30, 2011 was $65,000.

Rent expense under this lease for the six months ended June 30, 2011 and 2010 was $70,000, and $61,000, respectively, and was $387,000 from Inception through June 30, 2011.

Below is a summary of the future minimum lease payments committed for the Company s facility in Broomfield, Colorado as of June 30, 2011 (in thousands):

Remainder of 2011	$ 96
2012	81
2013	40
Total future minimum rental payments	$ 217

University of Cincinnati

In April 2011, the Company entered into a license agreement with the University of Cincinnati to license exclusive worldwide rights to a portfolio of U.S. and international patents, which includes certain U.S. and international diagnostic patents covering genetic markers for ARCA s lead drug candidate, Gencaro. These patents provide the basis for exclusive worldwide development, use and commercialization of the genetic test which may indicate a patient s likely response to Gencaro as a treatment for chronic HF, AF, and other indications. Under the terms of the agreement, ARCA agreed to pay the University of Cincinnati annual license fees of $15,000 and is obligated to future milestone payments for each United States patent issued subsequent to the date of the agreement. The agreement also requires royalty payments on net sales from genetic testing performed expressly for the purpose of prescribing bucindolol. The Company s potential future royalty obligations have been transferred through a sublicense of rights to Laboratory Corporation of America. If LabCorp does not fulfill its royalty payment and other fee obligations, the Company is responsible for the payments.

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 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. 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 to 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.

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Dendreon

In February 2004, Nuvelo obtained exclusive worldwide rights to all indications of rNAPc2 and all other rNAP molecules owned by Dendreon Corporation as a result of a licensing agreement entered into with them. Under the terms of the agreement, Nuvelo paid Dendreon an upfront fee of $4.0 million ($0.5 million in cash and $3.5 million in Nuvelo common stock) in 2004. Future milestone payments to Dendreon could reach as much as $2.5 million if rNAPc2 is successfully developed and all commercialization milestones are achieved for the indication of treatment for Ebola virus infection. In addition, such milestones could reach as much as $23.5 million if rNAPc2 is developed and commercialized for indications other than Ebola virus infection. ARCA currently cannot predict if or when any of these milestones will be achieved. If rNAPc2 is commercialized, ARCA will be responsible for paying royalties to Dendreon based on sales of rNAPc2.

(7) Equity Distribution Agreement

On December 8, 2009, the Company entered into an equity distribution agreement, or the Agreement, with Wedbush Securities Inc., or the Agent, under which the Company could, from time to time, offer and sell its common stock through the Agent. On April 30, 2010, the Company amended the Agreement to permit it to sell up to an aggregate of $20 million in shares, which were registered on a registration statement on Form S-3 (File No. 333-148288). In the year ended December 31, 2010, the Company sold 1,164,600 shares of common stock under this Agreement and realized $7.2 million of proceeds, net of $338,000 of offering costs. On May 23, 2011 the Company terminated this agreement. No shares of common stock were sold during 2011 under this agreement.

(8) Registered Direct Offering

On April 18, 2011, the Company entered into a placement agency agreement with Roth Capital Partners, LLC (the Placement Agent), pursuant to which the Placement Agent agreed to use its reasonable efforts to arrange for the sale of up to 1,680,672 shares of ARCA s common stock and warrants to purchase up to 1,176,471 shares of ARCA s common stock in a registered direct public offering (the Offering). The Company paid the Placement Agent an aggregate fee equal to 7% of the gross proceeds received in the Offering and reimbursed the Placement Agent for its expenses incurred in connection with the Offering, with a maximum expense reimbursement that, when aggregated with the 7% fee, did not exceed 8% of the gross proceeds received by the Company.

On April 18, 2011, ARCA entered into separate subscription agreements (the Subscription Agreements) with certain institutional investors (the Investors) in connection with the Offering, pursuant to which ARCA sold an aggregate of 1,680,672 shares of its common stock and warrants to purchase a total of 1,176,471 shares of its common stock to the Investors for aggregate gross proceeds, before deducting fees to the Placement Agent and other estimated offering expenses payable by the Company, of approximately $3.0 million. The net proceeds to the Company after deducting placement agent fees and offering expenses were approximately $2.5 million and the Offering closed on April 21, 2011.

The common stock and warrants were sold in units, with each unit consisting of one share of common stock and a warrant to purchase 0.7 shares of common stock. The purchase price per unit was $1.785. Subject to certain ownership limitations, the warrants are exercisable on October 21, 2011 and will remain exercisable for five years thereafter at an exercise price of $2.52 per share. The exercise price of the warrants is subject to adjustment in the case of stock splits, stock dividends, combinations of shares and similar recapitalization transactions.

(9) Legal Matters

On February 9, 2007, Nuvelo and certain of Nuvelo s former and then 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. In July 2007, the Court granted Nuvelo s motion to transfer the cases to the Northern District of California. The cases were consolidated with the original lawsuit, and plaintiffs filed a 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. On June 12, 2008, the Court held a hearing on the motion to dismiss. On December 4, 2008, the Court issued an order dismissing plaintiffs 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.

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On December 29, 2010, ARCA and the other defendants reached a settlement of the litigation with the plaintiffs, after participating in mediation before a retired federal judge. On February 25, 2011, the parties entered into a settlement agreement, which was submitted to the Court for approval. ARCA s insurance carriers have agreed to fund the settlement, subject to a reservation of rights by one carrier. On June 20, 2011 the court issued a final judgment and order approving the settlement of, and dismissing with prejudice, the purported securities class action lawsuit. On July 25, 2011 the order became effective when no appeals or motions to alter or amend the judgment were filed. Members of the class are bound by the settlement and the release therein, which prevents them from ever asserting any related claims against the defendants. Although ARCA s insurance carriers have agreed to pay most of the legal fees that have been incurred in defending this litigation, ARCA has separately agreed with its legal counsel to pay $167,000 in legal defense costs incurred, but only if ARCA obtains additional funding of at least $10 million in 2011. If ARCA does not obtain such additional funding in 2011, ARCA will have no such payment obligation.

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 its 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.

(10) Share-based Compensation

For the three-month and six- month periods ended June 30, 2011 and 2010 and for the period from Inception through June 30, 2011, the Company recognized the following non-cash, share-based compensation expense in the consolidated statement of operations (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,		Period from December 17, 2001 (date of inception) to June 30, 2011
	2011	2010	2011	2010	
Research and Development	$ 30	$ 33	$ 60	$ 62	$ 439
Selling, General and Administrative	45	86	93	162	1,301
Restructuring					387
Total	$ 75	$ 119	$ 153	$ 224	$ 2,127

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The fair values of employee stock options granted in the three- and six-month periods ended June 30, 2011 and 2010 were estimated at the date of grant using the Black-Scholes model with the following assumptions:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2011	2010	2011	2010
Expected term	5.8 years	*	5.8 years	5.7 years
Expected volatility	110%	*	110%	85%
Risk-free interest rate	2.20%	*	2.20%	2.70%
Expected dividend yield	0%	*	0%	0%
Weighted-average grant date fair value per share	$ 1.83	*	$ 1.83	$ 2.01

* No options were granted during the three months ended June 30, 2010.

Stock option transactions for the six-month period ended June 30, 2011 under all plans are as follows:

	# of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Options outstanding at December 31, 2010	953,238	$ 31.87	7.06	$ 764,622
Changes during the period:				
Granted	164,700	2.24		
Exercised	(500)	1.83		
Forfeited, cancelled or expired	(196,614)	137.45		
Options outstanding at June 30, 2011	920,824	$ 4.05	7.29	$ 160,167
Options exercisable at June 30, 2011	574,181	$ 4.75	6.40	$ 160,167
Options vested and expected to vest	899,314	$ 4.08	7.22	$ 160,167

(11) 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. The Company believes its tax filing positions and deductions related to tax periods subject to examination will be sustained upon audit and, therefore, has no reserve for uncertain tax positions.

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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, the prospects for further development of rNAPc2 or other non-Gencaro product candidates 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, plan, anticipate, believe, intend, 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, 2010. Actual results and performance could also differ materially from time to time from those projected in our filings with the SEC.

The terms ARCA, we, us, our and similar terms refer to ARCA biopharma, Inc.

Overview

ARCA biopharma, Inc., or the Company or ARCA, a Delaware corporation, is headquartered in Broomfield, Colorado and is principally focused on developing genetically-targeted therapies for cardiovascular diseases. Our lead product candidate, Gencaro™ (bucindolol hydrochloride), a pharmacologically unique beta-blocker and mild vasodilator, is being developed for the treatment of chronic heart failure, or HF, and for the prevention of atrial fibrillation, or AF, in patients with HF. We have identified common genetic variations in the cardiovascular system that we believe interact with Gencaro s pharmacology and may predict patient response. We have collaborated with LabCorp to develop the Gencaro Test, a companion test for the genetic markers that identify these common genetic variations.

We have licensed exclusive, worldwide rights to Gencaro and have been granted patents in the U.S. and Europe for methods of treating HF and cardiac arrhythmia patients, which includes AF patients, with bucindolol based on genetic testing, which we believe will provide market exclusivity for Gencaro into at least 2025 in those markets. In addition, we believe that if Gencaro is approved, the U.S. Gencaro patent, as well as the patents issued in Europe, will be eligible for patent term extension which, if granted in the U.S., could provide an additional period of market exclusivity in the U.S. of approximately three years, and if granted in Europe, could provide an additional five years of market exclusivity.

