ARCA biopharma, Inc.
Form 10-K
March 09, 2011
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, 2010

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 200, 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 ¨ 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 30, 2010, the last business day of the most recently completed second fiscal quarter, was $22,764,848 based on the last sale price of the common stock as reported on that day by the Nasdaq Global Market.

As of March 7, 2011, the Registrant had 8,834,535 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 2011 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 additional trial regarding Gencaro required under the complete response letter received from the FDA, the timing of the commercial launch of Gencaro, if any, our ability to obtain additional funding or enter into a strategic or other transaction, the periods for which and 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, the expected saving from our February 2011 workforce reduction, 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 heart failure and other cardiovascular diseases. Our lead product candidate is Gencaro™ (bucindolol hydrochloride), a pharmacologically unique beta-blocker and mild vasodilator being developed for the treatment of chronic heart failure, or HF. We have collaborated with LabCorp to develop the Gencaro Test, a companion test for the genetic markers that may predict clinical response to Gencaro.

We have identified common genetic variations in the cardiovascular system that we believe interact with Gencaro s pharmacology and may predict patient response to Gencaro treatment. We currently hold worldwide rights to Gencaro and have been granted patents in the U.S. and Europe for methods of treating heart failure patients with bucindolol based on genetic testing, which we believe will provide market exclusivity for Gencaro into 2025 in those markets. In addition, we believe that if Gencaro is approved, the U.S. Gencaro patent, as well as the patent issued in Europe, will be eligible for patent term extension which, if granted in the U.S., could provide an additional period of market exclusivity in the U.S. of approximately three years, and if granted in Europe could provide an additional five years of market exclusivity.

Table of Contents

Gencaro has been the subject of extensive clinical development, culminating in a Phase 3 heart failure study known as the BEST trial. In September 2008, the U.S. Food and Drug Administration, or FDA, formally accepted for filing our New Drug Application, or NDA, for Gencaro as a potential treatment for HF. In May 2009, the FDA notified us through a Complete Response Letter, or CRL, that our NDA for Gencaro was not approvable in its current form, and specified additional actions and information required for approval of the NDA including the need for an additional Phase 3 clinical trial as described below. In May 2010, we reached agreement with the FDA on a Special Protocol Assessment, or SPA, for the design of an additional Phase 3 clinical trial to assess the safety and efficacy of Gencaro in approximately 3,200 patients with chronic heart failure who have the genotype that appears to respond most favorably to Gencaro. The SPA signifies the FDA s agreement that this trial, if successful, could serve as the clinical effectiveness basis for the approval of Gencaro. The trial is designed as an international, multi-center, randomized, double-blind clinical trial. The trial is intended to be a superiority comparison of Gencaro to the beta-blocker metoprolol CR/XL, which is approved for heart failure and other indications. The primary endpoint of the trial is a composite of cardiovascular mortality and cardiovascular hospitalization. The trial protocol includes two interim data analyses at pre-specified numbers of primary endpoint events. If the results of either interim analysis meet the pre-specified criteria, we believe that a complete response to the CRL could be formally submitted at that time. The first interim data analysis is planned at 630 primary endpoint events (57% of the projected total number). The trial protocol estimates reaching the first interim analysis 24-30 months into the trial. Even with a positive outcome at either interim analysis, the planned trial is designed to proceed to conclusion, estimated to take 3.5 years (including the time to reach the interim analysis). In order not to influence the planned trial s subsequent completion, even if the results of an interim data analysis are adequate to support approval of Gencaro, Gencaro would not be commercially available until after the conclusion of the trial. We currently expect we could begin the trial approximately one year after obtaining sufficient funding.

The investigation of Gencaro for the reduction of cardiovascular mortality and cardiovascular hospitalizations in a genotype-defined HF population was designated by the FDA as a fast track development program. According to the FDA s Fast Track Guidance document, fast track programs are designed to facilitate the development and expedite the review of new drugs that are intended to treat serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs.

We also hold exclusive rights to rNAPc2, a single-chain, small recombinant protein, originally isolated from the saliva of the canine hookworm. rNAPc2 is a potent, long acting, and selective inhibitor of tissue factor, the protein responsible for initiating the extrinsic coagulation pathway, the primary coagulation mechanism in humans. rNAPc2 was originally developed as a cardiovascular therapy for thrombosis and other indications. As a result, it has been safely tested in over 700 human patients in nine Phase 1 and Phase 2 clinical trials. Previously, pilot studies of rNAPc2 conducted in non-human primates demonstrated potential efficacy against two of the most deadly strains of hemorrhagic fever virus, Ebola and Marburg. We are currently seeking government funding to further develop rNAPc2, as a potential treatment for viral hemorrhagic fevers. Considering the substantial cost associated with the development of rNAPc2 and our limited financial resources, further development of rNAPc2 will be dependent upon receipt of government funding, which may not be available.

In light of the substantial additional time and costs associated with the development of Gencaro and the need to raise a significant amount of capital on acceptable terms to finance the additional clinical trial and our ongoing operations, we are evaluating strategic alternatives for funding continued operations and development programs. In 2010, we raised $7.2 million, net of offering costs, through the sale of our common stock pursuant to an equity distribution agreement, and we may seek additional funding that could allow us to operate while we continue to pursue strategic combination, partnering, additional financing and licensing opportunities. If we are delayed in completing or are unable to complete additional financing and/or a strategic transaction, we may discontinue our development activities or discontinue our operations. To preserve our capital resources, in February 2011, we reduced our research and development and general and administrative workforce by 36%. The reduction is expected to reduce our projected cash use by approximately $200,000 per quarter. We currently believe our cash and cash equivalents balance as of December 31, 2010 will be sufficient to fund our operations

Table of Contents

through September 30, 2011. 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, 2011. We may not be able to raise sufficient capital on acceptable terms, or at all, to continue development activities or to otherwise continue operations and may not be able to execute any strategic transaction. Changing circumstances may cause us to consume capital significantly faster or slower than we currently anticipate. We have based these estimates on assumptions that may prove to be wrong, and we could exhaust our available financial resources sooner than we currently expect.

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.

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. In May 2010, we reached agreement with the FDA on a SPA for the design of an additional Phase 3 clinical trial to assess the safety and efficacy of Gencaro in approximately 3,200 patients with chronic heart failure who have the genotype that appears to respond most favorably to Gencaro. The SPA signifies the FDA s agreement that this trial, if successful, could serve as the clinical effectiveness basis for the approval of Gencaro. We currently expect that we could begin the trial approximately one year after obtaining sufficient funding, if at all.

Complete a strategic transaction or raise substantial additional funding. We are seeking to complete a strategic transaction or raise substantial additional funding, through government funding or public or private debt or equity securities, to support the continued clinical development of Gencaro, including the additional clinical trial.

Leverage our existing assets. We are pursuing opportunities to leverage certain of our development-stage product candidates, including pursuing government funding for the further development of rNAPc2, a recombinant protein and potent tissue-factor inhibitor. We are also pursuing licensing transactions for certain of our other compounds which are in early stages of development for various indications.

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.

Heart Failure Market Background and Opportunity

HF is one of the world s most significant health care challenges. Industry sources estimate that about 5.7 million Americans have HF and nearly 670,000 new patients are diagnosed annually. In addition, HF is the underlying reason for approximately 12 to 15 million annual visits to physicians, 6.5 million annual hospital days and over $39 billion in estimated direct and indirect healthcare costs in the U.S. Some sources estimate that the number of chronic heart failure patients in countries within the European Union is significantly higher than in the U.S.

Table of Contents

Medical therapy has made progress in treating HF, but morbidity and mortality remain high. The current standard of care for HF involves the use of various therapies that operate to inhibit the activity of the renin-angiotensin-aldosterone system (these include angiotensin converting enzyme, or ACE, inhibitors, angiotensin II receptor blockers, or ARB s, and aldosterone receptor antagonists), diuretics, and drugs in the class known as beta-blockers.

Beta-blockers are named for their characteristic mechanism of binding to certain receptors in the nervous system of the heart, and in doing so, blocking those receptors from being activated by binding with other molecules. This drug class is part of the current standard of care in patients with HF and left ventricular dysfunction. The American Heart Association and the American College of Cardiology physician guidelines for the treatment of HF state the following:

Beta-blockers should be prescribed to all patients with stable heart failure due to reduced left ventricular ejection fraction, unless they have a contraindication to their use or have been shown to be unable to tolerate treatment with the drugs. Because of favorable effects of beta-blockers on survival and disease progression, treatment with a beta-blocker should be initiated as soon as left ventricular dysfunction is diagnosed.

The benefits of beta-blockade are well established. Beta-blockers are potentially usable by a majority of the HF population; they are effective in reducing mortality; and they are considered to be the most effective drugs overall for the treatment of HF. However, many patients who could potentially benefit from therapy are not being treated. It is estimated that approximately 40% of eligible HF patients in the U.S., and 50% in the European Union, are not being treated with beta-blockers. Further, it is believed that a substantial portion of patients being treated with beta-blockers are not receiving the target dose. Based on analysis of this market and expert opinion, we believe this lack of adoption may be due in part to the fact that a significant percentage of chronic heart failure patients do not tolerate one or more of the beta-blockers currently approved for HF, or do not respond well to them.

In addition, due to the fact that patients respond unevenly to beta-blockers, it is difficult to predict what a particular patient s response is likely to be in advance of therapy. This uncertainty creates special problems in the context of HF. The current standard of practice in administering a beta-blocker for HF involves a lengthy, often months-long, process in which the patient is gradually moved from a low initial dose up to one that has been proven to be clinically beneficial. This extended protocol is necessary because the therapeutic mechanism of this drug class inhibits processes in the failing heart that, while deleterious over the long term, initially provide support for diminished cardiac function. Thus, the dosage must be increased slowly to allow the patient to adjust to the therapy, and it may be months before it is known whether the patient will both tolerate the therapy and will benefit from it.

During this process, the patient may feel worse and exhibit no objective benefit. However, it can be difficult for the physician to determine whether this is due to the mechanism of the drug class, or whether it is a problem with the particular drug. A serious adverse event, such as hospitalization for an acute episode, or death, may be the first substantial evidence that the patient is not responding well to the particular therapy. We believe that many HF patients on beta-blockers never reach their target dose, whether due to actual side effects or the perception that the patient is not benefiting. Some patients simply do not respond after enduring this long and potentially difficult process. Unfortunately, the physician has no good method to determine, in advance of therapy, whether a patient is likely to benefit, introducing an element of trial and error into the use of these agents that is frustrating to prescribers, potentially harmful to patients, and costly to payors. We believe that a new HF therapy that includes a simple test to identify those patients likely to benefit, can help alleviate some of the problems encountered with the current standard of practice.

Gencaro

Gencaro (bucindolol hydrochloride) is a pharmacologically unique beta-blocker and mild vasodilator being developed for the treatment of chronic heart failure. Gencaro is considered part of the beta-blocker class because

Table of Contents

of its property of blocking both beta-1, or $ß_1$, and beta-2, or $ß_2$, receptors in the cardiac nervous system. The blocking of these receptors prevents binding with other molecules that serve to activate these receptors. Because of its mild vasodilator effects, we believe that Gencaro is well-tolerated in patients with advanced HF. 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 heart failure 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 the $ß_1$, and alpha2C, or a_{2C}, receptors, which are important receptors that regulate cardiac 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 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, heart failure progression and hospitalization, relative to the general patient population of the BEST trial. We believe that these genetically determined receptor variations, which are detectable using standard genetic 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 heart failure patients with Gencaro based on genetic testing in the U.S. and Europe.

Pharmacology and Pharmacogenetics

Gencaro s pharmacology appears to be different from other compounds in the beta-blocker class in two fundamental respects. First, studies conducted by our researchers indicate that in human myocardial preparations, Gencaro leads to inactivation of constitutively active (i.e. functional in the absence of bound agonist) $ß_1$ receptors through a mechanism separate from $ß_1$-blockade, in addition to inhibiting the binding activity of the $ß_1$ receptor like a typical beta-blocker. Second, these same studies indicate that Gencaro lowers the systemic levels of the neurotransmitter norepinephrine, or NE, which is released by cardiac and other sympathetic nerves. These two properties interact with common genetic variations in two cardiac receptors, the $ß_1$ and a_{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 $ß_1$ receptor found on muscle cells, or cardiac myocytes, of the heart. The general role of the $ß_1$ 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 β 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 heart failure patients the $ß_1$ receptor also initiates harmful, or cardiomyopathic, signaling which, over time, exacerbates the heart s functional and structural decline. Beta-blockers counteract this destructive process by reducing βreceptor 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 $ß_1$ receptors that are constitutively active (active in the absence of NE stimulation).

There are two common genetic variations of the $ß_1$ receptor, each of which we estimate is present in approximately 50% of the U.S. population. One of these variations is known as the β389 Arg/Arg variant. Laboratory studies indicate that this variation results in a higher functioning β receptor, one which has a greater ability to mediate the stimulatory effects of NE. In addition, this variation is also more likely to be constitutively active and signal the cardiac myocyte to contract in the absence of NE. The other variation, the β389 Gly carrier , also present in about 50% of the U.S. population, results in a $ß_1$ receptor that is much lower functioning and, according to laboratory studies, has less probability of being in a constitutively active state compared to the $ß_1$-389 Arg/Arg receptor.

