ARCA biopharma, Inc.
Form 10-K
March 21, 2013
Table of Contents

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

þ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2012

or

¨ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to

Commission File Number: 000-22873

ARCA BIOPHARMA, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	36-3855489
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
8001 Arista Place, Suite 430, Broomfield, CO	80021
(Address of Principal Executive Offices)	(Zip Code)

(720) 940-2200

(Registrant s telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Exchange Act:

Title of Each Class	Name of Each Exchange on Which Registered
Common Stock $0.001 par value	Nasdaq Capital Market

Securities registered pursuant to Section 12(g) of the Exchange Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in rule 405 of the Securities Act. Yes ¨ No þ

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 and Section 15(d) of the Act. Yes ¨ No þ

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 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 þ No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes þ No ¨

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. þ

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 small reporting company in Rule 12b-2 of the Exchange Act.

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

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

The aggregate market value of the common stock held by non-affiliates of the Registrant on June 29, 2012, the last business day of the most recently completed second fiscal quarter, was $5,847,840 based on the last sale price of the common stock as reported on that day by the Nasdaq Capital Market.

As of March 18, 2013 the Registrant had 3,185,562 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant s Definitive Proxy Statement, which will be filed with the Commission pursuant to Section 14A in connection with the 2012 annual meeting of stockholders, are incorporated by reference into Part III of this Form 10-K.

Table of Contents

TABLE OF CONTENTS

Table of Contents

PART I

Item 1. ***Business***

Some of the statements under Business, Risk Factors, Management s Discussion and Analysis of Financial Condition and Results of Operations and elsewhere in this Annual Report constitute forward-looking statements. In some cases, you can identify forward-looking statements by the following words: may, will, could, would, should, expect, intend, plan, anticipate, believe, estimate, predict, project, potential, continue, ongoing or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. Examples of these statements include, but are not limited to, statements regarding the following: the timing and results of any clinical trials, including the planned Gencaro trial for the prevention of atrial fibrillation-our ability to obtain additional funding or enter into a strategic or other transaction, the extent to which our issued and pending patents may protect our products and technology, the potential of such product candidates to lead to the development of safe or effective therapies, our ability to enter into collaborations, our ability to maintain listing of our common stock on a national exchange, our future operating expenses, our future losses, our future expenditures, and the sufficiency of our cash resources to maintain operations. These statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. While we believe that we have a reasonable basis for each forward-looking statement contained in this Annual Report, we caution you that these statements are based on a combination of facts and factors currently known by us and our projections of the future, about which we cannot be certain.

In addition, you should refer to the Risk Factors section of this Annual Report for a discussion of other important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this Annual Report will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all.

We undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise. You are advised, however, to consult any further disclosures we make on related subjects in our Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and our website.

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

Overview

We are a biopharmaceutical company whose principal focus is 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 new clinical trial for the treatment of atrial fibrillation, or AF, in patients with heart failure and 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.

We plan to test this hypothesis in a Phase 2b/3 clinical trial of Gencaro, known as GENETIC-AF. We plan to pursue this indication for Gencaro because data from the previously conducted Phase 3 HF trial of Gencaro in 2,708 HF patients, or the BEST trial, suggest that Gencaro may be successful in reducing or preventing AF.

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 is

Table of Contents

considered an epidemic cardiovascular disease with an estimated prevalence of at least 2.7 million Americans in 2010. 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.

GENETIC-AF is planned as a multi-center, randomized, double-blind clinical trial designed to compare the safety and efficacy of Gencaro to an active comparator in beta-1 389 arginine homozygous genotype HFREF patients recently diagnosed with persistent AF. The primary endpoint will be measured over a twenty-four week period after the patient s AF has been electrically cardioverted through the administration of a direct current shock to restore normal heart rhythm.

We have created an adaptive design for GENETIC-AF, which we plan to initiate with a Phase 2b study in approximately 200 HFREF patients with recent onset, persistent AF who also have a genetic variant of the beta-1 adrenergic receptor which we believe responds most favorably to Gencaro. The secondary endpoint of the proposed Phase 2b portion of the trial will be AF burden, defined as a patient s actual percentage of time in AF, regardless of symptoms. Under the proposed design, all 200 patients in the Phase 2b portion of the trial will have AF burden measured by continuous monitoring, either by previously implanted cardiac resynchronization or defibrillation devices, or newly or previously inserted loop recorders. At the end of enrollment of the first 200 patients, the primary endpoint of the combination of recurrent symptomatic AF or all-cause mortality, and the secondary endpoint of AF burden will be evaluated by the trial s Data and Safety Monitoring Board for evidence of an efficacy signal. If a sufficient efficacy signal is detected and acceptable safety is observed, the trial could then proceed to the Phase 3 portion. We estimate that GENETIC-AF could begin approximately 6 months after we obtain sufficient funding. We believe the Phase 2b study would take approximately two years to complete.

The trial is designed to compare Gencaro to the beta-blocker metoprolol CR/XL in patients with the beta-1 389 arginine homozygous genotype, which we believe responds most favorably to Gencaro. 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 metoprolol CR/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.

Medtronic, Inc., a leader in medical technologies to improve the treatment of chronic diseases including cardiac rhythm disorders, has signed a non-binding Letter of Intent, or LOI, with us to collaborate on the Phase 2b portion of the proposed trial to support GENETIC-AF. The proposed collaboration involves a substudy of the Phase 2b portion of GENETIC-AF that will measure the AF burden data by means of their continuous monitoring devices. Under the proposed collaboration, Medtronic would provide support for the AF burden substudy and for collection and analysis of the substudy data.

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 will provide market exclusivity for these uses of Gencaro into at least 2026 in the U.S. 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 U.S. and Europe.

Table of Contents

To support the continued development of Gencaro, including the planned GENETIC-AF clinical trial and our ongoing operations, we plan to pursue an underwritten public offering to fund the Phase 2b portion of the GENETIC-AF trial and our general and administrative costs through the projected completion of the Phase 2b portion. We may seek additional interim funding that could allow us to operate while we continue to pursue financing options, a strategic combination, partnering and licensing opportunities. 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. We believe our cash and cash equivalents balance as of December 31, 2012, along with the net proceeds from our recently completed financings, will be sufficient to fund our operations, at our current cost structure, through September 2013. We are unable to assert that our current cash and cash equivalents are sufficient to fund operations beyond that date, and as a result, there is substantial doubt about our ability to continue as a going concern beyond September 2013. 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.

On January 27, 2009, we completed a business combination (the Merger) with ARCA Colorado in accordance with the terms of that Agreement and Plan of Merger and Reorganization, dated September 24, 2008, and amended on October 28, 2008 (as amended, the Merger Agreement), in which a wholly-owned subsidiary of Nuvelo, Inc. merged with and into ARCA Colorado, with ARCA Colorado continuing after the Merger as the surviving corporation and a wholly-owned subsidiary of Nuvelo, Inc. Immediately following the Merger, we changed our name from Nuvelo, Inc. to ARCA biopharma, Inc., and our common stock began trading on the Nasdaq Global Market under the symbol ABIO on January 28, 2009. On March 7, 2011, the listing of our common stock was transferred from the Nasdaq Global Market to the Nasdaq Capital Market.

On February 25, 2013, we held a special meeting of our stockholders in order to approve a series of certificates of amendment to our Restated Certificate of Incorporation, as amended, to effect a reverse split of our outstanding common stock, pursuant to which any whole number of outstanding shares between, and including, three and twenty would be combined into one share of common stock and to authorize our board of directors to select and file one such certificate of amendment and abandon the other certificates of amendment, or to abandon all such certificates of amendment as permitted under Section 242(c) of the Delaware General Corporation Law, to be determined by the board of directors within one year of approval.

On March 4, 2013, we filed a Certificate of Amendment to our Amended and Restated Certificate of Incorporation, to implement a six-for-one reverse split of our common stock, as previously authorized and approved at our special meeting of stockholders on February 25, 2013. The reverse split was effective as of 5:01 p.m. (Eastern Time) on March 4, 2013, and our common stock continued trading on The NASDAQ Capital Market on a post-split basis on March 5, 2013.

As a result of the reverse split, every six shares of issued and outstanding common stock were combined into one share of issued and outstanding common stock. In addition, the reverse split effected a proportionate adjustment to the per share exercise price and the number of shares issuable upon the exercise or settlement of all outstanding options and warrants to purchase shares of our common stock, and the number of shares reserved for issuance pursuant to our existing stock option plans were reduced proportionately. No fractional shares were issued as a result of the reverse split, and stockholders who otherwise would have been entitled to a fractional share received in lieu thereof, a cash payment based on the closing sale price of our common stock as reported on The NASDAQ Capital Market on March 4, 2013. The reverse split did not alter the par value of our common stock or modify any voting rights or other terms of the common stock.

Table of Contents

Our Strategy

Our mission is to become a leading biopharmaceutical company developing cardiovascular therapies with an emphasis on genetically-targeted therapies. To achieve this goal, we are pursuing the following strategies:

Advance the development of Gencaro. We plan to focus our efforts on initiating and completing the GENETIC-AF Trial.

Raise substantial additional funding or complete a strategic transaction. To support the continued clinical development of Gencaro, including the planned GENETIC-AF clinical trial, we are seeking to raise substantial additional funding, through the sale of public or private equity securities or the completion of a strategic transaction.

Build a cardiovascular pipeline. Our management and employees, including our chief executive officer, have extensive experience in cardiovascular research, molecular genetics and clinical development of cardiovascular therapies. We are seeking to leverage this expertise to identify, acquire and develop other cardiovascular products or candidates, with an emphasis on pharmacogenetic applications.

Leverage our existing assets. We are pursuing opportunities to leverage certain of our development-stage product candidates. We are also pursuing licensing transactions for certain of our other compounds which are in early stages of development for various indications. For example, in 2011, we raised $2 million through the assignment of certain patent rights for one of these compounds to a large pharmaceutical company.

Atrial Fibrillation Market Background and Opportunity

AF is a disorder in which the normally regular and coordinated contraction pattern of the heart s two small upper chambers becomes irregular and uncoordinated. The irregular contraction pattern associated with AF causes blood to pool in the atria, predisposing to the formation of clots. These clots may travel from the heart and become lodged in the arteries leading to the brain and other organs, thereby blocking necessary blood flow and potentially resulting in stroke. In addition, we also believe that the development of AF in a HFREF patient can be associated with increased risk of death and other heart failure related adverse outcomes. AF is considered an epidemic cardiovascular disease with an estimated prevalence of at least 2.7 million Americans in 2010. Approximately 300,000-400,000 treated AF patients currently receive a form of beta-blocker as pharmaceutical intervention.

The goals of current medical therapy for AF are to maintain sinus rhythm or permanent AF control of the ventricular rate response, avoid the risk of complications including stroke and to minimize patient symptoms. Current treatments include pharmaceutical intervention and device intervention. There are several antiarrhythmic drugs approved by the FDA for the treatment and/or prevention of recurrent AF. However, these drugs have safety and/or administration concerns and all but one have contraindications or label warnings regarding their prescription in patients with HFREF.

Current device interventions for the treatment of AF include:

Electrical cardioversion which is used to restore normal heart rhythm with administration of a direct current shock;

Radiofrequency ablation which can be effective in patients for whom medications are ineffective; and,

Atrial pacemakers which are implanted under the skin and then intravenously into the heart to regulate heart rhythm.

Table of Contents

Gencaro

Gencaro (bucindolol hydrochloride) is a pharmacologically unique beta-blocker and mild vasodilator being developed for the treatment of AF. Gencaro is considered part of the beta-blocker class of compounds because of its property of blocking both beta-1 and beta-2, receptors in the heart. The blocking of these receptors prevents binding with other molecules, primarily the neurotransmitter norepinephrine (NE), which activate these receptors. We believe that Gencaro is well-tolerated in cardiovascular patients because of its mild vasodilator effects. Originally developed by Bristol-Myers Squibb, or BMS, the active pharmaceutical ingredient, or API, in Gencaro, bucindolol hydrochloride, has been tested clinically in approximately 4,500 patients. Gencaro was the subject of a Phase 3 HF mortality trial of over 2,700 patients, mostly in the U.S., known as the BEST trial. The BEST trial included a DNA bank of over 1,000 patients, which was used to evaluate the effect of genetic variation on patients response to Gencaro.

At the time of the BEST trial, our founding scientists, Dr. Michael Bristow and Dr. Stephen Liggett, hypothesized that the unique pharmacologic properties of Gencaro would interact with common genetic variations of beta-1, beta-2 and alpha-2C, adrenergic receptors, which are important receptors that regulate cardiac or adrenergic (sympathetic) nerve function. They tested this hypothesis prospectively in a substudy conducted using data from the BEST DNA bank. On the basis of this study, Drs. Bristow and Liggett have determined that patients with certain variations in these receptors had substantially improved outcomes on primary and certain secondary clinical endpoints in the trial, such as mortality, HF progression, hospitalization and prevention of arrhythmias, relative to the counterpart genotype groups and the general patient population of the BEST trial. We believe that these genetically determined receptor variations, which are detectable using standard DNA testing technology, can serve as diagnostic markers for predicting enhanced therapeutic response to Gencaro, and potentially avoiding adverse events, in individual patients. We have patented our methods for treating AF and HF patients with Gencaro in the U.S. and Europe based on genetic testing.

Pharmacology and Pharmacogenetics

Gencaro s pharmacology appears to be different from other compounds in the beta-blocker class in two fundamental respects. First, the National Heart, Lung and Blood Institute of the National Institutes of Health (NHLBI) and the Cooperative Studies Program of the Department of Veterans Affairs sponsored studies conducted by Drs. Bristow and Liggett indicated that in human myocardial preparations, Gencaro leads to inactivation of constitutively active (i.e. functional in the absence of bound agonist) beta-1 receptors through a mechanism separate from beta-blockade, in addition to inhibiting the binding activity of the beta-1 receptor like a typical beta-blocker. Second, other studies, including BEST, indicated that Gencaro lowers the systemic levels of the neurotransmitter NE, released by cardiac and other adrenergic nerves. These two properties interact with common genetic variations in two cardiac receptors, the beta-1 and alpha-2C receptors, to produce the unique pharmacogenetic profile of Gencaro. We believe that these two properties, and their pharmacogenetic implications, are unique to Gencaro.

Gencaro has an important interaction with the beta-1 receptor found on muscle cells, or cardiac myocytes, of the heart. The general role of the beta-1 receptor and its downstream signaling cascades is to regulate the strength and rate of the heart s contractions. NE serves as an activator of the beta-1 receptor, causing the receptor to initiate signaling to the cardiac myocyte. Although this signaling may be beneficial to the failing heart in the short term, in chronic HFREF patients the beta-1 receptor also initiates harmful, or cardiomyopathic, signaling which, over time, exacerbates the heart s structural and functional decline. Beta-blockers counteract this destructive process by reducing beta-1 receptor signaling. They do this by binding to the receptor and blocking NE molecules from binding and activating the signaling activity and, in Gencaro s case, by also inactivating certain beta-1 receptors that are constitutively active (active in the absence of NE stimulation) as well as by lowering NE levels.

There are two common genetic variations of the beta-1 receptor, each of which we estimate is present in approximately 50% of the U.S. population. One of these variations is known as the beta-1 389 arginine receptor

Table of Contents

variant, exclusively present in the beta-1 389 arginine homozygous or, genotype. Laboratory studies indicate that this variation results in a higher functioning beta-1 receptor, which has a greater ability to mediate the stimulatory effects of NE than the counterpart beta-1 389 glycine or beta-1 389 Gly version of the beta-1 receptor. In addition, the beta-1 389 arginine variant is also more likely to be constitutively active and signal the cardiac myocyte to contract in the absence of NE. The beta-1 389 arginine receptor also has much higher affinity for NE as compared to the beta-1 389 glycine version, present in patients with either one or two copies of the beta-1 389 glycine gene allele (Gly carriers). Patients with the beta-1 389 glycine version, also present in approximately 50% of the U.S. population who are Gly carriers, results in a beta-1 receptor that is much lower functioning and, according to laboratory studies, has less probability of being in a constitutively active state and has lower NE affinity compared to the beta-1 389 arginine receptor.

We believe Gencaro has a powerful interaction with the higher-function beta-1 389 arginine variation of the beta-1 receptor. Laboratory studies show that constitutively active receptors will continue to signal in the presence of standard beta-blockade with neutral antagonists. Laboratory studies in isolated human heart preparations also show that Gencaro has the novel ability of being able to reduce the signaling of constitutively active receptors. We believe that this property contributes to the enhanced lowering of heart failure and arrhythmia event rates in HFREF patients who are beta-1 389 arginine homozygous genotype relative to individuals who are beta-1 389 Gly carriers or to the general population. In addition, we believe the unique NE lowering properties of Gencaro have a selectively beneficial effect in patients who have only beta-1 389 arginine receptors, because of the high affinity of these receptors for NE.

The efficacy of Gencaro also appears to be influenced by the alpha-2C receptor, located on the terminus of cardiac adrenergic nerves, at the neuromuscular junction with the cardiac myocyte. The role of this receptor is to modulate the release of NE at this junction, which in turn affects the activation of beta-1 receptors and the heart s activity. There are two important genetic variations of this receptor that appear to affect the effects of Gencaro; the alpha-2C -wild type , which is the normal functioning version of the receptor (approximately 87-90% of the U.S. general population), and the deletion variant , a version of the receptor that functions poorly (present in at least one copy in approximately 10-13% of the U.S. general population). The DNA substudy of patients from the BEST trial, conducted by Drs. Bristow and Liggett, indicated that these two variations of the alpha-2C receptor appear to affect Gencaro s heart failure and arrhythmia responses in HFREF patients only if the 389 Gly variant of the beta-1 receptor is also present; in patients with the beta-1 389 Gly variant, the wild type version of the alpha-2C receptor enhances clinical response, whereas the alpha-2C deletion variant reduces efficacy. When only the arginine version of the beta-1 receptor is present (beta-1 389 arginine homozygous genotype), the efficacy of Gencaro does not appear to depend on which version of the alpha-2C receptor is present.

The DNA substudy from the BEST HFREF trial indicated that the combinations of these receptor variations in individual patients appear to influence the response to Gencaro with respect to significant clinical endpoints. However, the beta-1 389 Arg/Arg variant appeared to have the most powerful beneficial effect on Gencaro heart failure and arrhythmia responses. While we believe that the beta-1 389 Gly carrier patients who also are alpha-2C wild type homozygotes may respond favorably to Gencaro, we believe that patients who possess only the beta-1 389 arginine variant (beta-1 389 arginine homozygous genotype) exhibit enhanced clinical responses to Gencaro, and should be the primary targeted population. The beta-1 389 arginine homozygous genotype constitutes an estimated 47-50% of the U.S. population.

The BEST trial

The NHLBI and Veterans Affairs Cooperative Studies funded BEST trial began in 1995. It was a double-blind, placebo-controlled, multi-center study of bucindolol s effect on reduction of mortality and morbidity in an advanced chronic HFREF population. The primary endpoint of the BEST trial was all cause mortality (ACM) and the pre-specified main secondary endpoint was progression of heart failure (HF), defined as death from HF, cardiac transplant, HF hospitalization, or emergency room visit for the treatment of worsening HF not requiring hospitalization. The trial was planned to run four and one-half years, and enroll 2,800 patients. The trial enrolled

Table of Contents

a total of 2,708 chronic HF patients, who were mostly from the United States. Under the umbrella of the BEST trial substudies program, a DNA bank and substudy was created, and 1,040 of the BEST patients participated by providing blood for DNA analysis. The DNA bank provided data for the DNA substudy of BEST patients conducted by Drs. Bristow and Liggett.

In 1999, the BEST trial was terminated prior to the completion of follow-up, in response to a recommendation of the BEST trial Data and Safety Monitoring Board. The primary reason for termination was loss of investigator equipoise; in other words, the fact that the BEST investigators were no longer uncertain regarding the comparative therapeutic merits of giving a placebo versus giving a beta-blocker to a HFREF patient. Positive mortality results from two other HF trials involving other beta-blockers had been reported, and a substantial number of BEST trial investigators concluded that it was unethical to continue to give placebo to BEST trial participants. As a result, some investigators began to prescribe these other beta-blockers to patients in the trial, which threatened to destroy the trial s integrity; therefore the trial was terminated early.

Clinical Results and the DNA Substudy

Following termination, the preliminary results of the study were analyzed and published. The preliminary determination and general perception were that the BEST trial had failed on the basis of not meeting its primary endpoint of ACM. The published values were a 10% risk reduction in mortality with a p-value of 0.10. Subsequently, we reanalyzed the results from BEST, in accordance with the FDA approved, pre-specified statistical analysis plans, which had not been performed by the sponsors of BEST when the trial was terminated. Our reanalysis appeared to show a 13% risk reduction on the primary endpoint of all-cause mortality in the BEST trial with a p-value of 0.053.

In 2003 and 2004, the results of the DNA substudy conducted by Drs. Bristow and Liggett began to be analyzed and released. The DNA substudy results indicated a significant enhancement of response on the major heart failure clinical endpoints from the BEST trial in patients with the beta-1 389 arginine homozygous genotype. The risk reduction on HF clinical efficacy endpoints such as mortality and hospitalization ranged from 34% to 48% in this genotype. In addition, in arrhythmia endpoints of atrial fibrillation or ventricular fibrillation/ventricular tachycardia, tracked by adverse events and surveillance ECGs, the risk reduction by bucindolol in the beta-1 389 arginine homozygous genotype appeared to be even greater, with hazard ratios of 74% for both endpoints.

Shown below are certain of the primary and secondary endpoint data from the BEST HF DNA substudy results, by genotype:

BEST Trial Clinical Responses by Genotype Groups

Endpoint	{beta-1 389 Arg/ Arg + any alpha-2C} Very Favorable Patient Type (47%)	{beta-1 389 Gly carrier+ alpha-2C Wt/Wt} Favorable Patient Type (40%)	{beta-1 389 Gly carrier + alpha-2C Del carrier} Unfavorable Patient Type (13%)
All Cause Mortality (ACM), TTE	i 38%*	i 25%	h 4%
Cardiovascular Mortality (CVM), TTE	i 48%*	i 40%*	h 11%
ACM + transplantation	i 43%*	i 24%	h 4%
HF (HF) Progression	i 34%**	i 20%	i 1%
HF Hosp days/patient	i 48%**	i 17%	h 19%
AF prevention (from AE and ECG db)	i 74%**	i 6%	h 33%
VT/VF prevention (from AE db)	i 74%**	i 49%*	i 24%

[1] Covariate adjusted, transplant censored analysis with 1 hazard ratio estimates presented

* p<0.05; **p£0.007; TTE: Time To Event; CRF: Case Report Form; Adj.: Adjudicated

Table of Contents

Analysis of BEST trial for AF

Recently, the BEST study data were further analyzed focusing on AF prevention, rate control in patients with persistent AF, and on clinical outcomes of patients with AF. Although there was no pre-determined AF endpoint, including reduction in risk of AF, in the BEST trial, according to our analysis of adverse events and surveillance ECG s during the trial, 7.9% of patients developed new onset AF, with a greater incidence observed in the placebo group (9.7%) compared to the bucindolol group (6.2%). This corresponded to a 36% reduction in the incidence of new onset AF (based on crude event rates) for patients receiving bucindolol ($p = 0.002$). In a time to event analysis, the risk of new onset AF was reduced by 41% ($p = 0.0004$) with bucindolol treatment. Patients in the BEST study with the beta-1 389 Arg/Arg genotype who received Gencaro had a 74% reduction in the risk of developing new onset AF ($p = 0.0003$).

