ARCA biopharma, Inc.
Form 10-Q
May 13, 2014

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

x QUARTERLY REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
FOR THE QUARTERLY PERIOD ENDED MARCH 31, 2014

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 (State or Other Jurisdiction of Incorporation or Organization)	36-3855489 (I.R.S. Employer Identification Number)
11080 CirclePoint Road, Suite 140, Westminster, CO (Address of Principal Executive Offices)	80020 (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 May 9, 2014: 21,010,815

ARCA BIOPHARMA, INC.

FORM 10-Q

FOR THE QUARTER ENDED MARCH 31, 2014

PART I. FINANCIAL INFORMATION

ITEM 1. CONSOLIDATED FINANCIAL STATEMENTS

ARCA BIOPHARMA, INC.

(a development stage enterprise)

CONSOLIDATED BALANCE SHEETS

(Unaudited)

	March 31, 2014	December 31, 2013
	(in thousands, except share and per share amounts)	
ASSETS		
Current assets:		
Cash and cash equivalents	$21,202	$16,756
Other current assets	599	169
Total current assets	21,801	16,925
Property and equipment, net	26	29
Other assets	828	130
Total assets	$22,655	$17,084
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$552	$597
Accrued compensation and employee benefits	111	459
Accrued expenses and other liabilities	457	446
Deferred rent, current portion	—	—
Total current liabilities	1,120	1,502
Deferred rent, net of current portion	1	1
Total liabilities	1,121	1,503
Commitments and contingencies		
Stockholders' equity:		
Series A convertible preferred stock, $0.001 par value; 135,000 shares authorized, no shares issued and outstanding at March 31, 2014 and December 31, 2013	—	—
Common stock, $0.001 par value; 100 million shares authorized	21	16

at March 31, 2014 and December 31, 2013; 21,001,690 and 15,685,562 shares issued and outstanding at March 31, 2014 and December 31, 2013, respectively		
Additional paid-in capital	98,835	90,498
Deficit accumulated during the development stage	(77,322)	(74,933)
Total stockholders' equity	21,534	15,581
Total liabilities and stockholders' equity	$22,655	$17,084

See accompanying Notes to Consolidated Financial Statements

ARCA BIOPHARMA, INC.

(a development stage enterprise)

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(unaudited)

	Three Months Ended March 31,		Period from December 17, 2001 (date of inception) to March 31,
	2014	2013	2014
	(in thousands, except share and per share amounts)		
Costs and expenses:			
Research and development	$1,308	$181	$46,913
Selling, general and administrative	1,082	889	47,677
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	2,390	1,070	108,473
Loss from operations	(2,390)	(1,070)	(108,473)
Gain on assignment of patent rights	—	—	2,000
Gain on bargain purchase	—	—	25,282
Interest and other income	2	—	2,035
Interest and other expense	(1)	(1)	(447)
Loss before income taxes	(2,389)	(1,071)	(79,603)
Benefit from income taxes	—	—	2,281
Net loss and comprehensive loss	$(2,389)	$(1,071)	$(77,322)
Less: Accretion of redeemable convertible preferred stock	—	—	(245)
Less: Deemed preferred stock dividend	—	—	(2,807)
Net loss available to common stockholders	$(2,389)	$(1,071)	$(80,374)
Net loss available to common stockholders per share:			
Basic and diluted	$(0.13)	$(0.35)	

Weighted average shares outstanding:		
Basic and diluted	18,785,418	3,034,763

See accompanying Notes to Consolidated Financial Statements

ARCA BIOPHARMA, INC.

(a development stage enterprise)

CONSOLIDATED STATEMENTS OF PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)

(unaudited)

							Stockholders' Equity (Deficit)				
	Series A Redeemable Convertible Preferred Stock		Series B Redeemable Convertible Preferred Stock		Series A Convertible Preferred Stock		Common Stock		Additional Paid In Capital	Deficit Accumulated During the Development Stage	Total
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
	(in thousands, except share and per share amounts)										
Balance, December 17, 2001 (date of inception)	—	$—	—	$ —	—	$ —	—	$ —	$—	$—	$—
Issuance of common stock to founders on December 31, 2002, for cash, at $0.36 per share	—	—	—	—	—	—	2,588	—	1	—	1
Net loss	—	—	—	—	—	—	—	—	—	(116)	(116)
Balance, December 31, 2003	—	—	—	—	—	—	2,588	—	1	(116)	(115)
Issuance of common stock on September 30, 2004, for cash, at $0.36 per share	—	—	—	—	—	—	19,720	—	7	—	7
Net loss	—	—	—	—	—	—	—	—	—	(511)	(511)
Balance, December 31, 2004	—	—	—	—	—	—	22,308	—	8	(627)	(619)
Issuance of common stock on January 3, 2005, for cash, at $0.36 per share	—	—	—	—	—	—	2,922	—	1	—	1
Issuance of common stock on January 3, 2005,	—	—	—	—	—	—	2,978	—	1	—	1

upon conversion of notes payable and related accrued interest at $0.36 per share											
Issuance of common stock on October 14, 2005, for intellectual property license rights, at $48.84 per share	—	—	—	—	—	—	903	—	44	—	44
Issuance of common stock on October 14, 2005, upon conversion of notes payable and related accrued interest	—	—	—	—	—	—	31,095	—	1,354	—	1,354
Net loss	—	—	—	—	—	—	—	—	—	(1,459)	(1,459)
Balance, December 31, 2005	—	—	—	—	—	—	60,206	—	1,408	(2,086)	(678)
Issuance of common stock on February 21, 2006, for intellectual property license rights, at $4.32 per share	—	—	—	—	—	—	17,372	—	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	—	—	—	—	—	—	8,019	—	3	—	3

See accompanying notes to consolidated financial statements

5

	Series A Redeemable Convertible Preferred Stock		Series B Redeemable Convertible Preferred Stock		Stockholders' Equity (Deficit)						
					Series A Convertible Preferred Stock		Common stock		Additional Paid In Capital	Deficit Accumulated During the Development Stage	Total
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
	(in thousands, except share and per share amounts)										
Issuance of common stock on February 22, 2006, for intellectual property and product license rights, at $4.32 per share	—	—	—	—	—	—	13,907	—	60	—	60
Issuance of common stock on June 23, 2006, for intellectual property license rights, at $5.40 per share	—	—	—	—	—	—	2,505	—	15	—	15
Issuance of common stock on November 7, 2006, for intellectual property license rights, at $5.40 per share		—	—	—	—	—	38	—	—	—	—
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	—	—	—	—	102,047	—	1,583	(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 $10.08 per share	—	—	—	—	—	—	1,303	—	13	—	13
Issuance of common stock for intellectual property	—	—	—	—	—	—	642	—	7	—	7

license rights, on June 30, 2007 at $10.80 per share											
Issuance of common stock for commercial license rights, on July 19, 2007, vests upon achievement of specified criteria	—	—	—	—	—	—	2,783	—	—	—	—
Share-based compensation	—	—	—	—	—	—	—	—	50	—	50
Issuance of shares to executive on February 19, 2007, vesting upon achievement of specified criteria, subject to repurchase	—	—	—	—	—	—	13,915	—	—	—	—

See accompanying notes to consolidated financial statements

	Series A Redeemable Convertible Preferred Stock		Series B Redeemable Convertible Preferred Stock		Stockholders' Equity (Deficit)						
					Series A Convertible Preferred Stock		Common stock		Additional Paid In Capital	Deficit Accumulated During the Development Stage	Total
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
	(in thousands, except share and per share amounts)										
Issuance of common stock upon exercise of stock options for cash	—	—	—	—	—	—	2,227	—	16	—	16
Net loss	—	—	—	—	—	—	—	—	—	(13,994)	(13,994)
Balance, December 31, 2007	9,222,257	14,938	6,455,579	17,871	—	—	122,917	—	1,632	(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	—	—	—	—	—	—	36,154	—	54	—	54
Net loss	—	—	—	—	—	—	—	—	—	(19,431)	(19,431)
Balance, December 31, 2008	9,222,257	14,958	6,455,579	17,907	—	—	159,071	—	2,574	(40,752)	(38,178)
Adjustment for fractional shares on	—	—	—	—	—	—	(7)	—	—	—	—

common conversion											
Deemed preferred stock dividend for additional common shares issuable under anti-dilution provision	—	—	—	781	—	—	—	—	(781)	—	(781)
Accretion of Series A offering costs	—	42	—	—	—	—	—	—	(42)	—	(42)
Accretion of Series B offering costs	—	—	—	93	—	—	—	—	(93)	—	(93)
Conversion of preferred stock	(9,222,257)	(15,000)	(6,455,579)	(18,781)	—	—	507,123	1	33,780	—	33,781
Restricted stock release from restriction	—	—	—	—	—	—	—	—	75	—	75
Conversion of convertible notes and related accrued interest	—	—	—	—	—	—	145,465	—	8,501	—	8,501
Conversion of warrants for preferred stock	—	—	—	—	—	—	—	—	36	—	36
Merger with Nuvelo, Inc.	—	—	—	—	—	—	447,826	—	11,913	—	11,913
Adjustment for fractional shares	—	—	—	—	—	—	(102)	—	—	—	—
Share-based compensation	—	—	—	—	—	—	—	—	845	—	845
Issuance of common stock upon exercise of stock options for cash	—	—	—	—	—	—	10,521	—	114	—	114
Issuance of common stock under	—	—	—	—	—	—	177	—	2	—	2

employee stock purchase plan and upon vesting of restricted stock units											
Estimated fair value of warrants issued in connection with lease termination	—	—	—	—	—	—	—	—	377	—	377
Net loss	—	—	—	—	—	—	—	—	—	(9,138)	(9,138)
Balance, December 31, 2009	—	—	—	—	—	—	1,270,074	1	57,301	(49,890)	7,412