Table of Contents

Gencaro has a powerful interaction with the higher-functioning ß$_1$-389 Arg/Arg variation of the ß$_1$ receptor. Laboratory studies show that constitutively active receptors will continue to signal in the presence of standard beta-blockade. Laboratory studies in isolated human heart preparations also show that Gencaro has the unusual ability of being able to stop the signaling of constitutively active receptors. We believe that individuals with the ß$_1$-389 Arg/Arg genotype potentially will recognize an enhanced therapeutic response to Gencaro because of the greater potential for active state, cardiomyopathic signaling among individuals with this genotype, and the larger reduction in signaling that these individuals experience when taking Gencaro, relative to individuals with the ß$_1$-389 Gly carrier genotype.

The efficacy of Gencaro also appears to be influenced by the a$_{2C}$ receptor, located on the terminus of the sympathetic cardiac nerve, at its junction with the cardiac myocyte. The role of this receptor is to modulate the amount of NE that is present at this junction, which in turn affects the activation of ß$_1$ receptors and the heart s activity. There are two important genetic variations of this receptor that appear to affect the performance of Gencaro; the deletion variant (approximately 10 - 13% of the general population in the U.S. has at least one copy of this modified a$_{2C}$ receptor) that functions poorly; and the a$_{2C}$-wild type (the remaining 85% of the population) a normal functioning version of this receptor. The DNA substudy of patients from the BEST trial conducted by Drs. Bristow and Liggett indicated that the deletion / wild type variant status of the a$_{2C}$ receptor appeared to only affect Gencaro responses when the ß$_1$-389 Gly variant is present, where the a$_{2C}$-wild type version of the a$_{2C}$ receptor enhances clinical response and the deletion variant reduces efficacy. When the Arg version of the ß$_1$ receptor is present (ß$_1$-389 Arg/Arg), the efficacy of Gencaro does not depend on which a$_{2C}$ receptor is present.

The DNA substudy from the BEST DNA bank 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 ß$_1$-389 Arg/Arg variant appeared to have the most powerful effect on Gencaro response. While we believe that the ß$_1$-389 Gly carrier patients may respond favorably to Gencaro depending on their a$_{2C}$ variation type, we believe that all patients that possess the ß$_1$-389 Arg/Arg variant may be candidates for Gencaro. The ß$_1$-389 Arg/Arg variant group, or very favorable group, constitutes an estimated 47-50% of the U.S. population. We believe these individuals may have an enhanced therapeutic response to Gencaro because of its effect on this higher-functioning/constitutively active ß$_1$ receptor variant, and a favorable response to NE lowering, regardless of their a$_{2C}$ receptor genotype. The additional clinical trial agreed upon with the FDA pursuant to the SPA will only enroll patients that possess this very favorable genotype.

The BEST Trial

The BEST trial began in 1995. It was a double-blind, placebo-controlled, multi-center study of bucindolol on mortality and morbidity in an advanced chronic heart failure population. The primary endpoint of the BEST trial was total mortality and the pre-specified main secondary endpoint was progression of heart failure, defined as heart failure death, cardiac transplant, heart failure hospitalization, or emergency room visit for the treatment of worsening heart failure not requiring hospitalization. The trial was planned to run four and one-half years, and enroll 2,800 patients. The trial enrolled a total of 2,708 chronic heart failure 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 HF patient. Positive mortality results from two other heart failure 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

Table of Contents

the trial, which threatened to destroy the trial s integrity. 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 total mortality. 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 FDA approved, pre-specified statistical analysis plans, which had not been performed by the sponsors when the BEST trial was terminated. As reanalyzed, there appeared to be a 13% risk reduction on the primary endpoint of all-cause mortality in the BEST trial with a p-value of 0.053.

Clinical Results and the DNA Substudy

In 2003 and 2004, the results of the DNA substudy conducted by Drs. Bristow and Liggett began to be released and analyzed. The DNA substudy results indicated a significant enhancement of response on the major clinical endpoints from the BEST trial in patients with the very favorable genotype. The risk reduction on clinical efficacy endpoints such as mortality and hospitalization ranged from approximately 34% to approximately 48% in this genotype. In addition, in arrhythmia endpoints of atrial fibrillation or ventricular fibrillation tracked by safety analyses, the risk reduction by bucindolol in the very favorable genotype appeared to be even greater, by 62-70%.

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

BEST Clinical Responses[1] by Genotype Groups

Endpoint (% of study population)	**Very Favorable patients (47%)**	**Favorable patients (40%)**	**Unfavorable patients (13%)**
All Cause Mortality (ACM), TTE	**38%***	25%	4%
Cardiovascular Mortality (CVM), TTE	**48%***	40%*	11%
ACM + transplantation	**43%***	24%	4%
Heart failure (HF) Progression	**34%****	20%	1%
HF Hosp days/patient	**48%****	17%	19%
AF prevention (from AE db)	**71%***	11%	4%
VT/VF prevention (from AE db)	**62%****	44%	9%

1 Covariate adjusted, transplant censored analysis

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

Clinical and Regulatory Strategy

In September 2008, the FDA formally accepted for filing our NDA for Gencaro as a potential treatment for HF, based on the BEST trial. On May 29, 2009, the FDA issued a CRL to us in which the FDA stated that it could not approve the Gencaro NDA in its current form no change and specified additional actions and information required for approval of the NDA. In the CRL, the FDA raised clinical effectiveness issues, asserting that the BEST trial did not adequately demonstrate efficacy of Gencaro in reducing all-cause mortality in HF patients. The CRL stated that in order to obtain approval of Gencaro, we must conduct an additional Phase 3 clinical trial of Gencaro in HF patients, among other things.

In May 2010, we reached agreement with the FDA on an SPA on the design of a clinical trial to assess the safety and efficacy of Gencaro for approximately 3,200 patients with chronic heart failure who have the genotype that appears to respond most favorably to Gencaro. An SPA is an agreement with the FDA that the proposed trial protocol design, clinical endpoints and statistical analyses are acceptable to support regulatory approval. The trial protocol includes a superiority comparison of bucindolol to the beta-blocker metoprolol CR/XL, which is approved for heart failure and other indications. The primary endpoint of the trial is a composite of cardiovascular mortality and cardiovascular hospitalization. The trial protocol includes two interim data analyses

Table of Contents

at pre-specified numbers of primary endpoints. If the results of either of the interim analyses meet the pre-specified criteria, we believe that a complete response to the FDA s CRL could be formally submitted at that time and the results of the interim analysis could serve as the clinical effectiveness basis for FDA approval. The first interim data analysis is planned at 630 primary endpoint events (57% of the projected total number). The trial protocol estimates reaching the first interim analysis 24-30 months into the trial. Even with a positive outcome at either interim analysis, the planned trial is designed to proceed to conclusion, estimated to take 3.5 years (including the time to reach the interim analysis). In order not to influence the planned trial s subsequent completion, even if the results of an interim data analysis are adequate to support approval of Gencaro, Gencaro would not be commercially available until after the conclusion of the trial. We currently expect we could begin the trial approximately one year after obtaining sufficient funding.

We believe that Gencaro will demonstrate superiority benefits compared to metoprolol CR/XL based on the following observations:

- Gencaro has been shown to produce enhanced benefits in patients that possess the $ß_1$-389 Arg/Arg polymorphism. Metoprolol CR/XL has not demonstrated a similar enhancement. Three studies have looked at the potential relationship between the presence of $ß_1$-389 Arg/Arg genotype and outcomes in patients treated with metoprolol CR/XL, and have failed to show correlation. We believe that this is likely related to the absence of an inverse agonism effect (the ability of being able to stop the signaling of constitutively active receptors) by metoprolol CR/XL at the $ß_1$-389 Arg/Arg receptor.

- In post-hoc analyses, patients in the overall BEST trial population that had similar clinical characteristics at baseline to the patients that were studied in the metoprolol and carvedilol pivotal trials derived similar benefits from Gencaro compared to those from carvedilol or metoprolol in their respective clinical trials. Therefore, we believe that Gencaro, even without identifying patients that are likely to experience an enhanced response, would produce comparable benefits to the other agents if used in similar patients. Based on this rationale, we believe that identifying likely responders through pharmacogenetic targeting would lead to more favorable outcomes in the group that is randomized to Gencaro.

- Patients treated in the BEST trial, which was performed primarily in the U.S., appeared to have superior mortality outcomes than patients treated in the U.S. with metoprolol CR/XL in the MERIT-HF trial. The MERIT-HF trial was a double-blind, placebo-controlled trial that enrolled nearly 4,000 patients from multiple countries, which was the basis of approval for the heart failure indication for Toprol-XL, the branded version of metoprolol CR/XL. The observation with U.S.-treated patients in the MERIT-HF trial prevented the sponsor from obtaining an FDA indication to reduce all-cause mortality with Toprol-XL.

For the planned trial, we based the trial size assumptions on the experience from the BEST clinical trial, as well as from the other trials that investigated beta blockade in heart failure. Based on event rate estimates from these trials and the expected reduction in events from Gencaro, we believe that a 3,200 patient trial will provide sufficient power to show a statistically and clinically significant benefit. We cannot be certain that the design of, or data collected from, the trial will be adequate to address the concerns raised by the FDA in the CRL or obtain the requisite regulatory approvals for Gencaro.

The FDA has designated the investigation of Gencaro for the reduction of cardiovascular mortality and cardiovascular hospitalizations in a genotype-defined heart failure population as a fast track development program. Fast track drug development designation is included in the FDA Modernization Act of 1997 as a formal process to enhance interactions with the FDA during drug development. Fast track drug development programs are reserved for drugs that are intended to treat serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs. A drug development program with fast track designation would be eligible for consideration for some or all of the following programs for expediting development and review: scheduled meetings to seek FDA input into development plans, priority review of the NDA, the option of

Table of Contents

submitting portions of an NDA prior to submission of the complete application and potential accelerated approval. Although the FDA has designated the investigation of Gencaro as a fast track development program, such designation does not provide any assurance that Gencaro will receive FDA approval, and such designation does not constrain the FDA s ability to deny approval for Gencaro.

In addition to requiring an additional efficacy trial of Gencaro, the CRL also required additional actions and raised additional issues. The CRL stated that we must conduct additional clinical pharmacology studies to address drug-drug interaction and pharmacokinetic issues, and additional non-clinical studies to further characterize Gencaro metabolites. If we reach agreement with the FDA on the CRL response strategy, we plan to submit a complete response to the CRL, except for the data from the Phase 3 trial as permitted under the rules of the fast track designation.

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; 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, we will owe CPEC a milestone payment of $8.0 million, which is due within six months after FDA approval. We also have the obligation under the CPEC license to make milestone payments of up to $5.0 million in the aggregate upon regulatory marketing approval in Europe and Japan. Under the CPEC and BMS licenses, our 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. We have 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.

We also have licensed worldwide rights to intellectual property covering the pharmacogenetic response of bucindolol hydrochloride 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.

The Gencaro Test

If cleared or approved, we believe that Gencaro will be the first cardiovascular drug to be integrated with a companion diagnostic to predict enhanced efficacy. 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 believe it is critical to the successful commercialization of Gencaro to develop a companion genetic test that is simple to administer and widely available.

We have collaborated with LabCorp to develop and commercialize the Gencaro Test. Under the terms of the collaboration, we have licensed to LabCorp certain rights to commercialize a receptor genotype diagnostic for the $ß_1$ and a_{2C} polymorphisms. In return, LabCorp has agreed to develop the Gencaro Test, obtain FDA clearance or approval of the Gencaro Test, and commercially launch the Gencaro Test in parallel with the commercial launch of Gencaro. The license agreement has a term of 10 years. Either party has the right to terminate the agreement.

LabCorp has developed the commercial method for the Gencaro Test, which will use a blood draw to obtain a sample. We believe that the Gencaro Test involves a straightforward genetic test that relies on well-validated technology. Based on FDA guidance, LabCorp has submitted a Premarket Approval, or PMA, regulatory submission, which was formally accepted by the FDA in January 2009 and the review was granted an extension

Table of Contents

until March 2010. LabCorp has voluntarily withdrawn the PMA and we have been informed that they plan to resubmit it when the complete response to the Gencaro NDA CRL is submitted, which will occur no earlier than after the first interim analysis of the additional Phase 3 trial. We and LabCorp believe that no further clinical trials will be required for the Gencaro Test PMA submission, though there is no guarantee that FDA will not require additional clinical data.

Development Pipeline

Our development activities are substantially focused on our lead product candidate, Gencaro. We believe Gencaro may have potential for the prevention of atrial fibrillation, and/or ventricular tachycardia/ventricular fibrillation, which could be attractive indications. We believe that data from the BEST trial suggest that Gencaro has potential to address these indications, and that the clinical response of patients with these diseases may be genetically influenced, based on the same genetic markers that we believe affect Gencaro s response in HF patients.