Further published analyses of the data from BEST suggest that Gencaro may also have potential efficacy for other clinical endpoints and outcomes related to AF. A published analysis of the BEST data revealed that of the 303 patients in the BEST trial with established AF, 67% of those who received Gencaro achieved ventricular response rate control, defined as a resting heart rate of less than or equal to 80 beats per minute without symptomatic bradycardia ($p < 0.005$). In AF patients who achieved ventricular response rate control, Gencaro produced a 39% reduction ($p = 0.025$) in cardiovascular mortality/cardiovascular hospitalizations. In addition, Gencaro also improved cardiovascular clinical endpoints for those AF patients possessing the beta-1 389 arginine genotype that ARCA believes is most favorable for Gencaro response. In a substudy of 1,040 patients in BEST in which patient genotypes were analyzed, Gencaro was associated with a 72% decrease ($p = 0.039$) in cardiovascular mortality/cardiovascular hospitalizations in those 52 AF patients in the substudy with the beta-1 389 arginine homozygous genotype.

Analysis of the BEST Study data also shows that Gencaro has potential efficacy against the serious arrhythmias of VT/VF, which also appears to be genetically regulated. A published report demonstrated that patients in the BEST Trial who received Gencaro experienced a 58% reduction in the incidence of VT/VF ($p = 0.00006$), adjusted for the competing risk of mortality. In addition, the authors of this report determined that Gencaro reduced the incidence of VT/VF by 74% ($p = 0.00005$) in patients with the beta-1 389 arginine homozygous genotype.

As with the overall study cohort, most patients (89%) in the 1,040 patient DNA substudy were free of AF (91% sinus rhythm, 9% other non-AF rhythms) at baseline. The proportion of patients free of AF at baseline was also similar in the two treatment groups for the overall DNA substudy cohort, as well as in the $ß_1389$ genotype subgroups. In the BEST DNA substudy, the proportion of patients who developed new onset AF was similar compared to the overall study cohort for both the placebo group (11% and 10%, respectively) and the Gencaro group in the DNA substudy population compared to the overall study cohort (7% and 6%, respectively). Also, there was a similar reduction in new onset AF observed in the bucindolol group compared to placebo (43% and 41%, respectively, by time to event analysis). Therefore, the overall results from the genetic substudy population are consistent with the results from the overall study population.

In patients with all genotypes, the AF risk reduction of 41-43% by Gencaro in BEST is based on an analysis of adverse events and surveillance ECG s which was similar to AF risk reductions observed in a meta analysis of data regarding seven placebo-controlled beta-blocker trials in HFREF patients. In the meta-analysis, beta-blockers appeared to reduce the incidence of new onset AF in all but one trial, with an overall relative risk reduction of 27%. Despite what we believe to be potential evidence for the prevention of AF in HFREF trials, no beta-blocker has FDA approval for use in this indication. However, the evidence of modest efficacy by beta-blockers approved for other indications will require that any Phase 3 trials with Gencaro will have an active beta-blocker comparator instead of a comparison against placebo. The Phase 2b/3 trial GENETIC-AF trial will only enroll patients with the beta-1 389 arginine homozygous genotype. In the BEST trial, the post hoc analysis of patients with the beta-1 389 arginine homozygous genotype who received Gencaro had a 74% reduction in the risk of developing AF. In another trial, the active comparator we plan to use in GENETIC-AF, metoprolol CR/XL, reduced the risk of

Table of Contents

developing AF by 48% in all genotypes. Because these are not the same trials, the results should not be relied on as direct comparisons. However, we believe that these two data points indicate that Gencaro may have an advantage in preventing AF when compared to metoprolol in GENETIC-AF, in part due to our plan to only enroll beta-1 389 arginine homozygous genotype patients who appear to respond best to Gencaro.

Clinical and Regulatory Strategy

The regulatory strategy for Gencaro is to conduct our adaptive design Phase 2b/3 clinical trial, GENETIC-AF, to obtain an AF approval in a genotype specific HFREF population. We will seek to enroll certain patients with the beta-1 389 arginine homozygous genotype in our AF clinical trial because our analysis of the BEST DNA substudy indicated this group had a 74% reduction in risk for new AF events.

We have created an adaptive design for GENETIC-AF, under which we plan to initiate a Phase 2b study in approximately 200 HFREF patients. Depending on the results of the Phase 2b portion, the trial could then be expanded to a Phase 3 study by enrolling an estimated additional 420 patients. The secondary endpoint of the proposed Phase 2b portion of the trial will be AF burden, defined as a patient s actual percentage of time in AF, regardless of symptoms. Under our proposed design, all 200 patients in the Phase 2b portion of the trial will have AF burden measured by continuous monitoring, either by previously implanted cardiac resynchronization or defibrillation devices, or newly or previously inserted implantable loop recorders. At the end of enrollment of the first 200 patients, the primary endpoint of recurrent symptomatic AF or all-cause mortality, and the secondary endpoint of AF burden will be evaluated by the trial s Data and Safety Monitoring Board for evidence of an efficacy signal. If a sufficient efficacy signal is detected and acceptable safety is observed, the trial would then proceed to the Phase 3 portion and full enrollment.

We have previously received guidance from the FDA regarding a Phase 3 clinical study comparing Gencaro to metoprolol for the prevention of AF in approximately 620 patients, with a design similar to GENETIC-AF, but without an adaptive feature. Based on this FDA guidance, we believe that a successful Phase 3 clinical study similar to GENETIC-AF, with a p-value of less than 0.01, could be sufficient evidence of efficacy upon which to base a New Drug Application (NDA) for the approval of Gencaro for an AF indication in HFREF patients. We plan to obtain further guidance from the FDA on the new trial design, which may affect the trial s design.

The Gencaro Test

If approved, we believe that Gencaro will be the first cardiovascular drug to be integrated with a companion diagnostic to predict enhanced efficacy. We believe the drug label being sought for Gencaro would identify the patient receptor genotypes that can expect enhanced efficacy, as well as those with a likelihood of a standard beta-blocker response and the small unfavorable subgroup with a low probability of benefit. The label being sought would recommend receptor genotype testing prior to initiation of therapy. Accordingly, we collaborated with LabCorp to develop a receptor genotype diagnostic, the Gencaro Test, and believe the test will be simple to administer and would be widely available. We currently intend to pursue a separate arrangement with LabCorp or another third party to provide the diagnostic services of the Gencaro Test needed to support our planned AF trial.

Through our existing agreement with LabCorp we have collaborated to develop and commercialize the Gencaro Test for the treatment of patients with HF. Under the terms of that collaboration, we licensed to LabCorp certain rights to commercialize a receptor genotype diagnostic for the beta-1 and alpha-2C polymorphisms. In return, LabCorp agreed to develop the Gencaro Test and obtain FDA clearance or approval of the Gencaro Test for HF.

Licensing and Royalty Obligations

We have 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. In addition, we have sublicensed CPEC s rights from BMS. CPEC is a licensing entity which holds the rights of the biotechnology companies that were the commercial sponsors of the BEST trial. If the FDA grants marketing approval for Gencaro, the license agreements require that we make a milestone payment of $8.0 million, which is

Table of Contents

due within six months after FDA approval. Under the license agreements, we are required to make milestone payments of up to $5.0 million in the aggregate upon regulatory marketing approval in Europe and Japan. Our royalty obligation under the licenses 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. We have the right to buy down the royalties to a range of 12.5% to 17% by making a payment within six months of regulatory approval. We also have licensed worldwide rights to intellectual property covering the pharmacogenetic response of Gencaro based on the cardiac receptor polymorphisms, which is owned by the University of Colorado. We have no material future financial obligations under this license. We also have an option to license exclusive, worldwide rights to develop and commercialize diagnostics for these receptor polymorphisms, for the purpose of prescribing Gencaro, from the licensee of these rights, the University of Cincinnati.

Development Pipeline

Our development activities are substantially focused on our lead product candidate, Gencaro, for the treatment of AF. We also believe, based upon data from the BEST trial, that Gencaro may have additional potential for the treatment of AF rate control, VT/VF and prevention of heart failure endpoints in HFREF patients. We do not expect to pursue development of Gencaro for disease indications beyond AF without entering into a strategic partnership or collaboration. We believe Gencaro has potential to address these additional indications, and that the clinical response of patients with these diseases may be genetically influenced, based on the same genetic markers we have identified for our proposed treatment of AF with Gencaro.

We also have exclusive pharmacogenetic and other patent rights to drug candidates that have potential indications in cardiovascular disease, oncology and other therapeutic areas, in both early and later stages of development. We may seek partners to assist us in the development of these candidates or who may license them.

Competition

Current treatments include pharmaceutical intervention and device intervention. There are several antiarrhythmic drugs approved by the FDA for the treatment and/or prevention of recurrent AF. However, these drugs have safety and/or administration concerns and all but one have contraindications or label warnings regarding their prescription in patients with heart failure.

Current device interventions for the treatment of AF include:

- Electrical cardioversion which is used to restore normal heart rhythm with administration of a direct current shock;
- Radiofrequency ablation which can be effective in patients for whom medications are ineffective; and,
- Atrial pacemakers which are implanted under the skin and then intravenously into the heart to regulate heart rhythm.

Considering that most of the approved drugs and device interventions for the treatment or prevention AF have notable risks or adverse side effects, we believe there is an unmet medical need for new AF treatments that have fewer side effects than currently available therapies and are more effective, particularly in patients with HF where the approved drugs are contra-indicated or have warnings regarding their prescribing information. We believe that Gencaro s prevention of AF in HF patients would provide this patient population a safer treatment option than other treatments currently approved by the FDA.

The pharmaceutical industry is highly competitive. We face significant competition from pharmaceutical companies and biotechnology companies that are researching and selling products designed to treat cardiovascular conditions. Most of these companies have significantly greater financial, product development, manufacturing, and commercial resources than we have.

Table of Contents

In addition, our proposed prescribing information for Gencaro includes a recommendation for genetic testing, which will add additional cost and procedures to the process of prescribing Gencaro, and which could make it more difficult for us to compete against existing therapies.

Manufacturing and Product Supply

Gencaro is a small molecule drug with an established manufacturing history. Multiple manufacturers of both the API and drug product have successfully produced Gencaro for use in clinical trials over the course of its clinical development. We outsource all manufacturing and analytical testing of the Gencaro API and drug product. We have selected third party contract manufacturing organizations on the basis of their technical and regulatory expertise. Our approach with our contract manufacturing partners has been to replicate the manufacturing processes that were used to support the prior pivotal clinical trial with Gencaro, and to minimize any changes from these baseline processes, thereby reducing technical and regulatory risk. We contracted with Groupe Novasep to complete the drug substance registration batches required for the Gencaro NDA. These batches were successful, and the resulting drug substance was used to supply the drug product registration campaign. Remaining inventory was placed in current Good Manufacturing Practice, or cGMP, storage to provide a backup supply for the planned Genetic-AF trial, and for use as an initial source of drug substance to support eventual product launch, if approved.

For drug product production, we have contracted with Patheon, Inc. to manufacture the Gencaro tablets. Gencaro is produced in a tablet form, utilizing standard solid oral dosage processing techniques. Six separate dosage strengths are manufactured, with the maximum recommended dose of 50mg twice daily for patient weighing 75kg or less and 100mg twice daily for patients weighing more than 75kg. Registration batches were successfully completed by Patheon, Inc. and tablets from these runs have been placed in cGMP storage to supply the planned GENETIC-AF trial.

If sufficient funding is obtained, our manufacturing focus for 2013 will be to prepare the blinded clinical trial supplies for Gencaro and the comparator compound, and to establish the appropriate packaging and clinical distribution channels necessary for the successful execution of the planned GENETIC-AF trial.

Research and Development Expenses

Our research and development expenses totaled $1.1 million for the year ended December 31, 2012 as compared to $2.3 million for 2011, a decrease of approximately $1.2 million. Our future R&D expenses are highly contingent upon our ability to raise substantial additional funding or complete a strategic transaction. Should we receive funds from one or a combination of these sources, R&D expense in 2013 could be substantially higher than 2012 as we initiate our planned GENETIC-AF clinical trial. Until substantial additional funding is obtained, R&D expenses in 2013 are expected to be comparable to 2012 levels.

Government Regulation

Governmental authorities in the U.S. at the federal, state, and local levels and foreign countries extensively regulate, among other things, the research, development, testing, manufacture, labeling, promotion, advertising, marketing, distribution, sampling, and import and export of pharmaceutical and medical device products. In the U.S., the Food and Drug Administration (FDA) regulates these activities at the federal level pursuant to the Federal Food Drug and Cosmetic Act (FDCA) and the regulations promulgated thereunder.

Premarket Approval of Drugs

FDA approval is required before any new drug, dosage form, indication, or strength can be marketed in the U.S. We anticipate that all of our products will require regulatory approval by governmental agencies prior to commercialization. The process of obtaining approval and the subsequent process of maintaining compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. In addition, these statutes, rules, regulations and policies may change and our products may be subject to new legislation or regulations. There are numerous FDA and other federal and state sanctions for non-compliance.

Table of Contents

The steps required before new human therapeutic drug products are marketed in the U.S. and foreign countries include rigorous preclinical and clinical testing and other approval requirements by regulatory agencies, such as the FDA and comparable agencies in foreign countries. There is no guarantee that products will be approved in a specific timeframe or at all.

Preclinical Phase. Preclinical studies are generally conducted in the laboratory to identify potential drug candidates and to evaluate their potential efficacy and safety. These studies include laboratory evaluation of product chemistry, formulation and stability, as well as studies to evaluate short and long-term toxicity in animals. Preclinical studies are governed by numerous regulations, including but not limited to FDA s Good Laboratory Practices.

Clinical Phase. Before human clinical trials can commence, an Investigational New Drug, or IND, application, submitted to FDA must become effective. For an IND to become effective, the applicant must submit, among other things, information on design of the proposed investigation, reports necessary to assess the safety of the drug for use in clinical investigation, and information on the chemistry and manufacturing of the drug, controls available for the drug, and primary data tabulations from animal or human studies. The clinical phase of development involves the performance of human studies, including adequate and well-controlled human clinical trials to establish the safety and efficacy of the product candidate for each proposed indication. Typically, clinical evaluation involves three sequential phases, which may overlap. During Phase 1, clinical trials are conducted with a relatively small number of subjects or patients to determine the early safety profile of a product candidate, as well as dose tolerance, absorption, and the pattern of drug distribution and drug metabolism. Phase 2 trials are conducted with groups of patients afflicted by a specific target disease to determine preliminary efficacy, optimal dosages and dosage tolerance and to identify possible adverse effects and safety risks. In Phase 3, larger-scale, multi- center trials are conducted with patients afflicted with a specific target disease to provide data for the statistical proof of efficacy and safety as required by regulatory agencies. The conduct of clinical trials is subject to extensive regulation. FDA may delay or suspend clinical trials through clinical holds.

NDA Submission. In the U.S., the results of preclinical and clinical testing along with chemistry, manufacturing and controls information, are submitted to the FDA in the form of an NDA. Under the Prescription Drug User Fee Act, or PDUFA, after submission of an NDA and payment, or waiver, of the required fee, the FDA s goal is to review most standard NDAs within 10 months from sponsor submission of the application by which time, the FDA must issue a complete response, or approve the NDA. While FDA s goal is to issue a complete response within 10 months, the process may take longer than 10 months, particularly if multiple review cycles are required.

In responding to an NDA, the FDA may grant marketing approval or deny the application if the FDA determines that the application does not satisfy the statutory and regulatory approval criteria. A denial may include a request for additional information, including additional clinical data and/or an additional Phase 3 clinical trial. Data from clinical trials are not always conclusive and FDA may interpret data differently than we interpret data. Under the Food and Drug Modernization Act of 1997, the FDA is authorized to approve a drug based on a single adequate and well-controlled study if such study and other confirmatory data are sufficient to establish the drug s effectiveness. However, it has long been the FDA s general position that the standard of proof of a drug s effectiveness generally requires at least two well-controlled and adequate Phase 3 clinical studies demonstrating statistically significant results as compared to a placebo or active control (with p-values of less than 0.05) with respect to the primary endpoint or endpoints of the trial.

In addition, in accordance with current FDA law and regulations, the FDA may refer a drug to an advisory committee for review prior to approval. Most new compounds are referred to an FDA advisory committee, which could add additional time to the review process. There is no guarantee that the advisory committee will recommend approval of a drug candidate. In some cases, FDA may require completion, within a specified time period, of additional clinical studies after approval, referred to as Phase 4 clinical studies, to monitor the effect of a new product and may prevent or limit future marketing of the product based on the results of these post-marketing programs. Furthermore, prior to granting approval, the FDA generally conducts an inspection of the

Table of Contents

facilities, including outsourced facilities that will be involved in the manufacture, production, packaging, testing and control of the drug substance and finished drug product for compliance with current Good Manufacturing Practice, or cGMP, requirements.

If the FDA approves the NDA, the sponsor is authorized to begin commercialization of the drug in accordance with the approval. Even if the FDA approves the NDA, the FDA may decide later to suspend or withdraw product approval if compliance with regulatory standards is not maintained or if safety problems are recognized after the product reaches the market. In addition, the FDA requires surveillance programs to monitor approved products that have been commercialized, and the agency has the power to require additional clinical studies, to require changes in labeling or to prevent further marketing of a product based on the results of these post-marketing programs. The FDA also has authority to request implementation of a risk evaluation and mitigation strategy, or REMS, that could restrict distribution of Gencaro or require us to provide additional risk information to prescribers. Whether or not FDA approval has been obtained, approval of a product candidate by comparable foreign regulatory authorities is necessary prior to the commencement of marketing of a product candidate in those countries. The approval procedures vary among countries and can involve additional testing. The time required to obtain approval may differ from that required for FDA approval.

Post-approval Compliance. If regulatory approval for a drug or medical device is obtained, the product and the facilities manufacturing the product are subject to periodic inspection and continued regulation by regulatory authorities, including compliance with cGMP, as well as labeling, advertising, promotion, recordkeeping, and reporting requirements, including the reporting of adverse events. In addition, the FDA closely regulates the post-approval marketing and promotion of drugs, including standards and regulations for labeling, promotion to health care professionals, direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the Internet. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved labeling. Companies are responsible for compliance with such requirements and would be responsible to ensure that all contract manufacturing organizations who perform work for them also comply with such requirements. Similarly, if a drug manufacturer hires contract sales representatives or consultants to promote its products, such organizations or individuals must comply with all of the same requirements applicable to the drug manufacturer. Failure to comply with these requirements can result in adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties.

Drug Price Competition and Patent Term Restoration Act of 1984. Under the Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, Congress created an abbreviated FDA review process for generic versions of pioneer (brand name) drug products. The Hatch-Waxman Act also provides for patent term restoration and the award, in certain circumstances, of non-patent marketing exclusivities.

Generic Drug Approval. The Hatch-Waxman Act established an abbreviated FDA review process for drugs that are shown to be equivalent to approved pioneer drugs. Approval for a generic drug is obtained by filing an abbreviated NDA, or ANDA. Generic drug applications are abbreviated because they generally do not include clinical data to demonstrate safety and effectiveness. Instead, an ANDA applicant must establish that its product is bioequivalent to an approved drug and that it is the same as the approved drug with respect to active ingredient(s), route of administration, dosage form, strength and recommended conditions of use (labeling). The FDA will approve the generic as suitable for an ANDA if it finds that the generic does not raise questions of safety and effectiveness as compared to the pioneer drug. A drug is not eligible for ANDA approval if the FDA determines that it is not equivalent to the pioneer drug or if it is intended for a different use. Any applicant who files an ANDA seeking approval of a generic version of an approved drug listed in FDA s Approved Drug Products with Therapeutic Equivalence Evaluations, or the Orange Book, before expiration of the patent(s) listed in the Orange Book for that approved drug, must certify to the FDA for each patent that (i) no patent information on the drug has been submitted to the FDA; (ii) that such patent has expired; (iii) the date on which such patent expires; or (iv) that such patent is invalid, unenforceable or will not be infringed by the manufacture, use or sale

Table of Contents

of the generic drug. If the ANDA applicant makes a certification pursuant to (iv) above, or a Paragraph IV certification, and the NDA holder files an infringement suit against the ANDA applicant within 45 days of receiving the Paragraph IV notification, the NDA owner is entitled to an automatic 30-month stay of FDA s ability to approve the ANDA. This 30-month stay will end early upon any decision by a court that the patent is invalid, unenforceable or not infringed by the generic drug.

Patent Term Restoration. The Hatch-Waxman Act provides for the restoration of a portion of the patent term lost during product development and FDA review of an application. However, the maximum period of restoration cannot exceed five years, or restore the total remaining term of the patent to greater than 14 years from the date of FDA approval of the product.

Patent Term Extension. While the term of a U.S. patent is 20 years from the earliest priority date of a patent application (excluding a provisional patent application) , a U.S. patent that covers subject matter requiring regulatory approval to market is eligible for an extension of that patent term. Patent Term Extension, or PTE, extends the term of an issued patent for generally 1) the length of the FDA approval process and 2) half of the time spent in clinical trials. However, there are certain limitations to PTE, including the limitation that the term cannot be extended more than 14 years after approval has been obtained.

Under 35 U.S.C. § 156(a), a patent covering a method of using a product is eligible for PTE if the following conditions are met:

(1) the patent has not yet expired;
(2) the patent was not previously extended;
(3) the patent owner submits an application for PTE that includes all necessary supporting information within 60 days of FDA approval;
(4) the product was subject to regulatory review before its commercial marketing or use; and
(5) the drug application is for the first permitted commercial marketing of the product.

We have obtained three U.S. patents (U.S. Patent Nos. 7,678,824; 8,080,578; 8,093,286), and have one pending U.S. patent application that generally concern methods for treating patients with Gencaro based on the presence of certain polymorphisms in the beta-1 and/or alpha-2C adrenergic receptors. We believe that, if approved by the FDA, one of the U.S. patents may be eligible for PTE, which could provide approximately 3 years or more of additional patent life based on our current clinical trial plans.