See accompanying notes to consolidated financial statements

	Stockholders' Equity (Deficit)										
	Series A Redeemable Convertible Preferred Stock		Series B Redeemable Convertible Preferred Stock		Series C Convertible Preferred Stock		Common Stock		Additional Paid In Capital	Deficit Accumulated During the Development Stage	Total
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
	(in thousands, except share and per share amounts)										
Issuance of common stock for cash, net of offering costs	—	—	—	—	—	—	194,100	—	7,182	—	7,182
Issuance of common stock upon exercise of stock options for cash	—	—	—	—	—	—	8,248	—	139	—	139
Share-based compensation	—	—	—	—	—	—	—	—	458	—	458
Net loss	—	—	—	—	—	—	—	—	—	(8,420)	(8,420)
Balance, December 31, 2010	—	—	—	—	—	—	1,472,422	1	65,080	(58,310)	6,771
Issuance of common stock for cash, net of offering costs	—	—	—	—	—	—	557,890	1	4,016	—	4,017
Issuance of common stock upon exercise of stock options for cash	—	—	—	—	—	—	188	—	—	—	—
Share-based compensation	—	—	—	—	—	—	—	—	308	—	308
Net loss	—	—	—	—	—	—	—	—	—	(5,364)	(5,364)
Balance, December 31, 2011	—	—	—	—	—	—	2,030,500	2	69,404	(63,674)	5,732
Issuance of common stock for cash, net of offering costs	—	—	—	—	—	—	629,815	1	1,188	—	1,189
Share-based compensation	—	—	—	—	—	—	—	—	306	—	306
Net loss	—	—	—	—	—	—	—	—	—	(4,320)	(4,320)
Balance, December 31,	—	—	—	—	—	—	2,660,315	3	70,898	(67,994)	2,907

2012											
Issuance of common stock for cash, net of offering costs	—	—	—	—	—	—	521,066	—	1,421	—	1,421
Adjustment for fractional shares	—	—	—	—	—	—	(64)	—	—	—	—
Issuance of common stock upon exercise of warrants for cash	—	—	—	—	—	—	4,245	—	12	—	12
Issuance of Series A convertible preferred stock, net of offering costs	—	—	—	—	125,000	—	—	—	17,917	—	17,917
Deemed preferred stock dividend for beneficial conversion feature	—	—	—	—	—	—	—	—	2,026	—	2,026
Impact of deemed preferred stock dividend for beneficial conversion feature on common stockholders	—	—	—	—	—	—	—	—	(2,026)	—	(2,026)
Conversion of preferred stock to common stock	—	—	—	—	(125,000)	—	12,500,000	13	(33)	—	(20)
Share-based compensation	—	—	—	—	—	—	—	—	283	—	283
Net loss	—	—	—	—	—	—	—	—	—	(6,939)	(6,939)
Balance, December 31, 2013	—	—	—	—	—	—	15,685,562	16	90,498	(74,933)	15,581
Issuance of common stock for cash, net of offering costs	—	—	—	—	—	—	5,116,228	5	7,861	—	7,866
Issuance of common stock upon exercise of warrants for	—	—	—	—	—	—	199,900	—	318	—	318

cash											
Share-based compensation	—	—	—	—	—	—	—	—	158	—	158
Net loss	—	—	—	—	—	—	—	—	—	(2,389)	(2,389)
Balance, March 31, 2014	—	$ —	—	$ —	—	$ —	21,001,690	$ 21	$ 98,835	$ (77,322)	$ 21,534

See accompanying notes to consolidated financial statements

ARCA BIOPHARMA, INC.

(a development stage enterprise)

CONSOLIDATED STATEMENTS OF CASH FLOWS

(unaudited)

	Three Months Ended March 31,		Period from December 17, 2001 (date of inception) to March 31,
	2014	2013	2014
	(in thousands)		
Cash flows from operating activities:			
Net loss	$(2,389)	$(1,071)	$(77,322)
Adjustments to reconcile net loss to net cash used in operating activities:			
Gain on patent rights assignment	—	—	(2,000)
Gain on bargain purchase	—	—	(25,282)
Depreciation and amortization	3	10	1,809
Non-cash interest expense	—	—	211
Share-based compensation	158	42	3,029
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	—	—	83
Other, net	—	—	267
Change in operating assets and liabilities (net of amounts acquired):			
Other current assets	(251)	(157)	2,699
Other assets	(698)	20	6,642
Accounts payable	(45)	312	(1,638)
Accrued expenses and other liabilities	(465)	88	(19,005)
Deferred rent	—	(8)	1
Net cash used in operating activities	(3,687)	(764)	(106,396)
Cash flows from investing activities:			

Cash received from merger	—	—	30,392
Payment of deferred transaction costs	—	—	(1,186)
Purchase of property and equipment	—	(9)	(1,911)
Proceeds from sale of marketable securities	—	—	15,369
Proceeds from sale of property and equipment	—	—	358
Proceeds from patent rights assignment	—	—	2,000
Net cash (used in) provided by investing activities	—	(9)	45,022
Cash flows from 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	—	—	52,316
Preferred stock offering costs	—	—	(2,329)
Proceeds from the issuance of common stock	9,018	1,741	24,868
Common stock offering costs	(834)	(308)	(2,548)
Repayment of principal on bank note payable	—	—	(4,000)
Repayment of principal on convertible notes payables	—	—	(105)
Repayment of principal on vendor finance agreement	(51)	(43)	(505)
Net cash provided by financing activities	8,133	1,390	82,576
Net increase in cash and cash equivalents	4,446	617	21,202
Cash and cash equivalents, beginning of period	16,756	2,920	—
Cash and cash equivalents, end of period	$21,202	$3,537	$21,202
Supplemental cash flow information:			
Interest paid	$1	$1	$119
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	$128	$131	$128

See accompanying Notes to Consolidated Financial Statements

ARCA BIOPHARMA, INC.

(a development stage enterprise)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(unaudited)

(1) The Company and Summary of Significant Accounting Policies

Description of Business

ARCA biopharma, Inc., or the Company or ARCA, a Delaware corporation, is headquartered in Westminster, Colorado and is a biopharmaceutical company principally focused on developing genetically-targeted therapies for cardiovascular diseases. The Company's lead product candidate, Gencaro™ (bucindolol hydrochloride), is a pharmacologically unique beta-blocker and mild vasodilator that ARCA plans to evaluate in a clinical trial for the treatment of atrial fibrillation, or AF, in patients with heart failure and/or left ventricular dysfunction, or HFREF. The Company has identified common genetic variations in receptors in the cardiovascular system that it believes interact with Gencaro's pharmacology and may predict patient response to the drug.

The Company plans to test this hypothesis in a Phase 2B/3 clinical trial of Gencaro, known as GENETIC-AF. The AF indication for Gencaro was chosen based on prior clinical data from the previously conducted Phase 3 heart failure (HF) trial of Gencaro in 2,708 HF patients, or the BEST trial, which suggested that Gencaro may be successful in reducing or preventing AF. GENETIC-AF is a multi-center, randomized, double-blind clinical trial designed to compare the safety and efficacy of Gencaro to an active comparator in HFREF patients recently diagnosed with persistent AF and having beta-1 389 arginine homozygous genotype, the genotype the Company believes responds most favorably to Gencaro. The primary endpoint of GENETIC-AF is time to recurrent symptomatic AF/atrial flutter (AFL) or all-cause mortality.