We are pursuing opportunities to leverage certain of our development-stage product candidates, which, due to limited resources, are not currently being developed. Our development pipeline includes:

rNAPc2, a single-chain, small recombinant protein, originally isolated from the saliva of the canine hookworm. rNAPc2 is a potent, long acting, and selective inhibitor of tissue factor, the protein responsible for initiating the extrinsic coagulation pathway, the primary coagulation mechanism in humans. rNAPc2 was originally developed as a cardiovascular therapy for thrombosis and other indications. As a result, it has been safely tested in over 700 human patients in nine Phase 1 and Phase 2 clinical trials. Previously, pilot studies of rNAPc2 conducted in non-human primates demonstrated potential efficacy against two of the most deadly strains of hemorrhagic fever virus, Ebola and Marburg. We are currently seeking government funding to further develop rNAPc2, as a potential treatment for viral hemorrhagic fevers. Considering the substantial cost associated with the development of rNAPc2 and our limited financial resources, further development of rNAPc2 will be dependent upon receipt of government funding, which may not be available.

Competition

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.

If approved, Gencaro will compete against existing beta-blockers approved for HF and their generic equivalents. Currently, there are two beta-blockers (three branded formulations) approved for the treatment of HF in the U.S.:

- Toprol-XL®;
- Coreg® and Coreg CR® (a sustained release formulation)

Toprol-XL and immediate release Coreg have generic equivalents commercially available in the U.S. (Metoprolol Succinate and Carvedilol respectively). It is anticipated that both of these generic equivalents will be priced at less than the price of Gencaro. Additionally, Gencaro may also compete against existing therapies whose follow-on indications may include treatment for HF.

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.

Table of Contents

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 Phase 3 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 additional Phase 3 trial.

Our manufacturing focus for 2011 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 additional Phase 3 trial, if sufficient funding is obtained.

Research and Development Expenses

Our research and development expenses totaled $3.1 million for the year ended December 31, 2010 as compared to $10.0 million for 2009, a decrease of approximately $6.9 million. Research and development costs associated with the development of Gencaro decreased $4.7 million for 2010 year compared to 2009 and decreased $2.2 million related to other compounds.

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.

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.

The steps required before new human therapeutic 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.

Table of Contents

Preclinical Phase. Preclinical studies are generally conducted in the laboratory to evaluate the potential efficacy and safety of a product candidate. These studies include laboratory evaluation of product chemistry, formulation and stability, as well as studies to evaluate toxicity in animals. Preclinical studies are governed by numerous regulations.

Clinical Phase. Before human clinical trials can commence, an Investigational New Drug, or IND, application, submitted to FDA must become effective. 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.

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. In September 2008, the FDA formally accepted for filing our NDA for Gencaro as a potential treatment for chronic heart failure, based on the BEST trial.

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. The PDUFA date for Gencaro was May 31, 2009. On May 29, 2009, the FDA issued a CRL to us in which the FDA stated that it could not approve the Gencaro NDA in its current form, and specified additional actions and information required for approval of the NDA, including conducting an additional Phase 3 clinical trial of Gencaro in patients with heart failure.

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 with p-values of less than 0.05 on the primary endpoint.

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. 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 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

Table of Contents

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. Although there are some centralized procedures for filings in the European Union countries, in general each country has its own procedures and requirements.

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 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 label. We would be responsible for compliance with such requirements and would be responsible to ensure that all contract manufacturing organizations who perform work for us also comply with such requirements. 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 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

Table of Contents

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 date a patent application was filed, 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, generally extends the term of an issued patent for 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 one U.S. patent (U.S. Patent No. 7,678,824), or the 824 patent, and have filed two patent applications that concern methods for treating patients with bucindolol based on the presence of certain polymorphisms in the $ß_1$ and/or a_{2C} adrenergic receptors. We believe that, if approved by the FDA, the 824 patent may be eligible for PTE, which could provide approximately 3 years of additional patent life.

Patent Term Extension, known as a Supplementary Protection Certificate, or SPC, is also available for pharmaceutical products approved for marketing in the European Union. We obtained a patent in Europe on methods for using bucindolol that is similar to the 824 patent (EP 1802775), and 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 bucindolol is approved for marketing in any European country in which the patent is in force, and 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.

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

Table of Contents

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 Approval of Medical Devices

Based on FDA guidance, LabCorp has submitted a PMA regulatory submission, which was formally accepted by the FDA in January 2009 and the review was granted an extension until March 2010. LabCorp has voluntarily withdrawn the PMA and we have been informed that they plan to resubmit it when the complete response to the Gencaro NDA CRL is submitted, which will occur no earlier than after the first interim analysis of the additional Phase 3 trial.

Unless an exemption applies, each medical device that a company wishes to market in the U.S. will require either approval of a PMA or 510(k) clearance 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. This process is generally known as 510(k) clearance. 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. 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, but it may take significantly longer.

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

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, LabCorp will be responsible for compliance with such requirements. The FDA has broad post-market and regulatory enforcement powers. Accordingly, LabCorp s facilities and the manufacturing facilities of certain of its suppliers will be subject to inspections by the FDA to determine those facilities level of compliance with various regulations.

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.

Table of Contents

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.

In addition to protection under data exclusivity statutes, we believe that Gencaro s patent portfolio will extend its market exclusivity. We have received patents in the United States and Europe that claim the use of Gencaro with the genetic polymorphisms of the $ß_1$ and a_{2C} receptors that predict Gencaro response. We believe that this patent strategy will effectively serve to exclude generic competition. 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 2025. In addition, we believe that if Gencaro is approved, the U.S. Gencaro patent, as well as the patents issued in Europe, will be eligible for patent term extension which, if granted in the U.S., could provide an additional period of market exclusivity in the U.S. of approximately three years, and if granted in Europe could provide an additional five years of market exclusivity. 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 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, 2010, we had 22 employees, of which 21 were full-time employees. Most of these employees operate out of the Broomfield, Colorado location while others operate from home-based offices in other states. None of our employees are represented by any collective bargaining unit. We believe that we maintain good relations with our employees.

Corporate Information

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

Table of Contents

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. 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.

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.

Table of Contents

Item 1A. ***Risk Factors***
Risks Related to Our Business and Financial Condition

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

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

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

On May 29, 2009, the FDA issued a Complete Response Letter, or CRL, to us in which the FDA stated that it could not approve the Gencaro NDA in its current form, and specified additional actions and information required for approval of the NDA, including conducting an additional Phase 3 clinical trial of Gencaro in patients with heart failure. In the second quarter of 2010, we reached agreement with the FDA regarding the special protocol assessment, or SPA, on the design of a clinical trial to assess the safety and efficacy of Gencaro in approximately 3,200 patients with chronic heart failure who have the genotype that appears to respond most favorably to Gencaro. We estimate the trial will take approximately 3.5 years (including the time to reach the interim analysis). We currently expect we could begin the trial approximately one year after obtaining sufficient funding.

In light of the expected development timeline to potentially obtain FDA approval for Gencaro, if at all, the substantial additional costs associated with the development of Gencaro, including the costs associated with the additional additional clinical trial, the substantial cost of commercializing Gencaro, if it is approved, and the need to raise a significant amount of capital on acceptable terms to finance the additional clinical trial and our ongoing operations, in 2009, we reduced our operating expenses, suspended significant expenditures on our development activities for programs other than Gencaro, and began evaluating strategic alternatives. Such activities were ongoing during 2010. We will need to complete a strategic transaction, such as a strategic combination or partnership, or raise substantial additional funding through public or private debt or equity securities or government funding to support the continued development of Gencaro, including the additional clinical trial. Even if we are able to fund continued development and Gencaro is approved, we expect that we will need to

Table of Contents

complete a strategic transaction or raise substantial additional funding through public or private debt or equity securities to successfully commercialize Gencaro. To preserve our capital resources, in February 2011, we reduced our research and development and general and administrative workforce by 36%. The reduction is expected to reduce our projected cash use by approximately $200,000 per quarter.

Our current equity distribution agreement with Wedbush Securities, Inc., may not provide us with access to additional capital. We currently have $12.5 million available for sale under the equity distribution agreement, but Securities Exchange Commission and Nasdaq Stock Market regulations may allow us to sell only a portion of the full amount in any particular twelve month period. As of March 1, 2011, we were unable to sell any common stock under the equity distribution agreement pursuant to applicable regulations. As of April 1, 2011, we estimate that we could sell up to approximately $6.3 million of common stock under the equity distribution agreement, but that amount may be reduced in the future.

We currently believe our cash and cash equivalents balance as of December 31, 2010 will be sufficient to fund our operations through September 30, 2011. 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, 2011. As a result of the significant additional required development of Gencaro, including the additional clinical trial, we may not be able to raise sufficient capital on acceptable terms, or at all, to continue development of Gencaro or to continue operations and may not be able to execute any strategic transaction. Changing circumstances may cause us to consume capital significantly faster or slower than we currently anticipate. We have based these estimates on assumptions that may prove to be wrong, and we could exhaust our available financial resources sooner than we currently expect.

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

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

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

Table of Contents

On March 7, 2011, the listing of our common stock was transferred from the Nasdaq Global Market to the Nasdaq Capital Market. If we are not able to maintain the requirements for listing on the Nasdaq Capital Market, we could be delisted, which could have a materially adverse effect on our ability to raise additional funds as well as the price and liquidity of our common stock.

The Nasdaq Global Market has certain compliance requirements for continued listing of common stock. Among other requirements, Nasdaq Rule 5450(b) requires that we keep a minimum stockholders equity of $10 million (the Rule). On November 17, 2010, we received a notice from the staff of the Nasdaq Stock Market (Nasdaq Staff) indicating that, as of September 30, 2010, we did not meet the minimum stockholders equity requirement. Subsequently, in accordance with the notice, we submitted a plan and other materials to the Nasdaq Staff, which outline the actions we have taken, or plan to take, to regain compliance with the Rule. On January 11, 2011, we received a letter from the Nasdaq Staff, which stated that they had granted us an extension of time to regain compliance with the Rule. On February 28, 2011, we applied to transfer the listing of our common stock to the Nasdaq Capital Market, which application was approved, and on March 7, 2011 our stock began trading on the Nasdaq Capital Market. There can be no assurances that we will continue to meet the requirements for continued listing on the Nasdaq Capital Market. The delisting of our common stock from a national exchange could materially adversely affect our access to the capital markets, and any limitation on market liquidity or reduction in the price of our common stock as a result of that delisting could adversely affect our ability to raise capital, if needed, on terms acceptable to us, or at all.

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

We are currently pursuing a strategic transaction, such as a potential combination or partnership. The failure to enter into a strategic transaction may materially and adversely affect our business.

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

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

Nasdaq rules impose restrictions on our ability to raise funds through a private offering of our common stock, convertible debt or similar instruments without obtaining stockholder approval. Under Nasdaq rules, an offering of more than 20% of our total shares outstanding for less than the greater of book or market value requires stockholder approval unless the offering qualifies as a public offering for purposes of the Nasdaq rules. As of December 31, 2010, we had 8,834,535 shares of common stock outstanding, 20% of which is approximately 1,766,907 shares. To the extent we seek to raise funds through a private offering of stock, convertible debt or similar instruments, we may be limited in how much funding we could raise privately without requiring a stockholder vote.

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. In September 2008, the FDA accepted for filing the Gencaro NDA. On May 29, 2009, the FDA issued a CRL to us in which the FDA stated that it could not approve the Gencaro NDA in its current form, and specified additional actions and information required for approval of the NDA, including conducting an additional Phase 3 clinical trial of Gencaro in patients with heart failure. In May 2010, we reached agreement with the FDA on an SPA on the design of a clinical trial to assess the safety and efficacy of Gencaro for approximately 3,200 patients with chronic heart failure who have the genotype that appears to respond most favorably to Gencaro. Clinical trials in heart failure are typically lengthy, complex and expensive and we do not currently have the resources to fund such a trial. Although the FDA has designated the investigation of Gencaro as a fast track development program, such designation does not provide any assurance that Gencaro will receive FDA approval, and such designation does not constrain the FDA s ability to deny approval for Gencaro.

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

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

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

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

The SPA does not guarantee any particular outcome from regulatory review of the clinical trial or Gencaro, including any regulatory approval.

FDA approval of Gencaro, if it occurs, is expected to require years of additional clinical development, including a new multi-year active comparator superiority trial involving approximately 3,200 patients in a genotype-defined heart failure population. The SPA process allows for FDA evaluation of a clinical trial protocol intended to form the primary basis of an efficacy claim in support of a new drug application, and provides a binding agreement that the design of the clinical trial, including trial size, clinical endpoints and/or data analyses, is acceptable to the FDA for the intended purpose. An SPA agreement is not a guarantee of approval, and we cannot assure you that the design of, or data collected from, the new Gencaro trial will be adequate to address the concerns raised by the FDA in the CRL or obtain the requisite regulatory approvals for Gencaro. Further, the SPA agreement is not binding on the FDA if public health concerns unrecognized at the time the SPA agreement is entered into become evident, other new scientific concerns regarding product safety or efficacy arise, or if we fail to comply with the agreed upon trial protocol. In addition, upon written agreement of both parties, the SPA agreement may be changed by us or the FDA, and the FDA retains significant latitude and discretion in interpreting the terms of an SPA agreement and the data and results from the planned Gencaro trial. As a result,

Table of Contents

we do not know how the FDA will interpret the parties respective commitments under the SPA agreement, how it will interpret the data and results from the planned Gencaro trial, or whether Gencaro will receive any regulatory approvals as a result of our SPA agreement with the FDA and the planned clinical trial.