Patent Term Extension, known as a Supplementary Protection Certificate, or SPC, is a form of patent term extension that is available for pharmaceutical products approved for marketing in the European Union. We obtained a patent in Europe on methods for using Gencaro that is similar to the 824 patent (EP 1802775); this patent is in force in certain countries in Europe, including the United Kingdom, France, Germany, Italy and Spain. We believe that this patent may be eligible for an SPC, if Gencaro is approved for marketing in any European country in which the patent is in force, which could provide up to five years of additional patent life.

Non-Patent Marketing Exclusivities. Separate and apart from patent protection, the Hatch-Waxman Act entitles approved drugs to various periods of non-patent statutory protection, known as marketing exclusivity. The Hatch-Waxman Act provides five years of new chemical entity marketing exclusivity to the first applicant to gain approval of an NDA for a product that contains an active moiety not found in any other approved product. This exclusivity means that another manufacturer cannot submit an ANDA or 505(b)(2) NDA until the marketing exclusivity period ends. This exclusivity protects the entire new chemical entity franchise, including all products containing the active ingredient for any use and in any strength or dosage form, but will not prevent the submission or approval of stand-alone NDAs where the applicants have conducted their own clinical studies to demonstrate safety and effectiveness. There is an exception, however, for a competitor that seeks to challenge a patent with a Paragraph IV certification. Four years into the five-year exclusivity period, a manufacturer who alleges that one or more of the patents listed with the NDA is invalid, unenforceable or not infringed may submit an ANDA or 505(b)(2) NDA for a generic or modified version of the product.

Table of Contents

The Hatch-Waxman Act also provides three years of new use marketing exclusivity for the approval of NDAs, and supplements, where those applications contain the results of new clinical investigations (other than bioavailability studies) essential to the FDA s approval of the applications. Such applications may be submitted for new indications, dosage forms, strengths, or new conditions of use of approved products. So long as the studies are essential to the FDA s approval or were conducted by or for the applicant, this three-year exclusivity prohibits the final approval of ANDAs or 505(b)(2) NDAs for products with the specific changes associated with those studies. It does not prohibit the FDA from approving ANDAs or 505(b)(2) NDAs for other products containing the same active ingredient, without those changes.

FDA Premarket Review of Medical Devices

Unless an exemption applies, each medical device that a company wishes to market in the U.S. requires either approval of a premarket approval PMA application or clearance of a premarket notification, commonly known as a 510(k) from the FDA. The FDA classifies medical devices into one of three classes. Devices deemed to pose lower risks are placed in either class I or II, which may require the manufacturer to submit to the FDA a 510(k) requesting permission to commercially distribute the device. Clearance of a 510(k) usually requires between three months and one year from the time of submission of the 510(k), although the process may take longer. The FDA s 510(k) clearance procedure is less rigorous than the PMA approval procedure, but is available only to companies who can establish that their device is substantially equivalent to a legally-marketed predicate device that was (i) on the market prior to the enactment of the Medical Device Amendments of 1976, (ii) reclassified from Class III to Class II, or (iii) has been cleared through the 510(k) procedure. 510(k)s must typically be supported by performance data, including preclinical data, bench testing, and in some cases, clinical data. Some low risk devices are exempted from this requirement. Devices deemed by the FDA to pose the greatest risks, or for which there is no predicate, are placed in class III, requiring approval of a PMA.

PMA Pathway. Generally, a PMA must be supported by extensive data including, but not limited to, technical, preclinical, clinical trials, manufacturing and labeling to demonstrate to the FDA s satisfaction a reasonable assurance of the safety and effectiveness of the device for its intended use. After a PMA is sufficiently complete, the FDA will accept the application and begin an in-depth review of the submitted information and will generally conduct a pre-approval inspection of the manufacturing facility or facilities to ensure compliance with FDA s Quality System Regulations (QSR). By statute, the FDA has 180 days to review the accepted application , although, generally, review of the application can take between one and three years, and it may take significantly longer. The PMA application process can be expensive, and there is a substantial user fee that must be paid to FDA in connection with the submission of a PMA application. If the FDA s evaluation of the PMA application or the manufacturing facility is not favorable, the FDA may deny approval of the PMA application or issue a not approvable letter. The FDA may also require additional clinical trials, which can delay the PMA approval process by several years. After the PMA is approved, if significant changes are made to a device, its manufacturing or labeling, a PMA supplement containing additional information must be filed for prior FDA approval. PMA supplements often must be approved by FDA before the modification to the device, the labeling, or the manufacturing process may be implemented.

Clinical Trials. Clinical trials are generally required to support a PMA application and are sometimes required for 510(k) clearance.

In Vitro Diagnostic Companion Diagnostic Devices. FDA has described IVD companion diagnostic devices as in vitro diagnostic devices that provide information that is essential for the safe and effective use of a corresponding therapeutic product. The use of an IVD companion diagnostic device with a particular therapeutic product is stipulated in the instructions for use in the labeling of both the diagnostic device and the corresponding therapeutic product, as well as in the labeling of any generic equivalents of the therapeutic product. An IVD companion diagnostic device could be used to (i) identify patients who are most likely to benefit from a particular therapeutic product; (ii) identify patients likely to be at increased risk for serious adverse reactions as a result of treatment with a particular therapeutic product; or (iii) monitor response to treatment for the purpose of adjusting treatment (e.g., schedule, dose, discontinuation) to achieve improved safety or effectiveness. Although FDA s regulation of IVD Companion

Table of Contents

Diagnostic Devices is evolving and implemented on a case-by-case basis, FDA s stated policy is that a therapeutic product and its corresponding IVD companion diagnostic device would be developed contemporaneously, with the clinical performance and clinical significance of the IVD companion diagnostic device established using data from the clinical development program of the corresponding therapeutic product. FDA s policy is that an IVD companion diagnostic device should be developed and approved or cleared contemporaneously to support the therapeutic product s safe and effective use. With respect to the Gencaro Test, there is no assurance that we will be able to develop and obtain approval or clearance contemporaneously with Gencaro. Failure to develop the Gencaro Test or obtain clearance or approval could delay approval of Gencaro, if FDA regards the Gencaro Test as an IVD companion diagnostic test that is essential to the safe and effective use of Gencaro.

Continuing Regulation. After a device is placed on the market, numerous regulatory requirements apply to the manufacturer, or holder of a PMA approval. With respect to the Gencaro Test, we intend to seek a new or amended collaborative arrangement with a diagnostic company in which we could license them certain rights to perform the diagnostic test for patients with AF. As part of such arrangement, we will seek to have the diagnostic company take responsibility for compliance with the FDA s device approval and on-going regulatory requirements.

International Marketing Approvals. International sales of medical devices are subject to foreign government regulations, which vary substantially from country to country and are subject to change. The time required to obtain approval by a foreign country may be longer or shorter than that required for FDA clearance or approval, and the requirements may differ.

Other Regulatory Requirements. We are also subject to various federal, state and local laws, regulations and recommendations relating to safe working conditions, laboratory and manufacturing practices, the experimental use of animals and the use and disposal of hazardous or potentially hazardous substances, including radioactive compounds and infectious disease agents, used in connection with our work. The extent and character of governmental regulation that might result from future legislation or administrative action cannot be accurately predicted.

Intellectual Property

The future success of our business will partly depend on our ability to maintain market exclusivity in the United States and important international markets for Gencaro, and for other products or product candidates that we may acquire or develop. We will rely on statutory protection, patent protection, trade secrets, know-how, and in-licensing of technology rights to maintain protection for our products.

We believe that both patent protection and data exclusivity statutes will give Gencaro market exclusivity in the U.S. and in major international markets. If approved by the FDA or international regulatory agencies, Gencaro will qualify as a New Chemical Entity, or NCE, as it has never received regulatory approval in any jurisdiction. As an NCE, Gencaro will enjoy market exclusivity in the United States and most international markets under data exclusivity statutes. These laws provide for an exclusivity period beginning from regulatory approval, during which any generic competitor is barred from submitting an application that relies on the data that has been submitted in connection with the approval of the NCE. In the U.S., the Hatch-Waxman Act provides for an initial period of four or five years from approval of the NCE, during which a generic application attempting to rely on the data submitted for the NCE cannot be filed with the FDA. This period can be extended under certain circumstances, and we believe that the maximum period of exclusivity under these provisions is seven and one-half years from FDA approval, as discussed below.

Many international markets have data exclusivity statutes that are analogous to Hatch-Waxman and often more protective. The analogous statute in the European Medicines Evaluation Agency will, in general, provide Gencaro with a minimum of ten years of protection before such a generic application may be approved. Protection under Hatch-Waxman and other data exclusivity statutes is sometimes considered superior to patent protection, as the generic cannot be marketed during the period of exclusivity, thus eliminating the need to initiate patent infringement litigation with its accompanying risks and costs.

Table of Contents

In addition to protection under data exclusivity statutes, we believe that Gencaro s patent portfolio provide alternative protection of market exclusivity. We have been granted patents in the United States and Europe that claim the use of Gencaro with the genetic polymorphisms of the beta-1 and alpha-2C receptors that predict Gencaro response. We believe that this patent strategy may effectively serve to exclude generic competition because of the threat of patent litigation. Consequently, if our patent strategy is successful, we believe that the possibility of generic competition with Gencaro will be significantly reduced or eliminated until at least the expiration of these patents, which would be no earlier than 2026 in the U.S 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 U.S. and Europe. We also believe that the initial period of statutory exclusivity for Gencaro in the U.S. may be extended to seven and one-half years from approval, under a special Hatch-Waxman provision that permits an automatic 30-month extension of the exclusivity period by pursuing litigation against any company attempting to enter the market with a generic for a drug that is covered by a composition of matter or method of use patent.

We also own or have rights in a number of patents and patent applications relating to a number of pre-clinical and clinical candidate molecules, including rNAPc2. We estimate that patents for rNAPc2 covering use as a treatment for hemorrhagic fever viruses will expire no earlier than 2023.

In some cases, certain of the U.S. patents may be entitled to an extension of their term and certain European patents may be entitled to supplemental protection in one or more countries in Europe. The length of any such extension, if an extension is granted, will vary by country. We cannot predict whether any such extensions will be granted.

Employees

As of December 31, 2012, we had 11 employees, of which 6 were full-time active employees. All of these employees operate out of the Broomfield, Colorado location. None of our employees are represented by any collective bargaining unit. We believe that we maintain good relations with our employees.

Corporate Information

On January 27, 2009, we completed a business combination (the Merger) with ARCA Colorado in accordance with the terms of that Agreement and Plan of Merger and Reorganization, dated September 24, 2008, and amended on October 28, 2008 in which a wholly-owned subsidiary of Nuvelo, Inc. merged with and into ARCA Colorado, with ARCA Colorado continuing after the Merger as the surviving corporation and a wholly-owned subsidiary of Nuvelo, Inc. Immediately following the Merger, we changed our name from Nuvelo, Inc. to ARCA biopharma, Inc. Nuvelo was originally incorporated as Hyseq, Inc. in Illinois in 1992 and reincorporated in Nevada in 1993. On January 31, 2003, Nuvelo merged with Variagenics, Inc., a publicly traded Delaware corporation based in Massachusetts, and, in connection with the merger, changed its name to Nuvelo, Inc. On March 25, 2004, Nuvelo was reincorporated from Nevada to Delaware. On January 27, 2009, in connection with the Merger with ARCA Colorado described above, Nuvelo changed its name to ARCA biopharma, Inc. Our principal offices are located in Broomfield, Colorado.

We file our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 electronically with the SEC. The public may read or copy any materials that have been filed with the SEC at the SEC s Public Reference Rooms at 100 F Street, N.E., Washington, D.C. 20549 on official business days during the hours of 10:00 a.m. and 3:00 p.m. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC maintains an Internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC. The address of that site is http://www.sec.gov.

Table of Contents

You may obtain a free copy of our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports on our website at http://www.arcabiopharma.com on the earliest practicable date following the filing with the SEC or by contacting the Investor Relations Department at our corporate office by calling (720) 940-2200. Information found on our website is not incorporated by reference into this report.

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, 2012, have concluded that due to our need for additional capital, and the uncertainties surrounding our ability to raise such funding, substantial doubt exists as to our ability to continue as a going concern.

Our audited financial statements for the fiscal year ended December 31, 2012 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 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. 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. These uncertainties raise substantial doubt about our ability to continue as a going concern. If we become unable to continue as a going concern, we may have to liquidate our assets, and might realize significantly less than the values at which they are carried on our financial statements, and stockholders may lose all or part of their investment in our common stock.

We will need to raise substantial additional funds through public or private equity transactions 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 planned GENETIC-AF clinical trial, the substantial cost of commercializing Gencaro, if it is approved, we will need to raise substantial additional funding through public or private r 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.

Table of Contents

We believe our cash and cash equivalents balance as of December 31, 2012, along with the net proceeds from our recently completed financings, will be sufficient to fund our operations, at our current cost structure, through September 30, 2013. As a result of the significant additional development effort required for Gencaro, including the additional clinical trials, we may not be able to raise sufficient capital on acceptable terms, or at all, to continue development of Gencaro or to continue operation and may not be able to execute any strategic transaction. We are unable to assert that our current cash and cash equivalents are sufficient to fund operations beyond that date, and as a result, there is substantial doubt about our ability to continue as a going concern beyond September 30, 2013. 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:

- 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 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 or minimum closing bid price

requirements, we would be subject to delisting from the Nasdaq Capital Market.

Table of Contents

As of March 18, 2013, the closing price of our common stock was $2.72 per share, and the total market value of our publicly held shares of our common stock (excluding shares held by our executive officers, directors and 10% or more stockholders) was approximately $6.8 million and the total market value of our listed securities was approximately $8.7 million. As of December 31, 2012, we had stockholders equity of $2.9 million.

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 through other means, we will need to complete a strategic transaction to continue the development of Gencaro or our other operations. The strategic transactions that we may consider include a potential combination or partnership. Our board of directors and management team has and will continue to devote substantial time and resources to 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 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 18, 2013, we had 3,185,562 shares of common stock outstanding, 20% of which is 637,112 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.

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 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. In addition, we agreed that, subject to certain exceptions, if we issue 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.

The restrictions imposed by the terms of these 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.

Table of Contents

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 plan to conduct a Phase 2b/Phase 3 clinical study of Gencaro in approximately 200-620 HFREF patients with AF. Clinical trials are typically lengthy, complex and expensive and we do not currently have the resources to fund such a trial.

Failure to demonstrate that a product candidate, particularly Gencaro, is safe and effective, or significant delays in demonstrating such safety and efficacy, would adversely affect 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 only receive regulatory approval for our product candidates if we can demonstrate in carefully designed and conducted clinical trials that the product candidate is safe and effective. We do not know whether any future clinical trials, including the planned 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. If we do not see sufficient efficacy and safety in the Phase 2b portion of the trial, we will not complete 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 expect that we will have to rely on contract research organizations to conduct certain of our clinical trials. While certain of our employees have experience in designing and administering clinical trials, these employees have no such experience since being with us.

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

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

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

Table of Contents

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

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

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

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

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

Patient enrollment is affected by factors including:

- design of the protocol;
- the size of the patient population;
- eligibility criteria for the study in question;
- perceived risks and benefits of the drug under study;
- availability of competing therapies, including the off-label use of therapies approved for related indications;
- efforts to facilitate timely enrollment in clinical trials;
- the success of our personnel in making the arrangements with potential clinical trial sites necessary for those sites to begin enrolling patients;
- patient referral practices of physicians;

availability of clinical trial sites; and

other clinical trials seeking to enroll subjects with similar profiles.

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

Table of Contents

We do not have a binding agreement with Medtronic for their participation in the GENETIC-AF trial and we may never complete a binding agreement with Medtronic.

We anticipate that Medtronic s participation in our planned GENETIC-AF trial will expand the data collection and monitoring of subjects in the Phase 2b portion of the trial. We do not currently have a binding agreement with Medtronic for their participation in the Phase 2b portion of the trial, and we may never enter into a binding agreement with Medtronic. If we do enter into a binding agreement with Medtronic, we cannot predict the terms of such an agreement or that the terms will be favorable to us. The final terms of any final agreement may differ significantly from the terms in the current letter of intent. If we are not successful in completing a definitive agreement with Medtronic or the terms of the agreement are different than we currently contemplate, we may be unable to complete, or we may be delayed in initiating, the Phase 2b portion of GENETIC-AF or we may be forced to alter the proposed design of the trial. If any of these events occur, our business and prospects will be materially and adversely affected and we may be unable to meet our expected timelines and milestones.

Our planned GENETIC-AF clinical trial will require 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. We do not currently have a third-party diagnostic services provider identified to perform this work for our planned clinical trial. If we have difficulty getting an arrangement for administering the Gencaro Test, the launch of our clinical trial could be delayed.

The planned GENETIC-AF clinical trial we intend to conduct with Gencaro requires a companion test that identifies the patient s receptor genotype, or Gencaro Test, and 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 will require use of a third-party diagnostic service to perform the Gencaro Test. Previously we entered into a collaboration arrangement with LabCorp to develop and commercialize the Gencaro Test for the treatment of patients with HF. Under the terms of that collaboration, we licensed to LabCorp certain rights to commercialize a receptor genotype diagnostic for the beta-1 and alpha-2C polymorphisms. We currently intend to pursue a separate arrangement with LabCorp or another third party to provide the diagnostic services of the Gencaro Test needed to support our GENETIC-AF trial Obtaining an arrangement with a third party for developing or administering the Gencaro Test for the clinical trial could delay the launch and/or affect the cost and complexity of our planned study.

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

Our historical losses have had and will continue to have an adverse effect on our stockholders equity and working capital, among other things. We are years away from commercializing a product and generating any product revenue. As a result, we expect to continue to incur significant operating losses for the foreseeable future. Even if we ultimately receive regulatory approval for Gencaro or our other product candidates, sales of such products may not generate sufficient revenue for it to achieve or maintain profitability. Because of the numerous risks and uncertainties associated with developing therapeutic drugs, we may experience larger than expected future losses and may never reach profitability.

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 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 current or future collaborative partners, the uncertainties inherent in the regulatory approval process and manufacturing scale-up and delays in achieving manufacturing or marketing arrangements sufficient to commercialize our products. FDA approval of Gencaro, if it occurs, is expected to require years of additional clinical development, including the completion of a new multi-year clinical study of Gencaro in approximately 200-620 HF patients with AF. There

Table of Contents

can be no assurance that our clinical trials will be completed, or that we will make regulatory submissions or receive regulatory approvals as planned. If we fail to achieve one or more of these milestones as planned, our business will be materially adversely affected.

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

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

To receive regulatory approval for the commercial sale of any product candidates, we must demonstrate safety and efficacy in humans to the satisfaction of regulatory authorities through preclinical studies and adequate and well-controlled clinical trials of the product candidates. This process is expensive and can take many years, and failure can occur at any stage of the testing. Our failure to adequately demonstrate the safety and efficacy of our product candidates will prevent regulatory approval and commercialization of such products. 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 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 plan to conduct a clinical study of Gencaro in AF patients HREF to assess its efficacy in reducing or preventing AF. We anticipate that GENETIC-AF could begin approximately six months after we obtain sufficient funding. This trial is planned to begin 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 would take approximately two years to complete. 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 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;

Table of Contents

delays or failures in obtaining approval of our clinical trial protocol from an institutional review board, or IRB, to conduct a clinical trial at a prospective study site;

delays in recruiting patients to participate in a clinical trial, which may be due to the size of the patient population, eligibility criteria, protocol design, perceived risks and benefits of the drug, availability of other approved and standard of care therapies, availability of clinical trial sites;

other clinical trials seeking to enroll subjects with similar profile;

failure of our clinical trials and clinical investigators to be in compliance with the FDA s Good Clinical Practices;

unforeseen safety issues, including negative results from ongoing preclinical studies;

inability to monitor patients adequately during or after treatment;

difficulty monitoring multiple study sites; and

failure of our third-party contract research organizations, clinical site organizations and other clinical trial managers, to satisfy their contractual duties, comply with regulations or meet expected deadlines.

In addition, any approvals we may obtain may not cover all of the clinical indications for which we seek approval or permit us to make claims of superiority over currently marketed competitive products. Also, an approval might contain significant limitations in the form of narrow indications, warnings, precautions or contraindications with respect to conditions of use. If the FDA determines that a risk evaluation and mitigation strategy, or REMS, is necessary to ensure that the benefits of the drug outweigh the risks, we may be required to include as part of the NDA a proposed REMS that may include a package insert directed to patients, a plan for communication with healthcare providers, restrictions on a drug s distribution, or a Medication Guide, to provide better information to consumers about the drug s risks and benefits. Finally, an approval could be conditioned on our commitment to conduct further clinical trials, which we may not have the resources to conduct or which may negatively impact our financial situation.

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

All of our product candidates are prone to the risks of failure inherent in drug development. The results from preclinical animal testing and early human clinical trials may not be predictive of results obtained in later human clinical trials. Further, although a new product may show promising results in preclinical or early human clinical trials, it may subsequently prove unfeasible or impossible to generate sufficient safety and efficacy data to obtain necessary regulatory 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.

Table of Contents

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 would likely 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 included 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.

Table of Contents

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;

Table of Contents

close the facilities of our contract manufacturers; or

impose civil or criminal penalties.

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

The drug label we intend to seek for Gencaro would identify the patient receptor genotype for which the drug is approved. Accordingly, we believe developing a Gencaro 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 planned GENETIC-AF clinical trial. The Gencaro 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 a third-party diagnostic services provider is unable to obtain FDA approval of the Gencaro Test at all or in parallel with the approval of Gencaro, or is unable to commercialize the test successfully and in a manner that effectively supports the commercial efforts for Gencaro, or if the information concerning the differential response to Gencaro resulting from certain genetic variation is not included in the approval label for Gencaro, the commercial launch of Gencaro may be significantly and adversely affected.

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

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

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

In the event we are unable to sell Gencaro and other selected product candidates, either directly or through third parties via a strategic transaction, the commercialization of Gencaro, if it is approved, may be delayed indefinitely.

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

The Gencaro Test is an important component of the commercial strategy for Gencaro in addition to being required to proceed with our planned AF trial. We believe that the Gencaro Test helps predict patient response to Gencaro, and that this aspect of the drug is important to its ability to compete effectively with current therapies. The Gencaro Test adds an additional step in the prescribing process, an additional cost for the patient and payors, the risk that the test results may not be rapidly available and the possibility that it may not be available at all to hospitals and medical centers. Although we anticipate that Gencaro, if approved in a timely manner, would be the first genetically-targeted cardiovascular drug, Gencaro will be one of a number of successful drugs in the beta-blocker class currently on the market. Prescribers may be more familiar with these other beta-blockers, and may be resistant to prescribing Gencaro as an AF or HF therapy. Any one of these factors could affect prescriber behavior, which in turn may substantially impede market acceptance of the Gencaro Test, which could cause significant harm to Gencaro s ability to compete, and in turn harm our business.

Table of Contents

We are dependent on our key personnel.