ARCA has created an adaptive design for GENETIC-AF. The Company has initiated screening of patients for the Phase 2B study of approximately 200 HFREF patients. The GENETIC-AF Data Safety Monitoring Board (DSMB) will analyze certain data from the Phase 2B portion of the trial and recommend, based on a comparison to the pre-trial statistical assumptions, whether the trial should proceed to Phase 3 and enroll an additional 420 patients. The DSMB will make their recommendation based on analysis of certain trial data after 200 patients have been enrolled and have completed 24 weeks of follow-up, the period for measuring the trial's primary end-point. The interim analysis will focus on available data regarding the trial's primary end point, AF event rates, AF burden, and safety. Should the DSMB interim analysis conclude the data is consistent with the pre-trial statistical assumptions and indicates potential for achieving statistical significance for the Phase 3 endpoint, then the DSMB may recommend the study proceed to Phase 3. The DSMB may also recommend changes to the study design before potentially proceeding to Phase 3, or it may recommend that the study not proceed to Phase 3. The Company, in consultation with the trial's clinical steering committee and the DSMB, will make the final determination on the trial's development steps. The Company believes the Phase 2B portion of the study would take approximately two and one-half years to complete from the time the first patient is enrolled until the planned DSMB interim analysis of data from the initial 200 patients.

The Company has been granted patents in the U.S., Europe, and other jurisdictions for methods of treating AF and HF patients with Gencaro based on genetic testing, which the Company believes may provide market exclusivity for these uses of Gencaro into at least 2026 in the U.S. and into 2025 in Europe. In addition, the Company believes that if Gencaro is approved, a Gencaro patent will be eligible for patent term extension based on our current clinical trial plans which, if granted, may provide market exclusivity for Gencaro into 2029 or 2030 in the U.S. and Europe.

To complete both phases of the GENETIC-AF clinical trial and submit for FDA approval, the Company will need to raise additional capital. If the Company is unable to obtain additional funding or is unable to complete a strategic transaction, it may have to discontinue development activities on Gencaro or discontinue its operations.

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 and raising capital necessary to fund its operations. The Company has not generated revenue to date and is subject to a number of risks similar to those of other development stage companies, including dependence on key individuals, the development of and regulatory approval of commercially viable products, the need to raise adequate additional financing necessary to fund the development and commercialization of its products, and competition from larger companies. The Company has historically funded its operations through issuances of 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 $108.5 million and had negative cash flows from operations of $106.4 million.

During 2013, the Company raised approximately $19.3 million, net of offering costs, through sales of its convertible preferred and common stock and warrants. In February 2014, the Company completed a public equity offering raising approximately $7.9 million in net proceeds to provide additional funds for the Phase 2B/3 GENETIC-AF trial and the Company's ongoing operations. The Company has initiated screening of patients for the Phase 2B/3 GENETIC-AF trial, and the Company anticipates that its current cash and cash equivalents will be sufficient to fund its operations, at its projected cost structure, through at least the end of 2015. However, in light of the significant uncertainties regarding clinical development timelines and costs for developing drugs such as Gencaro, the Company expects to need to raise additional capital to finance the completion of GENETIC-AF and the Company's ongoing operations. 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 operations.

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:

progress of GENETIC-AF enrollment and any data that may become available;
the costs and timing for the GENETIC-AF 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;
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;
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, 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.

The significant uncertainties surrounding the clinical development timelines and costs and the need to raise a significant amount of capital raises substantial doubt about the Company's ability to continue as a going concern for a reasonable period of time. 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.

Reverse Stock Split

On March 4, 2013, the Company completed a 1-for-6 reverse split of its common stock. All common shares and per common share amounts in the financial statements and footnotes have been adjusted retroactively to reflect the effects of this action.

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 results of operations for the three months ended March 31, 2014 are not necessarily indicative of results expected for the full year ending December 31, 2014. The Company has generated no revenue to date and its activities have consisted of seeking regulatory approval, research and development, exploring strategic alternatives for further developing and commercializing Gencaro, and raising capital. Accordingly, the Company continues to be considered in the development stage at March 31, 2014. 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, 2013 included in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission, as amended. 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) Net Loss Per Share

The Company calculates basic earnings per share by dividing loss attributable to common stockholders by the weighted average common shares outstanding during the period, excluding common stock subject to vesting provisions. Diluted earnings per share is computed by dividing loss attributable to common stockholders by the weighted average number of common shares outstanding during the period increased to include, if dilutive, the number of additional common shares that would have been outstanding if the potential common shares had been issued. The Company's potentially dilutive shares include stock options and warrants for common stock.

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

	Three Months Ended March 31,	
	2014	2013
(In thousands, except shares and per share data)		
Net loss	$(2,389)	$(1,071)
Net loss available to common shareholders	$(2,389)	$(1,071)
Weighted average shares of common stock outstanding	18,785,418	3,037,546
Less: Weighted-average shares of unvested common stock	—	(2,783)
Total weighted-average shares used in computing net loss per share attributed to common stockholders	18,785,418	3,034,763
Basic and diluted loss per share	$(0.13)	$(0.35)

Potentially dilutive securities representing 10.2 million and 1.3 million weighted average shares of common stock were excluded for the three months ended March 31, 2014 and 2013, respectively, because including them would have an anti-dilutive effect on net 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 March 31, 2014, the Company had $21.1 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 period ended March 31, 2014.

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.

(5) Property and Equipment

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

		March 31,	December 31,
	Estimated Life	2014	2013
Computer equipment	3 years	$99	$ 99
Lab equipment	5 years	142	142
Furniture and fixtures	5 years	89	89
Computer software	3 years	176	176
Leasehold improvements	Lesser of useful life or life of the lease	8	8
		514	514
Accumulated depreciation and amortization		(488)	(485)
Property and equipment, net		$26	$ 29

For the three months ended March 31, 2014 and 2013, and for the period from Inception through March 31, 2014, depreciation and amortization expense was $3,000, $10,000, and $1.8 million respectively.

(6) Commitments and Contingencies

The Company has or is subject to the following commitments and contingencies:

Employment Agreements

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

Operating Lease

On August 1, 2013 the Company entered into a lease agreement for approximately 5,300 square feet of office facilities in Westminster, Colorado which has served as the Company’s primary business office since October 1, 2013. The lease has a three year term and expires on September 30, 2016. The Company’s previous office lease, entered into on February 8, 2008 for office facilities in Broomfield, Colorado, served as the Company’s primary business office through September 30, 2013. Below is a summary of the future minimum lease payments committed for the Company’s facility in Westminster, Colorado as of March 31, 2014 (in thousands):

Remainder of 2014	$59

2015	80
2016	62
Total future minimum lease payments	$201

Rent expense under these leases for the three months ended March 31, 2014 and 2013 was $19,000 and $12,000, respectively, and was $597,000 from Inception through March 31, 2014.

Duke University

In November 2013, the Company entered into a clinical research agreement with Duke University (Duke) to serve as the clinical research organization for the Company's GENETIC-AF clinical study. Under the agreement the Company is responsible to pay Duke for its work managing certain aspects of the clinical study, including clinical site recruitment and clinical site management. Upon completion of the clinical study, the agreement will terminate. The agreement can be terminated earlier by the Company for any reason with 90 days written notice to Duke. In the event of an early termination, the Company and Duke would coordinate efforts for an orderly wind-down of the study, and the Company would be responsible to pay Duke for time and effort incurred through the date of termination and through the wind-down period.

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 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.

Cardiovascular Pharmacology and Engineering Consultants, LLC, or CPEC

ARCA has licensed worldwide rights to Gencaro, including all preclinical and clinical data from Cardiovascular Pharmacology and Engineering Consultants, LLC, or CPEC, who has licensed rights in Gencaro from BMS. CPEC is a licensing subsidiary of Indevus Pharmaceuticals Inc. (a wholly owned subsidiary of Endo Pharmaceuticals), holding ownership rights to certain clinical trial data of Gencaro. Under the terms of its license agreement with CPEC, the Company will incur milestone and royalty obligations upon the occurrence of certain events. If the FDA grants marketing approval for Gencaro, the license agreement states that the Company will owe CPEC a milestone payment of $8.0 million within six months after FDA approval. The license agreement states that a milestone payment of up to $5.0 million in the aggregate shall be paid upon regulatory marketing approval in Europe and Japan. The license agreement also states that 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.

(7) Equity Financings and Warrants

2013 Equity Financings

Private Investment in Public Equity (PIPE) Transaction

On January 22, 2013, the Company entered into a Subscription Agreement (the "January 2013 Purchase Agreement") with various accredited investors and its Chief Executive Officer in connection with a private placement of its common stock and warrants. Pursuant to the January 2013 Purchase Agreement, the Company sold an aggregate of 356,430 shares of its common stock and warrants to purchase up to 249,501 additional shares of its common stock for aggregate gross proceeds of approximately $1 million, before deducting estimated offering expenses payable by the Company. The net proceeds to the Company were approximately $805,000, and the private placement closed on January 25, 2013.