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

We, and our collaborators, will only receive regulatory approval for our product candidates if we can demonstrate in carefully designed and conducted clinical trials that the product candidate is safe and effective. We do not know whether any future clinical trials, including the anticipated additional clinical trial for Gencaro, will demonstrate sufficient safety and efficacy to obtain the requisite regulatory approvals or will result in marketable products. Clinical trials are lengthy, complex and expensive processes with uncertain results. We have spent, and expect to continue to spend, significant amounts of time and money in the clinical development of our product candidates. We have never conducted a Phase 3 clinical trial and do not currently have sufficient staff with the requisite experience to do so, and we therefore expect that we will have to rely on contract research organizations to conduct certain of our clinical trials. While certain of our employees have experience in designing and administering Phase 3 clinical trials, these employees have no such experience since being with us.

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

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

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

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

We expect that we, or any strategic partners, will rely primarily on third parties to conduct clinical trials, including the Gencaro clinical trial we hope to begin pursuant to the specifications in the SPA. 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

Table of Contents

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.

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 submission of responses to the CRL, the commencement and completion of clinical trials, the disclosure of trial

Table of Contents

results, the obtainment of regulatory approval and the sale of drug product, which we sometimes refer to as milestones. These milestones may not be achieved, and the actual timing of these events can vary dramatically due to a number of factors such as delays or failures in our clinical trials, disagreements with current or future collaborative partners, the uncertainties inherent in the regulatory approval process and manufacturing scale-up and delays in achieving manufacturing or marketing arrangements sufficient to commercialize our products. FDA approval of Gencaro, if it occurs, is expected to require years of additional clinical development, including the completion of a new multi-year active comparator superiority trial involving approximately 3,200 patients in a genotype-defined heart failure population pursuant to the SPA agreed to by us and the FDA. There can be no assurance that our clinical trials will be completed, or that we will make regulatory submissions or receive regulatory approvals as planned. If we fail to achieve one or more of these milestones as planned, our business will be materially adversely affected.

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

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

To receive regulatory approval for the commercial sale of any product candidates, we must demonstrate safety and efficacy in humans to the satisfaction of regulatory authorities through preclinical studies and adequate and well-controlled clinical trials of the product candidates. This process is expensive and can take many years, and failure can occur at any stage of the testing. Our failure to adequately demonstrate the safety and efficacy of our product candidates will prevent regulatory approval and commercialization of such products. On May 29, 2009, the FDA issued a CRL to us in which the FDA stated that it could not approve the Gencaro NDA in its current form, and specified additional actions and information required for approval of the NDA including conducting an additional Phase 3 clinical trial of Gencaro in patients with heart failure. We reached agreement with the FDA regarding the SPA on the design of a clinical trial to assess the safety and efficacy of Gencaro in approximately 3,200 patients in a genotype-defined heart failure population. This product candidate will require years of additional clinical development. Even if we conduct additional studies in accordance with the SPA and submit the attendant data requested in the CRL, 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 incorrectly design or carry out human clinical trials 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 candidates 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 candidates. 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;

Table of Contents

- delays or failures in obtaining clinical materials and manufacturing sufficient quantities of the product candidate for use in trials;
- delays or failures in reaching agreement on acceptable terms with prospective study sites;
- delays or failures in obtaining approval of 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 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;

Table of Contents

- the fact that the FDA or other regulatory officials may not approve our or our third party manufacturer s processes or facilities; or

- the fact that new regulations may be enacted by the FDA or other regulators may change their approval policies or adopt new regulations requiring new or different evidence of safety and efficacy for the intended use of a product candidate.

In light of widely publicized events concerning the safety of certain drug products, regulatory authorities, members of Congress, the Government Accountability Office, medical professionals and the general public have raised concerns about potential drug safety issues. These events have resulted in the withdrawal of certain drug products, revisions to certain drug labeling that further limit use of the drug products and establishment of risk management programs that may, for instance, restrict distribution of drug products. The increased attention to drug safety issues may result in a more cautious approach by the FDA to clinical trials and approval. Data from clinical trials may receive greater scrutiny with respect to safety and the product s risk/benefit profile, which may make the FDA or other regulatory authorities more likely to terminate clinical trials before completion, or require longer or additional clinical trials that may result in substantial additional expense, and a delay or failure in obtaining approval or approval for a more limited indication than originally sought. Aside from issues concerning the quality and sufficiency of submitted preclinical and clinical data, the FDA may be constrained by limited resources from reviewing and determining the approvability of the Gencaro NDA in a timely manner.

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

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

Table of Contents

manufactured or promoted, often require FDA approval before the product, as modified, can be marketed. We and our third-party manufacturers will also be subject to ongoing FDA requirements for submission of safety and other post-market information.

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

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

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

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

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

- issue untitled or warning letters;
- suspend or withdraw our regulatory approval for approved products;

28.1

Table of Contents

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;

close the facilities of our contract manufacturers; or

impose civil or criminal penalties.

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

The drug label being sought for Gencaro would identify the patient receptor genotypes with a potential for enhanced efficacy, as well as those with a likelihood of a standard beta-blocker response and the smaller unfavorable subgroup with a low probability of benefit. Accordingly, we believe it will be critical to the successful commercialization of Gencaro to develop a companion genetic test, or the Gencaro Test, that is simple to administer and widely available.

The Gencaro Test is subject to regulation by the FDA and by comparable agencies in various foreign countries. The process of complying with the requirements of the FDA and comparable agencies is costly, time consuming and burdensome.

Under our agreement with LabCorp, LabCorp is responsible for determining the appropriate regulatory pathway for the Gencaro Test and obtaining market clearance or approval from the FDA. Based on FDA guidance, LabCorp submitted a PMA regulatory submission, which the FDA formally accepted in January 2009 and the review was granted an extension until March 2010. LabCorp has voluntarily withdrawn the PMA and we have been informed that they plan to resubmit it when the complete response to the Gencaro NDA CRL is submitted, which will occur no earlier than after the first interim analysis of the additional Phase 3 trial. The FDA may decide that the Gencaro Test should be evaluated for clearance under the FDA s 510(k) notification process. We and LabCorp do not believe that any further clinical trials will be required for the Gencaro Test PMA, though there is no guarantee that the FDA will not require additional clinical data.

Despite the time and expense expended, regulatory clearance or approval is never guaranteed. If regulatory clearance or approval is delayed, or if LabCorp is unable to obtain FDA approval of the Gencaro Test at all or in parallel with the approval of Gencaro, or is unable to commercialize the test successfully and in a manner that effectively supports the commercial efforts for Gencaro, or if the information concerning the differential response to Gencaro resulting from certain genetic variation is not included in the approval label for Gencaro, the commercial launch of Gencaro may be significantly and adversely affected. If we believe it is necessary to identify a new third-party test provider, obtaining regulatory approval for that provider s genetic test could substantially delay and negatively affect the commercial prospects for Gencaro and our ability to continue as a going concern.

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

Commercialization of Gencaro, particularly the establishment of a sales organization, will require substantial additional capital resources. We currently intend to pursue a strategic alternative for the

Table of Contents

commercialization of Gencaro, if it is approved, and we have suspended our efforts to build internal sales, marketing and distribution capabilities. If we elect to rely on third parties to sell Gencaro and any other products, then we may receive less revenue than if we sold such products directly. In addition, we may have little or no control over the sales efforts of those third parties.

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

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

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

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

We are dependent on our key personnel.

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

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

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

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

We do not currently operate manufacturing facilities for clinical or commercial production of our product candidates, including their active pharmaceutical ingredients, or API. We have no experience in drug formulation

Table of Contents

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 law 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.

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

Any medical device for which LabCorp obtains clearance or approval, and the manufacturing processes, reporting requirements, post-approval clinical data and promotional activities for such product, will be subject to continued regulatory review, oversight and periodic inspections by the FDA and other domestic and foreign regulatory bodies. With respect to the Gencaro Test, to the extent applicable, LabCorp and certain of its suppliers will be required to comply with the FDA s Quality System Regulation, or QSR, and International Standards Organization, or ISO, requirements which cover the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage and shipping of any product for which clearance or approval is obtained. Regulatory bodies, such as the FDA, enforce the QSR and other regulations

Table of Contents

through periodic inspections. The failure by LabCorp, or certain of its third-party manufacturers or suppliers, as the case may be, to comply with applicable statutes and regulations administered by the FDA and other regulatory bodies, or the failure to timely and adequately respond to any adverse inspectional observations or product safety issues, could result in, among other things, enforcement actions. If any of these actions were to occur, it could harm our reputation and cause product sales and profitability of Gencaro to suffer and may prevent us from generating revenue.

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

If LabCorp or certain of its third party suppliers fail to supply the Gencaro Test, we may be unable to obtain FDA approval for Gencaro or the product sales and profitability of Gencaro may suffer.

LabCorp is our single-source supplier of the Gencaro Test and has the right to terminate its agreement with us for any reason. If LabCorp or its third party suppliers were to terminate their agreements with us or cease or interrupt production of or otherwise fail to supply the Gencaro Test, or the materials required to produce it, in a timely manner, or at all, we could be unable to complete any additional clinical trials with Gencaro or to obtain a contract manufacturer of companion genetic test for Gencaro for an indeterminate period of time. This could adversely affect our ability to complete clinical development of Gencaro, including the additional clinical trial, or to commercialize Gencaro if it is ultimately approved, either of which could have an adverse effect on our financial condition and results of operations.

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

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

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

Development of sufficient and appropriate clinical protocols to demonstrate safety and efficacy are required, and we or LabCorp may not adequately develop such protocols to support clearance and approval. The trials will require the submission and approval of an investigational device exemption, or IDE, from the FDA. There is no guarantee that the FDA will approve LabCorp s or our future IDE submissions. Further, the FDA may require LabCorp or us to submit data on a greater number of patients than originally anticipated and/or for a longer

Table of Contents

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

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.

Table of Contents

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

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

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

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

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

One of our strategies is to license or acquire clinical-stage products or product candidates and further develop them for commercialization. The market for licensing and acquiring products and product candidates is intensely competitive and many of our competitors may have greater resources than us. If we undertake any additional acquisitions, whether of product candidates or other biopharmaceutical companies, the process of integrating an acquired product candidate or complementary company into our business may put a strain on our operations, divert personnel, financial resources and management s attention. In 2011, we expect our research and development activities, other than those associated with Gencaro, will be limited, unless government funding is received for the further development of rNAPc2. If we are not able to substantially expand our research and

34

Table of Contents

development efforts, or identify, or license or acquire other products or product candidates or complete future acquisitions, then we will likely be unable expand our pipeline of product candidates. In addition, any future acquisition would give rise to additional operating costs and will likely require us to seek additional financing. Future acquisitions could result in additional issuances of equity securities that would dilute the ownership of existing stockholders. Future acquisitions could also result in the incurrence of debt, contingent liabilities or the amortization of expenses related to other intangible assets, any of which could adversely affect our operating results.

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

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 determine to pursue regulatory approvals and commercialization of our product candidates internationally, we may not be able to obtain the required foreign regulatory approvals on a timely basis, if at all, and any failure to do so may cause us to incur additional costs or prevent us from marketing our products in foreign countries, which may have a material adverse effect on our business, financial condition and results of operations.

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

As a public company, we have incurred and will continue to incur significant levels of legal, accounting and other expenses. The Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, and related rules of the SEC and Nasdaq regulate corporate governance practices of public companies and impose significant requirements relating to disclosure controls and procedures and internal control over financial reporting. On July 21, 2010, the Dodd-Frank Wall Street Reform and Protection Act, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive compensation-related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas. Compliance with these public company requirements has increased our costs, required additional resources and made some activities more expensive and time consuming. We are required to expend considerable time and resources complying with public company regulations.

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

Section 404 of the Sarbanes-Oxley Act of 2002 requires us to evaluate the effectiveness of our internal control over financial reporting as of the end of each fiscal year, and to include a management report assessing the effectiveness of our internal control over financial reporting in our annual report on Form 10-K for that fiscal year. Our management, including our chief executive officer and chief financial officer, does not expect that our internal control over financial reporting will prevent all error and all fraud. We have also recently reduced our overall staff, some of whom had responsibility for reviewing and maintaining our internal controls. These reductions may result in material weaknesses or deficiencies in our internal controls. 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

Table of Contents

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

We are party to securities litigation and defending these lawsuits could hurt our business. The volatility of the market price could engender additional class action securities litigation.

Following periods of volatility in the market price of a company s securities, class action securities litigation has often been instituted against such a company. This risk is especially acute for biotechnology companies, which have experienced greater than average stock price volatility in recent years and, as a result, have been subject to, on average, a greater number of securities class action claims than companies in other industries. Any such litigation instigated against us could result in substantial costs and a diversion of management s attention and resources, which could significantly harm our business, financial condition and operating results.