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

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

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

We have contracted with Groupe Novasep to manufacture commercial quantities of the API for Gencaro. For drug production, we have contracted with Patheon, Inc. to manufacture the Gencaro tablets. These contract manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required to successfully produce, store and distribute our products. In addition, these manufacturers may have staffing difficulties, may not be able to manufacture our products on a timely basis or may become financially distressed. In the event of errors in forecasting production quantities required to meet demand, natural disaster, equipment malfunctions or failures, technology malfunctions, strikes, lock-outs or work stoppages, regional power outages, product tampering, war or terrorist activities, actions of regulatory authorities, business failure, strike or other difficulty, we may be unable to find an alternative third-party manufacturer in a timely manner and the production of our product candidates would be interrupted, resulting in delays and additional costs, which could impact our ability to commercialize and sell our product candidates.

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

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

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

Table of Contents

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

Any medical device 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 Gencaro 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 Gencaro 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.

A third-party diagnostics provider may need to conduct clinical trials to support current or future versions of the Gencaro Test. Delays or failures in any such clinical trials may prevent a third-party diagnostics provider from commercializing any modified or new versions of the Gencaro Test and will adversely affect our business, operating results and prospects.

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

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

Development of sufficient and appropriate clinical protocols to demonstrate safety and efficacy are required, and we or the third-party diagnostics provider may not adequately develop such protocols to support clearance and approval. The trials will require the submission and approval of an investigational device exemption, or IDE,

Table of Contents

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

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

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

- conduct an additional clinical trial and develop and obtain regulatory approval for Gencaro or other product candidates;
- successfully partner a companion genetic test with the commercial launch of Gencaro;
- enter into a strategic transaction enabling the continued development and commercialization of Gencaro, or alternatively, raise significant additional capital to enable these activities;
- pursue additional indications for Gencaro and develop other product candidates, including other cardiovascular therapies; and
- obtain commercial quantities of Gencaro or other product candidates at acceptable cost levels.

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

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

Gencaro is a new type of beta-blocker and vasodilator being developed for AF. While we anticipate that this drug, if approved, would be the first genetically-targeted cardiovascular drug, and potentially the only beta-blocker approved for AF. Gencaro will be one of a number of successful drugs in the beta-blocker class currently on the market. For example, currently, there are three branded beta-blockers indicated for chronic HF in New York Health Association, or NYHA, class II-IV patients: Toprol-XL (once-a-day formulation), Coreg and Coreg CR (once-a-day). Toprol-XL and Coreg have generic equivalents commercially available in the U.S. (metoprolol succinate and carvedilol, respectively). The price of the generic forms of these drugs will be less than the anticipated price of Gencaro, if approved. As a result, Gencaro may not be successful in competing against these existing drugs.

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

Table of Contents

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

Gencaro or our other product candidates may not gain market acceptance among physicians, patients and the medical community. The degree of market acceptance of Gencaro or our other product candidates will depend on a number of factors, such as its effectiveness and tolerability, as compared with competitive drugs. Also, prevalence and severity of side-effects could negatively affect market acceptance of Gencaro or our other product candidates. Failure to achieve market acceptance of Gencaro would significantly harm our business.

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

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

governmental payors, such as Medicare and Medicaid;

private health insurers, including managed-care organizations; and

other third-party payors.

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

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

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

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

Some states are also considering legislation that would control the prices of drugs, and state Medicaid programs are increasingly requesting manufacturers to pay supplemental rebates and requiring prior authorization

Table of Contents

by the state program for use of any drug for which supplemental rebates are not being paid. Managed care organizations continue to seek price discounts and, in some cases, to impose restrictions on the coverage of particular drugs. Government efforts to reduce Medicaid expenses may lead to increased use of managed care organizations by Medicaid programs. This may result in managed care organizations influencing prescription decisions for a larger segment of the population and a corresponding constraint on prices and reimbursement for drugs. It is likely that federal and state legislatures and health agencies will continue to focus on additional health care reform in the future although we are unable to predict what additional legislation or regulation, if any, relating to the health care industry or third-party coverage and reimbursement may be enacted in the future or what effect such legislation or regulation would have on our business. We or any strategic partner s ability to commercialize Gencaro, or any other product candidates that we may seek to commercialize, is highly dependent on the extent to which coverage and reimbursement for these product candidates will be available from government payors, such as Medicare and Medicaid, private health insurers, including managed care organizations, and other third-party payors, and any change in reimbursement levels could materially and adversely affect our business. Further, the pendency or approval of future proposals or reforms could result in a decrease in our stock price or limit our ability to raise capital or to obtain strategic partnerships or licenses.

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

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

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

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

One of our strategies is to license or acquire clinical-stage products or product candidates and further develop them for commercialization. The market for licensing and acquiring products and product candidates is intensely competitive and many of our competitors may have greater resources than us. If we undertake any additional acquisitions, whether of product candidates or other biopharmaceutical companies, the process of integrating an acquired product candidate or complementary company into our business may put a strain on our operations, divert personnel, financial resources and management s attention. In 2013, we expect our research and development activities will be dedicated to Gencaro. If we are not able to substantially expand our research and development efforts, or identify, or license or acquire other products or product candidates or complete future acquisitions, then we will likely be unable expand our pipeline of product candidates. In addition, any future acquisition would give rise to additional operating costs and will likely require us to seek additional financing. Future acquisitions could result in additional issuances of equity securities that would dilute the

33

Table of Contents

ownership of existing stockholders. Future acquisitions could also result in the incurrence of debt, contingent liabilities or the amortization of expenses related to other intangible assets, any of which could adversely affect our operating results.

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

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

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

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

Risks Related to Intellectual Property and Other Legal Matters

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

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

Table of Contents

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

- decreased demand for our products and product candidates;
- injury to our reputation;
- withdrawal of clinical trial participants;
- costs of related litigation;
- substantial monetary awards to patients and others;
- loss of revenues; and
- the inability to commercialize our products and product candidates.

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

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

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

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

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

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

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

harmed.

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

Our or any strategic partner s ability to commercialize Gencaro and other product candidates depends upon our ability to develop, manufacture, market and sell these drugs without infringing the proprietary rights of third parties. A number of pharmaceutical and biotechnology companies, universities and research institutions have or

Table of Contents

may be granted patents that cover technologies similar to the technologies owned by or licensed to us. We may choose to seek, or be required to seek, licenses under third party patents, which would likely require the payment of license fees or royalties or both. We may also be unaware of existing patents that may be infringed by Gencaro, the genetic testing we intend to use in connection with Gencaro or our other product candidates. Because patent applications can take many years to issue, there may be other currently pending applications that may later result in issued patents that are infringed by Gencaro or our other product candidates. Moreover, a license may not be available to us on commercially reasonable terms, or at all.

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

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

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

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

Our competitive success will depend, in part, on our ability to obtain and maintain patent protection for our inventions, technologies and discoveries, including intellectual property that we license. The patent positions of biotechnology companies involve complex legal and factual questions, and we cannot be certain that our patents and licenses will successfully preclude others from using our technology. Consequently, we cannot be certain that any of our patents will provide significant market protection or will not be circumvented or challenged and found to be unenforceable or invalid. In some cases, patent applications in the U.S. and certain other jurisdictions are maintained in secrecy until patents issue, and since publication of discoveries in the scientific or patent literature often lags behind actual discoveries, we cannot be certain of the priority of inventions covered by pending patent applications. Moreover, we may have to participate in interference proceedings declared by the U.S. Patent and Trademark Office to determine priority of invention or in opposition proceedings in a foreign patent office, any of which could result in substantial cost to us, even if the eventual outcome is favorable. There can be no assurance that a court of competent jurisdiction would hold any claims in any issued patent to be valid. An adverse outcome could subject us to significant liabilities to third parties, require disputed rights to be licensed from third parties or require us to cease using such technology. Regardless of merit, the listing of patents in the FDA Orange Book for Gencaro may be challenged as being improperly listed. We may have to defend against such claims and possible associated antitrust issues. We could also incur substantial costs in seeking to enforce our proprietary rights against infringement.

While the composition of matter patents on the compound that comprises Gencaro have expired, we hold the intellectual property concerning the interaction of Gencaro with the polymorphisms of the ß1 and 2C receptors. We have obtained patents that claim methods involving Gencaro after a patient s receptor genotype has been determined. Our NDA requested a label that will include a claim that efficacy varies based on receptor genotype and a recommendation in the prescribing information that prospective patients be tested for their receptor genotype. We believe that under applicable law, a generic bucindolol label would likely be required to include this recommendation as it pertains directly to the safe or efficacious use of the drug. Such a label may be considered as inducing infringement, carrying the same liability as direct infringement. If the label with the

Table of Contents

genotype information for Gencaro is not approved, or if generic labels are not required to copy the approved label, competitors could have an easier path to introduce competing products and our business may suffer. The approved label may not contain language covered by the patents, or we may be unsuccessful in enforcing them.

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

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

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

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

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

Extensive litigation regarding patents and other intellectual property rights has been common in the biopharmaceutical industry. Litigation may be necessary to assert infringement claims, enforce patent rights, protect trade secrets or know-how and determine the enforceability, scope and validity of certain proprietary rights. Litigation may even be necessary to defend disputes of inventorship or ownership of proprietary rights. The defense and prosecution of intellectual property lawsuits, U.S. Patent and Trademark Office interference proceedings, and related legal and administrative proceedings (e.g., a reexamination) in the U.S. and internationally involve complex legal and factual questions. As a result, such proceedings are costly and time-consuming to pursue, and their outcome is uncertain.

Regardless of merit or outcome, our involvement in any litigation, interference or other administrative proceedings could cause us to incur substantial expense and could significantly divert the efforts of our technical and management personnel. Any public announcements related to litigation or interference proceedings initiated or threatened against us could cause our stock price to decline. Adverse outcomes in patent litigation may potentially subject us to antitrust litigation which, regardless of the outcome, would adversely affect our business. An adverse determination may subject us to the loss of our proprietary position or to significant liabilities, or require us to seek licenses that may include substantial cost and ongoing royalties. Licenses may not be available from third parties, or may not be obtainable on satisfactory terms. An adverse determination or a failure to obtain necessary licenses may restrict or prevent us from manufacturing and selling our products, if any. These outcomes could materially harm our business, financial condition and results of operations.

Table of Contents

Risks Related to Stock Price Volatility

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

Our executive officers, directors and their affiliates beneficially owned approximately 29% of our outstanding common stock as of March 18, 2013. Accordingly, these executive officers, directors and their affiliates, acting individually or as a group, have substantial influence over the outcome of a corporate action of ours requiring stockholder approval, including the election of directors, any merger, consolidation or sale of all or substantially all of our assets or any other significant corporate transaction. These stockholders may also delay or prevent a change in control of us, even if such change in control would benefit our other stockholders. The significant concentration of stock ownership may adversely affect the value of our common stock due to investors perception that conflicts of interest may exist or arise.

Our stock price is expected to be volatile.

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

- the regulatory status of Gencaro and the Gencaro Test, and whether and when they are approved for sale, if at all, and the labeling or other conditions of use imposed by the FDA;
- our ability to secure substantial additional funding or complete a strategic transaction or to complete development of and commercialize Gencaro;
- potential receipt of government or third party funding to further develop Gencaro;
- the results of our future clinical trials and any future NDAs of our current and future product candidates;
- the entry into, or termination of, key agreements, including key strategic alliance agreements;
- the results and timing of regulatory reviews relating to our product candidates;
- failure of any of our product candidates, if approved, to achieve commercial success;
- general and industry-specific economic conditions that may affect our research and development expenditures;
- the results of clinical trials conducted by others on drugs that would compete with our product candidates;
- issues in manufacturing our product candidates or any approved products;

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

the loss of key employees;

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

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

future sales of our common stock;

changes in the structure of health care payment systems;

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

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

Moreover, the stock markets in general have experienced substantial volatility that has often been unrelated to the operating performance of individual companies. These broad market fluctuations may also adversely affect the trading price of our common stock. In the past, following periods of volatility in the market price of a

Table of Contents

company s securities, stockholders have often instituted class action securities litigation against those companies. Such litigation, if instituted, could result in substantial costs and diversion of management attention and resources, which could significantly harm our profitability and reputation.

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

Sales in the public market of substantial amounts of our common stock could depress prevailing market prices of our common stock. As of March 18, 2013, 3,185,562 shares of common stock were outstanding. All of these shares are freely transferable without restriction or further registration under the Securities Act, except for shares held by our directors, officers and other affiliates and unregistered shares held by non-affiliates. The sale of these additional shares, or the perception that such sales may occur, could depress the market price of our common stock.

As of March 18, 2013 approximately 1.3 million shares of our common stock were issuable upon the exercise of outstanding warrants. Once a warrant is exercised, if the shares of our common stock issued upon the exercise of any such warrant are not available for sale in the open market without further registration under the Securities Act, then the holder can arrange for the resale of shares either by invoking any applicable registration rights, causing the shares to be registered under the Securities Act and thus freely transferable, or by relying on an exemption to the Securities Act. If these registration rights, or similar registration rights that may apply to securities we may issue in the future, are exercised, it could result in additional sales of our common stock in the market, which may have an adverse effect on our stock price.

As of March 18, 2013, there were approximately 138,000 shares of our common stock which may be issued upon exercise of outstanding stock options. If and when these options are exercised, such shares will be available for sale in the open market without further registration under the Securities Act. The existence of these outstanding options may negatively affect our ability to complete future equity financings at acceptable prices and on acceptable terms. The exercise of those options, and the prompt resale of shares of our common stock received, may also result in downward pressure on the price of our common stock.

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

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

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

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

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

- establish a classified board of directors so that not all members of our board may be elected at one time;
- authorize the issuance of up to 5 million additional shares of preferred stock that could be issued by our board of directors to increase the number of outstanding shares and hinder a takeover attempt;
- limit who may call a special meeting of stockholders;

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

Table of Contents

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

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

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

We are subject to the Delaware anti-takeover laws regulating corporate takeovers. These anti-takeover laws prevent a Delaware corporation from engaging in a merger or sale of more than 10% of its assets with any stockholder, including all affiliates and associates of the stockholder, who owns 15% or more of the corporation s outstanding voting stock, for three years following the date that the stockholder acquired 15% or more of the corporation s stock unless:

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

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

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

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

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

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

generally deter efforts to obtain control of us.

Item 1B. ***Unresolved Staff Comments***

Not applicable.

Item 2. ***Properties***

Our headquarters facility consists of approximately 4,500 square feet of office space in Broomfield, Colorado, which is leased until June 2013. We believe that this facility is adequate to meet our current needs.

Item 3. ***Legal Proceedings***

Not applicable.

Item 4. ***Mine Safety Disclosures***

Not applicable.

Table of Contents

PART II

Item 5. ***Market for Registrant s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities***

As of March 7, 2011, our common stock began trading on the Nasdaq Capital Market under the symbol ABIO , and was previously traded under the same symbol on the Nasdaq Global Market. Prior to completion of the merger with Nuvelo, Nuvelo s common stock traded under the symbol NUVO on the Nasdaq Global Market from January 31, 2003 to January 27, 2009 (except for the period between June 19, 2003 and March 19, 2004, where it temporarily traded under the symbol NUVOD).

The following table sets forth, for the periods indicated, the high and low sales prices for our common stock, as reported by the Nasdaq Capital Market in 2012 and 2011 (adjusted for the one-for-six reverse stock split effective March 4, 2013):

Year ended December 31, 2012	**High**	**Low**
First quarter	$ 6.90	$ 5.22
Second quarter	$ 5.70	$ 2.22
Third quarter	$ 3.66	$ 1.86
Fourth quarter	$ 3.18	$ 1.44

Year ended December 31, 2011	**High**	**Low**
First quarter	$ 20.04	$ 13.50
Second quarter	$ 15.84	$ 8.46
Third quarter	$ 10.08	$ 6.00
Fourth quarter	$ 14.70	$ 5.70

Stockholders

As of March 18, 2013, we had approximately 122 stockholders of record of our common stock, and the last sale price reported on the Nasdaq Capital Market for our common stock was $2.72 per share.

Dividend Policy

The holders of our common stock are entitled to dividends in such amounts and at such times, if any, as may be declared by our Board of Directors out of legally available funds. We have not paid any dividends on our common stock and do not anticipate paying any cash dividends in the foreseeable future.

Securities Authorized for Issuance Under Equity Compensation Plans

Information relating to our equity compensation plans as of December 31, 2012, under which our equity securities were authorized for issuance, is included in Item 12 of Part III of this Annual Report.

Unregistered Sales of Equity Securities and Use of Proceeds

On October 22, 2012, ARCA sold approximately $325,000 of our common stock and warrants for common stock in a private placement transaction. Certain Directors, Officers and Affiliates of ARCA were investors in the private placement. ARCA issued to investors 137,530 shares of common stock together with warrants to purchase 103,148 shares of common stock. The net proceeds, after deducting offering expenses, were approximately $280,000, and these proceeds are being used solely for general working capital purposes. Each unit consisting of a share of common stock and a warrant to purchase 0.75 shares of common stock was sold at a purchase price of $2.36 per unit.

Table of Contents

The warrants were exercisable upon issuance, expire 5 years from the date of issuance, and have an exercise price of $1.80 per share, equal to 100% of the closing sales price of ARCA s common stock on the Nasdaq Capital Market on October 22, 2012.

On December 18, 2012, ARCA sold approximately $250,000 of our common stock and warrants for common stock in a private placement transaction with its Chief Executive Officer, Dr. Michael Bristow. ARCA issued 86,186 shares of common stock together with warrants to purchase 64,640 shares of common stock. The net proceeds, after deducting offering expenses were approximately $230,000, and these proceeds are being used solely for general working capital purposes. Each unit consisting of a share of common stock and a warrant to purchase 0.75 shares of common stock was sold at a purchase price of $2.90 per unit.

The warrants were exercisable upon issuance, expire 5 years from the date of issuance, and have an exercise price of $2.34 per share, equal to 100% of the closing sales price of ARCA s common stock on the Nasdaq Capital Market on December 18, 2012.

On January 22, 2013, ARCA sold approximately $1 million of its common stock and warrants for common stock in a private placement transaction with accredited investors and its Chief Executive Officer. ARCA issued 356,430 shares of common stock together with warrants to purchase 249,501 shares of common stock. The net proceeds, after deducting a placement agent fee and other offering expenses, were approximately $850,000, and these proceeds are being used solely for general working capital purposes. Each unit consisting of a share of common stock and a warrant to purchase 0.70 shares of common stock was sold at a purchase price of $2.81 per unit.

The warrants were exercisable upon issuance, expire 7 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.

Pursuant to the terms of the Registration Rights Agreements (the Rights Agreements) entered into as part of each of these transactions, ARCA granted to the investors certain registration rights related to the shares underlying the units sold in these private placements. ARCA filed a registration statement, in accordance with the terms of the Rights Agreements, for the resale of the shares underlying the units sold in these private placements. That registration statement was declared effective by the Securities and Exchange Commission on February 14, 2013.

The foregoing is only a brief description of the material terms of the private placements and the associated Purchase Agreements, the Rights Agreements and the Warrants and does not purport to be a complete description of the rights and obligations of the parties hereunder. The foregoing is qualified in its entirety by reference to the forms of Purchase agreements the forms of Rights Agreements and forms of Warrants, which were filed as Exhibits to our reports on Forms 8-K filed October 23, 2012, December 19, 2012, January 23, 2013.

Issuer Purchases of Equity Securities

None.

Item 6. ***Selected Financial Data***

Not applicable.

Item 7. ***Management s Discussion and Analysis of Financial Condition and Results of Operations***

We have included or incorporated by reference into this Management s Discussion and Analysis of Financial Condition and Results of Operations and elsewhere in this Annual Report on Form 10-K, and from time to time our management may make, statements that constitute forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act. Forward-looking statements may be

Table of Contents

identified by words including anticipate, plan, believe, intend, estimate, expect, should, may, potential and similar expressions. T involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. While we believe that we have a reasonable basis for each forward-looking statement contained in this Annual Report, we caution you that these statements are based on a combination of facts and factors currently known by us and our projections of the future, about which we cannot be certain. We undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise. You are advised, however, to consult any further disclosures we make on related subjects in our Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and our website.

Overview

We are a biopharmaceutical company whose principal focus is 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 study in a new clinical trial for the treatment of atrial fibrillation, or AF, in patients with heart failure and reduced left ventricular ejection fraction (HFREF). We have identified common genetic variations in receptors in the cardiac nervous system that we believe interact with Gencaro s pharmacology and may enhance patient response.

We have been granted patents in the U.S., Europe, and other jurisdictions for methods of treating patients who have these genetic variations with Gencaro. We believe that if Gencaro is approved, the Gencaro patents may provide market exclusivity into 2029 or 2030 in the U.S. and in Europe.

We believe that that Gencaro has potential efficacy in reducing or preventing AF, and this efficacy may be genetically regulated. We plan to test this hypothesis in a clinical trial of Gencaro, known as GENETIC-AF. GENETIC-AF is projected to be a Phase 2b/3 trial comparing Gencaro to metoprolol CR/XL for prevention of AF in patients with HFREF.

We have created an adaptive design for GENETIC-AF, under which the trial is intended to be initiated as a Phase 2b study in approximately 200 HFREF patients. Depending on the results of the Phase 2b portion, the trial may then be expanded to a Phase 3 study by enrolling an estimated additional 420 patients. We estimate that GENETIC-AF could begin approximately 6 months after we obtain sufficient funding, and we believe the Phase 2b study would take approximately two years to complete.

To support the continued development of Gencaro, including the planned GENETIC-AF clinical trial and our ongoing operations, we plan to pursue an underwritten public equity offering within the next quarter to fund, at least, the Phase 2b portion of the GENETIC-AF trial and our general and administrative costs through its projected completion. We may also seek additional funding that could allow us to operate while we continue to pursue financing options, a strategic combination, partnering, and licensing opportunities. 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. We believe our cash and cash equivalents balance as of December 31, 2012, along with the net proceeds from our recently completed financings, will be sufficient to fund our operations, at our current cost structure, through September 2013. We are unable to assert that our current cash and cash equivalents are sufficient to fund operations beyond that date, and as a result, there is substantial doubt about our ability to continue as a going concern beyond September 2013. 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.

Table of Contents

Results of Operations

Research and Development Expenses

Research and development, or R&D, expenses comprise research & development, regulatory, and manufacturing process development activities and costs. Our research and development expenses totaled $1.1 million for the year ended December 31, 2012 as compared to $2.3 million for 2011, a decrease of approximately $1.2 million. During 2012, our R&D efforts and costs were almost entirely for the development of Gencaro. The research and regulatory components of our R&D costs decreased approximately $883,000 due primarily to reduced personnel costs from staff furloughs implemented in the third quarter of 2012, and decreased consulting costs in association with our reduced clinical development activities compared to the prior year. Manufacturing process development costs decreased approximately $342,000 for the year. In 2011, we incurred milestone costs for ongoing, long-term drug stability studies of Gencaro and new costs for preliminary analysis and development of clinical trial materials for our planned GENETIC-AF clinical trial. During 2012 we did not have similar activities and the cost decrease reflects our lower utilization of outside support services in connection with our reduced level of operations.