The common stock and warrants were sold in units consisting of one share of common stock and a warrant to purchase 0.70 shares of common stock. The purchase price for each unit was $2.81. The warrants were exercisable upon issuance, expire seven years from the date of issuance, and have an exercise price of $2.28 per share, equal to 100% of the closing bid price of ARCA's common stock on the Nasdaq Capital Market on January 22, 2013.

The Company filed a registration statement for the resale of the shares underlying the units sold in the private placement. That registration statement was declared effective by the Securities and Exchange Commission on

February 14, 2013.

In connection with this transaction, the Company agreed that, subject to certain exceptions, it would not, while the warrants are outstanding, effect or enter into an agreement to effect any issuance of common stock or securities convertible into, exercisable for or exchangeable for common stock in a "variable rate transaction," which means a transaction in which the Company issues or sells any convertible securities either (A) at a conversion price, exercise price or exchange rate or other price that is based upon and/or varies with the trading prices of, or quotations for, the shares of common stock at any time after the initial issuance of such convertible securities, or (B) with a conversion, exercise or exchange price that is subject to being reset at some future date after the initial issuance of the convertible securities or upon the occurrence of the specified or contingent events directly or indirectly related to our business or the market for our common stock. In addition, the Company agreed that, subject to certain exceptions, if it issues securities within one year following the closing of the offering, each investor would have the right to purchase its pro rata share of a specified portion of the securities in the future offering on the same terms, conditions and price provided for in the proposed issuance of securities.

Registered Direct Offering

On January 31, 2013, the Company entered into a subscription agreement with certain institutional investors (the "Investors") in connection with its Registered Direct public offering, pursuant to which the Company sold an aggregate of 164,636 shares of its common stock and warrants to purchase up to 65,855 additional shares of its common stock to the Investors for aggregate gross proceeds of approximately $730,000, before deducting placement agent fee and other estimated offering expenses payable by the Company. The net proceeds to the Company were approximately $616,000, and the offering closed on February 4, 2013.

The common stock and warrants were sold in units consisting of one share of common stock and a warrant to purchase 0.40 shares of common stock. The purchase price for each unit was $4.43. The warrants were exercisable upon issuance, expire five years from the date of issuance, and have an exercise price of $4.13 per share, equal to the closing bid price of ARCA's common stock on the Nasdaq Capital Market on January 31, 2013. The Offering was effected as a takedown of the Company's Registration Statement on Form S-3, as amended, which became effective on April 4, 2011, pursuant to a prospectus supplement filed with the Securities and Exchange Commission on February 1, 2013. The warrants provide for cashless exercise and settlement in unregistered shares if there is no effective registration statement registering, or the prospectus contained therein is not available for the issuance of the shares of common stock underlying the warrants at the time of exercise.

Public Offering

On June 4, 2013, the Company sold shares of its Series A Convertible Preferred Stock (Preferred Stock) and warrants to purchase common stock in a public offering for aggregate gross proceeds of $20.0 million. The Company issued 125,000 shares of Preferred Stock and warrants to purchase up to 6,250,000 shares of common stock at a purchase price of $160 per share of Preferred Stock. The net proceeds, after deducting placement agent fees and other offering expenses payable by the Company, were approximately $17.9 million. ARCA's Director and Chief Executive Officer participated in the offering, purchasing 781 shares of Preferred Stock and warrants to purchase 39,050 shares of common stock.

Each share of Preferred Stock was convertible into 100 shares of the Company's common stock at any time at the option of the holder. Each share of Preferred Stock had a liquidation preference of $.001 per share. The shares of Preferred Stock had no preferential dividends or redemption rights, and no voting rights except as required by law. During 2013, all of the shares of the Preferred Stock were converted into shares of ARCA common stock.

Each purchaser in the offering was issued a warrant to purchase 50 shares of the Company's common stock for each share of Preferred Stock purchased. The warrants have an exercise price of $1.60 per share, will expire on the five year anniversary of the date of issuance, and were exercisable immediately upon issuance, provided that the holder will be prohibited from exercising the warrants if, as a result of such exercise, the holder, together with its affiliates, would beneficially own more than 9.99% of the total number of shares of common stock then issued and outstanding.

The securities were sold pursuant to a placement agreement and have been registered under the Securities Act of 1933 pursuant to the Company's Registration Statement on Form S-1, as amended (No.333-187508), which was declared effective by the Securities and Exchange Commission on May 29, 2013, and the Preferred Stock and Warrants were offered and sold pursuant to a prospectus dated May 30, 2013.

In connection with the Preferred Stock financing, the Company recorded a non-cash dividend of approximately $2.0 million to recognize the intrinsic value of the embedded beneficial conversion feature. Typically, such a deemed dividend would be represented as a reduction in a company's retained earnings and an increase in additional paid in capital in recognition of the reapportionment of common shareholder value to the preferred stock purchasers.

However, since ARCA has an accumulated deficit, the deemed dividend is recognized by a reapportionment of additional paid in capital from common shareholders to additional paid in capital of preferred stock purchasers, which are combined in the Company's statement of stockholders' equity.

2014 Equity Financing

Registered Direct Offering

On February 3, 2014, the Company agreed to sell to certain investors an aggregate of 5,116,228 shares of the Company's common stock and warrants to purchase an aggregate of 1,279,057 shares of the Company's common stock at a purchase price of $1.70 per share of Common Stock, for aggregate gross proceeds of approximately of $8.7 million, before deducting placement agent fees and other offering related expenses. The offering closed on February 7, 2014, and the net proceeds to the Company were approximately $7.9 million.

The common stock and warrants were sold in combination consisting of one share of common stock and a warrant to purchase 0.25 shares of common stock. The warrants were exercisable upon issuance, expire five years from the date of issuance, and have an exercise price of $2.125 per share, equal to 125% of the closing bid price of ARCA's common stock on the Nasdaq Capital Market on February 3, 2014. The offering was effected as a takedown off the Company's Registration Statement on Form S-3, as amended, which became effective on April 4, 2011, pursuant to a prospectus supplement filed with the Securities and Exchange Commission on February 4, 2014. The warrants provide for cashless exercise and settlement in unregistered shares if there is no effective registration statement registering, or the prospectus contained therein is not available for the issuance of the shares of common stock underlying the warrants at the time of exercise.

Warrants

As of March 31, 2014, warrants to purchase approximately 9.4 million shares of common stock were outstanding at exercise prices ranging from $1.60 to $116.89, with a weighted average exercise price per share of $2.31. These warrants, which were granted as part of various financing and business agreements, expire at various times between April 2016 and January 2020. Warrants were recorded in additional paid-in capital at their estimated fair market value at the date of grant using a Black-Scholes option-pricing model.

(8) Share-based Compensation

For the three month period ended March 31, 2014 and 2013 and for the period from Inception through March 31, 2014, the Company recognized the following non-cash, share-based compensation expense in the consolidated statement of operations (in thousands):

	Three Months Ended March 31,		Period from December 17, 2001 (date of inception) to March 31,
	2014	2013	2014
Research and Development	$40	$ 15	$ 707
Selling, General and Administrative	118	27	1,935
Restructuring Expense	—	—	387
Total	$158	$ 42	$ 3,029

Stock option and stock award transactions for the three month period ended March 31, 2014 under the Company's stock incentive plans were as follows:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)
Options outstanding at December 31, 2013	843,442	$3.76	8.94
Granted	200,079	1.91	
Exercised	—	—	
Forfeited and cancelled	(27)	1,908.00	
Options outstanding at March 31, 2014	1,043,494	$3.35	8.93
Options exercisable at March 31, 2014	266,655	$8.42	7.13
Options vested and expected to vest	1,031,382	$3.37	8.92

	Number of Shares	Weighted Average Grant Date Fair Value
Restricted stock units outstanding at December 31, 2013	419,000	$ 1.39
Granted	191,700	1.95
Vested and released	—	—
Forfeited and cancelled	—	—
Restricted stock units outstanding at March 31, 2014	610,700	$ 1.57

(9) Income Taxes

In accordance with United States Generally Accepted Accounting Principles, 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.