In September 2008, the U.S. Food and Drug Administration, or FDA, formally accepted for filing the New Drug Application, or NDA, for Gencaro as a potential treatment for HF. In May 2009, the FDA notified us through a Complete Response Letter, or CRL, that our NDA for Gencaro was not approvable in its current form, and specified additional actions and information required for approval of the NDA including conducting an additional Phase 3 clinical trial. In May 2010, we reached agreement with the FDA on a Special Protocol Assessment, or SPA, for the design of an additional Phase 3 clinical trial to assess the safety and efficacy of Gencaro in approximately 3,200 patients with HF who have the genotype that appears to respond most favorably to Gencaro. We believe the SPA agreement would permit this trial, if successful, to serve as the clinical effectiveness basis for the approval of Gencaro in HF. In light of the substantial costs associated with the Phase 3 clinical HF trial, we do not plan to initiate the trial until such time as government funding, or a strategic transaction, such as a strategic combination or partnership is secured or the planned AF trial is completed.

We are planning to initiate a Phase 3 clinical study of Gencaro in AF patients with heart failure and left ventricular dysfunction. We believe AF is an attractive indication for Gencaro because data from the previously conducted Phase 3

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HF trial involving Gencaro in 2,708 HF patients, or the BEST HF trial, suggest Gencaro may have a potentially significant effect in reducing and/or preventing AF. Based on the BEST trial we believe Gencaro s prevention of AF in HF patients is pharmacogenetically regulated, similar to the effects on HF clinical endpoints, and plan to enroll approximately 300-400 patients with recent onset AF who have the genotype that appears to respond most favorably to Gencaro. We anticipate that the trial could begin approximately 6 months after we obtain sufficient funding.

Atrial fibrillation is a disorder in which the normally regular and coordinated contraction pattern of the heart s two small upper chambers (the atria) becomes irregular and uncoordinated. The irregular contraction pattern associated with AF causes blood to pool in the atria, predisposing the formation of clots. These clots may travel from the heart and become lodged in the arteries leading to the brain and other organs, thereby blocking necessary blood flow and potentially resulting in stroke. AF is considered an epidemic cardiovascular disease that affects approximately 2-3 million Americans, making it one of the most common heart rhythm disorders.

The AF clinical trial is designed to be a multi-center, randomized, double-blind clinical trial to assess the safety and efficacy of Gencaro in AF patients with left ventricular dysfunction/HF, with the primary endpoint being time to recurrent symptomatic AF after direct current cardioversion. The planned AF trial is designed to compare Gencaro to the beta-blocker metoprolol CR/XL in the genotype (homozygous arginine position 389 of the beta-1 adrenergic receptor), or the genotype the Company believes responds most favorably to Gencaro. Metoprolol CR/XL does not appear to be enhanced in patients with this genotype. Data from the BEST trial indicate that Gencaro may have a potentially significant effect in reducing and/or preventing AF, and this effect may be one that is regulated genetically, similar to the effect we believe Gencaro has on heart failure. The entire cohort of patients in the BEST trial that were treated with Gencaro had a 41% reduction in the risk of new onset atrial fibrillation (time-to-event) compared to placebo ($p = 0.0004$), based on an analysis of adverse events and surveillance ECGs. In the DNA sub study, patients with the most favorable genotype for Gencaro experienced a 74% ($p = 0.0003$) reduction in risk of atrial fibrillation, based on the same analysis. This most favorable genotype was present in about 47% of the patients in the sub study, and we estimate it is present in about 50% of the US general population. We believe the AF study would take approximately two and one half years from enrollment of the first patient through completion. We believe there is an unmet medical need for new AF treatments that have fewer side effects than currently available therapies and are more effective, particularly in patients with HF where most of the approved drugs are contra-indicated or have warnings in their prescribing information.

To support the continued development of Gencaro, including the additional proposed clinical trials, we will need to raise substantial additional funding through public or private debt or equity transactions or a strategic combination or partnership, or government funding. If we are delayed in completing or are unable to complete additional funding, we may discontinue our development activities on Gencaro or discontinue our operations. We believe our cash and cash equivalents balance as of June 30, 2011 will be sufficient to fund our operations, at our current cost structure, through March 31, 2012. We are unable to assert that our current cash and cash equivalents are sufficient to fund operations beyond that date, and as a result, there is substantial doubt about our ability to continue as a going concern beyond March 31, 2012. We may not be able to raise sufficient capital on acceptable terms or at all to continue development of Gencaro or to otherwise continue operations and may not be able to execute any additional funding transactions.

We also hold exclusive rights to rNAPc2, a single-chain, small recombinant protein. rNAPc2 is a potent, long acting, selective inhibitor of signaling by tissue factor, the protein responsible for initiating the extrinsic coagulation pathway, the primary coagulation mechanism in humans. rNAPc2 was originally developed as a cardiovascular therapy for thrombosis and other indications. As a result, it has an extensive human clinical record, and has been safely tested in over 700 human patients in nine Phase 1 and Phase 2 clinical trials. Previously, pilot studies of

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rNAPc2 conducted in non-human primates showed evidence of potential efficacy against lethal hemorrhagic viruses. We are currently seeking government funding to further develop rNAPc2, as a potential treatment for viral hemorrhagic fevers and other afflictions involving hemorrhagic disease syndromes. Considering the substantial cost associated with the development of rNAPc2 and our limited financial resources, further development of rNAPc2 will be dependent upon receipt of government or third party funding, which may not be available.

We have exclusive patent rights to other compounds that have potential indications in cardiovascular disease, oncology and other therapeutic areas, some of which are in early and others of which are in later stage development, . We are seeking partners to assist us in the development of these compounds.

Results of Operations

Research and Development Expense

Research and development, or R&D, expense was $497,000 for the three months ended June 30, 2011 as compared to $700,000 for the corresponding period in 2010, a decrease of approximately $203,000. R&D expense was $1,187,000 for the six months ended June 30, 2011 as compared to $1,520,000 for the corresponding period of 2010, a decrease of $333,000. R&D expense decreased $106,000 for the three months and $191,000 for the six months ended June 30, 2011 due to reduced personnel costs and because certain pre-clinical studies in process during the comparative periods of 2010 were concluded with no similar costs in 2011. Regulatory and manufacturing process costs decreased by $97,000 for the three months and $142,000 for the six months ended June 30, 2011 compared to the corresponding period in 2010 due to reduced personnel costs and the conclusion of certain Gencaro related regulatory activities in the 2010 period.

R&D expenses in 2011 are expected to be less than in 2010 due to a workforce reduction completed during the first quarter and are expected to be primarily related to Gencaro and our development of the clinical program for AF. However, R&D expenses are contingent upon our ability to raise substantial additional funding through public or private debt or equity transactions or a strategic combination or partnership, or government funding. Should we receive funds from one or a combination of these sources, R&D expense in future periods could be substantially higher to support increased activities.

Selling, General and Administrative Expense

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

SG&A expense was $1.2 million for the three months ended June 30, 2011 as compared to $1.6 million for the corresponding period in 2010, a decrease of $362,000. For the six months ended June 30, 2011, SG&A expense was $2.7 million as compared to $3.2 million in the corresponding period of 2010, a decrease of $478,000. The decreases in the three month and six month periods is comprised of reduced personnel, consulting, legal and accounting expenses, as a result of our reduced operations. SG&A expenses in 2011 are expected to decrease from 2010 levels as a result of our reduction in workforce completed during the first quarter, but are contingent upon our ability to raise substantial additional funding through public or private debt or equity transactions or a strategic combination or partnership, or government funding. Should we receive funds from one or a combination of these sources, SG&A expense in future periods could be substantially higher to support increased activities.

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Merger Transaction Costs

These costs were exclusive to 2009 during which we expensed nearly $5.5 million in transaction costs related to the Merger. These costs were comprised of financial advisory fees paid upon completion of the Merger and legal fees incurred in 2009 totaling approximately $3.8 million. Prior to December 31, 2008 we incurred merger transaction expenses, including legal, accounting and due diligence costs of approximately $1.7 million. These costs were recorded on our consolidated balance sheet as deferred transaction costs on December 31, 2008. On January 1, 2009, as part of our adoption of ASC 805, these deferred transaction costs were expensed.

Restructuring Expense

These costs were exclusive to 2009, during which we implemented a restructuring plan under which we terminated 44 employees from our research and development and selling, general and administrative functions, in the second quarter of 2009. The restructuring plan was implemented in connection with our strategy to seek strategic alternatives for commercializing Gencaro, rather than establish our own internal sales, marketing and distribution capabilities and to lower operating expenses to preserve capital resources. As result of the restructuring plan, we recorded a restructuring charge of $1.1 million for personnel-related termination costs and completed all payments associated with these charges in 2009.

Also during 2009, we negotiated early terminations of the lease obligations related to the facilities which were assumed in the Merger, resulting in a net charge of approximately $1.2 million. As part of the restructuring and lease terminations, management reviewed excess computer and office equipment for impairment, and recorded impairment charges of $125,000 in 2009, 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

This gain was exclusive to 2009. In accordance with ASC 805, any excess of fair value of acquired net assets over the acquisition consideration in a business combination results in a gain on bargain purchase, and as a result, we recorded a gain on bargain purchase of $25.3 million in connection with the Merger. The acquisition consideration was largely determined by the trading price of Nuvelo s common stock on the Nasdaq prior to the Merger, which we believed was the most reliable measure of the consideration effectively transferred to effect the acquisition of Nuvelo. We believe 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.

Gain on Assignment of Patent Rights

During the quarter and six months ended June 30, 2011 we entered into an agreement in which we assigned certain patent rights to a large pharmaceutical company. In exchange for the patent rights we received a $2.0 million payment during the quarter. There are no similar transactions in the comparative periods of 2010.

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Interest and Other Income

Interest and other income was zero in the three months ended June 30, 2011 and $1,000 in the six months ended June 30, 2011 as compared to $1,000 and $2,000, respectively, in the three months and six months ended June 30, 2010. We expect interest income to continue to be nominal in 2011 due to low investment yields and declining cash, cash equivalent, and investment balances.