Our R&D expenses are highly contingent upon our ability to raise substantial additional funding or complete a strategic transaction. Should we receive funds from one or a combination of these sources, R&D expense in 2013 will be substantially higher than 2012 if we initiate our GENETIC-AF clinical trial. Until substantial additional funding is obtained, R&D expenses in 2013 are expected to be comparable to 2012 levels.

Selling, General and Administrative Expenses

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

SG&A expenses were $3.2 million for the year ended December 31, 2012, compared to $5.0 million for 2011, a decrease of approximately $1.8 million. Cost decreases of approximately $940,000 were comprised primarily of reduced personnel, consulting, board advisory, and legal expenses.

Approximately $772,000 of the total cost decrease was attributable to lower depreciation and occupancy expense, and the balance of the decrease is due to our reduced operations overall. During the fourth quarter of 2011 we relocated our corporate office to a smaller suite. The move necessitated additional depreciation of certain leasehold improvements, furniture and equipment that were not useable in the new office suite. The reductions in depreciation and occupancy related expenses in 2012 are the result of this office move.

SG&A expenses for 2013 are expected to be comparable to 2012 levels, but are contingent upon our ability to raise substantial additional funding or complete a strategic transaction. Should we receive funds from one or a combination of these sources, SG&A expense in 2013 could be substantially higher than 2012 as we increase activities to support initiating our GENETIC-AF clinical trial.

Gain on Assignment of Patent Rights

During the year ended December 31, 2011, we entered into an agreement in which we assigned certain patent rights to a large pharmaceutical company. In exchange for the patent rights we received a $2.0 million non-recourse payment during the second quarter of 2011. The gain was exclusive to 2011.

Interest and Other Income

Interest and other income was $2,000 for the year ended December 31, 2012, as compared to $2,000 for 2011, remaining essentially unchanged. Interest income was nominal in both years due to low investment yields and declining cash balances. We expect interest income to continue to be nominal in 2013.

Table of Contents

Interest and Other Expense

Interest and other expense was $3,000 for the year ended December 31, 2012, as compared to $5,000 for 2011. The amounts and related change between years are nominal to our overall operations. Based on our current capital structure, interest expense for 2013 is expected to be comparable to 2012.

Liquidity and Capital Resources

Cash and Cash Equivalents

	December 31, 2012	December 31, 2011
Cash and cash equivalents	$ 2,920	$ 5,943

Cash Flows from Operating, Investing and Financing Activities

	Year Ended December 31, 2012	2011
Net cash (used in) provided by:		
Operating activities	$ (4,078)	$ (6,959)
Investing activities		2,006
Financing activities	1,055	3,871
Net decrease in cash and cash equivalents	$ (3,023)	$ (1,082)

Net cash used in operating activities for the year ended December 31, 2012 decreased nearly $2.9 million compared with the 2011 period due to decreased R&D and SG&A expenses discussed above.

Net cash flows provided by investing activities for the year ended December 31, 2011 was primarily due to $2 million of cash received from the assignment of patent rights during 2011. There were no such transactions during 2012. Net cash provided by financing activities of approximately $1.1 million for the year ended December 31, 2012 is comprised of approximately $1.2 million of net proceeds from the sales of our common stock, less $134,000 in payments made on a vendor financing arrangement. For the year ended December 31, 2011, net cash provided by financing activities was $3.9 million of net proceeds from sales of our common stock, less $146,000 in payments made 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 common and preferred stock, issuance of convertible promissory notes, and funds provided by the Merger. The primary uses of our capital resources to date have been to fund operating activities, including research, clinical development and drug manufacturing expenses, license payments, and spending on capital items.

Considering the substantial additional time and costs associated with the development of Gencaro and our need to raise a significant amount of capital on acceptable terms to finance the planned GENETIC-AF clinical trial and our ongoing operations, we are evaluating strategic alternatives for funding our operations and development programs. We plan to pursue an underwritten public offering to fund, at least, the Phase 2b portion of the GENETIC-AF trial and our general and administrative costs through its projected completion. We may also seek additional funding that could allow us to operate while we continue to pursue financing alternatives, a strategic combination, or partnership to support the continued clinical development of Gencaro, including the planned GENETIC-AF clinical trial.

On August 2, 2012, we sold approximately $953,000 of ARCA s common stock and warrants for common stock in a Registered Direct Offering under the Company s registration statement on Form S-3 (File No.333-172686)

45

Table of Contents

(the Registration Statement) in which we issued 406,099 shares of common stock and warrants to purchase 304,575 shares of common stock. The net proceeds, after deducting placement agent fees and other offering expenses payable by us, was approximately $741,000, and these proceeds are being used solely for general working capital purposes. Each unit, consisting of a share of common stock and a warrant to purchase 0.75 shares of common stock, was sold at a purchase price of $2.35 per unit, which was a 15 percent discount to the consolidated price of the stock and warrants, based on the closing bid price of $2.76 as reported on the Nasdaq Capital Market on August 2, 2012. The warrants become exercisable six months after issuance, expire 6 years thereafter, and have an exercise price of $2.76 per share, equal to 100% of the closing bid price of ARCA s common stock on the Nasdaq Capital Market on August 2, 1012. The Registered Direct Offering was effected as a takedown off the Registration Statement, which became effective on April 4, 2011, pursuant to a prospectus supplement filed with the Securities and Exchange Commission on August 3, 2012. The warrant agreements provide for settlement of the warrants in unregistered shares should an effective registration statement or current prospectus not be in place at the time a warrant is exercised.

On October 22, 2012, we sold approximately $325,000 of ARCA common stock and warrants for common stock in a private placement transaction. Certain Directors, Officers and Affiliates of ARCA were investors in the private placement. We issued to investors 137,530 shares of common stock together with warrants to purchase 103,148 shares of common stock. The net proceeds, after deducting offering expenses, were approximately $280,000, and these proceeds are being used solely for general working capital purposes. Each unit consisting of a share of common stock and a warrant to purchase 0.75 shares of common stock was sold at a purchase price of $2.36 per unit. The warrants were exercisable upon issuance, expire 5 years from the date of issuance, and have an exercise price of $1.80 per share, equal to 100% of the closing sales price of ARCA s common stock on the Nasdaq Capital Market on October 22, 2012.

On December 18, 2012, we sold approximately $250,000 of our common stock and warrants for common stock in a private placement transaction with our Chief Executive Officer, Dr. Michael Bristow. We issued 86,186 shares of common stock together with warrants to purchase 64,640 shares of common stock. The net proceeds, after deducting offering expenses were approximately $230,000, and these proceeds are being used solely for general working capital purposes. Each unit consisting of a share of common stock and a warrant to purchase 0.75 shares of common stock was sold at a purchase price of $2.90 per unit. The warrants were exercisable upon issuance, expire 5 years from the date of issuance, and have an exercise price of $2.34 per share, equal to 100% of the closing sales price of ARCA s common stock on the Nasdaq Capital Market on December 18, 2012.

On January 22, 2013, we sold approximately $1 million of our common stock and warrants for common stock in a private placement transaction with accredited investors and our Chief Executive Officer. We issued 356,430 shares of common stock together with warrants to purchase 249,501 shares of common stock. The net proceeds, after deducting placement agent fees and other offering expenses, were approximately $850,000, and these proceeds are being used solely for general working capital purposes. Each unit, consisting of a share of common stock and a warrant to purchase 0.70 shares of common stock, was sold at a purchase price of $2.81 per unit. The warrants were exercisable upon issuance, expire 7 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.

Pursuant to the terms of the Registration Rights Agreements (the Rights Agreements) entered into as part of each of these Private Placement transactions, we granted to the investors certain registration rights related to the shares underlying the units sold in these private placements. We filed a registration statement, in accordance with the terms of the Rights Agreements, for the resale of the shares underlying the units sold in these private placements. That registration statement was declared effective by the Securities and Exchange Commission on February 14, 2013.

On January 31, 2013, we sold approximately $730,000 of ARCA s common stock and warrants for common stock in a Registered Direct Offering under the Company s registration statement on Form S-3 (File No.333-172686) (the

Table of Contents

Registration Statement) in which we issued 164,636 shares of common stock and warrants to purchase 65,855 shares of common stock. The net proceeds, after deducting placement agent fees and other offering expenses payable by us, was approximately $630,000, and these proceeds are being used solely for general working capital purposes. Each unit, consisting of a share of common stock and a warrant to purchase 0.40 shares of common stock, was sold at a purchase price of $4.43 per unit. The warrants were exercisable upon issuance, expire 5 years from the date of issuance, and have an exercise price of $4.13 per share, equal to 100% of the closing bid price of ARCA s common stock on the Nasdaq Capital Market on January 30, 2013. The Registered Direct Offering was effected as a takedown off the Registration Statement, which became effective on April 4, 2011, pursuant to a prospectus supplement filed with the Securities and Exchange Commission on February 1, 2013. The warrant agreements provide for settlement of the warrants in unregistered shares should an effective registration statement or current prospectus not be in place at the time a warrant is exercised.

We believe our cash and cash equivalents balance as of December 31, 2012, along with the net proceeds from our recently completed financings, will be sufficient to fund our operations, at our current cost structure, through September 30, 2013. However, we are unable to assert that these funds are sufficient to fund operations beyond that date, and as a result, there is substantial doubt about our ability to continue as a going concern beyond September 30, 2013. The consolidated financial statements contained in this report have been prepared with the assumption that we will continue as a going concern and will be able to realize our assets and discharge our liabilities in the normal course of business and do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from our inability to continue as a going concern. We may not be able to raise sufficient capital on acceptable terms or at all to continue development of Gencaro or to continue operations and may not be able to execute any strategic transaction.

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

- the costs and timing for an additional clinical trial in order to gain possible FDA approval for Gencaro;
- the market price of our stock and the availability and cost of additional equity capital from existing and potential new investors;
- 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 additional dilution to our stockholders. If we raise additional funds through the incurrence of indebtedness, the obligations related to such indebtedness would be senior to rights of holders of our capital stock and could contain covenants that would restrict our operations. We also cannot predict what consideration might be available, if any, to us or our stockholders, in connection with any strategic transaction. Should strategic alternatives or additional capital not be available to us in the near term, or not be available on acceptable terms, we may be unable to realize value from our assets and discharge our liabilities in the normal course of business which may, among other alternatives, cause us to further delay, substantially reduce or discontinue operational activities to conserve its cash resources.

Critical Accounting Policies and Estimates

A critical accounting policy is one that is both important to the portrayal of our financial condition and results of operation and requires management s most difficult, subjective or complex judgments, often as a result

Table of Contents

of the need to make estimates about the effect of matters that are inherently uncertain. While our significant accounting policies are described in Note 1 of Notes to Consolidated Financial Statements included within Item 8 in this report, we believe the following critical accounting policy affected our most significant judgments, assumptions, and estimates used in the preparation of our consolidated financial statements and, therefore, is important in understanding our financial condition and results of operations.

Long-Lived Assets and Impairments

We review long-lived assets whenever events or changes in circumstances indicate that the carrying value of such assets may not be recoverable. As a development stage company, we have not generated positive cash flows from operations, and such cash flows may not materialize for a significant period in the future, if ever. Additionally, we may make changes to our business plan that would result in changes to expected cash flows from long-lived assets. It is reasonably possible that future evaluations of long-lived assets, including changes from our current expected use of long-lived assets, may result in impairments.

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

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 7A. ***Quantitative and Qualitative Disclosures About Market Risk***

Not applicable.

Table of Contents

Item 8. ***Financial Statements and Supplementary Data***

Table of Contents

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders

ARCA biopharma, Inc.:

We have audited the accompanying consolidated balance sheets of ARCA biopharma, Inc. (a development stage enterprise) and subsidiaries (the Company) as of December 31, 2012 and 2011, and the related consolidated statements of operations and comprehensive loss, preferred stock and stockholders equity (deficit), and cash flows for each of the years in the two-year period ended December 31, 2012 and for the period from December 17, 2001 (date of inception) to December 31, 2012. These consolidated financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of ARCA biopharma, Inc. (a development stage enterprise) and subsidiaries as of December 31, 2012 and 2011, and the results of their operations and their cash flows for each of the years in the two-year period ended December 31, 2012 and for the period from December 17, 2001 (date of inception) to December 31, 2012, in conformity with U.S. generally accepted accounting principles.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in note 1 to the consolidated financial statements, the Company has suffered recurring losses from operations and is dependent upon raising additional funds from strategic transactions, sales of equity, and/or issuance of debt. The Company s ability to consummate such transactions is uncertain. As a result, there is substantial doubt about the Company s ability to continue as a going concern. Management s plans in regard to these matters are also described in note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ KPMG LLP

Denver, Colorado

March 21, 2013

Table of Contents

ARCA BIOPHARMA, INC.

(a development stage enterprise)

CONSOLIDATED BALANCE SHEETS

	As of December 31,	
	2012	2011
	(in thousands, except share and per share amounts)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 2,920	$ 5,943
Other current assets	125	269
Total current assets	3,045	6,212
Property and equipment, net	23	66
Other assets	144	224
Total assets	$ 3,212	$ 6,502
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 65	$ 260
Accrued compensation and employee benefits	103	111
Accrued expenses and other liabilities	121	350
Deferred rent, current portion	16	33
Total current liabilities	305	754
Deferred rent, net of current portion		16
Total liabilities	305	770
Commitments and contingencies		
Stockholders equity:		
Common stock, $0.001 par value; 100,000,000 shares authorized at December 31, 2012 and December 31, 2011; 2,660,315 and 2,030,500 shares issued and outstanding at December 31, 2012 and December 31, 2011, respectively	3	2
Additional paid-in capital	70,898	69,404
Deficit accumulated during the development stage	(67,994)	(63,674)
Total stockholders equity	2,907	5,732
Total liabilities and stockholders equity	$ 3,212	$ 6,502

See accompanying Notes to Consolidated Financial Statements.

Table of Contents

ARCA BIOPHARMA, INC.

(a development stage enterprise)

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

	Year Ended December 31,		Period from December 17, 2001 (date of inception) to December 31, 2012
	2012	2011	
	(in thousands, except share and per share amounts)		
Costs and expenses:			
Research and development	$ 1,092	$ 2,315	$ 42,677
Selling, general and administrative	3,227	5,046	42,583
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	4,319	7,361	99,143
Loss from operations	(4,319)	(7,361)	(99,143)
Gain on assignment of patent rights		2,000	2,000
Gain on bargain purchase			25,282
Interest and other income	2	2	2,028
Interest and other expense	(3)	(5)	(442)
Loss before income taxes	(4,320)	(5,364)	(70,275)
Benefit from income taxes			2,281
Net loss and comprehensive loss	$ (4,320)	$ (5,364)	$ (67,994)
Less: Accretion of redeemable convertible preferred stock			(245)
Less: Deemed preferred stock dividend for additional common shares issuable under anti-dilution provisions			(781)
Net loss available to common stockholders	$ (4,320)	$ (5,364)	$ (69,020)
Net loss available to common stockholders per share:			
Basic and diluted	$ (1.94)	$ (3.21)	
Weighted average shares outstanding:			
Basic and diluted	2,223,516	1,673,041	

See accompanying Notes to Consolidated Financial Statements.

Table of Contents

ARCA BIOPHARMA, INC.

(a development stage enterprise)

CONSOLIDATED STATEMENTS OF PREFERRED STOCK AND STOCKHOLDERS EQUITY (DEFICIT)

	Preferred Stock				Stockholders Equity (Deficit)				
	Series A Redeemable Convertible Preferred Stock		Series B Redeemable Convertible Preferred Stock		Common stock		Additional Paid In Capital	Deficit Accumulated During the Development Stage	Total
	Shares	Amount	Shares	Amount	Shares	Amount			
	(in thousands, except share and per share amounts)								
Balance, December 17, 2001 (date of inception)		$		$		$	$	$	$
Issuance of common stock to founders on December 31, 2002, for cash, at $0.36 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, upon conversion of notes payable and related accrued interest at $0.36 per share					2,978		1		1
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
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								
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 license rights, on June 30, 2007 at $10.80 per share					642	7		7
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			
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)

See accompanying Notes to Consolidated Financial Statements.

Table of Contents

ARCA BIOPHARMA, INC.

(a development stage enterprise)

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

	Preferred Stock				Stockholders Equity (Deficit)				
	Series A Redeemable Convertible Preferred Stock		Series B Redeemable Convertible Preferred Stock		Common stock		Additional Paid In Capital	Deficit Accumulated During the Development Stage	Total
	Shares	Amount	Shares	Amount	Shares	Amount			
	(in thousands, except share and per share amounts)								
Balance, December 31, 2007	9,222,257	14,938	6,455,579	17,871	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 common conversion					(7)				
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 employee stock purchase plan and upon vesting of restricted stock units					177		2		2
Estimated fair value of warrants issued in connection with lease termination							377		377
Net loss								(9,138)	(9,138)
Balance, December 31, 2009					1,270,074	1	57,301	(49,890)	7,412
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
Issuance of common stock upon exercise of stock options for cash							
Share-based compensation					306		306
Net loss						(4,320)	(4,320)
Balance, December 31, 2012	**$**	**$**	**2,660,315**	**$ 3**	**$ 70,898**	**$ (67,994)**	**$ 2,907**

See accompanying Notes to Consolidated Financial Statements.

Table of Contents

ARCA BIOPHARMA, INC.

(a development stage enterprise)

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Years Ended December 31,		Period from December 17, 2001 (date of inception) to December 31, 2012
	2012	2011	
	(in thousands)		
Cash flows used in operating activities:			
Net loss	$ (4,320)	$ (5,364)	$ (67,994)
Adjustments to reconcile net loss to net cash used in operating activities:			
Gain on patent rights assignment		(2,000)	(2,000)
Gain on bargain purchase			(25,282)
Depreciation and amortization	43	602	1,780
Non-cash interest expense			211
Share-based compensation	306	308	2,588
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		16	83
Other, net			267
Change in operating assets and liabilities (net of amounts acquired):			
Other current assets	278	14	2,820
Other assets	80	80	7,326
Accounts payable	(195)	(128)	(2,125)
Accrued expenses and other liabilities	(237)	(220)	(19,221)
Deferred rent	(33)	(267)	16
Net cash used in operating activities	(4,078)	(6,959)	(97,421)
Cash flows provided by investing activities:			
Cash received from merger			30,392
Payment of deferred transaction costs			(1,186)
Purchase of property and equipment		(19)	(1,879)
Proceeds from sale of marketable securities			15,369
Proceeds from sale of property and equipment		25	358
Proceeds from patent rights assignment		2,000	2,000
Net cash provided by investing activities		2,006	45,054
Cash flows provided by financing activities:			
Proceeds from issuance of convertible notes payable and related warrants for common stock			10,841
Proceeds from issuance of bank note payable			4,000
Proceeds from stock subject to repurchase			38
Proceeds from the issuance of preferred stock			32,316
Preferred stock offering costs			(246)
Proceeds from the issuance of common stock	1,528	4,726	14,109
Payment of offering costs	(339)	(709)	(1,386)
Repayment of principal on bank note payable			(4,000)
Repayment of principal on convertible notes payables			(105)
Repayment of principal on vendor finance agreement	(134)	(146)	(280)

Net cash provided by financing activities	1,055	3,871	55,287
Net (decrease) increase in cash and cash equivalents	(3,023)	(1,082)	2,920
Cash and cash equivalents, beginning of period	5,943	7,025	
Cash and cash equivalents, end of period	$ 2,920	$ 5,943	$ 2,920
Supplemental cash flow information:			
Interest paid	$ 3	$ 5	$ 115
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

See accompanying Notes to Consolidated Financial Statements.

Table of Contents

ARCA BIOPHARMA, INC.

(a development stage enterprise)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(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 Broomfield, 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), a pharmacologically unique beta-blocker and mild vasodilator, is being developed for the treatment and the prevention of atrial fibrillation, or AF, in patients with heart failure, or HF. The Company has identified common genetic variations in the cardiovascular system that it believes interact with Gencaro s pharmacology and may predict patient response to Gencaro treatment. 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 it believes will 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 US and Europe.

The Company believes that that Gencaro has potential efficacy in reducing or preventing AF, and this efficacy may be genetically regulated. The Company plans to test this hypothesis in a clinical trial of Gencaro, known as GENETIC-AF, which the Company plans to initiate pending receipt of the necessary funding, which it intends to seek through equity financing or a strategic partnership. The Company has created an adaptive design for GENETIC-AF under which the trial is intended to be initiated as a Phase 2b study in approximately 200 patients with heart failure and left ventricular dysfunction, or HFREF. Depending on the results of the Phase 2b portion, the trial may then be expanded to a Phase 3 study by enrolling an estimated additional 420 patients. The Company anticipates that GENETIC-AF could begin approximately 6 months after the Company obtains sufficient funding, which it intends to seek through equity financing or a strategic partnership.

To support the continued development of Gencaro, including the planned GENETIC-AF clinical trial and ongoing operations, the Company will need to raise substantial additional funding through public or private equity transactions or a strategic combination or partnership. If the Company is delayed in obtaining 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, exploring strategic alternatives for further developing Gencaro, and raising capital necessary to fund its operations. The Company has not generated revenue to date and is subject to a number of risks similar to those of other development stage companies, including dependence on key individuals, the development of and regulatory approval of commercially viable products, the need to raise adequate additional financing necessary to fund the development and commercialization of its products, and competition from larger companies. The Company has historically funded its operations through issuances of convertible promissory notes and shares of its common and preferred stock, as 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 $99.1 million and had negative cash flows from operations of $97.4 million.

In light of the substantial additional time and costs associated with the development of Gencaro and the need to raise a significant amount of capital on acceptable terms to finance the planned clinical trial and the Company s

Table of Contents

ongoing operations, the Company is evaluating strategic alternatives for funding continued operations and development programs. The Company will need to complete a substantial equity financing, or a strategic transaction, such as a strategic combination or partnership to support the continued development of Gencaro, including the planned GENETIC-AF clinical trial. In 2012, the Company raised approximately $1.2 million, net of offering costs, through the sales of our common stock and may seek additional funding that could allow it to operate while it continues to pursue financing options, a strategic combination, partnering, and licensing opportunities. If the Company is delayed in completing or is unable to complete additional funding and/or a strategic transaction, the Company may discontinue its development activities or discontinue its operations. The Company currently believes its cash and cash equivalents balance as of December 31, 2012 plus the $1.5 million of new funds raised in the January 2013 (see Note 8) will be sufficient to fund its operations through September 30, 2013. The Company is unable to assert that its current cash and cash equivalents are sufficient to fund operations beyond that date, and as a result, there is substantial doubt about the Company s ability to continue as a going concern beyond September 30, 2013. These consolidated financial statements have been prepared with the assumption that the Company will continue as a going concern and will be able to realize its assets and discharge its liabilities in the normal course of business and do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the inability of the Company to continue as a going concern. The Company may not be able to raise sufficient capital on acceptable terms, or at all, to continue development of Gencaro or to otherwise continue operations and may not be able to execute any strategic transaction.