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" within the meaning of Section 27A of the Securities Act of 1933, as amended, Section 21E of the Securities Exchange Act of 1934, as amended and the Private Securities Litigation Reform Act of 1995. These statements include, but are not limited to, statements regarding the Company's anticipated timing for initiation or completion of its clinical trials for any of its product candidates; the potential for Gencaro to be an effective potential treatment for atrial fibrillation and, the Company's ability to fund future operations. 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, including, without limitation, the risks and uncertainties associated with: the Company's financial resources and whether they will be sufficient to meet the Company's business objectives and operational requirements; and/or obtain additional financing; the Company's anticipated timing for initiation or completion of its clinical trials for any of its product candidates; the Company's ability to identify, develop and achieve commercial success for products and technologies; drug discovery and the regulatory approval process; estimated timelines for regulatory filings and the implications of interim or final results of the Company's clinical trials; the extent to which the Company's issued and pending patents may protect its products and technology; the potential of the Company's clinical development program to lead to the approval of the Company's New Drug Application for Gencaro; and, the impact of competitive products and technological changes. 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. These and other factors are identified and described in more detail in ARCA's filings with the SEC, including without limitation the Company's annual report on Form 10-K for the year ended December 31, 2012, as amended, the Company's Registration Statement on Form S-1 (Registration No. 333-187508), and subsequent filings. Forward-looking statements may be identified by words including "will," "plan," "anticipate," "believe," "intend," "estimates," "expect," "should," "may," "potent similar expressions. The Company disclaims any intent or obligation to update these forward-looking statements.

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

Overview

We are a biopharmaceutical company principally focused on developing genetically-targeted therapies for cardiovascular diseases. Our lead product candidate is Gencaro™ (bucindolol hydrochloride), a pharmacologically unique beta-blocker and mild vasodilator that we plan to evaluate in a clinical trial for the treatment of atrial fibrillation, or AF, in patients with heart failure and/or left ventricular dysfunction, or HFREF. We have identified common genetic variations in receptors in the cardiovascular system that we believe interact with Gencaro's pharmacology and may predict patient response to the drug.

AF is considered an epidemic cardiovascular disease. The estimated number of individuals with AF globally in 2010 was 33.5 million. According to the 2014 American Heart Association report on Heart Disease and Stroke Statistics, the estimated number of individuals with AF in the U.S. in 2010 ranged from 2.7 million to 6.1 million people. AF 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 potentially resulting in stroke. AF increases the risk of stroke and may also contribute to worsening heart failure. The approved therapies for the treatment or prevention AF have certain disadvantages in HFREF patients, such as toxic or cardiovascular adverse effects, and most of the approved drugs for AF are contra indicated or have warnings in their prescribing information for such patients. 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 HFREF patients.

Our GENETIC-AF clinical trial is a multi-center, randomized, double-blind clinical trial designed to compare the safety and efficacy of Gencaro to an active comparator, the beta-blocker Toprol XL (metoprolol succinate), in HFREF patients recently diagnosed with persistent AF and having beta-1 389 arginine homozygous genotype, the genotype we believe responds most favorably to Gencaro. The primary endpoint of GENETIC-AF, time to recurrent symptomatic AF/atrial flutter (AFL) or all-cause mortality, will be measured over a twenty-four week period after a patient has been electrically cardioverted to restore normal heart rhythm.

The AF indication for Gencaro was chosen based on clinical data from the previously conducted Phase 3 heart failure trial of 2,708 patients, or the BEST trial. We believe data from the BEST trial indicate that Gencaro may have a genetically regulated effect in reducing or preventing AF, whereas we believe the therapeutic benefit of Toprol XL does not appear to be enhanced in patients with this genotype. A retrospective analysis of data from the BEST trial shows that the entire cohort of patients in the BEST trial treated with Gencaro had a 41% reduction in the risk of new onset AF (time-to-event) compared to placebo ($p = 0.0004$). In the BEST DNA substudy, patients with the beta-1 389 arginine homozygous genotype experienced a 74% ($p = 0.0003$) reduction in risk of AF when receiving Gencaro, based on the same analysis. The beta-1 389 arginine homozygous genotype was present in about 47% of the patients in the BEST pharmacogenetic substudy, and we estimate it is present in about 50% of the US general population.

We have created an adaptive design for GENETIC-AF. We have initiated screening of patients for the Phase 2B study of approximately 200 HFREF patients with recent onset, persistent AF who have the beta-1 389 arginine homozygous genotype that we believe responds most favorably to Gencaro. In addition to measuring the primary endpoint of recurrent symptomatic AF/atrial flutter (AFL) or all-cause mortality, an additional efficacy measure in the Phase 2B portion of GENETIC-AF is AF burden, defined as a patient's percentage of time in AF per day, regardless of symptoms. Certain patients in the Phase 2B portion of the trial will have either a newly or previously implanted Medtronic device that measures and records AF burden. The GENETIC-AF Data Safety Monitoring Board (DSMB) will analyze certain data from the Phase 2B portion of the trial and recommend, based on a comparison to our pre-trial statistical assumptions, whether the trial should proceed to Phase 3 and seek to enroll an additional 420 patients. The DSMB will make their recommendation based on analysis of certain trial data after 200 patients have been enrolled and have completed 24 weeks of follow-up, the period for measuring the trial's primary end-point. The interim analysis will focus on available data regarding the trial's primary endpoint, AF event rates, AF burden, and safety. Should the DSMB interim analysis conclude that the interim data is consistent with pre-trial statistical assumptions, including the potential for achieving statistical significance for the Phase 3 endpoint, then the DSMB may recommend the study proceed to Phase 3. The DSMB may also recommend changes to the study design before the trial proceeds to Phase 3, or it may recommend that the study not proceed to Phase 3. Based on the DSMB recommendation, and other factors, the Company, in consultation with the trial's clinical steering committee, will make the final determination on the trial's development steps. The full Phase 2B/3 trial is designed for 90 percent power at a p-value of less than 0.01 significance level to detect a 25 percent reduction in the risk of AF/AFL recurrence or death in patients in the Gencaro arm compared to patients in the Toprol XL arm. The Company believes the Phase 2B portion of the study will take approximately two and one-half years to complete from the time the first patient is enrolled until the planned DSMB interim analysis of data from the initial 200 patients.

Our GENETIC-AF clinical trial of Gencaro requires a companion diagnostic test to identify the patient's receptor genotype. Accordingly, the GENETIC AF trial requires the use of a third party diagnostic service to perform the genetic testing. We have an agreement with Laboratory Corporation of America, or LabCorp, to provide the companion diagnostic test and services to support our GENETIC-AF trial. LabCorp has developed the genetic test and obtained an Investigational Device Exemption, or IDE, from the FDA for the companion diagnostic test which is being used in our GENETIC-AF clinical trial.

Medtronic, Inc., a leader in medical technologies to improve the treatment of chronic diseases including cardiac rhythm disorders is collaborating with us on the GENETIC-AF trial. Under the collaboration with Medtronic, we plan to conduct a substudy that will include continuous monitoring of the cardiac rhythms of certain patients enrolled during the Phase 2B portion of the trial and approximately 100 additional patients in the Phase 3 portion of GENETIC-AF. The collaboration is being administered by a joint ARCA-Medtronic committee. Medtronic will use its proprietary CareLink System to collect and analyze the cardiac rhythm data from the implanted Medtronic devices and the data will be used by the DSMB as part of the interim analysis. Medtronic will support the reimbursement process for patients enrolled in the Phase 2B portion, and agreed to provide financial support of unreimbursed costs for a certain number of patients in the Phase 2B portion up to a certain maximum amount per patient. If GENETIC-AF proceeds to Phase 3, we will seek to enroll an additional 100 patients with Medtronic devices for monitoring and recording AF burden. Medtronic will provide the agreed-on CareLink System cardiac rhythm data collection and analysis for the Phase 3 portion of the substudy and support the reimbursement process.

We have been granted patents in the U.S., Europe, and other jurisdictions for methods of treating AF and HF patients with Gencaro based on genetic testing, which we believe may provide market exclusivity for these uses of Gencaro into at least 2026 in the US and into 2025 in Europe. In addition, we believe that if Gencaro is approved, a Gencaro patent will be eligible for patent term extension based on our current clinical trial plans which, if granted, may provide market exclusivity for Gencaro into 2029 or 2030 in the US and Europe.

To support the continued development of Gencaro, we completed a public equity offering in February 2014 that raised approximately $7.9 million of net proceeds as additional funds for the Phase 2B portion of the GENETIC-AF trial and to support our ongoing operations. In light of the significant uncertainties regarding clinical development timelines and costs for developing drugs such as Gencaro, we will need to raise a significant amount of additional capital to finance the completion of GENETIC-AF and our ongoing operations. We anticipate that our current cash and cash equivalents will be sufficient to fund our operations, at our projected cost structure, through at least the end of 2015. However, 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 anticipate.

Results of Operations

Research and Development Expenses

Research and development, or R&D, expense is comprised of clinical, regulatory, and manufacturing process development activities and costs. Our R&D expense continues to be almost entirely generated by our activities relating to the development of Gencaro.