Interest and Other Expense

Interest and other expense was $2,000 in the three months ended June 30, 2011 and $7,000 in the six months ended June 30, 2011 as compared to $2,000 and $4,000, respectively, in the three months and six months ended June 30, 2010. Based on our current capital structure, interest expense for 2011 is expected to be minimal.

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Liquidity and Capital Resources

Cash and Cash Equivalents

	June 30, 2011	December 31, 2010
	(in thousands)	
Cash and cash equivalents	$ 7,463	$ 7,025

As of June 30, 2011, we had total cash and cash equivalents of approximately $7.4 million, as compared to $7.0 million as of December 31, 2010. The net increase of $438,000 in the six month period reflects cash from investing activities of $2.0 million and net proceeds from financing activities of $2.5 million, less cash used to fund operating activities of approximately $4.1 million.

Cash Flows from Operating, Investing and Financing Activities

	Six Months Ended June 30	
	2011	2010
	(in thousands)	
Net cash (used in) provided by:		
Operating activities	$ (4,047)	$ (5,170)
Investing activities	2,000	4
Financing activities	2,485	7,320
Net increase (decrease) in cash and cash equivalents	$ 438	$ 2,154

Net cash used in operating activities for the six months ended June 30, 2011 decreased approximately $1.1 million compared with the 2010 period primarily due to decreased R&D and SG&A expenses discussed above.

Net cash flows from investing activities in the six months ended June 30, 2011 and 2010 were $2 million and $4,000, respectively, and represents proceeds from the assignment of patent rights in the current period and the sale of property and equipment in the 2010 period.

Net cash provided by financing activities of $2.5 million for the six months ended June 30, 2011 is the net proceeds from the sale of our common stock completed in April 2011. In the six months ended June 30, 2010, the $7.3 million of cash provided by financing activities is comprised of $7.2 million of net proceeds from the sale of our common stock and $138,000 of proceeds received upon exercise of stock options.

Sources and Uses of Capital

Our primary sources of liquidity to date have been capital raised from issuances of shares of our common and preferred stock, issuance of convertible promissory notes, and funds provided by the Merger. The primary uses of our 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.

Considering the substantial additional time and costs associated with the development of Gencaro and our need to raise a significant amount of capital on acceptable terms to finance the additional clinical trial(s) and our ongoing operations, we

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are evaluating strategic alternatives for funding our continued operations and development programs. We will need to raise substantial additional funding through public or private debt or equity transactions or a strategic combination or partnership, or government funding to support the continued clinical development of Gencaro, including additional clinical trials. In evaluating the substantial costs associated with development of rNAPc2 and our limited financial resources, further development of rNAPc2 will be dependent upon receipt of government or third party funding, which may not be available.

On December 8, 2009, we entered into an equity distribution agreement, or the Agreement, with Wedbush Securities Inc., or the Agent, under which we could, from time to time, offer and sell its common stock through the Agent. On April 30, 2010, we amended the Agreement to permit us to sell up to an aggregate of $20 million in shares, which were registered on a registration statement on Form S-3 (File No. 333-148288). In the year ended December 31, 2010, we sold 1,164,600 shares of our common stock under this Agreement and realized $7.2 million of proceeds, net of $338,000 of offering costs. No shares have been sold under this arrangement during 2011, and on May 23, 2011 the arrangement was terminated.

On April 18, 2011, we entered into a placement agency agreement with Roth Capital Partners, LLC, pursuant to which it agreed to use its reasonable efforts to arrange for the sale of up to 1,680,672 shares of ARCA s common stock and warrants to purchase up to 1,176,471 shares of ARCA s common stock in a registered direct public offering. We paid the placement agent an aggregate fee equal to 7% of the gross proceeds received in the offering and reimbursed the Placement Agent for its expenses incurred in connection with the offering, with a maximum expense reimbursement that, when aggregated with the 7% fee, did not exceed 8% of our gross proceeds.

On April 18, 2011, we also entered into separate subscription agreements with certain institutional investors in connection with the offering, pursuant to which we sold an aggregate of 1,680,672 shares of our common stock and warrants to purchase a total of 1,176,471 shares of our common stock to the investors for aggregate gross proceeds, before deducting fees to the placement agent and other offering expenses payable by us, of approximately $3.0 million. Our net proceeds after deducting placement agent fees and offering expenses were approximately $2.5 million and the offering closed on April 21, 2011.

The common stock and warrants were sold in units, with each unit consisting of one share of our common stock and a warrant to purchase 0.7 shares of our common stock. The purchase price per unit is $1.785. Subject to certain ownership limitations, the warrants are exercisable on October 21, 2011 and will remain exercisable for five years thereafter at an exercise price of $2.52 per share. In addition to the proceeds of the stock sales, we may seek more interim funding that will allow us to continue operations while we pursue a strategic combination, partnering, financing and licensing opportunities. We believe our cash and cash equivalents balance as of June 30, 2011 will be sufficient to fund our operations, at our current cost structure, through March 31, 2012. However, we are unable to assert that these funds are sufficient to fund operations beyond that date, and as a result, there is substantial doubt about our ability to continue as a going concern beyond March 31, 2012. The consolidated financial statements contained in this report have been prepared with the assumption that we will continue as a going concern and will be able to realize our assets and discharge our 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 our inability to continue as a going concern. We 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.

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

- the costs and timing for an additional clinical trial in order to gain possible FDA approval for Gencaro;
- the market price of our stock and the availability and cost of additional equity capital from existing and potential new investors;

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our ability to retain the listing of our common stock on the Nasdaq Capital Market;

general economic and industry conditions affecting the availability and cost of capital;

potential receipt of government or third party funding to further develop Gencaro or rNAPc2;

our ability to control costs associated with our operations;

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

the terms and conditions of our existing collaborative and licensing agreements.

The sale of additional equity or convertible debt securities would likely result in substantial additional dilution to our stockholders. If we raise additional funds through the incurrence of indebtedness, the obligations related to such indebtedness would be senior to rights of holders of our capital stock and could contain covenants that would restrict our operations. We also cannot predict what consideration might be available, if any, to us or our stockholders, in connection with any strategic transaction. Should strategic alternatives or additional capital not be available to us in the near term, or not be available on acceptable terms, we may be unable to realize value from our assets and discharge our liabilities in the normal course of business which may, among other alternatives, cause us 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 our financial condition and results of operation and requires our 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. Our significant accounting policies are described in Note 1 of Notes to the Consolidated Financial Statements included within our 2010 Annual Report on Form 10-K filed with the Securities and Exchange Commission. Following is a discussion of the accounting policies that we believe involve the most difficult, subjective or complex judgments and estimates.

Long-Lived Assets and Impairments

We review 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, we have not generated positive cash flows from operations, and such cash flows may not materialize for a significant period in the future, if ever. Additionally, we may make changes to our 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 our current expected use of long-lived assets, may result in material impairments.

Accrued Expenses

As part of the process of preparing its financial statements, we are required to estimate accrued expenses. This process involves identifying services that third parties have performed on our the Company s behalf and estimating the level of service performed and the associated cost incurred for these services as of the balance sheet date. Examples of estimated accrued expenses include contract service fees, such as fees payable to contract manufacturers in connection with the

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production of materials related to our drug product, and professional service fees, such as attorneys, consultants, and clinical research organizations. We develop estimates of liabilities using our judgment based upon the facts and circumstances known at the time.

Share-based Compensation

Our share-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. We recognize compensation costs for our share-based awards on a straight-line basis over the requisite service period for the entire award, as adjusted for expected forfeitures.

From Inception through December 31, 2005, we accounted for issuances of share-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.

Off-Balance Sheet Arrangements

We have not participated in any transactions with unconsolidated entities, such as special purpose entities, which would have been established for the purpose of facilitating off-balance sheet arrangements.

Indemnifications

In the ordinary course of business, we enter into contractual arrangements under which we may agree to indemnify certain parties from any losses incurred relating to the services they perform on our behalf or for losses arising from certain events as defined within the particular contract. Such indemnification obligations may not be subject to maximum loss clauses. We have entered into indemnity agreements with each of our 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. We also maintain an insurance policy for our directors and executive officers insuring against certain liabilities arising in their capacities as such.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

We maintain 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 our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosures. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

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

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Changes in Internal Control over Financial Reporting

During the first quarter of the year there was a reduction in our workforce which included personnel involved in financial reporting and our internal control processes. Though the process and design of our internal controls over financial reporting have not been altered, the reduction in staff may limit our ability to properly segregate internal control procedures. There have been no other changes in our internal control over financial reporting during the six months ended June 30, 2011 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

On February 9, 2007, Nuvelo and certain of Nuvelo s former and then 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. In July 2007, the Court granted Nuvelo s motion to transfer the cases to the Northern District of California. The cases were consolidated with the original lawsuit, and plaintiffs filed a 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. On June 12, 2008, the Court held a hearing on the motion to dismiss. On December 4, 2008, the Court issued an order dismissing plaintiffs 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. We filed our answer to plaintiff s complaint on October 1, 2009.

On December 29, 2010, we and the other defendants reached a settlement of the litigation with the plaintiffs, after participating in mediation before a retired federal judge. On February 25, 2011, the parties entered into a settlement agreement, which was submitted to the Court for approval. Our insurance carriers have agreed to fund the settlement, subject to a reservation of rights by one carrier. On June 20, 2011 the court issued a final judgment and order approving the settlement of, and dismissing with prejudice, the purported securities class action lawsuit. On July 25, 2011 the order became effective when no appeals or motions to alter or amend the judgment were filed. Members of the class are bound by the settlement and the release therein, which prevents them from ever asserting any related claims against the defendants. Although our insurance carriers agreed to pay most of the legal fees that were incurred in defending this litigation, we have separately agreed with our legal counsel to pay $167,000 in legal defense costs incurred, but only if we obtain additional funding of at least $10 million in 2011. If we do not obtain such additional funding in 2011, we will have no such payment obligation.