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

- the costs and timing for the planned 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 from existing and potential new investors;
- the Company s ability to retain the listing of its common stock on the Nasdaq Capital Market;
- general economic and industry conditions affecting the availability and cost of capital;
- the Company s ability to control costs associated with its operations;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights; and
- the terms and conditions of the Company s existing collaborative and licensing agreements.

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

Merger with Nuvelo, Inc.

On January 27, 2009, the Company completed a business combination, or the Merger, with ARCA Colorado in accordance with the terms of that Agreement and Plan of Merger and Reorganization, dated September 24, 2008, and amended on October 28, 2008 (as amended, the Merger Agreement), in which a wholly-owned subsidiary

57

Table of Contents

of Nuvelo merged with and into ARCA Colorado, with ARCA Colorado continuing after the Merger as the surviving corporation and a wholly-owned subsidiary of Nuvelo. Immediately following the Merger, the Company changed its name from Nuvelo, Inc. to ARCA biopharma, Inc. The business combination is treated as a reverse merger for accounting purposes, and ARCA Colorado is the accounting acquirer, and the entity formerly known as Nuvelo, Inc. is the acquired company (Nuvelo). 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 the acquired company, and the disclosures in this report relating to the pre-Merger business of the Company, unless noted as being the business of Nuvelo prior to the Merger, pertain to the business of ARCA Colorado prior to the Merger. See Note 3 for further discussion of the Merger.

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

Reverse Stock Split

On February 25, 2013 the Company s stockholders approved for the Company to execute a reverse split of the common tock. ARCA s Board of Directors then approved a 1-for-6 reverse split which became effective on March 4, 2013. 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 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 is considered to be in the development stage at December 31, 2012.

Recent Accounting Pronouncements

In June 2011, the FASB issued FASB Accounting Standards Update (ASU) No. 2011-05, Comprehensive Income (Topic 220): Presentation of Comprehensive Income in U.S. GAAP and IFRS. This ASU provides companies the option to present the components of net income and other comprehensive income either as one continuous statement of comprehensive income or as two separate but consecutive statements. It eliminates the option to present components of other comprehensive income as part of the statement of changes in stockholders equity. The provisions of this new guidance were effective for fiscal years, and interim periods within those years, beginning after December 15, 2011. The Company adopted this new guidance effective January 1, 2012 and it did not have a material impact on our results of operations or cash flows. For the periods ending December 31, 2012 and 2011, the Company does not any have elements of Comprehensive Income therefore it has not recognized any tax effects of other comprehensive income. The adoption of this new guidance had no impact on the Company s financial position, results of operations or cash flows.

Accounting Estimates in the Preparation of Financial Statements

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. The Company bases estimates on

Table of Contents

various assumptions that are believed to be reasonable under the circumstances. The Company believes significant judgment was involved in estimating the fair value of assets acquired and liabilities assumed in the Merger, including in-process research and development, facility exit costs, clinical trial accruals, and in estimating other accrued liabilities, stock-based compensation, and income taxes. Management is continually evaluating and updating these estimates, and it is possible that these estimates will change in the future or that actual results may differ from these estimates.

Cash Equivalents

Cash equivalents generally consist of money market funds and debt securities with maturities of 90 days or less at the time of purchase. The Company invests its excess cash in securities with strong ratings and has established guidelines relative to diversification and maturity with the objective of maintaining safety of principal and liquidity.

The Company classifies all cash equivalents as available-for-sale securities, and records investments at fair value. The specific identification method is utilized to calculate the cost to determine realized gains and losses from the sale of available-for-sale securities. Realized gains and losses are included in interest income in the consolidated statements of operations.

Concentrations of Credit Risk

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

Property and Equipment

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

Long-Lived Assets and Impairments

The Company reviews long-lived assets whenever events or changes in circumstances indicate that the carrying value of such assets may not be recoverable. As a development stage company, the Company has not generated positive cash flows from operations, and such cash flows may not materialize for a significant period in the future, if ever. Additionally, the Company may make changes to its business plan that would result in changes to expected cash flows from long-lived assets. It is reasonably possible that future evaluations of long-lived assets, including changes from the Company s current expected use of long-lived assets, may result in impairments.

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

Table of Contents

sheet date. Examples of estimated accrued expenses include contract service fees, such as fees payable to contract manufacturers in connection with the production of materials related to the Company s drug product, and professional service fees, such as attorneys, consultants, and clinical research organizations. The Company develops estimates of liabilities using its judgment based upon the facts and circumstances known at the time.

Segments

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

Research and Development

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

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

Stock-Based Compensation

The Company s stock-based compensation cost recognized includes: (a) compensation costs for current period vesting of all share-based awards granted prior to January 1, 2006, based on the intrinsic value method, and (b) compensation cost for current period vesting of all share-based awards granted or modified subsequent to January 1, 2006, based on the estimated grant date fair value. The Company recognizes compensation costs for its share-based awards on a straight-line basis over the requisite service period for the entire award, as adjusted for expected forfeitures.

From Inception through December 31, 2005, the Company accounted for issuances of stock-based compensation under the intrinsic-value-based method of accounting. Under this method, compensation expense is generally recorded on the date of grant only if the estimated fair value of the underlying stock exceeds the exercise price.

Income Taxes

The current benefit for income taxes represents actual or estimated amounts payable or refundable on tax returns filed or to be filed each year. Deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in the period that includes the enactment date. The overall change in deferred tax assets and liabilities for the period measures the deferred tax expense or benefit for the period. The measurement of deferred tax assets may be reduced by a valuation allowance based on judgmental assessment of available evidence if deemed more likely than not that some or all of the deferred tax assets will not be realized. The Company has recorded a valuation allowance against all of its deferred tax assets, as management has concluded that it is more likely than not that the net deferred tax asset will not be realized through future taxable income, based primarily on the Company s history of operating losses. The Company has not performed an Internal Revenue Code Section 382 limitation study. Depending on the outcome of such a study, the gross amount of net operating losses recognizable in future tax periods could be limited.

Table of Contents

(2) Net Loss Per Share

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

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

	Years Ended December 31,	
	2012	2011
(In thousands, except shares and per share data)		
Net loss	$ (4,320)	$ (5,364)
Net loss available to common shareholders	$ (4,320)	$ (5,364)
Weighted average shares of common stock outstanding	2,226,299	1,675,824
Less: Weighted-average shares of unvested common stock	(2,783)	(2,783)
Total weighted-average shares used in computing net loss per share attributed to common stockholders	2,223,516	1,673,041
Basic and diluted loss per share	$ (1.94)	$ (3.21)

Potentially dilutive securities representing 762,000 and 349,000 weighted average shares of common stock were excluded for the years ended December 31, 2012 and 2011, respectively, because including them would have an anti-dilutive effect on net loss attributable to common stockholders per share.

Subsequent to December 31, 2012, the Company sold 521,066 shares of ARCA common stock and warrants to purchase 315,356 shares of ARCA common stock in two separate equity financings (see Note 8). Those shares, and the potentially dilutive securities represented by the warrants, had the transactions occurred before December 31, 2012, would have changed the number of common shares and potential common shares outstanding as of December 31, 2012.

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

On January 27, 2009, the Company completed the Merger, with ARCA Colorado 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.

The Merger was treated as a reverse merger and accounted for as a business combination using the acquisition method of accounting in accordance with Accounting Standards Codification (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. 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.

Table of Contents

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) Financial Instruments

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date (exit price). Inputs used to measure fair value are classified into the following hierarchy:

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

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

Level 3 Unobservable inputs for the asset or liability

The Company s financial assets include $2.8 million at December 31, 2012 and $5.9 million at December 31, 2011, in money market funds, classified as cash equivalents, which are measured at fair value based on Level 1 inputs on a recurring basis. There were no transfers between any fair value hierarchy levels in 2012 or 2011.

Fair Value of Other Financial Instruments

The carrying amount of other financial instruments, including cash and accounts payable, approximated fair value due to their short maturities. As of December 31, 2012 and 2011, the Company did not have any debt outstanding.

(5) Property and Equipment

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

	Estimated Life	December 31, 2012	December 31, 2011
Computer equipment	3 years	$ 104	$ 104
Lab equipment	5 years	142	142
Furniture and fixtures	5 years	93	93
Computer software	3 years	176	176
Leasehold improvements	Lesser of useful life or life of the lease	18	18
		533	533
Less accumulated depreciation and amortization		(510)	(467)
		$ 23	$ 66

For the years ended December 31, 2012 and 2011, and for the period from Inception through December 31, 2012, depreciation and amortization expense was $43,000, $602,000 and $1.8 million, respectively.

62

Table of Contents

(6) Related Party Arrangements

Transactions with the Company s President and Chief Executive Officer

The Company has entered into unrestricted research grants with its President and Chief Executive Officer s academic research laboratory at the University of Colorado, or the Lab. Funding of any unrestricted research grants is contingent upon the Company s financial condition, and can be deferred or terminated at the Company s discretion. Total expense under these arrangements for the years ended December 31, 2012 and 2011 was $63,000 and $155,000 respectively, and $1.5 million from Inception through December 31, 2012.

The Company was previously a party to a materials transfer agreement with the University of Colorado, under which the Company paid to support a heart tissue bank associated with the President and Chief Executive Officer s research lab at the University of Colorado. This agreement has expired and has not been renewed. Total expense under this arrangement was $227,000 from Inception through December 31, 2012.

(7) Commitments and Contingencies

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

Employment Agreements

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

Operating Leases

The Company is party to a lease agreement, dated February 8, 2008. The original lease provided for approximately 15,000 square feet of an office facility in Broomfield, Colorado, which serves as the Company s primary business offices. The lease has a term of five years with rights to extend the term for two additional three year periods. On June 14, 2011, the Company entered into a first amendment (the Amendment) to the lease agreement. Under the terms of the Amendment, the Company and its landlord mutually agreed for the Company to relocate from its previous office suite of approximately 15,000 square feet, to another suite within the same building, comprising approximately 4,500 square feet. The office location continues to serve as the Company s primary business office. The Amendment also modified the annual per square foot rate of rent and allows the Company to terminate with three months notice. As part of the agreement, the Company made a one-time payment to the landlord of $200,000, which the landlord agreed to use for the landlord s improvements in the new leased premises prior to the Company occupying the space. The original five year term of the Lease remains unchanged. Per the lease agreement, base rent is subject to annual increases of approximately three percent per year. The rent expense for the lease is being recognized on a straight-line basis over the lease term.

Under the original lease, the Company received tenant improvement reimbursements from the landlord totaling $593,000 which were recorded as deferred rent and were amortized as reductions to rent expense. The $200,000 payment made to the landlord in conjunction with the Amendment was recorded against the existing deferred rent balance. The net deferred rent balance is being amortized as reductions to rent expense over the remaining term of the lease. The unamortized deferred rent balance as of December 31, 2012 was $16,000.

Rent expense under this lease for the years ended December 31, 2012 and 2011 was $48,000 and $150,000, respectively, and was $515,000 from Inception through December 31, 2012.

The Company s facility lease in Broomfield, Colorado expires in June 2013. The minimum lease payments committed under the lease through June 2013 are $40,000. The lease has an option to renew for an additional three year term under comparable terms, however, the Company has not yet determined if it will renew the lease.

Table of Contents

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

Under the terms of its strategic license agreement with CPEC, a licensing subsidiary of Indevus Pharmaceuticals Inc. (a wholly owned subsidiary of Endo Pharmaceuticals), holding ownership rights to certain clinical trial data of Gencaro, the Company will incur milestone and royalty obligations upon the occurrence of certain events. In August 2008, the Company paid CPEC a milestone payment of $500,000 based on the July 31, 2008 submission of its NDA with the FDA. If the FDA grants marketing approval for Gencaro, the Company will owe CPEC another milestone payment of $8.0 million, which is due within six months after FDA approval. The Company also has the obligation to make milestone payments of up to $5.0 million in the aggregate upon regulatory marketing approval in Europe and Japan. The Company s royalty obligation ranges from 12.5% to 25% of revenue from the related product based on achievement of specified product sales levels, including a 5% royalty that CPEC is obligated to pay under its original license agreement for Gencaro. The Company has the right to buy down the royalties to a range of 12.5% to 17% by making a payment to CPEC within six months of regulatory approval.

(8) Equity Financings and Warrants

2011 Equity Financings

Registered Direct Offering

On April 18, 2011, the Company entered into a subscription agreement with certain institutional investors (the Investors) in connection with its Registered Direct public offering (the 2011 Offering), pursuant to which the Company sold an aggregate of 280,112 shares of its common stock and warrants to purchase up to 196,079 additional shares of its common stock to the Investors for aggregate gross proceeds of approximately $3.0 million, before deducting placement agent fees and other estimated offering expenses payable by the Company. The net proceeds to the Company were approximately $2.5 million and the 2011 Offering closed on April 21, 2011.

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 $10.71. Subject to certain ownership limitations, the warrants became exercisable as of October 21, 2011, expire five years from their initial exercise date, and have an exercise price of $15.12 per share, equal to 120% of the closing bid price of ARCA s common stock on the Nasdaq Capital Market on April 15, 2011. The Offering was effected as a takedown off the Company s S-3 Registration Statement, which became effective on April 4, 2011, pursuant to a prospectus supplement filed with the Securities and Exchange Commission on April 18, 2011.

The warrant agreements provide for settlement of the warrants in unregistered shares should an effective registration statement or current prospectus not be in place at the time a warrant is exercised.

Private Investment in Public Equity (PIPE) Transaction

On December 21, 2011, the Company entered into separate Subscription Agreements (the 2011 Purchase Agreements) with various institutional investors in connection with a private placement of its common stock

Table of Contents

and warrants. Pursuant to the 2011 Purchase Agreements, the Company sold an aggregate of 277,778 shares of its common stock and warrants to purchase up to 208,333 additional shares of its common stock for aggregate gross proceeds of approximately $1.75 million, before deducting estimated offering expenses payable by the Company. The net proceeds to the Company were approximately $1.5 million, and the private placement closed on December 21, 2011.

The common stock and warrants were sold in units consisting of one share of common stock and a warrant to purchase 0.75 shares of common stock. The purchase price for each unit was $6.30. The warrants became exercisable six months after the closing date, expire five years from their initial exercise date, and have an exercise price of $8.91 per share, equal to 110% of the closing bid price of ARCA s common stock on the Nasdaq Capital Market on December 21, 2011.

The Company filed a registration statement for the resale of the shares underlying the units sold in these private placements, and incurred, in 2012, approximately $61,000 of additional costs related to completing the registration statement. On January 26, 2012, that registration statement was declared effective by the Securities and Exchange Commission.

2012 Equity Financings

Registered Direct Offering

On August 2, 2012, the Company entered into subscription agreements with certain institutional investors (the Investors) in connection with its Registered Direct public offering (the 2012 Offering), pursuant to which the Company sold an aggregate of 406,099 shares of its common stock and warrants to purchase up to 304,575 additional shares of its common stock to the Investors for aggregate gross proceeds of approximately $953,000, before deducting placement agent fees and other estimated offering expenses payable by the Company. The net proceeds to the Company were approximately $741,000, and the 2012 Offering closed on August 8, 2011.

The common stock and warrants were sold in units consisting of one share of common stock and a warrant to purchase 0.75 shares of common stock. The purchase price for each unit was $2.35. Subject to certain ownership limitations, the warrants became exercisable six months after the issuance date, expire six years from their initial exercise date, and have an exercise price of $2.76 per share, equal to the closing bid price of ARCA s common stock on the Nasdaq Capital Market on August 2, 2012. The 2012 Offering was effected as a takedown off the Company s S-3 Registration Statement, which became effective on April 4, 2011, pursuant to a prospectus supplement filed with the Securities and Exchange Commission on August 3, 2012. The warrant agreements provide for settlement of the warrants in unregistered shares should an effective registration statement or current prospectus not be in place at the time a warrant is exercised.

Private Investment in Public Equity (PIPE) Transactions

On October 22, 2012, the Company entered into a Subscription Agreement (the October 2012 Purchase Agreements) with various accredited investors in connection with a private placement of its common stock and warrants. Certain Directors, Officers and Affiliates of ARCA were investors in the private placement. Pursuant to the October 2012 Purchase Agreement, the Company sold an aggregate of 137,530 shares of its common stock and warrants to purchase up to 103,148 additional shares of its common stock for aggregate gross proceeds of approximately $325,000, before deducting estimated offering expenses payable by the Company. The net proceeds to the Company were approximately $280,000, and the private placement closed on October 25, 2012.

The common stock and warrants were sold in units consisting of one share of common stock and a warrant to purchase 0.75 shares of common stock. The purchase price for each unit was $2.36. The warrants were exercisable upon issuance, expire five years from the closing date, and have an exercise price of $1.80 per share, equal to 100% of the closing bid price of ARCA s common stock on the NASDAQ Capital Market on October 22, 2012.

Table of Contents

On December 18, 2012, the Company entered into a Subscription Agreement (the December 2012 Purchase Agreement) with its Chief Executive Officer in connection with a private placement of ARCA s common stock and warrants. Pursuant to the December 2012 Purchase Agreement, the Company sold an aggregate of 86,186 shares of its common stock and warrants to purchase up to 64,640 additional shares of its common stock for aggregate gross proceeds of approximately $250,000, before deducting estimated offering expenses payable by the Company. The net proceeds to the Company were approximately $230,000, and the private placement closed on December 20, 2012.

The common stock and warrants were sold in units consisting of one share of common stock and a warrant to purchase 0.75 shares of common stock. The purchase price for each unit was $2.90. The warrants were exercisable upon issuance, expire five years from the closing date, and have an exercise price of $2.34 per share, equal to 100% of the closing bid price of ARCA s common stock on the Nasdaq Capital Market on December 18, 2012.

The Company filed a registration statement for the resale of the shares underlying the units sold in these private placements. The registration statement was declared effective by the Securities and Exchange Commission on February 14, 2013.

2013 Equity Financings

Subsequent to December 31, 2012, the Company completed the following equity financing transactions:

Private Investment in Public Equity (PIPE) Transactions

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 $850,000, 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 these private placements. The 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.

Table of Contents

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 (the 2013 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 $630,000, and the 2013 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 off the Company s S-3 Registration Statement, which became effective on April 4, 2011, pursuant to a prospectus supplement filed with the Securities and Exchange Commission on February 1, 2013. The warrant agreements provide for settlement of the warrants in unregistered shares should an effective registration statement or current prospectus not be in place at the time a warrant is exercised.

Warrants

As of December 31, 2012, warrants to purchase 930,725 shares of common stock were outstanding at exercise prices ranging from $1.80 to $116.89, with a weighted average exercise price per share of $9.10. These warrants, which were granted as part of various financing and business agreements, expire at various times between October 2013 and February 2019. Warrants were recorded in additional paid-in capital at their estimated fair market value at the date of grant using the Black-Scholes option-pricing model.

(9) Stock-based Compensation

Stock Plans

The Company s equity incentive plan was amended, as approved by stockholders on June 25, 2009, to (i) change the name of the plan from the *Amended and Restated Nuvelo, Inc. 2004 Equity Incentive Plan* to the *Amended and Restated ARCA biopharma, Inc. 2004 Equity Incentive Plan*, or the Equity Plan, (ii) increase the maximum number of shares issuable under the plan, revise the formula for determining the maximum number of shares issuable under the plan and implement new share usage rules; and (iii) adjust the award limitations for stock options and stock appreciation rights. As a result of such amendment, the maximum number of shares issuable under the Equity Plan was increased by 54,387 shares.

The Equity Plan provides for the granting of stock options (including indexed options), stock appreciation rights, restricted stock purchase rights, restricted stock bonuses, restricted stock units, performance shares, performance units and deferred stock units. Under the Equity Plan, awards may be granted to employees, directors and consultants of ARCA, except for incentive stock options, which may be granted only to employees. As of December 31, 2012, options to purchase 67,630 shares were outstanding under the Equity Plan, and 80,255 shares were reserved for future awards.

In general, the Equity Plan authorizes the grant of stock options that vest at rates set by the Board of Directors or the Compensation Committee thereof. Generally, stock options granted by ARCA under the equity incentive plans become exercisable ratably for a period of three to four years from the date of grant and have a maximum term of ten years. The exercise prices of stock options under the equity incentive plan generally meet the following criteria: the exercise price of incentive stock options must be at least 100% of the fair market value on the grant date and exercise price of options granted to 10% (or greater) stockholders must be at least 110% of the fair market value on the grant date. ARCA s other stock plans under which options remained outstanding as of December 31, 2012 are the Non-Employee Director Stock Option Plan. As of December 31, 2012, options to purchase 83 shares were outstanding under this stock plan.

Table of Contents

In conjunction with the Merger, the Company discontinued grants under its 2004 Stock Option Plan effective January 27, 2009. As of December 31, 2012, options to purchase 76,305 shares with a weighted average exercise price of $14.04 per share were outstanding under this plan. Options and awards outstanding under this plan will continue to vest according to the original terms of each grant. No new awards will be granted under this plan. Subsequent to the Merger, the Company has granted stock-based compensation awards under the Equity Plan.

The Company granted options to purchase 5,833 and 27,450 shares of common stock in the years ended December 31, 2012 and 2011, respectively. The fair values of employee stock options granted in the years ended December 31, 2012 and 2011 were estimated at the date of grant using the Black-Scholes model with the following assumptions and had the following estimated weighted average grant date fair value per share:

	Years Ended December 31,	
	2012	2011
Expected term	5.3 years	5.8 years
Expected volatility	108%	110%
Risk-free interest rate	0.15%	2.20%
Expected dividend yield	0%	0%
Weighted-average grant date fair value per share	$ 4.68	$ 10.95

A summary of ARCA s stock option activities for the years ended December 31, 2012 and 2011, and related information as of December 31, 2012, is as follows:

	For the years ended December 31,			
	2012		2011	
	# of Options	Weighted Average Exercise Price	# of Options	Weighted Average Exercise Price
Options outstanding, beginning of period	144,039	$ 19.20	158,873	$ 191.22
Granted	5,833	6.00	27,450	13.44
Exercised		0.00	(188)	7.86
Forfeited and cancelled	(5,853)	27.96	(42,096)	664.86
Options outstanding, end of period	144,019	$ 18.28	144,039	$ 19.20
Options exercisable, end of period	125,666	$ 18.77	102,691	$ 20.10
Options vested and expected to vest	142,227	$ 18.30		

The total intrinsic value of options exercised for the years ended December 31, 2012 and 2011 was $0 and $1,000, respectively. As of December 31, 2012, the unrecognized compensation expense related to unvested options, excluding estimated forfeitures, was $150,000 which is expected to be recognized over a weighted average period of 0.9 years. The Company recognizes compensation costs for its share-based awards on a straight-line basis over the requisite service period for the entire award, as adjusted for expected forfeitures.