For example, in December 2006, after Nuvelo announced that alfimeprase did not meet its primary endpoint in the first of two planned Phase 3 trials for the treatment of acute peripheral arterial occlusion and in the first of two planned Phase 3 trials for the treatment of catheter occlusion, the closing price of one share of Nuvelo s common stock was $81 (as adjusted for the 20-to-1 reverse stock split) on the day of the announcement, as compared with a closing price of $391 (as adjusted for the 20-to-1 reverse stock split) on the trading day prior to the announcement. On February 9, 2007, Nuvelo and certain of Nuvelo s former and then current officers and directors were named as defendants in a purported securities class action lawsuit filed in the United States District Court for the Southern District of New York. The suit alleges violations of the Securities Exchange Act of 1934 related to the clinical trial results of alfimeprase, which Nuvelo announced on December 11, 2006, and seeks damages on behalf of purchasers of Nuvelo s common stock during the period between January 5, 2006 and December 8, 2006. Specifically, the suit alleges that Nuvelo misled investors regarding the efficacy of alfimeprase and the drug s likelihood of success. The plaintiff seeks unspecified damages and injunctive relief. Three additional lawsuits were filed in the Southern District of New York on February 16, 2007, March 1, 2007 and March 6, 2007, respectively. In July 2007, the Court granted Nuvelo s motion to transfer the cases to the Northern District of California. The cases were consolidated with the original lawsuit, and plaintiffs filed a consolidated complaint in the Northern District of California on November 9, 2007. Nuvelo filed a motion to dismiss plaintiffs consolidated complaint on December 21, 2007. On June 12, 2008, the Court held a hearing on the motion to dismiss. On December 4, 2008, the Court issued an order dismissing plaintiffs complaint, and granting leave to amend. On January 23, 2009, plaintiffs filed an amended complaint, alleging similar claims. On March 24, 2009, defendants filed a motion to dismiss the amended complaint. On July 15, 2009, the Court held a hearing on the motion to dismiss. On August 17, 2009, the Court granted in part and denied in part defendants motion. We filed our answer to plaintiff s complaint on October 1, 2009.

On December 29, 2010, we and the other defendants reached a settlement of the litigation with the plaintiffs, after participating in mediation before a retired federal judge. On February 25, 2011, the parties entered into a settlement agreement, which has been submitted to the Court for approval. Our insurance carriers have agreed to fund the settlement, subject to a reservation of rights by one carrier. If the Court approves the settlement, the litigation will be dismissed against all the defendants. Members of the class who participate in the settlement will provide a release to the defendants, which prevents them from ever asserting any related claims against the defendants. Members of the class, if any, who opt out of the settlement, would not be bound by this release. Although our insurance carriers have agreed to pay most of the legal fees that have been incurred in defending this litigation, we have separately agreed with our legal counsel to pay $167,000 in legal defense costs incurred on or before December 29, 2010, but only if we obtain additional funding of at least $10 million in 2011. If we do not obtain such additional funding in 2011, we will have no such payment obligation.

Table of Contents

In addition, Variagenics, with which Nuvelo merged in 2003, has been named as a defendant in a securities class action lawsuit alleging the failure to disclose additional and excessive commissions purportedly solicited by and paid to underwriters who are also named defendants in the lawsuit. Plaintiffs in the suit allege that underwriters took these commissions and in exchange allocated shares of Variagenics stock to their preferred customers through alleged agreements with these preferred customers that tied the allocation of initial public offering shares to agreements by the customers to make additional aftermarket purchases at pre-determined prices. As a result of Nuvelo s merger with Variagenics, we are obligated to continue to defend against this litigation. On April 1, 2009 the parties entered into a settlement agreement and have filed a motion to approve the settlement with the Court. On October 5, 2009, the Court approved the settlement agreement. Our share of the settlement is approximately $385,000. Although the settlement has been approved, it has been appealed by members of the class. We believe that any attorneys fees, loss or settlement payment with respect to this suit will be paid by our insurance provider. However, it is possible that we could be forced to incur material expenses in the litigation if the parties cannot complete a settlement, and, in the event of an adverse outcome, our business could be harmed.

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

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

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

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

Table of Contents

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 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

Table of Contents

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 patents issued valid. An adverse outcome could subject us to significant liabilities to third parties, require disputed rights to be licensed from third parties or require us to cease using such technology. Regardless of merit, the listing of patents in the FDA Orange Book for Gencaro may be challenged as being improperly listed. We may have to defend against such claims and possible associated antitrust issues. We could also incur substantial costs in seeking to enforce our proprietary rights against infringement.

While the composition of matter patents on the compound that comprises Gencaro have expired, we hold the intellectual property arising from the discovery of the interaction of Gencaro with the polymorphisms of the $ß_1$ and a_{2C} receptors. We have obtained patents that claim the use of Gencaro with the diagnosis of a patient s receptor genotype. Our NDA requested a label that will include a claim that efficacy varies based on receptor genotype and a recommendation in the prescribing information that prospective patients be tested for their receptor genotype. We believe that under applicable law, a generic bucindolol label would likely be required to include this recommendation as it pertains directly to the safe or efficacious use of the drug. Such a label could be considered as inducing infringement, carrying the same liability as direct infringement. If the label with the genotype information for Gencaro is not approved, or if generic labels are not required to copy the approved label, competitors could have an easier path to introduce bioequivalent products and our business may suffer. The approved label may not contain language covered by the patents, or we may be unsuccessful in enforcing them.

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

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

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

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

Table of Contents

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

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

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

Risks Related to Stock Price Volatility

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

Our executive officers, directors and their affiliates beneficially owned approximately 30% of our outstanding common stock as of December 31, 2010. 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 or rNAPc2;
- the results of our future clinical trials and any future NDAs of our current and future product candidates;

Table of Contents

- 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 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, including pursuant to our equity distribution agreement with Wedbush Securities Inc., could depress prevailing market prices of our common stock. As of December 31, 2010, we had 8,834,535 shares of common

stock outstanding. All of these shares are freely transferable without restriction or further registration under the Securities Act, except for shares held by 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 December 31, 2010, there were approximately 953,000 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.

Table of Contents

As of December 31, 2010, approximately 341,000 shares of our common stock were issuable upon the exercise of outstanding warrants, all of which were exercisable as of this date. 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.

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
- 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.

Table of Contents

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 15,000 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***

On February 9, 2007, Nuvelo and certain of Nuvelo s former and then current officers and directors were named as defendants in a purported securities class action lawsuit filed in the United States District Court for the Southern District of New York. The suit alleges violations of the Securities Exchange Act of 1934 related to the clinical trial results of alfimeprase, which Nuvelo announced on December 11, 2006, and seeks damages on behalf of purchasers of Nuvelo s common stock during the period between January 5, 2006 and December 8, 2006. Specifically, the suit alleges that Nuvelo misled investors regarding the efficacy of alfimeprase and the drug s likelihood of success. The plaintiff seeks unspecified damages and injunctive relief. Three additional lawsuits were filed in the Southern District of New York on February 16, 2007, March 1, 2007 and March 6, 2007, respectively. In July 2007, the Court granted Nuvelo s motion to transfer the cases to the Northern District of California. The cases were consolidated with the original lawsuit, and plaintiffs filed a consolidated complaint in the Northern District

of California on November 9, 2007. Nuvelo filed a motion to dismiss plaintiffs consolidated complaint on December 21, 2007. On June 12, 2008, the Court held a hearing on the motion to dismiss. On December 4, 2008, the Court issued an order dismissing plaintiffs complaint, and granting leave to amend. On January 23, 2009, plaintiffs filed an amended complaint, alleging similar claims. On March 24, 2009, defendants filed a motion to dismiss the amended complaint. On July 15, 2009, the Court held a hearing on the motion to dismiss. On August 17, 2009, the Court granted in part and denied in part defendants motion. We filed our answer to plaintiff s complaint on October 1, 2009.

Table of Contents

On December 29, 2010, we and the other defendants reached a settlement of the litigation with the plaintiffs, after participating in mediation before a retired federal judge. On February 25, 2011, the parties entered into a settlement agreement, which has been submitted to the Court for approval. Our insurance carriers have agreed to fund the settlement, subject to a reservation of rights by one carrier. If the Court approves the settlement, the litigation will be dismissed against all the defendants. Members of the class who participate in the settlement will provide a release to the defendants, which prevents them from ever asserting any related claims against the defendants. Members of the class, if any, who opt out of the settlement, would not be bound by this release. Although our insurance carriers have agreed to pay most of the legal fees that have been incurred in defending this litigation, we have separately agreed with our legal counsel to pay $167,000 in legal defense costs incurred on or before December 29, 2010, but only if we obtain additional funding of at least $10 million in 2011. If we do not obtain such additional funding in 2011, we will have no such payment obligation.

In addition, on or about December 6, 2001, Variagenics, Inc. was sued in a complaint filed in the United States District Court for the Southern District of New York naming it and certain of its officers and underwriters as defendants. The complaint purportedly is filed on behalf of persons purchasing Variagenics stock between July 21, 2000 and December 6, 2000, and alleges violations of Sections 11, 12(a)(2) and 15 of the Securities Act of 1933, as amended and Section 10(b) of the Securities Exchange Act of 1934, as amended, and Rule 10b-5 promulgated thereunder. The complaint alleges that, in connection with Variagenics July 21, 2000 initial public offering, or IPO, the defendants failed to disclose additional and excessive commissions purportedly solicited by and paid to the underwriter defendants in exchange for allocating shares of Variagenics stock to preferred customers and alleged agreements among the underwriter defendants and preferred customers tying the allocation of IPO shares to agreements to make additional aftermarket purchases at predetermined prices. Plaintiffs claim that the failure to disclose these alleged arrangements made Variagenics registration statement on Form S-1 filed with the SEC in July 2000 and the prospectus, a part of the registration statement, materially false and misleading. Plaintiffs seek unspecified damages. On or about April 19, 2002, an amended complaint was filed which makes essentially the same allegations. We are involved in this litigation as a result of Nuvelo s merger with Variagenics in January 2003. On April 1, 2009, the parties entered into a settlement agreement. On October 5, 2009, the Court approved the settlement agreement. Our share of the settlement is approximately $385,000. Although the settlement has been approved, it has been appealed by members of the class. We believe that any attorneys fees, loss or settlement payment with respect to this suit will be paid by our insurance provider. However, it is possible that we could be forced to incur material expenses in the litigation if the parties cannot complete a settlement, and, in the event of an adverse outcome, our business could be harmed.

Item 4. ***Removed and Reserved***

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 Global Market:

	High	Low
Year ended December 31, 2010		
First quarter	$ 9.23	$ 2.60
Second quarter	6.06	3.38
Third quarter	4.31	3.01
Fourth quarter	4.38	3.00
Year ended December 31, 2009		
First quarter	$ 6.60	$ 2.00
Second quarter	13.45	2.50
Third quarter	4.88	2.20
Fourth quarter	4.50	2.21

Stockholders

As of March 7, 2011, we had approximately 139 stockholders of record of our common stock, and the last sale price reported on the Nasdaq Capital Market for our common stock was $3.01 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, 2010, 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

None.

Issuer Purchases of Equity Securities

None.

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

Not applicable.

45

Table of Contents

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 identified by words including anticipate, plan, believe, intend, estimate, expect, should, may, potential and sim expressions. 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. 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 heart failure and other cardiovascular diseases. Our lead product candidate is Gencaro™ (bucindolol hydrochloride), a pharmacologically unique beta-blocker and mild vasodilator being developed for the treatment of chronic heart failure, or HF. We have collaborated with LabCorp to develop the Gencaro Test, a companion test for the genetic markers that may predict clinical response to Gencaro.

We have identified common genetic variations in the cardiovascular system that we believe interact with Gencaro s pharmacology and may predict patient response to Gencaro treatment. We currently hold worldwide rights to Gencaro and have been granted patents in the U.S. and Europe for methods of treating heart failure patients with bucindolol based on genetic testing, which we believe will provide market exclusivity for Gencaro into 2025 in those markets. In addition, we believe that if Gencaro is approved, the U.S. Gencaro patent, as well as the patent issued in Europe, will be eligible for patent term extension which, if granted in the U.S., could provide an additional period of market exclusivity in the U.S. of approximately three years, and if granted in Europe could provide an additional five years of market exclusivity.

Gencaro has been the subject of extensive clinical development, culminating in a Phase 3 heart failure study known as the BEST trial. In September 2008, the U.S. Food and Drug Administration, or FDA, formally accepted for filing our New Drug Application, or NDA, for Gencaro as a potential treatment for HF. In May 2009, the FDA notified us through a Complete Response Letter, or CRL, that our NDA for Gencaro was not approvable in its current form, and specified additional actions and information required for approval of the NDA including the need for an additional Phase 3 clinical trial as described below. In May 2010, we reached agreement with the FDA on a Special Protocol Assessment, or SPA, for the design of an additional Phase 3 clinical trial to assess the safety and efficacy of Gencaro in approximately 3,200 patients with chronic heart failure who have the genotype that appears to respond most favorably to Gencaro. We believe that the SPA would permit this trial, if successful, to serve as the clinical effectiveness basis for the approval of Gencaro. The trial is designed as an international, multi-center, randomized, double-blind clinical trial. The trial is intended to be a superiority comparison of Gencaro to the beta-blocker metoprolol CR/XL, which is approved for heart failure and other indications. The primary endpoint of the trial is a composite of cardiovascular mortality and cardiovascular hospitalization. The trial protocol includes two interim data analyses at pre-specified numbers of primary endpoint events. If the results of either interim analysis meet the pre-specified criteria, we believe that a complete response to the CRL could be formally submitted at that time. The first interim data analysis is planned at 630 primary endpoint events (57% of the projected total number). The trial protocol estimates reaching the first interim analysis 24-30 months into the trial. Even with a positive outcome at either interim analysis, the planned trial is designed to proceed to conclusion, estimated to take 3.5 years (including the time to reach the

Table of Contents

interim analysis). In order not to influence the planned trial s subsequent completion, even if the results of an interim data analysis are adequate to support approval of Gencaro, Gencaro would not be commercially available until after the conclusion of the trial. We currently expect we could begin the trial approximately one year after obtaining sufficient funding.