R&D expense for the three months ended March 31, 2014 was $1.3 million compared to $181,000 for the corresponding period of 2013, an increase of approximately $1.1 million.

Clinical expense increased approximately $563,000 for the three months ended March 31, 2014. The increase in the three month period is primarily due to costs incurred through clinical research organizations (CRO's) and related support services in preparing for and initiating our GENETIC-AF trial as well as increased personnel costs. During the comparative three months of 2013 we had no clinical staff or clinical trial expenses. The clinical staff roles were added in the latter part of 2013 as we began preparing to initiate our GENETIC-AF clinical trial.

Regulatory and manufacturing process costs increased $419,000 for the three months ended March 31, 2014 compared to the corresponding period of 2013. The increase in the three month period ended March 31, 2014 compared to the corresponding period of 2013 is primarily due to costs of production, packaging and distribution of clinical trial drug materials for our GENETIC-AF clinical trial. A portion of the increase is also attributable to increased personnel costs as we increased staff in the latter part of 2013 in preparation of the clinical trial.

R&D expenses for the remainder of 2014 are expected to increase as our GENETIC-AF trial begins enrolling and treating patients.

General and Administrative Expenses

General and administrative expenses, or G&A, primarily consist of personnel costs, consulting and professional fees, insurance, facilities and depreciation expenses, and various other administrative costs.

G&A expense was $1.1 million for the three months ended March 31, 2014 as compared to $889,000 for the corresponding period in 2013, an increase of $193,000. The increase in the three months ended March 31, 2014 as compared to the corresponding period of 2013 is comprised of increased personnel costs of approximately $266,000, primarily attributable to personnel returned from furlough and salary changes for executives and other administrative employees. During the first quarter of 2013, employees were working at reduced levels and salaries or were furloughed. In the latter part of 2013 we returned personnel to work to support initiating our GENETIC-AF clinical trial. A portion of the personnel cost is attributable to increased non-cash, stock-based compensation for stock awards made during the third quarter of 2013 and the first quarter of 2014.

The increased personnel costs were partially offset by decreased consulting, legal, accounting and other professional services of approximately $130,000. During the first quarter of 2013 we incurred additional costs for a special proxy and shareholder meeting. These activities and related costs were not recurring in the first quarter of 2014.

G&A expenses for the remainder of 2014 are expected to increase as we increase our activities to support our GENETIC-AF clinical trial.

Interest and Other Income

Interest and other income was $2,000 in the three months ended March 31, 2014. Interest and other income for the comparative three month period ended March 31, 2013 was less than $1,000. We expect interest income to continue to be nominal for 2014 due to low investment yields and utilizing our cash and cash equivalents to fund our operations.

Interest and Other Expense

Interest and other expense was less than $1,000 in the three months ended March 31, 2014 and in the three months ended March 31, 2013. Based on our current capital structure, interest expense for the remainder of 2014 is expected to be minimal.

Liquidity and Capital Resources

Cash and Cash Equivalents

	March 31, 2014	December 31, 2013
Cash and cash equivalents	$21,202	$ 16,756

As of March 31, 2014, we had total cash and cash equivalents of approximately $21.2 million, as compared to $16.8 million as of December 31, 2013. The net increase of $4.4 million in the three month period reflects the $8.1 million of net proceeds from our equity offering and proceeds from common stock issued for warrant exercises less approximately $3.7 million of cash used to fund operating activities and approximately $51,000 in payments on a vendor financing arrangement during the three months ended March 31, 2014.

Cash Flows from Operating, Investing and Financing Activities

	Three Months Ended March 31,	
	2014	2013
Net cash (used in) provided by:		
Operating activities	$(3,687)	$(764)
Investing activities	—	(9)
Financing activities	8,133	1,390
Net increase in cash and cash equivalents	$4,446	$617

Net cash used in operating activities for the three months ended March 31, 2014 increased approximately $2.9 million compared with the same period in 2013 primarily due to trial initiation activities and increased expenses discussed above.

Net cash used in investing activities for the three months ended March 31, 2014 was $0 compared to $9,000 used in investing activities in the three months ended March 31, 2013.

Net cash provided by financing activities was $8.1 million for the three months ended March 31, 2014 representing approximately $7.9 million of net proceeds from our stock offering completed in February 2014, plus approximately $318,000 of net proceeds from common stock issued for warrant exercises, less approximately $51,000 in payments on a vendor financing arrangement.

Sources and Uses of Capital

Our primary sources of liquidity to date have been capital raised from issuances of shares of our preferred and common stock and funds provided by the merger with Nuvelo. 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.

On February 3, 2014, we agreed to sell to certain investors an aggregate of 5,116,228 shares of our common stock and warrants to purchase an aggregate of 1,279,057 shares of our common stock at a purchase price of $1.70 per share of

common stock, for aggregate gross proceeds of approximately $8.7 million, before deducting placement agent fees and other offering related expenses. The offering closed on February 7, 2014, and the net proceeds to us were approximately $7.9 million.

The common stock and warrants were sold in combination consisting of one share of common stock and a warrant to purchase 0.25 shares of common stock. The warrants were exercisable upon issuance, expire five years from the date of issuance, and have an exercise price of $2.125 per share, equal to 125% of the closing bid price of our common stock on the Nasdaq Capital Market on February 3, 2014. The offering was effected as a takedown off our Registration Statement on Form S-3, as amended, which became effective on April 4, 2011, pursuant to a prospectus supplement filed with the Securities and Exchange Commission on February 4, 2014. The warrants provide for cashless exercise and settlement in unregistered shares if there is no effective registration statement registering, or the prospectus contained therein is not available for, the issuance of the shares of common stock underlying the warrants at the time of exercise. The common stock and warrants were sold pursuant to a placement agency agreement dated January 21, 2014, as amended.

In addition to the cash compensation paid to the placement agent in conjunction with the transaction and pursuant to the placement agency agreement, we issued warrants to the placement agent to purchase 153,486 shares of our common stock, which have not been registered under the Securities Act of 1933, as amended. The warrants issued to the placement agent have substantially the same terms as the warrants issued to the purchasers in the offering, except that such warrants expire on April 4, 2016, or the five year anniversary of the effective date of the registration statement, and are restricted from transfer for a period of 180 days from the date of commencement of sales in connection with the offering.

Our ability to execute our GENETIC-AF Phase 2B trial in accordance with our projected time line depends on a number of factors, including, but not limited to, the following:

- recruitment of sufficient clinical trial sites, enrollment of patients and enrollment at a rate consistent with our projected timeline;
- our ability to control costs associated with the clinical trial and our operations;
- our ability to retain the listing of our common stock on the Nasdaq Capital Market;
- the market price of our stock and the availability and cost of additional equity capital from existing and potential new investors; general economic and industry conditions affecting the availability and cost of capital;
- the 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 will be necessary for us to complete both Phase 2B and Phase 3 of the GENETIC-AF clinical trial and submit for FDA approval of Gencaro. Such financing would likely result in additional dilution to our existing 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 anticipate that our current cash and cash equivalents will be sufficient to fund our operations, at our projected cost structure, through at least the end of 2015. However, our forecast of the period of time through which our financial resources will be adequate to support our current and forecasted operations could vary materially.

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 Consolidated Financial Statements” included within our 2013 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.

Accrued Expenses

As part of the process of preparing our financial statements, we are required to estimate accrued expenses. This process involves identifying services that third parties have performed on our 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 clinical research organizations and contract manufacturers in connection with the execution of our clinical trial program, and professional service fees, such as attorneys and consultants. We develop our 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 estimated 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 we file under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosures. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

As required by Rule 13a-15(b) of the Securities Exchange Act of 1934, 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.

Changes in Internal Control over Financial Reporting

There has been no change in our internal control over financial reporting during our most recent fiscal quarter that would materially affect or is reasonably likely to materially affect, our internal control over financial reporting.

24

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

None

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, 2013, 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 consolidated financial statements for the fiscal year ended December 31, 2013 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 accountants concluded as of December 31, 2013 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. In February 2014, the Company completed an equity financing transaction that raised aggregate net proceeds of $7.9 million. We believe our cash and cash equivalents balance as of March 31, 2014, will be sufficient to fund our operations, at our projected cost structure, through at least the end of 2015. 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 anticipate. We may be forced to 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. If we cannot raise sufficient funds, 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 public or private equity transactions and/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.

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 GENETIC-AF clinical trial, and the substantial cost of commercializing Gencaro, if it is approved, we will need to raise substantial additional funding through public or private equity transactions or a strategic combination or partnership. If we are delayed in obtaining funding or are unable to complete a strategic transaction, we may discontinue our development activities on Gencaro or discontinue our operations. 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.

We believe our cash and cash equivalents balance as of March 31, 2014 will be sufficient to fund our operations, at our projected cost structure, through at least the end of 2015. 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 anticipate.