Table of Contents

The following table summarizes information about stock options outstanding and exercisable as of December 31, 2012:

		Options Outstanding			Options Exercisable	
Range of Exercise Prices		Number Outstanding	Weighted Average Remaining Contractual Term (in years)	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
$0.36	$ 3.60	1,248	2.42	$ 3.13	1,248	$ 3.13
5.40	5.40	33,844	1.20	5.40	33,844	5.40
6.00	11.16	22,078	5.19	9.73	21,883	9.76
13.44	13.44	25,363	7.87	13.44	14,115	13.44
16.14	17.40	26,354	5.91	16.96	20,386	17.09
17.82	33.42	34,570	5.55	27.85	33,628	27.95
87.47	1,908.00	562	3.43	856.14	562	856.14
		144,019	4.91	$ 18.28	125,666	$ 18.77

For the years ended December 31, 2012 and 2011 and for the period from Inception through December 31, 2012, the Company recognized the following non-cash, share-based compensation expense (in thousands):

	Years Ended December 31,		Period from December 17, 2001 (date of inception) to December 31, 2012
	2012	2011	
Research and Development	$ 94	$ 117	$ 590
Selling, General and Administrative	212	191	1,611
Restructuring Expense			387
Total	$ 306	$ 308	$ 2,588

Stock-based compensation expense related to non-employees was negligible in 2012 and 2011. ARCA did not recognize any tax benefit related to employee stock-based compensation cost as a result of the full valuation allowance on its net deferred tax assets.

(10) Employee Benefit Plans

The Company has a 401(k) plan and makes a matching contribution equal to 100% of the employee s first 3% of the employee s contributions and 50% of the employee s next 2% of contributions. The Company adopted the plan in 2006 and contributed $57,000 and $80,000 for the years ended December 31, 2012 and 2011, respectively, and has contributed $640,000 from Inception through December 31, 2012.

(11) Income Taxes

Effective June 1, 2005, the Company changed from an S-Corporation to a C-Corporation. As an S-Corporation, the net operating loss carryforwards were distributed to the Company s stockholders; such amounts were not significant. Since June 2005 through December 31, 2012, for federal income tax purposes, the Company has net operating loss carryforwards of approximately $98.1 million, and approximately $687,000 of research and development credits that may be used to offset future taxable income. The net operating loss carryforwards will expire beginning 2025 through 2032. Utilization of net operating losses and tax credits, including those acquired as a result of the Merger, will be subject to an annual limitation due to ownership change limitations provided by IRC Section 382. The annual limitation may result in the expiration of the net operating losses and credits before utilization. As such, a portion of the Company s net operating loss carryforwards may be limited.

69

Table of Contents

In assessing the realizability of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the period in which those temporary differences become deductible. Management considers the scheduled reversal of deferred tax liabilities, projected future taxable income and tax planning strategies in making this assessment. Due primarily to the Company s history of operating losses, management is unable to conclude that it is more likely than not that the Company will realize the benefits of these deductible differences, and accordingly has provided a valuation allowance against the entire net deferred tax asset of approximately $42.2 million at December 31, 2012, reflecting an increase of approximately $1.5 million from December 31, 2011. The deferred tax assets are primarily comprised of net operating loss carryforwards and research and experimentation credit carryforwards. As of December 31, 2012 the Company has not performed an Internal Revenue Code Section 382 limitation study. Depending on the outcome of such a study, the gross amount of net operating losses recognizable in future tax periods could be limited. A limitation in the carryforwards would decrease the carrying amount of the gross amount of the net operating loss carryforwards, with a corresponding decrease in the valuation allowance recorded against these gross deferred tax assets.

Income tax benefit attributable to our loss from operations before income taxes differs from the amounts computed by applying the U.S. federal statutory income tax rate of 35%, as a result of the following (in thousands):

	Year ended December 31,	
	2012	2011
U.S. federal income tax benefit at statutory rates	(1,512)	$ (1,877)
State income tax benefit, net of federal benefit	(130)	(161)
Research and experimentation credits		(71)
Settlement of liabilities assumed in the Merger		
Adjustment in tax basis of tangible and intangible assets acquired in the Merger		
Other	196	154
Change in valuation allowance	1,446	1,955
	$	$

Without regard to the deferred tax liability on the impaired IPR&D, the Company has had no provision for income taxes since inception due to its S-corporation status and its subsequent net operating losses.

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting and the amounts used for income tax purposes, as well as operating loss and

Table of Contents

tax credit carryforwards. The income tax effects of temporary differences and carryforwards that give rise to significant portions of the Company s net deferred tax assets are as follows (in thousands):

	Year ended December 31,	
	2012	2011
Deferred tax assets:		
Current deferred tax assets:		
Vacation accrual	$ 26	$ 21
Total current deferred tax assets	26	21
Valuation allowance	(26)	(21)
Net current deferred tax assets	$	$
Noncurrent deferred tax assets:		
Net operating loss carryforwards	$ 37,295	$ 35,751
Charitable contribution carryforwards	368	406
Research and experimentation credits	687	687
Capitalized intangibles	3,413	3,432
Stock based compensation	416	399
Depreciation and amortization	11	23
Other	25	76
Total noncurrent deferred tax assets	42,215	40,774
Valuation allowance	(42,215)	(40,774)
Net noncurrent deferred tax assets	$	$
Deferred tax liabilities:		
Current deferred tax liabilities	$	$
Noncurrent deferred tax liabilities		
Net deferred tax liabilities	$	$
Net noncurrent deferred tax assets	$	$

Since the Company is in a loss carryforward position, the Company is generally subject to U.S. federal and state income tax examinations by tax authorities for all years for which a loss carryforward is available. Thus, the Company s open tax years extend back to 2009. The Company believes that its tax filing positions and deductions related to tax periods subject to examination will be sustained upon audit and does not anticipate any adjustment will result in a material adverse effect on the Company s financial condition, result of operations, or cash flow. For the years ended December 31, 2012 and 2011, the Company has no reserve for uncertain tax positions. The Company does not expect that the total amounts of unrecognized tax benefits will significantly increase or decrease within the subsequent twelve months. In the event the Company concludes it is subject to interest or penalties arising from uncertain tax positions, the Company will record interest and penalties as a component of other income and expense. No amounts of interest or penalties were recognized in the financial statements for the years ended December 31, 2012 and 2011.

(12) Legal Matters

On or about December 6, 2001, Variagenics, Inc. was sued in a complaint filed in the United States District Court for the Southern District of New York naming it and certain of its officers and underwriters as defendants. The complaint purportedly was filed on behalf of persons purchasing Variagenics stock between July 21, 2000 and December 6, 2000, and alleged violations of certain sections of the Securities Act of 1933, as amended, and the Securities Exchange Act of 1934, as amended. The complaint alleged that, in connection with Variagenics July 21, 2000 initial public offering, or IPO, the defendants failed to disclose additional and excessive commissions purportedly solicited by and paid to the underwriter defendants in exchange for allocating shares of

71

Table of Contents

Variagenics stock to preferred customers and alleged agreements among the underwriter defendants and preferred customers tying the allocation of IPO shares to agreements to make additional aftermarket purchases at predetermined prices. ARCA was involved in this litigation as a result of Nuvelo s merger with Variagenics in January 2003. On April 1, 2009 the parties entered into a settlement agreement. On October 5, 2009, the Court approved the settlement agreement. ARCA s share of the settlement was approximately $385,000 and was funded by ARCA s insurance carrier. Although the settlement was approved by the Court, it had been appealed by members of the class. On January 9, 2012 the appeal was dismissed by the Court and the suit was settled.

Table of Contents

Item 9. ***Changes in and Disagreements with Accountants on Accounting and Financial Disclosure***

Not applicable.

Item 9A. ***Controls and Procedures***

Evaluation of Disclosure Controls and Procedures

Under the supervision and with the participation of management, including our Chief Executive Officer and our Chief Financial Officer, we have evaluated the effectiveness of the design and operation of our disclosure controls and procedures. Disclosure controls and procedures are controls and procedures that are designed to ensure that information required to be disclosed in our reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC s rules and forms. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were effective as of the end of the period covered by this annual report.

Management s Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rules 13a-15(f) and 15(d)-15(f) under the Exchange Act). Our internal control system was designed to provide reasonable assurance to management and our board of directors regarding the preparation and fair presentation of published financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Under the supervision and with the participation of management, including our Chief Executive Officer and Chief Financial Officer, we have assessed the effectiveness of our internal control over financial reporting as of December 31, 2012. In making our assessment of internal control over financial reporting, we used the criteria issued in the report Internal Control-Integrated Framework by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). We have concluded that our internal control over financial reporting was effective as of December 31, 2012 based on these criteria.

This annual report does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting. Management s report was not subject to attestation by our independent registered public accounting firm pursuant to the exemption from Section 404(b) of the Sarbanes-Oxley Act for non-accelerated filers provided by the Dodd-Frank Wall Street Reform and Consumer Protection Act.

Changes in Internal Control over Financial Reporting

During the fourth quarter of 2012, there were no changes in our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Limitations on the Effectiveness of Controls

Our management, including the Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within our company have been detected.

Item 9B. ***Other Information***

None

Table of Contents

PART III

Item 10. ***Directors, Executive Officers and Corporate Governance***

The information required by this item is incorporated by reference to Election of Board of Directors, Section 16(a) Beneficial Ownership Reporting Compliance and Executive Officers in our Definitive Proxy Statement to be filed pursuant to Regulation 14A under the Securities Exchange Act of 1934, relating to our 2012 Annual Meeting of Stockholders.

Item 11. ***Executive Compensation***

The response to this item is incorporated by reference to Executive Compensation in our Definitive Proxy Statement to be filed pursuant to Regulation 14A under the Exchange Act, relating to our 2012 Annual Meeting of Stockholders.

Item 12. ***Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters***

The response to this item is incorporated by reference to Equity Compensation Plan Information and Security Ownership of Certain Beneficial Owners and Management in our Definitive Proxy Statement to be filed pursuant to Regulation 14A under the Exchange Act, relating to our 2012 Annual Meeting of Stockholders.

Item 13. ***Certain Relationships and Related Transactions, and Director Independence***

The response to this item is incorporated by reference to Certain Relationships and Related Transactions in our Definitive Proxy Statement to be filed pursuant to Regulation 14A under the Securities Exchange Act of 1934, relating to our 2012 Annual Meeting of Stockholders.

Item 14. ***Principal Accountant Fees and Services***

The response to this item is incorporated by reference to Ratification of Selection of Independent Auditors in our Definitive Proxy Statement to be filed pursuant to Regulation 14A under the Securities Exchange Act of 1934, relating to our 2012 Annual Meeting of Stockholders.

Table of Contents

PART IV

Item 15. ***Exhibits and Financial Statement Schedules***

(a) The following documents are filed as part of this Report:

1. Consolidated financial statements filed as part of this Report are listed under Part II, Item 8, page 47 of this Form 10-K.

2. No schedules are required because either the required information is not present or is not present in amounts sufficient to require submission of the schedule, or because the information required is included in the consolidated financial statements or the notes thereto.

(b) Exhibits

The following documents are filed as part of this annual report on Form 10-K. We will furnish a copy of any exhibit listed to requesting stockholders upon payment of our reasonable expenses in furnishing those materials.

Exhibit Number	Description
2.1	Agreement and Plan of Merger and Reorganization, dated September 24, 2008, among Nuvelo, Inc., Dawn Acquisition Sub, Inc. and ARCA biopharma, Inc.(5)
2.2	Amendment No. 1 to Agreement and Plan of Merger and Reorganization, dated October 28, 2008, by and among Nuvelo, Inc., Dawn Acquisition Sub, Inc. and ARCA biopharma, Inc.(6)
3.1	Amended and Restated Certificate of Incorporation of the Registrant, as amended.(28)
3.1(a)	Certificate of Amendment to Restated Certificate of Incorporation.(34)
3.2	Second Amended and Restated Bylaws of the Registrant, as amended.(28)
4.1	Form of Common Stock Certificate.(7)
4.2	Certificate of Designations of Series A Junior Participating Preferred Stock. (included as part of Exhibit 3.1)
4.3	Warrant to Purchase Stock Agreement, dated July 17, 2007, by and between ARCA Discovery, Inc. and Silicon Valley Bank.(8)
4.4	Amendment No. 1 to Warrant to Purchase Stock Agreement, dated February 19, 2009, by and between ARCA biopharma, Inc. and SVB Financial Group.(8)
4.5	Warrant to Purchase Stock Agreement, dated August 19, 2008, by and between ARCA biopharma, Inc. and Silicon Valley Bank.(8)
4.6	Amendment No. 1 to Warrant to Purchase Stock Agreement, dated February 19, 2009, by and between ARCA biopharma, Inc. and SVB Financial Group.(8)
4.7	Warrant to Purchase Stock Agreement, dated October 10, 2008, by and between ARCA biopharma, Inc. and Boulder Ventures IV, L.P.(8)
4.8	Amendment No. 1 to Warrant to Purchase Stock Agreement, dated February 19, 2009, by and between ARCA biopharma, Inc. and Boulder Ventures IV, L.P.(8)
4.9	Warrant to Purchase Stock Agreement, dated October 10, 2008, by and between ARCA biopharma, Inc. and Boulder Ventures IV (Annex), L.P.(8)
4.10	Amendment No. 1 to Warrant to Purchase Stock Agreement, dated February 19, 2009, by and between ARCA biopharma, Inc. and Boulder Ventures IV (Annex), L.P.(8)
4.11	Warrant to Purchase Stock Agreement, dated October 10, 2008, by and between ARCA biopharma, Inc. and InterWest Partners IX, LP.(8)
4.12	Amendment No. 1 to Warrant to Purchase Stock Agreement, dated February 19, 2009, by and between ARCA biopharma, Inc. and InterWest Partners IX, LP.(8)
4.13	Warrant to Purchase Stock Agreement, dated October 10, 2008, by and between ARCA biopharma, Inc. and Atlas Venture Fund VII, L.P.(8)
4.14	

Amendment No. 1 to Warrant to Purchase Stock Agreement, dated February 19, 2009, by and between ARCA biopharma, Inc. and Atlas Venture Fund VII, L.P.(8)

Table of Contents

4.15	Warrant to Purchase Stock Agreement, dated October 10, 2008, by and between ARCA biopharma, Inc. and The Peierls Foundation, Inc.(8)
4.16	Amendment No. 1 to Warrant to Purchase Stock Agreement, dated February 19, 2009, by and between ARCA biopharma, Inc. and The Peierls Foundation, Inc.(8)
4.17	Warrant to Purchase Stock Agreement, dated October 10, 2008, by and between ARCA biopharma, Inc. and Skyline Venture Partners Qualified Purchaser Fund IV, L.P.(8)
4.18	Amendment No. 1 to Warrant to Purchase Stock Agreement, dated February 19, 2009, by and between ARCA biopharma, Inc. and Skyline Venture Partners Qualified Purchaser Fund IV, L.P.(8)
4.19	Warrant to Purchase Stock Agreement, dated October 18, 2009, by and between ARCA biopharma, Inc. and BioMed Realty, L.P.(16)
4.20	Form of Common Stock Purchase Warrant.(23)
4.21	Form of Warrant to Purchase Common Stock.(27)
4.22	Form of Common Stock Purchase Warrant.(29)
4.23	Form of Warrants to Purchase Shares of Common Stock, dated October 22, 2012.(30)
4.24	Form of Warrants to Purchase Shares of Common Stock, dated December 20, 2012.(31)
4.25	Form of Warrants to Purchase Shares of Common Stock.(32)
4.26	Form of Common Stock Purchase Warrant.(33)
10.1§	Amended and Restated Collaboration and License Agreement, dated July 31, 2006, by and between Nuvelo, Inc. and Archemix Corp.(2)
10.2§	Second Amended and Restated Collaboration and License Agreement, dated April 20, 2010, by and between ARCA biopharma, Inc. and Archemix Corp.(17)
10.3	Lease, dated February 8, 2008, by and between ARCA Discovery, Inc. and Arista Place, LLC.(8)
10.4	Loan and Security Agreement, dated July 17, 2007, by and between ARCA Discovery, Inc. and Silicon Valley Bank.(8)
10.5	First Amendment to Loan and Security Agreement, dated January 21, 2009, by and between ARCA biopharma, Inc. and Silicon Valley Bank.(8)
10.6	Second Amendment to Loan and Security Agreement, dated March 23, 2009, by and between ARCA biopharma Colorado, Inc. and Silicon Valley Bank.(8)
10.7	Third Amendment to Loan and Security Agreement, dated April 6, 2009, by and between ARCA biopharma Colorado, Inc. and Silicon Valley Bank(14)
10.8	Fourth Amendment to Assumption of Loan and Security Agreement, dated April 10, 2009, by and between ARCA biopharma, Inc., ARCA biopharma Colorado, Inc. and Silicon Valley Bank(14)
10.9§	License and Sublicense Agreement, dated October 28, 2003, by and between ARCA Discovery, Inc. and CPEC, L.L.C.(12)
10.10§	Amendment to License and Sublicense Agreement, dated February 22, 2006, by and between ARCA Discovery, Inc. and CPEC L.L.C.(13)
10.11§	Exclusive License Agreement, dated October 14, 2005, by and between ARCA Discovery, Inc. and the University of Colorado s License Equity Holdings, Inc.(12)
10.12§	First Amendment to Exclusive License Agreement, dated June 23, 2006, by and between ARCA Discovery, Inc. and the University of Colorado s License Equity Holdings, Inc.(12)
10.13§	Second Amendment to Exclusive License Agreement, dated July 20, 2006, by and between ARCA Discovery, Inc. and the University of Colorado s License Equity Holdings, Inc.(12)
10.14	Third Amendment to Exclusive License Agreement, dated July 19, 2007, by and between ARCA Discovery, Inc. and the University of Colorado s License Equity Holdings, Inc.(12)
10.15§	Fourth Amendment to Exclusive License Agreement, dated August 22, 2007, by and between ARCA Discovery, Inc. and the University of Colorado s License Equity Holdings, Inc.(12)
10.16§	Diagnostic, Collaboration and Option Agreement, dated June 23, 2006, by and between ARCA Discovery, Inc. and CardioDX, Inc.(12)
10.17§	Amendment to Diagnostic, Collaboration and Option Agreement, dated October 1, 2007, by and between ARCA Discovery, Inc. and CardioDX, Inc.(12)
10.18§	Manufacturing Agreement, dated September 11, 2006, by and between ARCA Discovery, Inc. and Patheon, Inc.(12)

Table of Contents

10.19§	Development, Commercialization and Licensing Agreement, dated February 1, 2007, by and between ARCA Discovery, Inc. and Laboratory Corporation of America Holdings, Inc.(13)
10.20	Amendment No. 1 to Development, Commercialization and Licensing Agreement, dated May 14, 2007, by and between ARCA Discovery, Inc. and Laboratory Corporation of America Holdings, Inc.(12)
10.21§	Amendment No. 2 to Development, Commercialization and Licensing Agreement, dated June 10, 2008, by and between ARCA Discovery, Inc. and Laboratory Corporation of America Holdings, Inc.(12)
10.22	Materials Transfer Agreement, dated October 14, 2005, by and between ARCA Discovery, Inc. and the University of Colorado.(12)
10.23	Lease Surrender and Termination Agreement, dated August 5, 2009, by and between ARCA biopharma, Inc. and The Irvine Company LLC.(9)
10.24	Lease Termination and Warrant Purchase Agreement, dated September 18, 2009, by and between ARCA biopharma, Inc., BMR-201 Industrial Road LLC and BioMed Realty, L.P.(10)
10.25§	Exclusive Option Agreement, dated December 2, 2009, by and between ARCA biopharma, Inc. and the University of Cincinnati.(16)
10.26	Agreement Term Extension Letter dated December 8, 2010, of the Exclusive Option Agreement by and between ARCA biopharma, Inc. and the University of Cincinnati.(19)
10.27	Agreement Term Extension Letter dated December 21, 2010, of the Exclusive Option Agreement by and between ARCA biopharma, Inc. and the University of Cincinnati.(20)
10.28	Agreement Term Extension Letter dated January 21, 2011, of the Exclusive Option Agreement by and between ARCA biopharma, Inc. and the University of Cincinnati.(21)
10.29	ARCA Discovery, Inc. 2004 Stock Incentive Plan.(7)
10.30	Amendment No. 1 to the ARCA Discovery, Inc. 2004 Stock Incentive Plan.(7)
10.31	Amendment No. 2 to the ARCA Discovery, Inc. 2004 Stock Incentive Plan.(7)
10.32	Amendment No. 3 to the ARCA Discovery, Inc. 2004 Stock Incentive Plan.(7)
10.33	Amendment No. 4 to the ARCA Discovery, Inc. 2004 Stock Incentive Plan.(7)
10.34	Amendment No. 5 to the ARCA Discovery, Inc. 2004 Stock Incentive Plan.(7)
10.35	Amendment No. 6 to the ARCA Discovery, Inc. 2004 Stock Incentive Plan.(7)
10.36	ARCA biopharma, Inc. 2004 Stock Incentive Plan, Form of Executive Incentive Stock Option Agreement.(7)
10.37	ARCA biopharma, Inc. 2004 Stock Incentive Plan, Form of Non-Executive Incentive Stock Option Agreement.(7)
10.38	ARCA biopharma, Inc. 2004 Stock Incentive Plan, Form of Nonqualified Stock Option Agreement.(7)
10.39	ARCA biopharma, Inc. 2004 Equity Incentive Plan (f/k/a Nuvelo, Inc. 2004 Equity Incentive Plan), Form of Partial Acceleration Stock Option Agreement.(8)
10.40	ARCA biopharma, Inc. 2004 Equity Incentive Plan (f/k/a Nuvelo, Inc. 2004 Equity Incentive Plan), Form of No Acceleration Stock Option Agreement.(8)
10.41	ARCA biopharma, Inc. 2004 Equity Incentive Plan (f/k/a Nuvelo, Inc. 2004 Equity Incentive Plan), Form of Director Stock Option Agreement.(8)
10.42	ARCA biopharma, Inc. 2004 Equity Incentive Plan (f/k/a Nuvelo, Inc. 2004 Equity Incentive Plan), Form of Notice of Grant of Stock Option.(8)
10.43	ARCA biopharma, Inc. 2004 Equity Incentive Plan (f/k/a Nuvelo, Inc. 2004 Equity Incentive Plan), Form of Notice of Director Grant of Stock Option.(8)
10.44	Form of Indemnification Agreement between Nuvelo, Inc. and its directors and officers.(1)
10.45	Nuvelo, Inc. Amended Executive Change in Control and Severance Benefit Plan.(4)
10.46	Amended and Restated Employment and Retention Agreement, dated June 4, 2008, by and between ARCA biopharma, Inc. and Michael R. Bristow.(8)
10.47	Assignment and Assumption Agreement, dated January 26, 2009, by and between ARCA biopharma, Inc. and ARCA biopharma Colorado, Inc.(8)

Table of Contents

10.48	Amended and Restated Employment Agreement, dated June 12, 2008, by and between ARCA biopharma, Inc. and Christopher D. Ozeroff.(8)
10.49	Assignment and Assumption Agreement, dated January 26, 2009, by and between ARCA biopharma, Inc. and ARCA biopharma Colorado, Inc.(8)
10.50	Amended and Restated ARCA biopharma, Inc. 2004 Equity Incentive Plan(11)
10.51	ARCA biopharma, Inc. Employee Severance Benefit Plan(18)
10.52	ARCA biopharma, Inc. 2009 Reduction in Force Severance Benefit Plan(18)
10.53	Form of Option Amendment pursuant to ARCA biopharma, Inc. 2004 Equity Incentive Plan and ARCA biopharma, Inc. 2004 Stock Option Plan (change of control)(18)
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10.57	Agreement Term Extension Letter dated March 31, 2011, of the Exclusive Option Agreement by and between ARCA biopharma, Inc. and the University of Cincinnati.(22)
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10.61§	Amended and Restated Exclusive License Agreement, dated August 12, 2011, by and between the Regents of the University of Colorado and ARCA biopharma, Inc.(26)
10.62	Form of Subscription Agreement.(27)
10.63	Form of Registration Rights Agreement.(27)
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10.69	Form of Registration Rights Agreement.(30)
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14.1	Code of Business Conduct and Ethics(9)
16.1	Letter from Ernst & Young LLP to the Securities and Exchange Commission, dated March 30, 2009.(15)
23.1*	Consent of KPMG LLP, Independent Registered Public Accounting Firm.
24.1*	Power of Attorney (included in the signature page hereto).
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32.1*	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. sec. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document (furnished electronically herewith)
101.SCH	XBRL Taxonomy Extension Schema Document (furnished electronically herewith)
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document (furnished electronically herewith)
101.LAB	XBRL Taxonomy Extension Label Linkbase Document (furnished electronically herewith)
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document (furnished electronically herewith)
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document (furnished electronically herewith)

* Filed herewith.
Compensatory plan or agreement.
§ Confidential treatment has been requested for portions of this document, which are omitted and filed separately with the SEC.
XBRL (Extensible Business Reporting Language) information is furnished and not filed or a part of a registration statement or prospectus for purposes of sections 11 or 12 of the Securities Act of 1933, as amended, is deemed not filed for purposes of section 18 of the Securities Exchange Act of 1934, as amended, and otherwise is not subject to liability under these sections.