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

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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. We are 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. Our share of the settlement is approximately $385,000. Although the settlement has been approved, it has been appealed by members of the class. We believe that any attorneys fees, loss or settlement payment with respect to this suit will be paid by our insurance provider. However, it is possible that we could be forced to incur material expenses in the litigation if the parties cannot complete a settlement, and, in the event of an adverse outcome, our 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.

Risks Related to Our Business and Financial Condition

Our management and our independent registered public accountant, in their report on our financial statements as of and for the year ended December 31, 2010, have concluded that due to our need for additional capital, and the uncertainties surrounding our ability to raise such funding, substantial doubt exists as to our ability to continue as a going concern.

Our audited financial statements for the fiscal year ended December 31, 2010 and unaudited interim financial statements for six months ended June 30, 2011, were prepared assuming that we will continue as a going concern. The going concern basis of presentation assumes that we will continue in operation for the foreseeable future and will be able to realize our assets and discharge our liabilities and commitments 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 our inability to continue as a going concern. Our management and our independent registered public accountant have concluded that due to our need for additional capital, and the uncertainties surrounding our ability to raise such funding, substantial doubt exists as to our ability to continue as a going concern. To preserve our capital resources, in February 2011, we reduced our research and development and general and administrative workforce by 36%. The reduction is expected to reduce our projected cash use by approximately $200,000 per quarter. We may be forced to further reduce our operating expenses and raise additional funds to meet our working capital needs, principally through the additional sales of our securities or debt financings. However, we cannot guarantee that will be able to obtain sufficient additional funds when needed or that such funds, if available, will be obtainable on terms satisfactory to us. If we are unable to raise sufficient additional capital or complete a strategic transaction, we may be unable to continue to fund our operations, develop Gencaro or our other product candidates, or realize value from our assets and discharge our liabilities in the normal course of business. These uncertainties raise substantial doubt about our ability to continue as a going concern. If we become unable to continue as a going concern, we may have to liquidate our assets, and might realize significantly less than the values at which they are carried on our financial statements, and stockholders may lose all or part of their investment in our common stock.

We will need to raise substantial additional funds through the public or private debt and equity securities, from government funding or complete one or more strategic transactions, to continue development of Gencaro. If we are unable to raise such financing or complete such a transaction, we may not be able to continue operations.

On May 29, 2009, the FDA issued a Complete Response Letter, or CRL, to us in which the FDA stated that it could not approve the Gencaro NDA in its current form, and specified additional actions and information required for approval of the NDA, including conducting an additional Phase 3 clinical trial of Gencaro in patients with HF. In the second quarter of 2010, we reached agreement with the FDA regarding the special protocol assessment, or SPA, on the design of a clinical trial to assess the safety and efficacy of Gencaro in approximately 3,200 patients with chronic HF who have the genotype that appears to respond most favorably to Gencaro. We now plan to conduct a Phase 3 clinical study of Gencaro in approximately 300-400 HF patients with AF, prior to conducting the clinical study outlined in the SPA, or other HF

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studies. In light of the expected development timeline to potentially obtain FDA approval for Gencaro, if at all, the substantial additional costs associated with the development of Gencaro, including the costs associated with the 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 additional clinical trial and our ongoing operations, in 2009 we reduced our operating expenses, suspended significant expenditures on our development activities for programs other than Gencaro, and began evaluating strategic alternatives. We will need to raise substantial additional funding through public or private debt or equity transactions or a strategic combination or partnership, or government funding to support the continued development of Gencaro, including additional clinical trials. Even if we are able to fund continued development and Gencaro is approved, we expect that we will need to complete a strategic transaction or raise substantial additional funding through public or private debt or equity securities to successfully commercialize Gencaro. To preserve our capital resources, in February 2011, we reduced our research and development and general and administrative workforce by 36%. The reduction is expected to reduce our projected cash use by approximately $200,000 per quarter.

Pursuant to the subscription agreements we entered into in April 2011, we are prohibited from selling shares of our common stock under the equity distribution agreement until July 20, 2011 and, in certain cases, until April 21, 2014. In addition, under the subscription agreements, we agreed with the investors that, subject to certain exceptions, if we issue securities within 180 days following the closing of the April 2011 offering, each investor in the offering would have the right to purchase the securities on the same terms, conditions and price provided for in the proposed issuance of securities. Complying with the terms of the subscription agreements relating to that right may make certain potential financing transactions more expensive, or in some cases, impracticable.

We currently believe our cash and cash equivalents balance as of June 30, 2011 will be sufficient to fund our operations, at our current cost structure through March 31, 2012. We are unable to assert that our current cash and cash equivalents are sufficient to fund operations beyond that date, and as a result, there is substantial doubt about our ability to continue as a going concern beyond March 31, 2012. As a result of the significant additional required development of Gencaro, including the additional clinical trial, we 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. Changing circumstances may cause us to consume capital significantly faster or slower than we currently anticipate. We have based these estimates on assumptions that may prove to be wrong, and we could exhaust our available financial resources sooner than we currently expect.

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

- the costs and timing for an additional clinical trial in order to gain possible FDA approval for Gencaro;
- the market price of our stock and the availability and cost of additional equity capital from existing and potential new investors;
- our ability to retain the listing of our common stock on the Nasdaq Capital Market;
- general economic and industry conditions affecting the availability and cost of capital;
- potential receipt of government or third party funding to further develop Gencaro or rNAPc2;
- our ability to control costs associated with our operations;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights; and

the terms and conditions of our existing collaborative and licensing agreements.

The sale of additional equity or convertible debt securities would likely result in substantial dilution to our stockholders. If we raise additional funds through the incurrence of indebtedness, the obligations related to such indebtedness would be

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senior to rights of holders of our capital stock and could contain covenants that would restrict our operations. We also cannot predict what consideration might be available, if any, to us or our stockholders, in connection with any strategic transaction. Should strategic alternatives or additional capital not be available to us in the near term, or not be available on acceptable terms, we may be unable to realize value from our assets and discharge our liabilities in the normal course of business which may, among other alternatives, cause us to further delay, substantially reduce or discontinue operational activities to conserve our cash resources.

If we are not able to maintain the requirements for listing on the Nasdaq Capital Market, we could be delisted, which could have a materially adverse effect on our ability to raise additional funds as well as the price and liquidity of our common stock.

The Nasdaq Capital Market has certain compliance requirements for continued listing of common stock. Among other requirements, Nasdaq Rule 5505(b) requires that we keep a minimum stockholders equity of $5 million (the Rule). There can be no assurances that we will continue to meet the requirements for continued listing on the Nasdaq Capital Market. The delisting of our common stock from a national exchange could materially adversely affect our access to the capital markets, and any limitation on market liquidity or reduction in the price of our common stock as a result of that delisting could adversely affect our ability to raise capital, if needed, on terms acceptable to us, or at all.

Further, delisting could reduce the ability of our stockholders to purchase or sell shares as quickly and as inexpensively as they have done historically. For instance, failure to obtain listing on another market or exchange may make it more difficult for traders to sell our securities. Broker-dealers may be less willing or able to sell or make a market in our common stock. Not maintaining our Nasdaq Capital Market listing may result in a decrease in the trading price of our common stock, lessen interest by institutions and individuals in investing in our common stock, make it more difficult to obtain analyst coverage, and make it more difficult for us to raise capital in the future.

Our failure to enter into a strategic transaction may materially and adversely affect our business.

Unless we are able to raise substantial additional funding through other means, we will need to complete a strategic transaction to continue the development of Gencaro or our other operations. The strategic transactions that we may consider include a potential combination or partnership. Our board of directors and management team has and will continue to devote substantial time and resources to the consideration and implementation of any such strategic transaction. In addition, conditions 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 our ability to negotiate favorable terms for any such transaction. Further, our current employees do not have experience in the strategic transaction process, and our 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 we 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 our business.

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

Nasdaq rules impose restrictions on our ability to raise funds through a private offering of our common stock, convertible debt or similar instruments without obtaining stockholder approval. Under Nasdaq rules, an offering of more than 20% of our 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 June 30, 2011 we had 10,515,707 shares of common stock outstanding 20% of which is 2,103,141 shares. To the extent we seek to raise funds through a private offering of stock, convertible debt or similar instruments, we are limited in how much funding we could raise privately without requiring a stockholder vote.

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If we are not able to successfully develop, obtain FDA approval for and provide for the commercialization of Gencaro in a timely manner, we may not be able to continue our business operations.

We currently have no products that have received regulatory approval for commercial sale. The process to develop, obtain regulatory approval for and commercialize potential product candidates is long, complex and costly. In September 2008, the FDA accepted for filing the Gencaro NDA. On May 29, 2009, the FDA issued a CRL to us in which the FDA stated that it could not approve the Gencaro NDA in its current form, and specified additional actions and information required for approval of the NDA, including conducting an additional Phase 3 clinical trial of Gencaro in patients with HF. In May 2010, we reached agreement with the FDA on an SPA on the design of a clinical trial to assess the safety and efficacy of Gencaro in approximately 3,200 patients with chronic HF who have the genotype that appears to respond most favorably to Gencaro. We now plan to conduct a Phase 3 clinical study of Gencaro in approximately 300-400 HF patients with AF, prior to the clinical trial outlined in the SPA, or other HF studies. Clinical trials in AF or HF are typically lengthy, complex and expensive and we do not currently have the resources to fund such a trial. Although the FDA has designated the investigation of Gencaro as a fast track development program, such designation does not provide any assurance that Gencaro will receive FDA approval, and such designation does not constrain the FDA s ability to deny approval for Gencaro.