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:

progress of GENETIC-AF enrollment and any data that may become available;
the costs and timing for additional clinical trials 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;
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 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 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. We have initiated screening of patients for our Phase 2B clinical study of Gencaro in 200 hundred HFREF patients with AF, and it could expand to a Phase 3 clinical study of approximately 420 HFREF additional patients with AF/atrial flutter (AFL). Clinical trials are typically lengthy, complex and expensive and we do not currently have the resources to fully fund such a trial.

Failure to demonstrate that a product candidate, including 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.

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 will receive regulatory approval for our product candidates only 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 GENETIC-AF clinical trial for Gencaro, will demonstrate sufficient safety and efficacy to obtain the requisite regulatory approvals or will result in marketable products.

For example, GENETIC-AF is designed to be an adaptive trial. The DSMB will analyze certain data from the Phase 2B portion and recommend whether the trial should proceed to Phase 3 and seek to enroll an additional 420 patients. The DSMB will make their recommendation after 200 patients have been enrolled and have completed 24 weeks of follow-up. The interim analysis will focus on data regarding the trial's primary endpoint, AF event rates, AF burden, and safety. Should the DSMB interim analysis conclude the data is consistent with the pre-trial statistical assumptions and that the data indicates potential for achieving statistical significance for the Phase 3 endpoint, then the DSMB may recommend the study proceed to Phase 3. The DSMB may also recommend changes to the study design before potentially proceeding to Phase 3, or it may recommend that the study not proceed to Phase 3. The Company, in consultation with the trial's Steering Committee and the DSMB, will make the final determination on the trial's development steps. If we do not see sufficient efficacy and safety in the Phase 2B portion of the trial, we will not initiate the Phase 3 portion of the trial.

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 2 or Phase 3 clinical trial and do not currently have sufficient staff with the requisite experience to do so, and we therefore 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 clinical trials, these employees have no such experience as employees of ARCA.

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.

We are relying on contract research organizations to conduct substantial portions of our GENETIC–AF clinical trial, and as a result, we will be unable to directly control the timing, conduct and expense of the clinical trial.

We do not currently have sufficient staff with the requisite experience to conduct our clinical trial and are therefore relying primarily on third parties to conduct our clinical trial. We have contracted with Duke University, as our contract research organization (CRO) to conduct the clinical component of our GENETIC-AF trial. As a result of this contract, we will have less control over many details and steps of the trial, the timing and completion of the trial, the required reporting of adverse events and the management of data developed through the trial 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, such as CROs, may have staffing difficulties, may undergo changes in priorities or may become financially distressed, adversely affecting their willingness or ability to conduct our trial. We may experience unexpected cost increases that are beyond our control. Problems with the timeliness or quality of the work of a CRO may lead us 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 though we are using a CRO to conduct our clinical trial, we have to devote substantial resources and rely on the expertise of our employees to manage the work being done by the CRO. We have never conducted a clinical trial and the inability of our current staff to adequately manage any CRO that we engage may exacerbate the risks associated with relying on a CRO.

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

The GENETIC-AF clinical trial requires that we identify and enroll a large number of patients with the condition under investigation and the trial will enroll only those patients having a specific genotype, and certain patients who have or are willing to have a Medtronic device implanted for monitoring and recording AF burden data. Because of the rigorous enrollment criteria, we may not be able to enroll a sufficient number of patients to complete our clinical trial in a timely manner.

Patient enrollment is affected by factors including:

design of the protocol;
the size of the patient population;
eligibility criteria for the study in question;
perceived risks and benefits of the drug under study;
availability of competing therapies, including the off-label use of therapies approved for related indications;
efforts to facilitate timely enrollment in clinical trials;
the success of 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;
other clinical trials seeking to enroll subjects with similar profiles;
the number of patients having the specific genotype needed for our trial; and,
the number of patients having, or willing to have, a Medtronic device implanted for monitoring and recording AF burden data.

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.

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

We set goals for, and make public statements regarding, the timing of certain accomplishments, such as, the commencement and completion of clinical trials, particularly with respect to steps for commencing and continuing GENETIC-AF, 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 any 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 genetic trials. There can be no assurance that our genetic trials will be initiated or 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.

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.

Our common stock is currently listed on the Nasdaq Capital Market. To maintain the listing of our common stock on the Nasdaq Capital Market we are required to meet certain listing requirements, including, among others, either: (i) a minimum closing bid price of $1.00 per share, a market value of publicly held shares (excluding shares held by our executive officers, directors and 10% or more stockholders) of at least $1 million and stockholders' equity of at least $2.5 million; or (ii) a minimum closing bid price of $1.00 per share, a market value of publicly held shares (excluding shares held by our executive officers, directors and 10% or more stockholders) of at least $1 million and a total market value of listed securities of at least $35 million.

During 2012 our stock price fell below the Nasdaq Capital Market's minimum bid price requirements and we became subject to delisting from the exchange. On March 4, 2013 we executed a 1 for 6 reverse split of our common stock and have subsequently regained compliance with the minimum bid price requirements. In future periods, if we do not meet the minimum stockholders' equity, minimum closing bid price requirements, or any other listing requirements, we would be subject to delisting from the Nasdaq Capital Market.

As of May 9, 2014, the closing price of our common stock was $1.39 per share, and the total market value of our listed securities was approximately $29.2 million. As of March 31, 2014, we had stockholders' equity of $21.5 million.

We expect to depend on existing and future collaborations with third parties for the development of some of our product candidates. If those collaborations are not successful, we may not be able to complete the development of these product candidates.

We currently have a collaboration agreement with Medtronic, Inc., or Medtronic for the support of our GENETIC-AF trial. Medtronic can terminate its collaboration with us for various reasons including uncured material breach, an ARCA bankruptcy, if, after FDA communication, it is reasonably concluded that the FDA will not allow GENETIC-AF to enroll or proceed, or if Medtronic's obligations are unilaterally expanded. We may seek additional third party collaborators for the development of Gencaro or other product candidates.

Under our current arrangement with Medtronic, we have limited control over the amount and timing of resources that they dedicate to the development of Gencaro. This is also likely to be true in any future collaboration with third parties. Our ability to benefit from these arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements.

Collaborations involving our product candidates pose the following risks to us:

collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborator's strategic focus or available funding, or external factors such as an acquisition that diverts resources or creates competing priorities;
collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our proprietary information or expose us to potential litigation;
disputes may arise between the collaborators and us that result in the delay or termination of the research, development or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management attention and resources;
collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates;
collaborators may elect to take over manufacturing rather than retain us as manufacturers and may encounter problems in starting up or gaining approval for their manufacturing facility and so be unable to continue development of product candidates;
we may be required to undertake the expenditure of substantial operational, financial and management resources in connection with any collaboration;
we may be required to issue equity securities to collaborators that would dilute our existing stockholders' percentage ownership;
we may be required to assume substantial actual or contingent liabilities;
collaborators may not commit adequate resources to the marketing and distribution of our product candidates, limiting our potential revenues from these products; and
collaborators may experience financial difficulties.

We face a number of challenges in seeking additional collaborations. Collaborations are complex and any potential discussions may not result in a definitive agreement for many reasons. For example, whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration, and the proposed collaborator's evaluation of a number of factors, such as the design or results of our clinical trials, the potential market for our product candidates, the costs and complexities of manufacturing and delivering our product candidates to patients, the potential of competing products, the existence of uncertainty with respect to ownership or the coverage of our intellectual property, and industry and market conditions generally. If we were to determine that additional collaborations for our Gencaro development is necessary and were unable to enter into such collaborations on acceptable terms, we might elect to delay or scale back the development or commercialization of Gencaro in order to preserve our financial resources or to allow us adequate time to develop the required physical resources and systems and expertise ourselves.

Collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner, or at all. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators. If a present or future collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program could be delayed, diminished or terminated.

Our GENETIC-AF clinical trial requires the use of a third-party diagnostic services provider to administer the genetic test needed to identify the patient receptor genotypes of clinical trial participants, and as a result, we will be unable to directly control the timing, conduct and expense of the genetic test.

Our GENETIC-AF clinical trial of Gencaro requires a companion diagnostic test that identifies the patient's receptor genotype. The trial will only enroll those patients with the receptor that has the potential for enhanced efficacy, the beta-1 389 Arg receptor as detected by a beta-1 389 Arg/Arg genotype. Accordingly, the GENETIC-AF trial requires use of a third-party diagnostic service to perform the genetic testing. There has been limited experience in our industry in prospective development of companion diagnostics required to perform the required molecular profiling. We entered into an agreement with Laboratory Corporation of America, LabCorp, to provide the diagnostic services of the genetic test needed to support our GENETIC-AF trial. To provide those services, LabCorp obtained from the FDA an Investigational Device Exemption, or IDE, for the companion diagnostic test to be used in our Genetic AF clinical trial.