(1) Previously filed with the SEC as an Exhibit to and incorporated herein by reference from Hyseq, Inc. s Form S-1, filed on June 12, 1997, as amended, File No. 333-29091.
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(16) Previously filed with the SEC as an Exhibit to and incorporated herein by reference from ARCA biopharma, Inc. s Form 10-K, filed on March 4, 2010, File No. 000-22873.

Table of Contents

(17) Previously filed with the SEC as an Exhibit to and incorporated herein by reference from ARCA biopharma, Inc. s Form 10-Q, filed on August 10, 2010, File No. 000-22873.
(18) Previously filed with the SEC as an Exhibit to and incorporated herein by reference from ARCA biopharma, Inc. s Form 10-Q, filed on August 10, 2009, File No. 000-22873.
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(22) Previously filed with the SEC as an Exhibit to and incorporated herein by reference from ARCA biopharma, Inc. s Form 8-K, filed on April 5, 2011, File No. 000-22873.
(23) Previously filed with the SEC as an Exhibit to and incorporated herein by reference from ARCA biopharma, Inc. s Form 8-K filed on April 18, 2011, File No. 000-22873.
(24) Previously filed with the SEC as an Exhibit to and incorporated herein by reference from ARCA biopharma, Inc. s Form 10-Q, filed on May 16, 2011, File No. 000-22873.
(25) Previously filed with the SEC as an Exhibit to and incorporated herein by reference from ARCA biopharma, Inc. s Form 8-K filed on June 20, 2011, File No. 000-22873.
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(27) Previously filed with the SEC as an Exhibit to and incorporated herein by reference from ARCA biopharma, Inc. s Form 8-K filed on December 22, 2011, File No. 000-22873.
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(29) Previously filed with the SEC as an exhibit and incorporated herein by reference from ARCA biopharma, Inc. s Form 8-K, filed on August 3, 2012, File No. 000-22873.
(30) Previously filed with the SEC as an exhibit and incorporated herein by reference from ARCA biopharma, Inc. s Form 8-K, filed on October 23, 2012, File No. 000-22873.
(31) Previously filed with the SEC as an exhibit and incorporated herein by reference from ARCA biopharma, Inc. s Form 8-K, filed on December 19, 2012, File No. 000-22873.
(32) Previously filed with the SEC as an exhibit and incorporated herein by reference from ARCA biopharma, Inc. s Form 8-K, filed on January 23, 2013, File No. 000-22873.
(33) Previously filed with the SEC as an exhibit and incorporated herein by reference from ARCA biopharma, Inc. s Form 8-K, filed on February 1, 2013, File No. 000-22873.
(34) Previously filed with the SEC as an exhibit and incorporated herein by reference from ARCA biopharma, Inc. s Form 8-K, filed on March 5, 2013, File No. 000-22873.

Table of Contents

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

ARCA biopharma, Inc.

By: /s/ Patrick M. Wheeler
Patrick M. Wheeler

Principal Accounting Officer

Date: March 21, 2013

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Michael R. Bristow and Patrick M. Wheeler, and each of them, as his true and lawful attorneys-in-fact and agents, with full power of substitution for him, and in his name in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done therewith, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, and any of them or his or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed by the following persons on behalf of ARCA biopharma, Inc., in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Michael R. Bristow **Michael R. Bristow**	President and Chief Executive Officer and Director (Principal Executive Officer)	March 21, 2013
/s/ Patrick M. Wheeler **Patrick M. Wheeler**	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 21, 2013
/s/ Jean-Francois Formela **Jean-Francois Formela**	Director	March 21, 2013
/s/ Linda Grais **Linda Grais**	Director	March 21, 2013
/s/ Burton E. Sobel **Burton E. Sobel**	Director	March 21, 2013

/s/ John L. Zabriskie	Director	March 21, 2013

John L. Zabriskie

Table of Contents

EXHIBIT INDEX

Exhibit Number	Description
2.1	Agreement and Plan of Merger and Reorganization, dated September 24, 2008, among Nuvelo, Inc., Dawn Acquisition Sub, Inc. and ARCA biopharma, Inc.(5)
2.2	Amendment No. 1 to Agreement and Plan of Merger and Reorganization, dated October 28, 2008, by and among Nuvelo, Inc., Dawn Acquisition Sub, Inc. and ARCA biopharma, Inc.(6)
3.1	Amended and Restated Certificate of Incorporation of the Registrant, as amended.(28)
3.1(a)	Certificate of Amendment to Restated Certificate of Incorporation.(34)
3.2	Second Amended and Restated Bylaws of the Registrant, as amended.(28)
4.1	Form of Common Stock Certificate.(7)
4.2	Certificate of Designations of Series A Junior Participating Preferred Stock. (included as part of Exhibit 3.1)
4.3	Warrant to Purchase Stock Agreement, dated July 17, 2007, by and between ARCA Discovery, Inc. and Silicon Valley Bank.(8)
4.4	Amendment No. 1 to Warrant to Purchase Stock Agreement, dated February 19, 2009, by and between ARCA biopharma, Inc. and SVB Financial Group.(8)
4.5	Warrant to Purchase Stock Agreement, dated August 19, 2008, by and between ARCA biopharma, Inc. and Silicon Valley Bank.(8)
4.6	Amendment No. 1 to Warrant to Purchase Stock Agreement, dated February 19, 2009, by and between ARCA biopharma, Inc. and SVB Financial Group.(8)
4.7	Warrant to Purchase Stock Agreement, dated October 10, 2008, by and between ARCA biopharma, Inc. and Boulder Ventures IV, L.P.(8)
4.8	Amendment No. 1 to Warrant to Purchase Stock Agreement, dated February 19, 2009, by and between ARCA biopharma, Inc. and Boulder Ventures IV, L.P.(8)
4.9	Warrant to Purchase Stock Agreement, dated October 10, 2008, by and between ARCA biopharma, Inc. and Boulder Ventures IV (Annex), L.P.(8)
4.10	Amendment No. 1 to Warrant to Purchase Stock Agreement, dated February 19, 2009, by and between ARCA biopharma, Inc. and Boulder Ventures IV (Annex), L.P.(8)
4.11	Warrant to Purchase Stock Agreement, dated October 10, 2008, by and between ARCA biopharma, Inc. and InterWest Partners IX, LP.(8)
4.12	Amendment No. 1 to Warrant to Purchase Stock Agreement, dated February 19, 2009, by and between ARCA biopharma, Inc. and InterWest Partners IX, LP.(8)
4.13	Warrant to Purchase Stock Agreement, dated October 10, 2008, by and between ARCA biopharma, Inc. and Atlas Venture Fund VII, L.P.(8)
4.14	Amendment No. 1 to Warrant to Purchase Stock Agreement, dated February 19, 2009, by and between ARCA biopharma, Inc. and Atlas Venture Fund VII, L.P.(8)
4.15	Warrant to Purchase Stock Agreement, dated October 10, 2008, by and between ARCA biopharma, Inc. and The Peierls Foundation, Inc.(8)
4.16	Amendment No. 1 to Warrant to Purchase Stock Agreement, dated February 19, 2009, by and between ARCA biopharma, Inc. and The Peierls Foundation, Inc.(8)
4.17	Warrant to Purchase Stock Agreement, dated October 10, 2008, by and between ARCA biopharma, Inc. and Skyline Venture Partners Qualified Purchaser Fund IV, L.P.(8)
4.18	Amendment No. 1 to Warrant to Purchase Stock Agreement, dated February 19, 2009, by and between ARCA biopharma, Inc. and Skyline Venture Partners Qualified Purchaser Fund IV, L.P.(8)
4.19	Warrant to Purchase Stock Agreement, dated October 18, 2009, by and between ARCA biopharma, Inc. and BioMed Realty, L.P.(16)
4.20	Form of Common Stock Purchase Warrant.(23)
4.21	Form of Warrant to Purchase Common Stock.(27)
4.22	Form of Common Stock Purchase Warrant.(29)
4.23	Form of Warrants to Purchase Shares of Common Stock, dated October 22, 2012.(30)
4.24	Form of Warrants to Purchase Shares of Common Stock, dated December 20, 2012.(31)
4.25	Form of Warrants to Purchase Shares of Common Stock.(32)
4.26	Form of Common Stock Purchase Warrant.(33)

Table of Contents

10.1§	Amended and Restated Collaboration and License Agreement, dated July 31, 2006, by and between Nuvelo, Inc. and Archemix Corp.(2)
10.2§	Second Amended and Restated Collaboration and License Agreement, dated April 20, 2010, by and between ARCA biopharma, Inc. and Archemix Corp.(17)
10.3	Lease, dated February 8, 2008, by and between ARCA Discovery, Inc. and Arista Place, LLC.(8)
10.4	Loan and Security Agreement, dated July 17, 2007, by and between ARCA Discovery, Inc. and Silicon Valley Bank.(8)
10.5	First Amendment to Loan and Security Agreement, dated January 21, 2009, by and between ARCA biopharma, Inc. and Silicon Valley Bank.(8)
10.6	Second Amendment to Loan and Security Agreement, dated March 23, 2009, by and between ARCA biopharma Colorado, Inc. and Silicon Valley Bank.(8)
10.7	Third Amendment to Loan and Security Agreement, dated April 6, 2009, by and between ARCA biopharma Colorado, Inc. and Silicon Valley Bank(14)
10.8	Fourth Amendment to Assumption of Loan and Security Agreement, dated April 10, 2009, by and between ARCA biopharma, Inc., ARCA biopharma Colorado, Inc. and Silicon Valley Bank(14)
10.9§	License and Sublicense Agreement, dated October 28, 2003, by and between ARCA Discovery, Inc. and CPEC, L.L.C.(12)
10.10§	Amendment to License and Sublicense Agreement, dated February 22, 2006, by and between ARCA Discovery, Inc. and CPEC L.L.C.(13)
10.11§	Exclusive License Agreement, dated October 14, 2005, by and between ARCA Discovery, Inc. and the University of Colorado s License Equity Holdings, Inc.(12)
10.12§	First Amendment to Exclusive License Agreement, dated June 23, 2006, by and between ARCA Discovery, Inc. and the University of Colorado s License Equity Holdings, Inc.(12)
10.13§	Second Amendment to Exclusive License Agreement, dated July 20, 2006, by and between ARCA Discovery, Inc. and the University of Colorado s License Equity Holdings, Inc.(12)
10.14	Third Amendment to Exclusive License Agreement, dated July 19, 2007, by and between ARCA Discovery, Inc. and the University of Colorado s License Equity Holdings, Inc.(12)
10.15§	Fourth Amendment to Exclusive License Agreement, dated August 22, 2007, by and between ARCA Discovery, Inc. and the University of Colorado s License Equity Holdings, Inc.(12)
10.16§	Diagnostic, Collaboration and Option Agreement, dated June 23, 2006, by and between ARCA Discovery, Inc. and CardioDX, Inc.(12)
10.17§	Amendment to Diagnostic, Collaboration and Option Agreement, dated October 1, 2007, by and between ARCA Discovery, Inc. and CardioDX, Inc.(12)
10.18§	Manufacturing Agreement, dated September 11, 2006, by and between ARCA Discovery, Inc. and Patheon, Inc.(12)
10.19§	Development, Commercialization and Licensing Agreement, dated February 1, 2007, by and between ARCA Discovery, Inc. and Laboratory Corporation of America Holdings, Inc.(13)
10.20	Amendment No. 1 to Development, Commercialization and Licensing Agreement, dated May 14, 2007, by and between ARCA Discovery, Inc. and Laboratory Corporation of America Holdings, Inc.(12)
10.21§	Amendment No. 2 to Development, Commercialization and Licensing Agreement, dated June 10, 2008, by and between ARCA Discovery, Inc. and Laboratory Corporation of America Holdings, Inc.(12)
10.22	Materials Transfer Agreement, dated October 14, 2005, by and between ARCA Discovery, Inc. and the University of Colorado.(12)
10.25§	Exclusive Option Agreement, dated December 2, 2009, by and between ARCA biopharma, Inc. and the University of Cincinnati.(16)
10.26	Agreement Term Extension Letter dated December 8, 2010, of the Exclusive Option Agreement by and between ARCA biopharma, Inc. and the University of Cincinnati.(19)
10.27	Agreement Term Extension Letter dated December 21, 2010, of the Exclusive Option Agreement by and between ARCA biopharma, Inc. and the University of Cincinnati.(20)
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10.29	ARCA Discovery, Inc. 2004 Stock Incentive Plan.(7)

Table of Contents

10.30	Amendment No. 1 to the ARCA Discovery, Inc. 2004 Stock Incentive Plan.(7)
10.31	Amendment No. 2 to the ARCA Discovery, Inc. 2004 Stock Incentive Plan.(7)
10.32	Amendment No. 3 to the ARCA Discovery, Inc. 2004 Stock Incentive Plan.(7)
10.33	Amendment No. 4 to the ARCA Discovery, Inc. 2004 Stock Incentive Plan.(7)
10.34	Amendment No. 5 to the ARCA Discovery, Inc. 2004 Stock Incentive Plan.(7)
10.35	Amendment No. 6 to the ARCA Discovery, Inc. 2004 Stock Incentive Plan.(7)
10.36	ARCA biopharma, Inc. 2004 Stock Incentive Plan, Form of Executive Incentive Stock Option Agreement.(7)
10.37	ARCA biopharma, Inc. 2004 Stock Incentive Plan, Form of Non-Executive Incentive Stock Option Agreement.(7)
10.38	ARCA biopharma, Inc. 2004 Stock Incentive Plan, Form of Nonqualified Stock Option Agreement.(7)
10.39	ARCA biopharma, Inc. 2004 Equity Incentive Plan (f/k/a Nuvelo, Inc. 2004 Equity Incentive Plan), Form of Partial Acceleration Stock Option Agreement.(8)
10.40	ARCA biopharma, Inc. 2004 Equity Incentive Plan (f/k/a Nuvelo, Inc. 2004 Equity Incentive Plan), Form of No Acceleration Stock Option Agreement.(8)
10.41	ARCA biopharma, Inc. 2004 Equity Incentive Plan (f/k/a Nuvelo, Inc. 2004 Equity Incentive Plan), Form of Director Stock Option Agreement.(8)
10.42	ARCA biopharma, Inc. 2004 Equity Incentive Plan (f/k/a Nuvelo, Inc. 2004 Equity Incentive Plan), Form of Notice of Grant of Stock Option.(8)
10.43	ARCA biopharma, Inc. 2004 Equity Incentive Plan (f/k/a Nuvelo, Inc. 2004 Equity Incentive Plan), Form of Notice of Director Grant of Stock Option.(8)
10.44	Form of Indemnification Agreement between Nuvelo, Inc. and its directors and officers.(1)
10.45	Nuvelo, Inc. Amended Executive Change in Control and Severance Benefit Plan.(4)
10.46	Amended and Restated Employment and Retention Agreement, dated June 4, 2008, by and between ARCA biopharma, Inc. and Michael R. Bristow.(8)
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(3) Previously filed with the SEC as an Appendix to and incorporated herein by reference from Nuvelo, Inc. s Proxy Statement on Schedule 14A, filed on April 18, 2007, File No. 000-22873.

Table of Contents

(4) Previously filed with the SEC as an Exhibit to and incorporated herein by reference from Nuvelo, Inc. s Form 10-Q, filed on November 7, 2007, File No. 000-22873.
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(6) Previously filed with the SEC as an Exhibit to and incorporated herein by reference from Nuvelo, Inc. s Form 8-K, filed on October 29, 2008, File No. 000-22873.
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(8) Previously filed with the SEC as an Exhibit to and incorporated herein by reference from ARCA biopharma, Inc. s Form 10-K, filed on March 27, 2009, File No. 000-22873.
(9) Previously filed with the SEC as an Exhibit to and incorporated herein by reference from ARCA biopharma, Inc. s Form 10-Q, filed on November 16, 2009, File No. 000-22873.
(10) Previously filed with the SEC as an Exhibit to and incorporated herein by reference from ARCA biopharma, Inc. s Form 8-K, filed on September 24, 2009, File No. 000-22873.
(11) Previously filed with the SEC as an Exhibit to and incorporated herein by reference from ARCA biopharma, Inc. s Form 10-Q/A, filed on August 21, 2009, File No. 000-22873.
(12) Previously filed with the SEC as an Exhibit to and incorporated herein by reference from ARCA biopharma, Inc. s Form 10-Q, filed on May 15, 2009, File No. 000-22873.
(13) Previously filed with the SEC as an Exhibit to and incorporated herein by reference from ARCA biopharma, Inc. s Form 10-Q/A, filed on November 6, 2009, File No. 000-22873.
(14) Previously filed with the SEC as an Exhibit to and incorporated herein by reference from ARCA biopharma, Inc. s Form 8-K, filed on April 10, 2009, File No. 000-22873.
(15) Previously filed with the SEC as an Exhibit to and incorporated herein by reference from ARCA biopharma, Inc. s Form 8-K, filed on March 30, 2009, File No. 000-22873.
(16) Previously filed with the SEC as an Exhibit to and incorporated herein by reference from ARCA biopharma, Inc. s Form 10-K, filed on March 4, 2010, File No. 000-22873.
(17) Previously filed with the SEC as an Exhibit to and incorporated herein by reference from ARCA biopharma, Inc. s Form 10-Q, filed on August 10, 2010, File No. 000-22873.
(18) Previously filed with the SEC as an Exhibit to and incorporated herein by reference from ARCA biopharma, Inc. s Form 10-Q, filed on August 10, 2009, File No. 000-22873.
(19) Previously filed with the SEC as an Exhibit to and incorporated herein by reference from ARCA biopharma, Inc. s Form 8-K, filed on December 14, 2010, File No. 000-22873.
(20) Previously filed with the SEC as an Exhibit to and incorporated herein by reference from ARCA biopharma, Inc. s Form 8-K, filed on December 22, 2010, File No. 000-22873.
(21) Previously filed with the SEC as an Exhibit to and incorporated herein by reference from ARCA biopharma, Inc. s Form 8-K, filed on January 26, 2011, File No. 000-22873.
(22) Previously filed with the SEC as an Exhibit to and incorporated herein by reference from ARCA biopharma, Inc. s Form 8-K, filed on April 5, 2011, File No. 000-22873.
(23) Previously filed with the SEC as an Exhibit to and incorporated herein by reference from ARCA biopharma, Inc. s Form 8-K filed on April 18, 2011, File No. 000-22873.
(24) Previously filed with the SEC as an Exhibit to and incorporated herein by reference from ARCA biopharma, Inc. s Form 10-Q, filed on May 16, 2011, File No. 000-22873.
(25) Previously filed with the SEC as an Exhibit to and incorporated herein by reference from ARCA biopharma, Inc. s Form 8-K filed on June 20, 2011, File No. 000-22873.
(26) Previously filed with the SEC as an Exhibit to and incorporated herein by reference from ARCA biopharma, Inc. s Form 10-Q, filed on August 15, 2011, File No. 000-22873.
(27) Previously filed with the SEC as an Exhibit to and incorporated herein by reference from ARCA biopharma, Inc. s Form 8-K filed on December 22, 2011, File No. 000-22873.
(28) Previously filed with the SEC as an Exhibit to and incorporated herein by reference from ARCA biopharma, Inc. s Form 10-Q, filed on May 14, 2012, File No. 000-22873.
(29) Previously filed with the SEC as an exhibit and incorporated herein by reference from ARCA biopharma, Inc. s Form 8-K, filed on August 3, 2012, File No. 000-22873.
(30) Previously filed with the SEC as an exhibit and incorporated herein by reference from ARCA biopharma, Inc. s Form 8-K, filed on October 23, 2012, File No. 000-22873.

Table of Contents

(31) Previously filed with the SEC as an exhibit and incorporated herein by reference from ARCA biopharma, Inc. s Form 8-K, filed on December 19, 2012, File No. 000-22873.
(32) Previously filed with the SEC as an exhibit and incorporated herein by reference from ARCA biopharma, Inc. s Form 8-K, filed on January 23, 2013, File No. 000-22873.
(33) Previously filed with the SEC as an exhibit and incorporated herein by reference from ARCA biopharma, Inc. s Form 8-K, filed on February 1, 2013, File No. 000-22873.
(34) Previously filed with the SEC as an exhibit and incorporated herein by reference from ARCA biopharma, Inc. s Form 8-K, filed on March 5, 2013, File No. 000-22873.