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 our business. Failure to obtain marketing approval of Gencaro from appropriate regulatory authorities, or significant delays in obtaining such approval, would also adversely affect our business and could, among other things, preclude us from completing a strategic transaction or obtaining additional financing necessary to continue as a going concern.

Even if approved for sale, a product candidate must be successfully commercialized to generate value. We do 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 our business.

Fast track designation does not guarantee approval, or expedited approval, of Gencaro and there is no guarantee that Gencaro will maintain fast track designation.

In November 2009, we announced that the FDA granted fast track designation to Gencaro s development program for the reduction of cardiovascular mortality and cardiovascular hospitalizations in a genotype-defined HF population. However, such designation does not constrain the FDA s ability to deny approval for Gencaro. Furthermore, the FDA may revoke fast track designation from a product candidate at any time if it determines that the criteria for such designation are no longer met. Additionally, we have not requested and do not have fast track designation for the development of Gencaro for preventing or reducing AF.

Our planned clinical trials do not guarantee any particular outcome from regulatory review of those clinical trials or Gencaro, including any regulatory approval.

FDA approval of Gencaro, if it occurs, is expected to require years of additional clinical development, including the clinical trial we plan to conduct in approximately 300-400 HF patients with AF, and potentially additional clinical trials in

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AF or HF. The HF clinical trial outlined under the SPA would be a new multi-year active comparator superiority trial involving approximately 3,200 patients in a genotype-defined HF population. 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, is acceptable to the FDA for the intended purpose. An SPA agreement is not a guarantee of approval, and if we conduct the HF study outlined in the SPA, we cannot assure 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 CRL or obtain the requisite regulatory approvals for Gencaro. Further, the 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 we fail to comply with the agreed upon trial protocol. In addition, upon written agreement of both parties, the SPA agreement may be changed by us or the FDA, and the FDA retains significant latitude and discretion in interpreting the terms of an SPA agreement and the data and results from the planned Gencaro trial. As a result, we do not know how the FDA will interpret the parties respective commitments under the SPA agreement, how it will interpret the data and results from the planned Gencaro trial, or whether Gencaro will receive any regulatory approvals as a result of our SPA agreement with the FDA and the planned clinical trial. In addition, we do not yet have guidance from the FDA on the AF protocol, which could substantially impact the trial size, and what additional clinical studies or analyses will be required for approval of Gencaro for an indication in AF.

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

We, and our collaborators, will only receive regulatory approval for our product candidates if we can demonstrate in carefully designed and conducted clinical trials that the product candidate is safe and effective. We do not know whether 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. We have spent, and expect to continue to spend, significant amounts of time and money in the clinical development of our product candidates. We have never conducted a Phase 3 clinical trial and do not currently have sufficient staff with the requisite experience to do so, and we therefore expect that we will have to rely on contract research organizations to conduct certain of our clinical trials. While certain of our employees have experience in designing and administering Phase 3 clinical trials, these employees have no such experience since being with us.

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

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

If clinical trials for a product candidate are unsuccessful, we will be unable to commercialize the product candidate. If one or more of our clinical trials are delayed, we will be unable to meet our anticipated development timelines. Either circumstance could cause the market price of our common stock to decline.

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We expect 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.

We expect that we, or any strategic partners, will rely primarily on third parties to conduct clinical trials, including the Gencaro clinical trial in HF patients with AF that we plan to conduct As a result, we 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 we were relying entirely upon our 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 our trials. We may experience unexpected cost increases that are beyond our control. Problems with the timeliness or quality of the work of a contract research organization may lead us 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 we do use a contract research organization to conduct clinical trials, we will have to devote substantial resources and rely on the expertise of our employees to manage the work being done by the contract research organization. We have never conducted a clinical trial and do not currently have sufficient staff with the requisite experience to do so. The inability of our current staff to adequately manage any contract research organization that we hire may exacerbate the risks associated with relying on a contract research organization.

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

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

Patient enrollment is affected by factors including:

- design of the protocol;
- the size of the patient population;
- eligibility criteria for the study in question;

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

patient referral practices of physicians;

availability of clinical trial sites; and

other clinical trials seeking to enroll subjects with similar profiles.

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

Unless we are able to generate sufficient product revenue, we will continue to incur losses from operations and may not achieve or maintain profitability. We are years away from commercializing a product and generating product revenue.

Our historical losses have had and will continue to have an adverse effect on our stockholders equity and working capital, among other things. We are years away from commercializing a product and generating any product revenue. As a result, we expect to continue to incur significant operating losses for the foreseeable future. Even if we ultimately receive regulatory approval for Gencaro or our 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, we may experience larger than expected future losses and may never reach profitability.

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

We set goals for, and make public statements regarding, the timing of certain accomplishments, such as the submission of responses to the CRL, the commencement and completion of clinical trials, the disclosure of trial results, the obtainment of regulatory approval and the sale of drug product, which we sometimes refer to as milestones. These milestones may not be achieved, and the actual timing of these events can vary dramatically due to a number of factors such as delays or failures in our clinical trials, disagreements with current or future collaborative partners, the uncertainties inherent in the regulatory approval process and manufacturing scale-up and delays in achieving manufacturing or marketing arrangements sufficient to commercialize our products. 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 300-400 patients in a genotype-defined HF population with AF, and additional Phase 3 clinical trials. There can be no assurance that our clinical trials will be completed, or that we will make regulatory submissions or receive regulatory approvals as planned. If we fail to achieve one or more of these milestones as planned, our business will be materially adversely affected.

Our product candidates are subject to extensive regulation, which can be costly and time-consuming, and unsuccessful or delayed regulatory approvals could increase our future development costs or impair our 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 our 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. We are not permitted to market a potential drug in the United States until we receive approval of an NDA from the FDA. We have not received an NDA approval from the FDA for Gencaro or any of our other product candidates. There can be no guarantees with respect to our 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, we 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. Our failure to adequately demonstrate the safety and efficacy of our product candidates will prevent regulatory approval and commercialization of such products. On May 29, 2009, the FDA issued a CRL to us in which the FDA stated that it could not approve the Gencaro NDA in its current form, and specified additional actions and information required for approval of the NDA including conducting an additional Phase 3 clinical trial of Gencaro in patients with HF. We reached agreement with the FDA regarding through the SPA process on the design of a clinical trial to assess the safety and efficacy of Gencaro in approximately 3,200 patients in a genotype-defined HF population. We are planning to conduct a Phase 3 clinical study of Gencaro in approximately 300-400 HF patients with AF, prior to a further HF endpoint study. This product candidate will require years of additional clinical development. Even if we conduct additional studies in accordance with further FDA guidance and submit the attendant data requested in the CRL, or file a new or amended NDA, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval.

In the event that we or our collaborators conduct preclinical studies that do not comply with Good Laboratory Practices or GLP or incorrectly design or carry out human clinical trials in accordance with Good Clinical Practices or GCP or those

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clinical trials fail to demonstrate clinical significance, it is unlikely that we will be able to obtain FDA approval for product development candidates. Our inability to successfully and effectively complete clinical trials for any product candidate on schedule, or at all, will severely harm our business. Significant delays in clinical development could materially increase product development costs or allow our competitors to bring products to market before we do, impairing our ability to effectively commercialize any future product candidate. We do 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 our product candidates or similar product candidates of our competitors or failure to follow regulatory guidelines;
- delays or failures in obtaining clinical materials and manufacturing sufficient quantities of the product candidates for use in trials;
- delays or failures in reaching agreement on acceptable terms with prospective study sites;
- delays or failures in obtaining approval of our 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 our 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 our 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 we may obtain may not cover all of the clinical indications for which we seek approval or permit us 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, we 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 our commitment to conduct further clinical trials, which we may not have the resources to conduct or which may negatively impact our financial situation.

The manufacture and tableting of Gencaro is done by third party suppliers, who must also meet current Good Manufacturing Practices, or cGMP, requirements and pass a pre-approval inspection of their facilities before we can obtain marketing approval.

All of our 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

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approvals. The data obtained from preclinical and clinical studies are susceptible to varying interpretations that may delay, limit or prevent regulatory approval, and the FDA and other regulatory authorities in the United States and elsewhere exercise substantial discretion in the drug approval process. The numbers, size and design of preclinical studies and clinical trials that will be required for FDA or other regulatory approval will vary depending on the product candidate, the disease or condition for which the product candidate is intended to be used and the regulations and guidance documents applicable to any particular product candidate. The FDA or other regulators can delay, limit or deny approval of any product candidate for many reasons, including, but not limited to:

- Side effects;
- Safety and efficacy;
- Defects in the design of clinical trials;
- The fact that the FDA or other regulatory officials may not approve our or our 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.

In our NDA, we have requested that the FDA approve Gencaro as a therapy that can be prescribed by physicians for patients with HF, and specifically for its effect on certain clinical outcomes for these HF patients. We have 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. If we pursue clinical development of Gencaro for an AF indication, we would also request in an amended or new NDA that similar information be included in the prescribing information distributed with Gencaro regarding the effect of genetic differences in patients on the clinical results. The FDA could approve Gencaro, but without including some or all of the prescribing information that we have 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 our ability to successfully commercialize Gencaro and effectively protect our intellectual property rights in Gencaro.

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

If a product candidate of ours is approved by the FDA or by another regulatory authority, we 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, our third-party manufacturers and the manufacturing facilities that they use to make our 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 us or our 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. We and our third-party manufacturers will also be subject to ongoing FDA requirements for submission of safety and other post-market information.