The investigation of Gencaro for the reduction of cardiovascular mortality and cardiovascular hospitalizations in a genotype-defined HF population was designated by the FDA as a fast track development program. According to the FDA s Fast Track Guidance document, fast track programs are designed to facilitate the development and expedite the review of new drugs that are intended to treat serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs.

We also hold exclusive rights to rNAPc2, a single-chain, small recombinant protein, originally isolated from the saliva of the canine hookworm. rNAPc2 is a potent, long acting, and selective inhibitor of tissue factor, the protein responsible for initiating the extrinsic coagulation pathway, the primary coagulation mechanism in humans. rNAPc2 was originally developed as a cardiovascular therapy for thrombosis and other indications. As a result, it has been safely tested in over 700 human patients in nine Phase 1 and Phase 2 clinical trials. Previously, pilot studies of rNAPc2 conducted in non-human primates demonstrated potential efficacy against two of the most deadly strains of hemorrhagic fever virus, Ebola and Marburg. We are currently seeking government funding to further develop rNAPc2, as a potential treatment for viral hemorrhagic fevers. Considering the substantial cost associated with the development of rNAPc2 and our limited financial resources, further development of rNAPc2 will be dependent upon receipt of government funding, which may not be available.

In light of the substantial additional time and costs associated with the development of Gencaro and the need to raise a significant amount of capital on acceptable terms to finance the additional clinical trial and our ongoing operations, we are evaluating strategic alternatives for funding continued operations and development programs. In 2010, we raised $7.2 million, net of offering costs, through the sale of our common stock pursuant to an equity distribution agreement, and we may seek additional funding that could allow us to operate while we continue to pursue strategic combination, partnering, additional financing and licensing opportunities. If we are delayed in completing or are unable to complete additional financing and/or a strategic transaction, we may discontinue our development activities or discontinue our operations. To preserve our capital resources, in February 2011, we reduced our research and development and general and administrative workforce by 36%. The reduction is expected to reduce our projected cash use by approximately $200,000 per quarter. We currently believe our cash and cash equivalents balance as of December 31, 2010 will be sufficient to fund our operations through September 30, 2011. 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, 2011. We may not be able to raise sufficient capital on acceptable terms, or at all, to continue development activities or to otherwise continue operations and may not be able to execute any strategic transaction. Changing circumstances may cause us to consume capital significantly faster or slower than we currently anticipate. We have based these estimates on assumptions that may prove to be wrong, and we could exhaust our available financial resources sooner than we currently expect.

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.

Table of Contents

Results of Operations

Research and Development Expenses

Research and development, or R&D, expense was $3.1 million for the year ended December 31, 2010 as compared to $10.0 million for 2009, a decrease of $6.9 million. R&D expense decreased by $2.2 million as a result of the discontinuation of clinical development projects, collaborative development arrangements and personnel costs assumed in the Merger with Nuvelo. R&D costs associated with the development of Gencaro decreased approximately $4.7 million in 2010 compared to 2009, primarily due to the following:

- Regulatory costs decreased $1.5 million, manufacturing and process controls costs decreased $970,000, and clinical costs decreased $478,000, primarily due to less activity in 2010 compared to 2009. In 2009, we incurred a higher level of costs in support of our NDA and subsequently in response to the CRL, which have decreased in 2010. Costs in these areas also decreased due to our change in strategy and restructuring plan implemented in the second quarter of 2009.

- Medical affairs expenses decreased $1.8 million from 2009 to 2010 due to our change in strategy and restructuring plan implemented in the second quarter of 2009.

Our R&D expenses are highly contingent upon our ability to complete a strategic transaction, raise substantial additional funding in combination with a strategic transaction or obtain government or third party funding. Should we receive funds from one or a combination of these sources, R&D expense in 2011 could be substantially higher than 2010 to support increased activities, otherwise, R&D expenses in 2011 are expected to decrease from 2010 levels as a result of our reduction in workforce implemented in February 2011.

Selling, General and Administrative Expenses

Selling, general and administrative expenses, or SG&A, primarily consist of personnel costs, consulting and professional fees, insurance, facilities and depreciation expenses, and various other administrative costs. Direct costs paid to third parties related to the Merger were classified as merger transaction costs on the consolidated statement of operations and costs of our restructuring plan implemented in the second quarter of 2009 are classified as restructuring expense on the consolidated statement of operations, and therefore are excluded from SG&A. Merger transaction costs and restructuring expenses are discussed below.

SG&A expenses were $6.1 million for the year ended December 31, 2010, compared to $12.8 million for 2009, a decrease of approximately $6.8 million.

The decrease in SG&A expenses for the year is comprised of the following:

- Commercialization infrastructure project costs and staffing reductions implemented as part of our change in strategy and restructuring plan in the second quarter of 2009 decreased expenses $1.8 million.

- Facilities costs decreased $1.6 million for the year ended December 31, 2010 due to the termination of two former Nuvelo leases in the third quarter of 2009.

- General and administrative personnel costs decreased $1.6 million for the year ended December 31, 2010 primarily due to merger-related transitional personnel costs and reductions due to the restructuring plan implemented in the second quarter of 2009.

- We incurred certain nonrecurring expenditures of $900,000 in the year ended December 31, 2009, primarily relating to professional and other related expenses incurred in connection with the Merger.

SG&A expenses for 2011 are expected to decrease from 2010 levels as a result of our reduction in workforce implemented in February 2011, but are somewhat contingent upon the cost of our efforts to complete a strategic transaction, raise substantial additional funding in combination with a strategic transaction or obtain government or third party funding.

Table of Contents

Merger Transaction Costs

During the year ended December 31, 2009, we expensed approximately $5.5 million in transaction costs related to the Merger. These costs are comprised primarily of financial advisory fees paid upon completion of the Merger and legal fees incurred in the first quarter of 2009 totaling approximately $3.8 million. Prior to December 31, 2008, we had incurred merger transaction expenses, including legal, accounting and due diligence costs of approximately $1.7 million. These costs were recorded on our consolidated balance sheet as deferred transaction costs on December 31, 2008. On January 1, 2009, as part of our adoption of Financial Accounting Standards Board Accounting Standards Codification Topic ASC 805, these deferred transaction costs were expensed.

Restructuring Expense, net

In the second quarter of 2009, we implemented a restructuring plan pursuant to which we terminated 44 employees from our research and development and selling, general and administrative functions. The restructuring plan was implemented in connection with our strategy to seek strategic alternatives for commercializing Gencaro, rather than establish our own internal sales, marketing and distribution capabilities and to lower operating expenses to preserve capital resources. As result of the restructuring plan, we recorded a restructuring charge of $1.2 million for personnel-related termination costs in the second quarter of 2009. In the third quarter of 2009, we reduced the restructuring charge by $120,000 due to a change in estimate of severance costs. We completed all payments associated with these restructuring charges in 2009.

During the third quarter of 2009, we negotiated early terminations of the lease obligations related to the facilities in Sunnyvale, CA and San Carlos, CA, which were assumed in the Merger, resulting in a net charge of approximately $1.2 million.

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

Loss on Impairment of In-process Research and Development

In the fourth quarter of 2009, we performed our annual test for impairment of the in-process research and development asset acquired in the Merger. The test considered multiple factors influencing the value of the assets including:

- the impact of capital market conditions, particularly increases in the cost of capital for the biopharmaceutical industry;
- the impact of delays in the drug development timeline, including, but not limited to,
  - the impact of the limited development activity subsequent to the Merger,
  - the impact on the drugs projected revenue as a result of a delay in commercialization, considering the fixed patent expiry, and
  - the impact of increased risk of competition; and
- the increasing likelihood of new healthcare legislation that could negatively impact the reimbursement and increase pricing pressure for the drug.

The evaluation of these factors, along with other uncertainties, lead us to believe that the in-process research and development asset no longer had value as the fair value indicated by our analysis was zero. Accordingly, we recorded a loss on impairment for the full balance of the asset totaling $6.0 million and wrote-off the related deferred tax liability of $2.3 million in the fourth quarter of 2009.

49

Table of Contents

Gain on Bargain Purchase

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, we recorded a gain on bargain purchase of $25.3 million for the year ended December 31, 2009 in connection with the Merger. This gain was largely determined by the trading price of Nuvelo s common stock on Nasdaq prior to the Merger, which we believed was the most reliable measure of the consideration effectively transferred to effect the acquisition of Nuvelo. We believe the gain on bargain purchase resulted from various factors that may have impacted the trading price of Nuvelo s common stock, including, without limitation, the significant declines in the securities markets during the fourth quarter of 2008; uncertainty concerning the combined entities ability to obtain regulatory approval of the Gencaro NDA, ability to successfully commercialize Gencaro, if approved, and to raise additional capital to support the commercialization of Gencaro and to fund other business objectives; uncertainty regarding the combined entity s ability to successfully integrate the business operations of Nuvelo; and uncertainty regarding the combined entities ability to further identify, develop and achieve commercial success for products and technologies; all of which may have impacted Nuvelo s market capitalization at the time the Merger was consummated.

Interest and Other Income

Interest and other income was $763,000 for the year ended December 31, 2010, as compared to $217,000 for 2009, representing an increase of $546,000. This increase is primarily comprised of grants totaling $489,000 under the Qualifying Therapeutic Discovery Project, provided under section 48D of the Internal Revenue Code and gains of $263,000 on the sale of marketable securities. These increases were offset by decreased investment income due to lower average investable balances. We expect interest income to be nominal in 2011 due to declining cash and investment balances and low investment yields.

Interest and Other Expense

Interest and other expense was $8,000 for the year ended December 31, 2010, as compared to $185,000 for 2009. The interest and other expense in 2009 was primarily comprised of interest on the outstanding indebtedness under the credit facility and convertible notes. The convertible notes were converted into common stock upon closing of the Merger on January 27, 2009. The outstanding indebtedness under the credit facility was repaid in full in July 2009. Based on our current capital structure, interest expense for 2011 is expected to be minimal.

Benefit from income taxes, net

Associated with the $6.0 million loss on impairment of the IPR&D asset, we wrote-off the related $2.3 million deferred tax liability. The write-off of the deferred tax liability was recorded as benefit from income taxes on the consolidated statement of operations.

Liquidity and Capital Resources

Cash and Cash Equivalents

	December 31, 2010	December 31, 2009
	(in thousands)	
Cash and cash equivalents	$ 7,025	$ 7,763

As of December 31, 2010, we had total cash and cash equivalents of $7.0 million, as compared to $7.8 million as of December 31, 2009. The net decrease of $738,000 is primarily due to $8.3 million of cash used for operating activities, offset by $7.2 million of net proceeds received from the sale of our common stock pursuant to an equity distribution agreement.

Table of Contents

Cash Flows from Operating, Investing and Financing Activities

	Year Ended December 31,	
	2010	2009
	(in thousands)	
Net cash (used in) provided by:		
Operating activities	$ (8,324)	$ (41,726)
Investing activities	265	45,635
Financing activities	7,321	(3,886)
Net (decrease) increase in cash and cash equivalents	$ (738)	$ 23

Net cash used in operating activities for the year ended December 31, 2010 decreased $33.4 million compared with the 2009 period primarily due to decreased R&D and SG&A expenses discussed above, and payments in the 2009 period of $11.4 million for lease terminations, $4.3 million for merger transaction costs and $4.0 million of restructuring costs.

Net cash flows provided by investing activities for the year ended December 31, 2009 was primarily due to $30.4 million of cash received from the Merger and $15.1 million of proceeds from the sale of marketable securities, also acquired in the Merger.

Net cash provided by financing activities for the year ended December 31, 2010 is comprised of $7.2 million of net proceeds from the sale of our common stock pursuant to an equity distribution agreement and $139,000 of proceeds received from upon exercise of stock options. For the year ended December 31, 2009, net cash used in financing activities was primarily due to repayments on the bank note.

Sources and Uses of Capital

Our primary sources of liquidity to date have been capital raised from issuances of shares of our common and preferred stock, issuance of convertible promissory notes, and funds provided by the Merger. The primary uses of our capital resources to date have been to fund operating activities, including research, clinical development and drug manufacturing expenses, license payments, and spending on capital items.

Considering the substantial additional time and costs associated with the development of Gencaro and our need to raise a significant amount of capital on acceptable terms to finance the additional clinical trial and our ongoing operations, we are evaluating strategic alternatives for funding our continued operations and development programs. We will need to complete a strategic transaction, such as a strategic combination or partnership, or raise substantial additional funding through public or private debt or equity securities or government funding to support the continued clinical development of Gencaro, including the additional clinical trial. In evaluating the substantial costs associated with development of rNAPc2 and our limited financial resources, further development of rNAPc2 will be dependent upon receipt of government funding, which may not be available.