The FDA and similar regulatory authorities outside the United States regulate companion diagnostics. Companion diagnostics require separate or coordinated regulatory approval prior to commercialization. Changes to regulatory advice could delay our development programs or delay or prevent eventual marketing approval for our product candidates that may otherwise be approvable. In July 2011, the FDA issued draft guidance that stated that if safe and effective use of a therapeutic depends on an in vitro diagnostic, then the FDA generally will not approve the therapeutic unless the FDA approves or clears this "in vitro companion diagnostic device" at the same time that the FDA approves the therapeutic. The approval or clearance of the companion diagnostic would occur through the FDA's Center for Devices and Radiological Health. The draft guidance on companion diagnostics remains in draft form, and it is unclear how closely the final guidance, when published, will track the 2011 draft guidance. It is also difficult to predict how FDA will implement the guidance once finalized. For example, the draft guidance allows for flexibility by the FDA in the case of therapeutic products to treat serious conditions for which no alternative treatment exists and the benefits of using the companion diagnostic outweigh the risk, but it is unclear how this discretion will be applied by the agency. The FDA's evolving position on the topic of companion diagnostics could affect our clinical development programs that utilize companion diagnostics. In particular, the FDA may limit our ability to use retrospective data, otherwise disagree with our approaches to trial design, biomarker qualification, clinical and analytical validity, and clinical utility, or make us repeat aspects of a trial or initiate new trials.

Given our limited experience in developing diagnostics, we expect to rely primarily on third parties for their design and manufacture. If we, or any third parties that we engage to assist us, are unable to successfully develop companion diagnostics for our product candidates that require such diagnostics, or experience delays in doing so, the development of our product candidates may be adversely affected, our product candidates may not receive marketing approval and we may not realize the full commercial potential of any products that receive marketing approval. As a result, our business could be materially harmed.

We will need to establish a collaborative arrangement with a third-party diagnostics services provider to obtain marketing clearance or approval of the companion genetic test. There is no guarantee that the FDA will grant timely clearance or approval of the genetic test, if at all, and failure to obtain such timely clearance or approval would adversely affect our ability to market Gencaro.

The drug label we intend to seek for Gencaro would identify the patient receptor genotype for which the drug is approved. Accordingly, we believe developing a genetic test that is simple to administer and widely available will be critical to the successful commercialization of Gencaro and also to the ability to conduct our GENETIC-AF clinical trial. The genetic test will be 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.

Despite the time and expense expended, regulatory clearance or approval is never guaranteed. If regulatory clearance or approval is delayed, or if one or more third-party diagnostic services providers are unable to obtain FDA approval of the genetic test at all or in parallel with the approval of Gencaro, or are unable to commercialize the test successfully and in a manner that effectively supports the commercial efforts for Gencaro, or if the information concerning the differential response to Gencaro resulting from certain genetic variation is not included in the approval label for Gencaro, the commercial launch of Gencaro may be significantly and adversely affected.

Regulatory approval is required for the genetic test to be used in the GENETIC-AF trial and to support the commercialization of the test, if approved. Delays or failures in obtaining such regulatory approval, including any required validation analyses may prevent a third-party diagnostics provider from commercializing such genetic test and will adversely affect our business, operating results and prospects.

Before a genetic test can be used commercially, including in conjunction with Gencaro, if it is approved for marketing, the third-party diagnostics provider must obtain FDA Premarket Approval, or PMA, for such test. The FDA may require additional validation of the genetic test we are using in GENETIC-AF prior to any approval of Gencaro or the genetic test. We anticipate the genetic test will be required as a condition to prescribing Gencaro. There is no guarantee the FDA will approve the anticipated PMA submission for the genetic test. Even if the genetic test is eventually approved, performing additional validation work necessary to support the PMA, if required, for current or future genetic test products, including one associated with Gencaro, would require additional time and expense and the outcome would be uncertain. Moreover, such delays or increased costs or failures could adversely affect our business, operating results and prospects for commercializing the genetic test.

If a third-party diagnostics provider responsible for the genetic test or certain of its third-party suppliers fails to comply with ongoing FDA or other foreign regulatory authority requirements, or if there are unanticipated problems with the genetic test, these products could be subject to restrictions or withdrawal from use in trial or from the market.

Any diagnostic for which a third-party diagnostics provider 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 genetic test, to the extent applicable, any third-party diagnostics provider 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 a third-party diagnostics provider, 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 or utilizing the genetic test further in any clinical trial. 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.

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

The genetic test is an important component of the commercial strategy for Gencaro in addition to being required to proceed with our GENETIC-AF trial. We believe that the genetic 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 genetic 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 therapy in patients with HF. Any one of these factors could affect prescriber behavior, which in turn may substantially impede market acceptance of the genetic test, which could cause significant harm to Gencaro's ability to compete, and in turn harm our business.

Our failure to raise substantial additional funding or enter into a strategic transaction may materially and adversely affect our business.

Unless we are able to raise substantial additional funding for the development of Gencaro through other means, we will need to complete a strategic transaction to continue the development of Gencaro through the clinical development and commercialization phases, and to continue 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 obtaining additional capital or 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 such 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 March 31, 2014 we had approximately 21 million shares of common stock outstanding, 20% of which is approximately 4.2 million 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. SEC rules impose restrictions on our ability to raise funds through the registered offering of our securities pursuant to our "shelf" registration statement on Form S-3. Under SEC rules, we are prohibited from selling securities under such registration statement if the aggregate market value of the securities sold thereunder in any twelve-month period exceeds one-third of the market value of our outstanding common stock held by non-affiliates. Our February 2014 equity financing substantially exhausted the availability under our shelf registration statement until the one year anniversary of such financing. In addition, we are currently subject to certain contractual rights of investors arising from our public and private equity financing transactions that limit the nature and price of future public and private financing transactions that we may effect. For example, in January 2013, we entered into separate subscription agreements with certain institutional investors in connection with a private investment in public equity, pursuant to which we sold shares of our common stock and warrants to purchase shares of our common stock to the investors. In connection with this transaction, we agreed that, subject to certain exceptions, we would not, while the warrants issued in such financing are outstanding, effect or enter into an agreement to effect any issuance of common stock or securities convertible into, exercisable for or exchangeable for common stock in a "variable rate transaction," which means a transaction in which we issue or sell any convertible securities either (A) at a conversion price, exercise price or exchange rate or other price that is based upon and/or varies with the trading prices of, or quotations for, the shares of common stock at any time after the initial issuance of such convertible securities, or (B) with a conversion, exercise or exchange price that is subject to being reset at some future date after the initial issuance of the convertible securities or upon the occurrence of the specified or contingent events directly or indirectly related to our business or the market for our common stock. The restrictions imposed by the terms of our previous offerings, and that could be imposed in future

offerings, may limit our access to capital on agreeable terms and delay or make impossible certain otherwise available equity financing opportunities and could severely restrict our access to the capital necessary to conduct our business.

Unless we are able to generate sufficient product revenue, we will continue to incur losses from operations and will 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.

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. In 2008, we submitted and the FDA accepted our NDA filing for Gencaro for the treatment of chronic HF. In 2009, the FDA issued a Complete Response Letter (CRL) in which the FDA stated that it could not approve the Gencaro NDA in its current form and specified actions required for approval of the NDA, including conducting an additional Phase 3 clinical trial of Gencaro in patients with HF. We have initiated screening of patients for our clinical study of Gencaro in HFREF patients to assess its efficacy in reducing or preventing AF. This trial has been initiated as a Phase 2B study in approximately 200 patients and, depending on the outcome of the Phase 2B portion, may be expanded to a Phase 3 study with up to an estimated additional 420 patients. We believe the Phase 2B study will take approximately two and a half years to complete from the time the first patient is enrolled. This product candidate will require years of clinical development. Even if we conduct additional studies in accordance with further FDA guidance and submit 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 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 initiate 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 recruiting and monitoring multiple study sites;
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; and
an insufficient number of patients who have, or are willing to have, a Medtronic device implanted for monitoring and recording AF burden data.

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 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 pursuing clinical development of Gencaro for an AF indication, we will be required to amend the Gencaro HF NDA or prepare a new NDA. The FDA could approve Gencaro, but without including some or all of the prescribing information that we have requested. For instance, the FDA could approve Gencaro for AF in a more limited patient population or include additional warnings in the drug's label. This, in turn, could substantially and detrimentally impact our ability to successfully commercialize Gencaro and effectively protect our intellectual property rights in Gencaro.

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 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;
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;