The marketing and advertising of our drug products by our collaborators or us will be regulated by the FDA, certain state agencies or foreign regulatory authorities. Violations of these laws and regulations, including promotion of our 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 our ability to market the product.

In addition to the FDA, state or foreign regulations, the marketing of our drug products by us or our 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, we may be required to discontinue one or more of our 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 us for violations of these laws, even if we successfully defend against it, could have a material adverse effect on our business, financial condition and results of operations.

We 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

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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. We may become subject to such litigation and, if we are not successful in defending against such actions, those actions may have a material adverse effect on our business, financial condition and results of operations. We 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 adopted that could prevent or delay regulatory approval of our product candidates or limit our ability to commercialize our products. We 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 we, our collaborators or our third-party manufacturers fail to comply with applicable continuing regulatory requirements, our business could be seriously harmed because a regulatory agency may:

issue untitled or warning letters;

suspend or withdraw our 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 us;

suspend our ongoing clinical trials;

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restrict our operations, including costly new manufacturing requirements, or restrict the sale, marketing and/or distribution of our products;

seek an injunction;

pursue criminal prosecutions;

close the facilities of our contract manufacturers; or

impose civil or criminal penalties.

We are 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 our 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, we believe 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 our 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 submitted a PMA regulatory submission, which the FDA formally accepted in January 2009 and the review was granted an extension until March 2010. LabCorp has voluntarily withdrawn the PMA. We believe that LabCorp will resubmit the PMA when the complete response to the Gencaro NDA CRL is submitted, or an amended or new NDA is filed, which will occur after additional clinical studies. The FDA may decide that the Gencaro Test should be evaluated for clearance under the FDA s 510(k) notification process. We and LabCorp 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

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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. If we believe it is necessary to identify a new third-party test provider, obtaining regulatory approval for that provider s genetic test could substantially delay and negatively affect the commercial prospects for Gencaro and our ability to continue as a going concern.

Reliance on third parties to commercialize Gencaro could negatively impact our business. If we are required to establish a direct sales force in the U.S. and are unable to do so, our business may be harmed.

Commercialization of Gencaro, particularly the establishment of a sales organization, will require substantial additional capital resources. We currently intend to pursue a strategic alternative for the commercialization of Gencaro, if it is approved, and we have suspended our efforts to build internal sales, marketing and distribution capabilities. If we elect to rely on third parties to sell Gencaro and any other products, then we may receive less revenue than if we sold such products directly. In addition, we may have little or no control over the sales efforts of those third parties.

If we are unable to complete a strategic transaction, we would be unable to commercialize Gencaro or any other product candidate without substantial additional capital. Even if such capital were secured, we would be required to build internal sales, marketing and distribution capabilities to market Gencaro in the U.S. None of our current employees have experience in establishing and managing a sales force.

In the event we are 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 we 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. We believe that the Gencaro Test helps predict patient response to Gencaro, and that this aspect of the drug is important to its ability to compete effectively with current therapies. The Gencaro Test adds an additional step in the prescribing process, an additional cost for the patient and payors, the risk that the test results may not be rapidly available and the possibility that it may not be available at all to hospitals and medical centers. Although we anticipate 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 AF or HF therapy. 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 our business.

We are dependent on our key personnel.

The success of our business is highly dependent on the principal members of our board of directors and executive management, including our Chairman of the Board, Richard B. Brewer, and our President and Chief Executive Officer, Michael R. Bristow. The loss of the services of any such individual might seriously harm our product development, partnering and financing efforts. Recruiting and training personnel with the requisite skills is challenging and we compete for talent with companies that are larger and have more financial resources.

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Our workforce reductions in February 2011 and any future workforce and expense reductions may have an adverse impact on our internal programs and may divert management attention.

In February 2011, we conducted a strategic reduction in our workforce of approximately 36% in order to preserve our capital resources and to manage our operating expenses. This reduction in force may limit our ability to complete all of our corporate objectives. We may be required to implement further workforce and expense reductions in the future. Further workforce and expense reductions could result in reduced progress on our internal programs. In addition, employees, whether or not directly affected by a reduction, may seek future employment with our business partners or competitors. Although our employees are required to sign a confidentiality agreement at the time of hire, the confidential nature of certain proprietary information may not be maintained in the course of any such future employment. In addition, the implementation of expense reduction programs may result in the diversion of efforts of our executive management team and other key employees, which could adversely affect our business.

We have no manufacturing capacity which puts us at risk of lengthy and costly delays of bringing our products to market.

We do not currently operate manufacturing facilities for clinical or commercial production of our product candidates, including their active pharmaceutical ingredients, or API. We have no experience in drug formulation or manufacturing, and we lack the resources and the capabilities to manufacture any of our product candidates on a clinical or commercial scale. We do not intend to develop facilities for the manufacture of product candidates for clinical trials or commercial purposes in the foreseeable future.

We have contracted with Groupe Novasep to manufacture commercial quantities of the API for Gencaro. For drug production, we have 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 our products. In addition, these manufacturers may have staffing difficulties, may not be able to manufacture our products on a timely basis or may become financially distressed. 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, we may be unable to find an alternative third-party manufacturer in a timely manner and the production of our product candidates would be interrupted, resulting in delays and additional costs, which could impact our ability to commercialize and sell our product candidates.

We or our 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 our business. Contract manufacturers also often encounter difficulties involving production yields, quality control and quality assurance, as well as shortages of qualified personnel. In addition, our contract manufacturers are subject to ongoing inspections and regulation by the FDA, the U.S. Drug Enforcement Agency and corresponding foreign and state agencies and they may fail to meet these agencies acceptable standards of compliance. If our contract manufacturers fail to comply with applicable governmental regulations, such as quality control, quality assurance and the maintenance of records and documentation, we 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 laws or for other reasons, this may jeopardize our regulatory approval for Gencaro and other product candidates, and we 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 we 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;

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the manufacturing process is complex and may require a significant learning curve; and

the FDA must approve any replacement prior to manufacturing, which requires new testing and compliance inspections.

If 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 our reputation and cause product sales and profitability of Gencaro to suffer and may prevent us 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 our 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, we may be unable to obtain FDA approval for Gencaro or the product sales and profitability of Gencaro may suffer.

LabCorp is our single-source supplier of the Gencaro Test and has the right to terminate its agreement with us for any

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reason. If LabCorp or its third party suppliers were to terminate their agreements with us 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, we 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 our ability to complete clinical development of Gencaro, including the additional clinical trial, or to commercialize Gencaro if it is ultimately approved, either of which could have an adverse effect on our financial condition and results of operations.

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 our business, operating results and prospects.

Based on discussions with the FDA, we and LabCorp do not believe that additional 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 we or our 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 our products or if they determine that the treatments received under the trial protocol 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 we or LabCorp may not adequately develop such protocols to support clearance and approval. The 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 our future IDE submissions. Further, the FDA may require LabCorp or us 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 our 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 our or our third party suppliers business, operating results and prospects.

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

We are a development stage biopharmaceutical company with a limited operating history. To date we have not generated any product revenue and have historically funded our operations through investment capital. Our future growth depends on our ability to emerge from the developmental stage and successfully commercialize or provide for the commercialization of Gencaro and our other product candidates, which in turn, will depend, among other things, on our 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;
- 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 our ability to successfully commercialize Gencaro and other product candidates, which could impact our ability to earn sufficient revenues to transition from a developmental stage company and continue our business.

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

Gencaro is a new type of beta-blocker and vasodilator being developed for AF, HF and other indications. While we anticipate that this drug, if approved, would be the first genetically-targeted cardiovascular drug, and potentially the only beta-blocker approved for AF, Gencaro will be one of a number of successful drugs in the beta-blocker class currently on the market. For example, currently, there are three branded beta-blockers indicated for chronic HF 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.

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Our 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 our common stock and the value of our assets.

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

Gencaro or our other product candidates may not gain market acceptance among physicians, patients and the medical community. The degree of market acceptance of Gencaro or our 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 our other product candidates. Failure to achieve market acceptance of Gencaro would significantly harm our business.

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

Our or any strategic partner s ability to commercialize Gencaro, or any other product candidates that we 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 our 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.

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

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Health care reform measures could materially and adversely affect our business.

The business and financial condition of pharmaceutical and biotechnology companies are affected by the efforts of governmental and third-party payors to contain or reduce the costs of health care. The U.S. Congress has enacted legislation to reform the health care system. While we anticipate that this legislation may, over time, increase the number of patients who have insurance coverage for pharmaceutical products, it also imposes cost containment measures that may adversely affect the amount of reimbursement for pharmaceutical products. These measures include increasing the minimum rebates for products covered by Medicaid programs and extending such rebates to drugs dispensed to Medicaid beneficiaries enrolled in Medicaid managed care organizations as well as expansion of the 340(B) Public Health Services drug discount program. In addition, such legislation contains a number of provisions designed to generate the revenues necessary to fund the coverage expansion, including new fees or taxes on certain health-related industries, including medical device manufacturers. Beginning in 2013, each medical device manufacturer will have to pay an excise tax (or sales tax) in an amount equal to 2.3% of the price for which such manufacturer sells its medical devices. Such excise taxes may impact any potential sales of the Gencaro Test if it is approved for marketing. In foreign jurisdictions there have been, and we expect that there will continue to be, a number of legislative and regulatory proposals aimed at changing the health care system. For example, in some countries other than the United States, pricing of prescription drugs is subject to government control and we expect to see continued efforts to reduce healthcare costs in international markets.