On December 8, 2009, we entered into an equity distribution agreement, or the Agreement, with Wedbush Securities Inc., or the Agent, under which we may, from time to time, offer and sell our common stock through the Agent. On April 30, 2010, we amended the Agreement to permit us to sell up to an aggregate of $20 million in shares, which have been registered on a registration statement on Form S-3 (File No. 333-148288). Subject to the filing and effectiveness of a Registration Statement on Form S-3, additional sales of our common stock through the Agent, if any, will be made by means of ordinary brokers transactions on the Nasdaq market or otherwise at market prices prevailing at the time of sale, in block transactions, or as otherwise agreed upon by us and the Agent. The Agent will use commercially reasonable efforts to sell our common stock from time to time, based upon instructions from us, including any price, time or size limits or other customary parameters or

Table of Contents

conditions we may impose. We will pay the Agent a commission, or allow a discount, as the case may be, in each case equal to 4.5% of the gross sales proceeds of any common stock sold through the Agent, acting as an agent, under the Agreement. We may also sell shares of common stock to the Agent, as principal for its own account, at a price to be agreed upon at the time of sale. In the year ended December 31, 2010, we sold 1,164,600 shares of common stock under this Agreement and realized $7.2 million of proceeds, net of $338,000 of offering costs. Although, after giving effect to the Amendment, we have up to $12.5 million available under the Agreement, SEC and Nasdaq regulations may allow us to sell only a portion of the full amount in any particular twelve month period. As of March 1, 2011, we were unable to sell any common stock under the Agreement pursuant to applicable regulations. As of April 1, 2011, we estimate that we could sell up to approximately $6.3 million of common stock under the Agreement, which amount may be reduced or increased in the future.

In addition to the proceeds of the stock sales, we may seek additional funding that will allow us to continue operations while we pursue a strategic combination, partnering, additional financing and licensing opportunities. To preserve our capital resources, in February 2011, we reduced our research and development and general and administrative workforce by 36%. The reduction is expected to reduce our projected cash use by approximately $200,000 per quarter. We currently believe our cash and cash equivalents balance as of December 31, 2010 will be sufficient to fund our operations through September 30, 2011. 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, 2011. 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;
- potential receipt of government or third party funding to further develop Gencaro or rNAPc2;
- our ability to control costs associated with our operations;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights; and
- the terms and conditions of our existing collaborative and licensing agreements.

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

activities to conserve our cash resources.

Table of Contents

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 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 the 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.

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

We acquired a significant in-process research and development (IPR&D) asset through the Merger related to NU172, a direct acting thrombin inhibitor that had completed Phase 1 development for use as a short-acting anticoagulant during medical or surgical procedures. A valuation firm was engaged to assist us in determining the estimated fair value of this asset as of the acquisition date. The discounted cash flow model used in this valuation was highly sensitive to changes in the underlying assumptions. We were required to make significant judgments and estimates when determining the underlying assumptions, including, but not limited to:

- projected development costs, timing of such costs, and outcomes of clinical trials,
- projecting regulatory approvals,
- estimating future cash flows from product sales resulting from completed products and in-process projects, and
- developing appropriate discount rates and probability rates by project.

The IPR&D asset was considered an indefinite-lived intangible asset and was not subject to amortization. The annual test for impairment in 2009 was performed as of November 30, 2009. The impairment test consisted of a comparison of the fair value of the IPR&D with its carrying amount. The initial determination and subsequent evaluation for impairment of the IPR&D asset required management to make significant judgments and estimates. See Note 6 of Notes to the Consolidated Financial Statements included within Item 8 in this report for discussion of the loss on impairment recorded as a result of the annual test for impairment performed in the fourth quarter of 2009.

Long-Lived Assets and Impairments

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

Accrued Expenses

As part of the process of preparing 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.

Table of Contents

Accounting Standards Updates

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

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, 2010 and 2009, and the related consolidated statements of operations, preferred stock and stockholders equity (deficit), and cash flows for each of the years in the two-year period ended December 31, 2010 and for the period from December 17, 2001 (inception) to December 31, 2010. 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, 2010 and 2009, and the results of their operations and their cash flows for each of the years in the two-year period ended December 31, 2010 and for the period from December 17, 2001 (inception) to December 31, 2010, 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 8, 2011

Table of Contents

ARCA BIOPHARMA, INC.

(a development stage enterprise)

CONSOLIDATED BALANCE SHEETS

	As of December 31, 2010	2009
	(in thousands, except share and per share amounts)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 7,025	$ 7,763
Other current assets	137	195
Total current assets	7,162	7,958
Property and equipment, net	690	1,026
Other assets	304	388
Total assets	$ 8,156	$ 9,372
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 388	$ 533
Accrued compensation and employee benefits	175	241
Accrued expenses and other liabilities	506	756
Deferred rent, current portion	121	114
Total current liabilities	1,190	1,644
Deferred rent, net of current portion	195	316
Total liabilities	1,385	1,960
Commitments and contingencies		
Stockholders equity:		
Common stock, $0.001 par value; 100 million shares authorized at December 31, 2010 and December 31, 2009; 8,834,535 and 7,620,448 shares issued and outstanding at December 31, 2010 and December 31, 2009, respectively	9	8
Additional paid-in capital	65,072	57,294
Deficit accumulated during the development stage	(58,310)	(49,890)
Total stockholders equity	6,771	7,412
Total liabilities and stockholders equity	$ 8,156	$ 9,372

See accompanying Notes to Consolidated Financial Statements.

Table of Contents

ARCA BIOPHARMA, INC.

(a development stage enterprise)

CONSOLIDATED STATEMENTS OF OPERATIONS

	Year Ended December 31,		Period from December 17, 2001 (date of inception) to December 31, 2010
	2010	2009	
	(in thousands, except share and per share amounts)		
Costs and expenses:			
Research and development	$ 3,106	$ 10,010	$ 39,270
Selling, general and administrative	6,069	12,840	34,310
Merger transaction costs		5,470	5,470
Restructuring expense, net		2,413	2,413
Loss on impairment of in-process research and development		6,000	6,000
Total costs and expenses	9,175	36,733	87,463
Loss from operations	(9,175)	(36,733)	(87,463)
Gain on bargain purchase		25,282	25,282
Interest and other income	763	217	2,024
Interest and other expense	(8)	(185)	(434)
Loss before income taxes	(8,420)	(11,419)	(60,591)
Benefit from income taxes		2,281	2,281
Net loss	$ (8,420)	$ (9,138)	$ (58,310)
Less: Accretion of redeemable convertible preferred stock		(135)	(245)
Less: Deemed preferred stock dividend for additional common shares issuable under anti-dilution provisions		(781)	(781)
Net loss available to common stockholders	$ (8,420)	$ (10,054)	$ (59,336)
Net loss available to common stockholders per share:			
Basic and diluted	$ (0.99)	$ (1.42)	
Weighted average shares outstanding:			
Basic and diluted	8,506,320	7,092,318	

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

	Preferred Stock				Stockholders Equity (Deficit)				
	Series A Redeemable Convertible Preferred Stock		Series B Redeemable Convertible Preferred Stock					Deficit Accumulated During the	
	Shares	Amount	Shares	Amount	Common stock Shares	Amount	Additional Paid In Capital	Development Stage	Total
	(in thousands, except share and per share amounts)								
Balance, December 17, 2001 (date of inception)		$		$		$	$	$	$
Issuance of common stock to founders on December 31, 2002, for cash, at $0.06 per share					15,529		1		1
Net loss								(116)	(116)
Balance, December 31, 2003					15,529		1	(116)	(115)
Issuance of common stock on September 30, 2004, for cash, at $0.06 per share					118,319		7		7
Net loss								(511)	(511)
Balance, December 31, 2004					133,848		8	(627)	(619)
Issuance of common stock on January 3, 2005, for cash, at $0.06 per share					17,533		1		1
Issuance of common stock on January 3, 2005, upon conversion of notes payable and related accrued interest at $0.06 per share					17,867		1		1
Issuance of common stock on October 14, 2005, for intellectual property license rights, at $8.14 per share					5,419		44		44
Issuance of common stock on October 14, 2005, upon conversion of notes payable and related accrued interest					186,571		1,354		1,354
Net loss								(1,459)	(1,459)
Balance, December 31, 2005					361,238		1,408	(2,086)	(678)
Issuance of common stock on February 21, 2006, for intellectual property license rights, at $0.72 per share					104,229		75		75
Issuance of Series A on February 22, 2006, for cash, at $1.6265 per share	5,727,354	9,316							
Issuance of Series A on February 22, 2006, upon conversion of notes payable and related accrued interest, at $1.6265 per share	420,817	684							
Issuance of common stock upon exercise of stock options, for cash					48,111		3		3
Issuance of common stock on February 22, 2006, for intellectual property and product license rights, at $0.72 per share					83,443	1	59		60
Issuance of common stock on June 23, 2006, for intellectual property license rights, at $0.90 per share					15,028		15		15
Issuance of common stock on November 7, 2006, for intellectual property license rights, at $0.90 per share					229				
Issuance of Series A on December 8, 2006, for cash, at $1.6265 per share	3,074,086	5,000							

Series A offering costs		(98)						
Share-based compensation						39		39
Accretion of offering costs of redeemable convertible preferred stock		17				(17)		(17)
Net loss							(5,241)	(5,241)
Balance, December 31, 2006	9,222,257	14,919			612,278	1,582	(7,327)	(5,744)
Issuance of Series B convertible redeemable preferred stock, on May 31, 2007 for $2.439 per share			3,688,902	9,000				
Issuance of Series B convertible redeemable preferred stock, on December 28, 2007 for $3.253 per share			2,766,677	9,000				
Series B offering Costs				(147)				
Accretion of Series A offering costs		19				(19)		(19)
Accretion of Series B offering costs				18		(18)		(18)

Table of Contents

ARCA BIOPHARMA, INC.

(a development stage enterprise)

CONSOLIDATED STATEMENTS OF PREFERRED STOCK AND STOCKHOLDERS EQUITY (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)								
Issuance of common stock for intellectual property license rights, on January 18, 2007 at $1.68 per share					7,817		13		13
Issuance of common stock for intellectual property license rights, on June 30, 2007 at $1.80 per share					3,852		7		7
Issuance of common stock for commercial license rights, on July 19, 2007, vests upon achievement of specified criteria					16,698				
Share-based compensation							50		50
Issuance of shares to executive on February 19, 2007, vesting upon achievement of specified criteria, subject to repurchase					83,490				
Issuance of common stock upon exercise of stock options for cash					13,359		16		16
Net loss								(13,994)	(13,994)
Balance, December 31, 2007	9,222,257	14,938	6,455,579	17,871	737,494	1	1,631	(21,321)	(19,689)
Accretion of Series A offering costs		20					(20)		(20)
Accretion of Series B offering costs				36			(36)		(36)
Share-based compensation							545		545
Estimated fair value of warrants issued in connection with convertible notes payable							399		399
Issuance of common stock upon exercise of stock options, for cash					216,926		54		54
Net loss								(19,431)	(19,431)
Balance, December 31, 2008	9,222,257	14,958	6,455,579	17,907	954,420	1	2,573	(40,752)	(38,178)
Adjustment for fractional shares on common conversion					(39)				
Deemed preferred stock dividend for additional common shares issuable under anti-dilution provision				781			(781)		(781)
Accretion of Series A offering costs		42					(42)		(42)
Accretion of Series B offering costs				93			(93)		(93)
Conversion of preferred stock	(9,222,257)	(15,000)	(6,455,579)	(18,781)	3,042,740	3	33,778		33,781
Restricted stock release from restriction							75		75
Conversion of convertible notes and related accrued interest					872,792	1	8,500		8,501
Conversion of warrants for preferred stock							36		36
Merger with Nuvelo, Inc.					2,686,957	3	11,910		11,913
Adjustment for fractional shares					(609)				
Share-based compensation							845		845
Issuance of common stock upon exercise of stock options for cash					63,123		114		114
					1,064		2		2

Issuance of common stock under employee stock purchase plan and upon vesting of restricted stock units							
Estimated fair value of warrants issued in connection with lease termination					377		377
Net loss						(9,138)	(9,138)
Balance, December 31, 2009		7,620,448	8		57,294	(49,890)	7,412
Issuance of common stock for cash, net of offering costs		1,164,600	1		7,181		7,182
Issuance of common stock upon exercise of stock options for cash		49,487			139		139
Share-based compensation					458		458
Net loss						(8,420)	(8,420)
Balance, December 31, 2010	$	8,834,535	$ 9	$	65,072	$ (58,310)	$ 6,771

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, 2010
	2010	2009	
	(in thousands)		
Cash flows used in operating activities:			
Net loss	$ (8,420)	$ (9,138)	$ (58,310)
Adjustments to reconcile net loss to net cash used in operating activities:			
Gain on bargain purchase		(25,282)	(25,282)
Depreciation and amortization	338	457	1,135
Non-cash interest expense		102	211
Share-based compensation	458	845	1,974
Issuance of warrants for lease termination		377	377
Accretion of liabilities		152	152
Impairment of property and equipment		125	125
Impairment of in-process research and development		6,000	6,000
Write-off of deferred tax liability		(2,281)	(2,281)
Gain on marketable securities available for sale	(263)		(263)
(Gain) loss from disposal of property and equipment	(4)	47	67
Other, net			267
Change in operating assets and liabilities (net of amounts acquired):			
Other current assets	58	2,734	2,528
Other assets	84	7,157	7,166
Accounts payable	(145)	(2,460)	(1,802)
Accrued expenses and other liabilities	(316)	(20,454)	(18,764)
Deferred rent	(114)	(107)	316
Net cash used in operating activities	(8,324)	(41,726)	(86,384)
Cash flows provided by investing activities:			
Cash received from Merger		30,392	30,392
Payment of deferred transaction costs			(1,186)
Purchase of property and equipment	(4)	(185)	(1,860)
Proceeds from sale of marketable securities	263	15,106	15,369
Proceeds from sale of property and equipment	6	322	333
Net cash provided by investing activities	265	45,635	43,048
Cash flows provided by (used in) 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	7,659	114	7,855
Payment of offering costs	(338)		(338)
Repayment of principal on bank note payable		(4,000)	(4,000)
Repayment of principal on convertible notes payables			(105)
Net cash provided by (used in) financing activities	7,321	(3,886)	50,361