Some states are also considering legislation that would control the prices of drugs, and state Medicaid programs are increasingly requesting manufacturers to pay supplemental rebates and requiring prior authorization by the state program for use of any drug for which supplemental rebates are not being paid. Managed care organizations continue to seek price discounts and, in some cases, to impose restrictions on the coverage of particular drugs. Government efforts to reduce Medicaid expenses may lead to increased use of managed care organizations by Medicaid programs. This may result in managed care organizations influencing prescription decisions for a larger segment of the population and a corresponding constraint on prices and reimbursement for drugs. It is likely that federal and state legislatures and health agencies will continue to focus on additional health care reform in the future although we are 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 our business. We or any strategic partner s ability to commercialize Gencaro, or any other product candidates that we 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 could materially and adversely affect our business. Further, the pendency or approval of future proposals or reforms could result in a decrease in our stock price or limit our ability to raise capital or to obtain strategic partnerships or licenses.

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

Many of our competitors currently have significantly greater financial resources and expertise in conducting clinical trials, obtaining regulatory approvals, managing manufacturing and marketing approved products than us. 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 us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring

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therapies and therapy licenses complementary to our programs or advantageous to our business. We expect that our ability to compete effectively will depend upon our 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 our products;
- develop competitive formulations of our product candidates;
- attract and retain key personnel; and
- identify and obtain other product candidates on commercially reasonable terms.

If we fail to identify and license or acquire other products or product candidates, then we may be unable to expand our business, and the acquisition or licensing of other products or product candidates may put a strain on our operations and will likely require us to seek additional financing.

One of our 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 our competitors may have greater resources than us. If we undertake any additional acquisitions, whether of product candidates or other biopharmaceutical companies, the process of integrating an acquired product candidate or complementary company into our business may put a strain on our operations, divert personnel, financial resources and management s attention. In 2011, we expect our research and development activities, other than those associated with Gencaro, will be limited, unless government funding is received for the further development of rNAPc2. If we are not able to substantially expand our research and development efforts, or identify, or license or acquire other products or product candidates or complete future acquisitions, then we will likely be unable expand our pipeline of product candidates. In addition, any future acquisition would give rise to additional operating costs and will likely require us 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 our operating results.

We would be subject to applicable regulatory approval requirements of the foreign countries in which we market our products, which are costly and may prevent or delay us from marketing our products in those countries.

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In addition to regulatory requirements in the United States, we would be subject to the regulatory approval requirements in each foreign country where we market our products. In addition, we might be required to identify one or more collaborators in these foreign countries to develop, seek approval for and manufacture our products and any companion genetic test for Gencaro. If we decide to pursue regulatory approvals and commercialization of our product candidates internationally, we 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 us to incur additional costs or prevent us from marketing our products in foreign countries, which may have a material adverse effect on our business, financial condition and results of operations.

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

As a public company, we have 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. On July 21, 2010, the Dodd-Frank Wall Street Reform and Protection Act, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive compensation-related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas. Compliance with these public company requirements has increased our costs, required additional resources and made some activities more expensive and time consuming. We are required to expend considerable time and resources complying with public company regulations.

If our internal control over financial reporting is not considered effective, our business and stock price could be adversely affected.

Section 404 of the Sarbanes-Oxley Act of 2002 requires us to evaluate the effectiveness of our internal control over financial reporting as of the end of each fiscal year, and to include a management report assessing the effectiveness of our internal control over financial reporting in our annual report on Form 10-K for that fiscal year. Our management, including our chief executive officer and chief financial officer, does not expect that our internal control over financial reporting will prevent all error and all fraud. During the first quarter of 2011 there was a reduction in our workforce which included personnel involved in financial reporting and our internal control processes. Though the process and design of our internal controls over financial reporting have not been altered, the reduction in staff may limit our ability to properly segregate internal control procedures which could result in deficiencies or material weaknesses in our internal controls in the future. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system s objectives will be met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud involving a company have been, or will be, detected. The design of any system of controls is based in part on certain assumptions about the likelihood of future events, and we cannot assure you that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become ineffective because of changes in conditions or deterioration in the degree of compliance with policies or procedures. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected. We cannot assure you that we or our independent registered public accounting firm will not identify a material weakness in our internal control over financial reporting in the future. A material weakness in our internal control over financial reporting would require management to consider our internal control over financial reporting as ineffective. If our internal control over financial reporting is not considered effective, we may experience a loss of public confidence, which could have an adverse effect on our business and on the market price of our common stock.

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Risks Related to Intellectual Property and Other Legal Matters

We are party to securities litigation and defending these lawsuits could hurt our 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 us could result in substantial costs and a diversion of management s attention and resources, which could significantly harm our business, financial condition and operating results.

For example, in December 2006, after 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 then 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. In July 2007, the Court granted Nuvelo s motion to transfer the cases to the Northern District of California. The cases were consolidated with the original lawsuit, and plaintiffs filed a 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. On June 12, 2008, the Court held a hearing on the motion to dismiss. On December 4, 2008, the Court issued an order dismissing plaintiffs 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. We filed our answer to plaintiff s complaint on October 1, 2009.

On December 29, 2010, we and the other defendants reached a settlement of the litigation with the plaintiffs, after participating in mediation before a retired federal judge. On February 25, 2011, the parties entered into a settlement agreement, which was submitted to the Court for approval. Our insurance carriers have agreed to fund the settlement, subject to a reservation of rights by one carrier. On June 20, 2011 the court issued a final judgment and order approving the settlement of, and dismissing with prejudice, the purported securities class action lawsuit. On July 25, 2011 the order became effective when no appeals or motions to alter or amend the judgment were filed. Members of the class are bound by the settlement and the release therein, which prevents them from ever asserting any related claims against the defendants. Although our insurance carriers agreed to pay most of the legal fees that were incurred in defending this litigation, we have separately agreed with our legal counsel to pay $167,000 in legal defense costs incurred, but only if we obtain additional funding of at least $10 million in 2011. If we do not obtain such additional funding in 2011, we will have no such payment obligation.

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In addition, Variagenics, with which Nuvelo merged in 2003, has been named as a defendant in a securities class action lawsuit alleging the failure to disclose additional and excessive commissions purportedly solicited by and paid to underwriters who are also named defendants in the lawsuit. Plaintiffs in the suit allege that underwriters took these commissions and in exchange allocated shares of Variagenics stock to their preferred customers through alleged agreements with these preferred customers that tied the allocation of initial public offering shares to agreements by the customers to make additional aftermarket purchases at pre-determined prices. As a result of Nuvelo s merger with Variagenics, we are 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. Our share of the settlement is approximately $385,000. Although the settlement has been approved, it has been appealed by members of the class. We believe that any attorneys fees, loss or settlement payment with respect to this suit will be paid by our insurance provider. However, it is possible that we could be forced to incur material expenses in the litigation if the parties cannot complete a settlement, and, in the event of an adverse outcome, our business could be harmed.

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

We face product liability exposure related to the testing of our product candidates in human clinical trials, and may face exposure to claims by an even greater number of persons once we begin marketing and distributing our products commercially. If we cannot successfully defend against product liability claims, then we will incur substantial liabilities.

Regardless of merit or eventual outcome, liability claims may result in:

decreased demand for our products and product candidates;

injury to our reputation;

withdrawal of clinical trial participants;

costs of related litigation;

substantial monetary awards to patients and others;

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loss of revenues; and

the inability to commercialize our products and product candidates.

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

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

Our research and development of product candidates may involve the controlled use of hazardous materials, including chemicals, radioactive and biological materials. We cannot eliminate the risk of accidental contamination or discharge and any resultant injury from the materials.

Various laws and regulations govern the use, manufacture, storage, handling and disposal of hazardous materials. We may be sued or be required to pay fines for any injury or contamination that results from our 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 our research, development and production efforts.

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

We have licensed from CPEC, who has licensed rights in Gencaro from Bristol Meyers Squibb (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 our commercial exclusivity in such country. This license includes a sublicense to us from BMS. We are obligated to use commercially reasonable efforts to develop and commercialize Gencaro, including obtaining regulatory approvals. Our ability to develop and commercialize Gencaro is dependent on numerous factors, including some factors that are outside of our control. CPEC has the right to terminate our license if we materially breach our obligations under the license agreement and fail to cure any such breach within the terms of the license.

If our license agreement with CPEC is terminated for reasons related to non-payment of fees, or for any other breach, then we 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 us to market a key product or product candidate, could significantly and adversely affect our business.

Certain intellectual property licensed by us is the subject of additional licensing arrangements to which the party that has licensed rights to us is subject. If such parties were to breach the terms of such licenses or such licenses were otherwise to terminate, our and our partners rights to use such technology and develop and commercialize their products such as the Gencaro Test may terminate and our business would be materially harmed.

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

Our or any strategic partner s ability to commercialize Gencaro and other product candidates depends upon our 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 us. We 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. We may also be unaware of existing patents that may be infringed by Gencaro, the genetic testing we intend to use in connection with Gencaro or our 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 our other product candidates. Moreover, a license may not be available to us 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 we are infringing on its technology, then our 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 our core business;
- monetary damage awards for past infringement can be substantial;
- a court may prohibit us from selling or licensing product candidates unless the patent holder chooses to license the patent to us; and
- if a license is available from a patent holder, we may have to pay substantial royalties.

We may also be forced to bring an infringement action if we believe that a competitor is infringing our 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 us.

Our intellectual property rights may not preclude competitors from developing competing products and our business may suffer.

Our competitive success will depend, in part, on our ability to obtain and maintain patent protection for our inventions, technologies and discoveries, including intellectual property that we license. The patent positions of biotechnology companies involve complex legal and factual questions, and we cannot be certain that our patents and licenses will successfully preclude others from using our technology. Consequently, we cannot be certain that any of our patents will

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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, we cannot be certain of the priority of inventions covered by pending patent applications. Moreover, we 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 us, 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 us to significant liabilities to third parties, require disputed rights to be licensed from third parties or require us to cease using such technology. Regardless of merit, the listing of patents in the FDA Orange Book for Gencaro may be challenged as being improperly listed. We may have to defend against such claims and possible associated antitrust issues. We could also incur substantial costs in seeking to enforce our proprietary rights against infringement.

While the composition of matter patents on the compound that comprises Gencaro have expired, we hold the intellectual property arising from the discovery of the interaction of Gencaro with the polymorphisms of the ß$_1$ and $_{2C}$ receptors. We have obtained patents that claim the use of Gencaro with the diagnosis of a patient s receptor genotype. Our 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. We believe that 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 our business may suffer. The approved label may not contain language covered by the patents, or we may be unsuccessful in enforcing them.

We may not be able to effectively protect our intellectual property rights in some foreign countries, as many countries do not offer the same level of legal protection for intellectual property as the U.S.

We require our employees, consultants, business partners and members of our scientific advisory board to execute confidentiality agreements upon the commencement of employment, consulting or business relationships with us. These agreements provide that all confidential information developed or made known during the course of the relationship with us 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 us, utilizing the property or relating to our business and conceived or completed by the individual during employment shall be our exclusive property to the extent permitted by applicable law.

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

If we are not able to protect our proprietary technology, trade secrets and know-how, then our competitors may develop competing products. Any issued patent may not be sufficient to prevent others from competing with us. Further, we have trade secrets relating to Gencaro, and such trade secrets may become known or independently discovered. Our issued patents and those that may issue in the future, or those licensed to us, may be challenged, opposed, invalidated or circumvented, which could allow competitors to market similar products or limit the patent protection term f our product candidates. . All of these factors may affect our competitive position.

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

Extensive litigation regarding patents and other intellectual property rights has been common in the biopharmaceutical industry. Litigation may be necessary to assert infringement claims, enforce patent rights, protect trade secrets or know-how and determine the enforceability, scope and validity of certain proprietary rights. 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, our involvement in any litigation, interference or other administrative proceedings could cause us to incur substantial expense and could significantly divert the efforts of our technical and management personnel. Any public announcements related to litigation or interference proceedings initiated or threatened against us could cause our stock price to decline. Adverse outcomes in patent litigation may potentially subject us to antitrust litigation which, regardless of the outcome, would adversely affect our business. An adverse determination may subject us to the loss of our proprietary position or to significant liabilities, or require us to seek licenses that may include substantial cost and ongoing royalties. Licenses may not be available from third parties, or may not be obtainable on satisfactory terms. An adverse determination or a failure to obtain necessary licenses may restrict or prevent us from manufacturing and selling our products, if any. These outcomes could materially harm our business, financial condition and results of operations.

Risks Related to Stock Price Volatility

Ownership of our 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 our stock price to decline.

Our executive officers, directors and their affiliates beneficially owned approximately 19% of our outstanding common stock as of June 30, 2011. 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 ours requiring stockholder approval, including the election of directors, any merger, consolidation or sale of all or substantially all of our assets or any other significant corporate transaction. These stockholders may also delay or prevent a change in control of us, even if such change in control would benefit our other stockholders. The significant concentration of stock ownership may adversely affect the value of our common stock due to investors perception that conflicts of interest may exist or arise.

Our stock price is expected to be volatile.

Our 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 our 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;

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

potential receipt of government or third party funding to further develop Gencaro or rNAPc2;

the results of our future clinical trials and any future NDAs of our current and future product candidates;

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

the results and timing of regulatory reviews relating to our product candidates;

failure of any of our product candidates, if approved, to achieve commercial success;

general and industry-specific economic conditions that may affect our research and development expenditures;

the results of clinical trials conducted by others on drugs that would compete with our product candidates;

issues in manufacturing our product candidates or any approved products;

the initiation of or material developments in or the conclusion of litigation to enforce or defend any of our intellectual property rights;

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the loss of key employees;

the introduction of technological innovations or new commercial products by our competitors;

changes in estimates or recommendations by securities analysts, if any, who cover our common stock;

future sales of our common stock;

changes in the structure of health care payment systems;

period-to-period fluctuations in our financial results; and

our ability to retain the listing of our common stock on the Nasdaq Capital Market.

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 our 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 our profitability and reputation.

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

Sales in the public market of substantial amounts of our common stock could depress prevailing market prices of our

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common stock. As of June 30, 2011 we had 10,515,707shares 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 our directors, officers and other affiliates and unregistered shares held by non-affiliates. The sale of these additional shares, or the perception that such sales may occur, could depress the market price of our common stock.

As of June 30, 2011 approximately 1.5 million shares of our common stock were issuable upon the exercise of outstanding warrants, of which 323,701are exercisable as of this date and 1,176,471were issued pursuant to our registered direct offering completed in April 2011 and will become exercisable on October 21, 2011. Once a warrant is exercised, if the shares of our 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 we may issue in the future, are exercised, it could result in additional sales of our common stock in the market, which may have an adverse effect on our stock price.

As of June 30, 2011 there were approximately 921,000 shares of our common stock which may be issued upon exercise of outstanding stock options. If and when these options are exercised, such shares will be available for sale in the open market without further registration under the Securities Act. The existence of these outstanding options may negatively affect our ability to complete future equity financings at acceptable prices and on acceptable terms. The exercise of those options, and the prompt resale of shares of our common stock received, may also result in downward pressure on the price of our common stock.

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

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

We anticipate that we will retain our earnings, if any, for future growth and therefore do not anticipate paying cash dividends in the future. As a result, only appreciation of the price of our common stock will provide a return to stockholders. Investors seeking cash dividends should not invest in our common stock.

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

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

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

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

limit who may call a special meeting of stockholders;

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

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

Specifically, our certificate of incorporation provides that all stockholder action must be effected at a duly called meeting and not by a written consent. The bylaws provide, however, that our stockholders may call a special meeting of stockholders only upon a request of stockholders owning at least 50% of our outstanding common stock. These provisions of our certificate of incorporation and bylaws could discourage potential acquisition proposals and could delay or prevent a change in control. We designed these provisions to reduce our vulnerability to unsolicited acquisition proposals and to discourage certain tactics that may be used in proxy fights. These provisions, however, could also have the effect of discouraging others from making tender offers for our shares. As a consequence, they also may inhibit fluctuations in the market price of our shares that could result from actual or rumored takeover attempts. Such provisions also may have the effect of preventing changes in our management.

We are permitted to issue shares of our preferred stock without stockholder approval upon such terms as our board of directors determines. Therefore, the rights of the holders of our common stock are subject to, and may be adversely affected by, the rights of the holders of our preferred stock that may be issued in the future. In addition, the issuance of preferred stock could have a dilutive effect on the holdings of our current stockholders.

We are subject to the Delaware anti-takeover laws regulating corporate takeovers. These anti-takeover laws prevent a Delaware corporation from engaging in a merger or sale of more than 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

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shares owned by directors, officers and employee stock plans in which employee participants do not have the right to determine confidentially whether shares held under the plan will be tendered in a tender or exchange offer; or

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

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

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

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

generally deter efforts to obtain control of us.

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

Not applicable.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

ITEM 4. RESERVED

Not applicable.

ITEM 5. OTHER INFORMATION

On August 12, 2011, we entered into an amendment and restatement of our license agreement with the University of Colorado (the Amended License). The Amended License grants us an exclusive license to certain intellectual property that we currently licenses from the University. The Amended License also grants us the right to license new inventions related to this intellectual property and certain other new inventions invented by University personnel. As in the current license, the Amended License requires us to pay an annual minimum royalty. There are no other payments obligations under the Amended License with respect to any intellectual property we currently license. The Amended License is filed as Exhibit 10.5 to this Quarterly Report on Form 10-Q, and the description of the Amended License is qualified in its entirety by reference to such exhibit.

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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
3.1	Amended and Restated Certificate of Incorporation of the Registrant, as amended.(1)
3.2	Second Amended and Restated Bylaws of the Registrant, as amended.(2)
4.1	Form of Common Stock Purchase Warrant.(3)
10.1§	License Agreement by and between ARCA biopharma, Inc. and the University of Cincinnati, dated April 15, 2011.(4)
10.2	Placement Agency Agreement by and between ARCA biopharma, Inc. and Roth Capital Partners, LLC, dated April 18, 2011.(3)
10.3	Form of Subscription Agreement.(3)
10.4	First Amendment to Lease Agreement, signed June 14, 2011, of the Lease dated February 8, 2008, between ARCA biopharma, Inc. and Arista Place, LLC.(5)
10.5*§	Amended and Restated Exclusive License Agreement by and between ARCA biopharma, Inc. and The Regents of the University of Colorado, dated August 12, 2011.
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.
101.INS	XBRL Instance Document (furnished electronically herewith)
101.SCH	XBRL Taxonomy Extension Schema Document (furnished electronically herewith)
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document (furnished electronically herewith)
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document (furnished electronically herewith)
101.LAB	XBRL Taxonomy Extension Label Linkbase Document (furnished electronically herewith)
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document (furnished electronically herewith)

* Filed herewith.
Furnished herewith.

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§ Confidential treatment has been requested for portions of this document, which are omitted and filed separately with the SEC.

(1) 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.

(2) Previously filed with the SEC as an Exhibit to and incorporated herein by reference from ARCA biopharma, Inc. s Form 10-Q, filed on November 16, 2009, File No. 000-22873.

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(4) Previously filed with the SEC as an Exhibit and incorporated herein by reference from ARCA biopharma, Inc. s Form 10Q, filed on May 16, 2011, 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/ Patrick M. Wheeler
Patrick M. Wheeler
Chief Financial Officer

Dated: August 15, 2011

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