Net (decrease) increase in cash and cash equivalents	(738)	23	7,025
Cash and cash equivalents, beginning of period	7,763	7,740	
Cash and cash equivalents, end of period	$ 7,025	$ 7,763	$ 7,025
Supplemental cash flow information:			
Interest paid	$	$ 97	$ 107
Supplemental disclosure of noncash investing and financing transactions:			
Accrued interest on notes payable converted to equity	$	$ 151	$ 163
Warrant issued in connection with credit facility	$	$	$ 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 principally focused on developing genetically-targeted therapies for heart failure and other cardiovascular diseases. The Company s lead product candidate is Gencaro™ (bucindolol hydrochloride), a pharmacologically unique beta-blocker and mild vasodilator for chronic heart failure, or HF. 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 licensed exclusive, worldwide rights to Gencaro and has been granted patents in the U.S. and Europe for methods of treating heart failure patients with bucindolol based on genetic testing, which ARCA believes will provide market exclusivity for Gencaro into 2025 in those markets. In addition, the Company believes that if Gencaro is approved, the U.S. Gencaro patent, as well as the patent issued in Europe, will be eligible for patent term extension which, if granted in the U.S., could provide an additional period of market exclusivity in the U.S. of approximately three years, and if granted in Europe could provide an additional five years of market exclusivity.

Gencaro has been the subject of extensive clinical development, culminating in a Phase 3 heart failure study known as the BEST trial. In September 2008, the U.S. Food and Drug Administration, or FDA, formally accepted for filing ARCA s New Drug Application, or NDA, for Gencaro as a potential treatment for HF. In May 2009, the U.S. Food and Drug Administration, or FDA, notified the Company through a Complete Response Letter, or CRL, that its NDA for Gencaro was not approvable in its current form, and specified additional actions and information required for approval of the NDA including the need for an additional Phase 3 clinical trial as described below. In May 2010, the Company reached agreement with the FDA on a Special Protocol Assessment, or SPA, for the design of an additional Phase 3 clinical trial to assess the safety and efficacy of Gencaro in approximately 3,200 patients with chronic heart failure who have the genotype that appears to respond most favorably to Gencaro. The SPA signifies the FDA s agreement that this trial, if successful, could serve as the clinical effectiveness basis for the approval of Gencaro. The trial protocol includes two interim data analyses at pre-specified numbers of primary endpoint events. If the results of either interim analysis meet the pre-specified criteria, the Company believes that a complete response to the CRL could be formally submitted at that time. Even with a positive outcome at either interim analysis, the planned trial is designed to proceed to conclusion, estimated to take 3.5 years (including the time to reach the interim analysis). The Company currently expects that it could begin the trial approximately one year after obtaining sufficient funding.

To support the continued development of Gencaro, including the additional clinical trial, ARCA will need to complete a strategic transaction, such as a strategic combination or partnership, or raise substantial additional funding through public or private debt or equity securities or government funding.

ARCA also holds exclusive rights to rNAPc2, a single-chain, small recombinant protein, originally isolated from the saliva of the canine hookworm. rNAPc2 is a potent, long acting, and selective inhibitor of tissue factor, the protein responsible for initiating the extrinsic coagulation pathway, the primary coagulation mechanism in humans. rNAPc2 was originally developed as a cardiovascular therapy for thrombosis and other indications. As a result, it has been safely tested in over 700 human patients in nine Phase 1 and Phase 2 clinical trials. Previously, pilot studies of rNAPc2 conducted in non-human primates demonstrated potential efficacy against two of the most deadly strains of hemorrhagic fever virus, Ebola and Marburg. ARCA is currently seeking government funding to further develop rNAPc2, as a potential treatment for viral hemorrhagic fevers. Considering the substantial cost associated with the development of rNAPc2 and ARCA s limited financial resources, further development of rNAPc2 will be dependent upon receipt of government funding, which may not be available.

Table of Contents

ARCA BIOPHARMA, INC.

(a development stage enterprise)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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 $87.5 million and had negative cash flows from operations of $86.4 million.

In light of the substantial additional time and costs associated with the development of Gencaro and the need to raise a significant amount of capital on acceptable terms to finance the additional clinical trial and the Company s ongoing operations, the Company is evaluating strategic alternatives for funding continued operations and development programs. The Company will need to complete a strategic transaction, such as a strategic combination or partnership, or raise substantial additional funding through public or private debt or equity securities, or government funding to support the continued development of Gencaro, including the additional clinical trial. In 2010, the Company raised $7.2 million, net of offering costs, through the sale of our common stock pursuant to an equity distribution agreement, and may seek additional funding that could allow it to operate while it continues to pursue strategic combination, partnering, additional financing and licensing opportunities. If the Company is delayed in completing or is unable to complete additional funding and/or a strategic transaction, the Company may discontinue its development activities or discontinue its operations. To preserve the Company s capital resources, in February 2011, the Company reduced its research and development and general and administrative workforce by 36%. The reduction is expected to reduce the Company s projected cash use by approximately $200,000 per quarter.

The Company currently believes its cash and cash equivalents balance as of December 31, 2010 will be sufficient to fund our operations through September 30, 2011. 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, 2011. These consolidated financial statements have been prepared with the assumption that the Company will continue as a going concern and will be able to realize its assets and discharge its liabilities in the normal course of business and do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the inability of the Company to continue as a going concern. The Company may not be able to raise sufficient capital on acceptable terms, or at all, to continue development of Gencaro or to otherwise continue operations and may not be able to execute any strategic transaction.

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

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

63

Table of Contents

ARCA BIOPHARMA, INC.

(a development stage enterprise)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

the Company s ability to retain the listing of its common stock on the Nasdaq Capital Market;

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

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

the Company s ability to control costs associated with its operations;

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

the terms and conditions of the Company s existing collaborative and licensing agreements.

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

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 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). The results of operations and cash flows for the year ended December 31, 2009 include the activities of the acquired company since the date of the Merger. Pursuant to the rules and regulations of the United States Securities and Exchange Commission, 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.

Merger Exchange Ratio and Reverse Stock Split

In conjunction with and immediately prior to the Merger, Nuvelo effected a 20-for-1 reverse stock split. As a result, and in accordance with the Merger Agreement, each outstanding common share and warrant or option to purchase ARCA Colorado s common stock prior to the Merger was converted into the right to receive or purchase 0.16698070, 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

64

Table of Contents

ARCA BIOPHARMA, INC.

(a development stage enterprise)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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, warrants to purchase preferred shares, and per preferred share amounts.

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, 2010.

Accounting Estimates in the Preparation of Financial Statements

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

Cash Equivalents

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

The Company classifies all cash equivalents as available-for-sale securities, and records investments at fair value. Unrealized holding gains and losses on available-for-sale securities, net of any tax effect, are excluded from earnings and are reported in accumulated other comprehensive income (loss), a separate component of stockholders equity, until realized. The specific identification method is utilized to calculate the cost to determine realized gains and losses from the sale of available-for-sale securities. Realized gains and losses are included in interest income in the 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 and other receivables. The Company has no off-balance-sheet concentrations of credit risk, such as foreign exchange contracts, option contracts, or foreign currency hedging arrangements. The Company maintains cash and cash equivalent balances in the form of bank demand deposits, money market fund accounts and debt securities with financial institutions that management believes are creditworthy. Such balances may at times exceed the insured amount.

Table of Contents

ARCA BIOPHARMA, INC.

(a development stage enterprise)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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 material 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 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,

Table of Contents

ARCA BIOPHARMA, INC.

(a development stage enterprise)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

Reclassifications

Certain reclassifications have been made in the prior year consolidated financial statements to conform to the 2010 financial statement presentation. These reclassifications have no impact on net income.

Accounting Standards Updates

In January 2010, the Financial Accounting Standards Board, or FASB, issued FASB Accounting Standards Update, or ASU, 2010-06, *Fair Value Measurements and Disclosures: Improving Disclosures about Fair Value Measurements*, or ASU 2010-06, which amends FASB Accounting Standards Codification, or ASC, Topic 820-10, *Fair Value Measurements and Disclosures*. The update provides additional disclosures for transfers in and out of Levels 1 and 2 and for activity in Level 3 and clarifies certain other existing disclosure requirements.

Table of Contents

ARCA BIOPHARMA, INC.

(a development stage enterprise)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The Company adopted ASU 2010-06 beginning January 1, 2010. This update had no impact on the Company s financial position, results of operations or cash flows.

(2) Earnings (Loss) Per Share

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

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

(In thousands, except shares and per share data)	Years Ended December 31, 2010	2009
Net loss	$ (8,420)	$ (9,138)
Less: Accretion of redeemable convertible preferred stock		(135)
Deemed preferred stock dividend for additional common shares issuable under anti-dilution provision		(781)
Net loss available to common shareholders	$ (8,420)	$ (10,054)
Weighted average shares of common stock outstanding	8,523,018	7,115,192
Less: Weighted average shares of unvested common stock	(16,698)	(22,874)
Total weighted average shares used in computing net loss per share available to common stockholders	8,506,320	7,092,318
Basic and diluted loss per share	$ (0.99)	$ (1.42)

Potentially dilutive securities representing 1.3 million and 1.7 million weighted average shares of common stock were excluded for the years ended December 31, 2010 and 2009, respectively, because including them would have an anti-dilutive effect on net loss attributable to common stockholders per share.

(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. On March 7, 2011, the listing of the Company s common stock was transferred from the Nasdaq Global Market to the Nasdaq Capital Market.

Table of Contents

ARCA BIOPHARMA, INC.

(a development stage enterprise)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The Merger was treated as a reverse merger and accounted for as a business combination using the acquisition method of accounting in accordance with ASC 805. For accounting purposes, ARCA Colorado was considered to have acquired Nuvelo in the Merger, as the stockholders of ARCA Colorado prior to the Merger had a controlling interest in the combined company and the Company s management is the former management of ARCA Colorado. The results of operations and cash flows include the activities of Nuvelo since the date of the Merger. Pursuant to the rules and regulations of the United States Securities and Exchange Commission, or the SEC, the historical financial statements of ARCA Colorado replaced the historical financial statements of Nuvelo, and the disclosures in this report relating to the pre-Merger business of the Company, unless noted as being the business of Nuvelo prior to the Merger, pertain to the business of ARCA Colorado prior to the Merger.

The estimated total acquisition consideration of $11.9 million to acquire Nuvelo was based on the market capitalization of Nuvelo as of January 27, 2009 and the estimated fair values of its vested stock options and warrants outstanding on that date, as this was deemed the most reliable measure of the consideration effectively transferred to acquire Nuvelo on that date. The Company estimated the net assets acquired in the Merger to be $37.2 million, including $45.5 million of cash, cash equivalents and marketable securities. In accordance with ASC 805, any excess of fair value of net assets acquired in a business combination over the acquisition consideration results in a gain on bargain purchase, and as a result, the Company recorded a gain on bargain purchase of $25.3 million.

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

(in thousands, except per share data)	Year Ended, December 31, 2009
Revenue	$
Net loss	(34,937)
Net loss per share, basic and diluted	$ (4.62)

(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 $7.0 million at December 31, 2010 and $7.4 million at December 31, 2009, in money market funds, classified as cash equivalents, which are measured at fair value based on Level 1 inputs on a recurring basis.

69

Table of Contents

ARCA BIOPHARMA, INC.

(a development stage enterprise)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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, 2010 and 2009, 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, 2010	December 31, 2009
Computer equipment	3 years	$ 206	$ 200
Lab equipment	5 years	142	142
Furniture and fixtures	5 years	398	398
Computer software	3 years	176	183
Leasehold improvements	Lesser of useful life or life of the lease	744	744
		1,666	1,667
Less accumulated depreciation and amortization		(976)	(641)
		$ 690	$ 1,026

For the years ended December 31, 2010 and 2009, and for the period from Inception through December 31, 2010, depreciation and amortization expense was $338,000, $457,000 and $1.1 million, respectively.

For the year ended December 31, 2009, the Company recorded an impairment charge of $125,000, based upon management s determination of excess carrying value of certain computer and office equipment over the fair value less cost to sell. This impairment charge is the result of the following two activities. In conjunction with the lease termination and exit of the San Carlos facility in the third quarter of 2009, the remaining office equipment was determined to be impaired resulting in a $42,000 charge. In the second quarter of 2009, as a result of the reduction in force, management reviewed excess computer and office equipment for impairment and recognized a charge of $83,000. The impairment charges are classified as restructuring expense in the consolidated statement of operations.

(6) In-Process Research and Development

The Company acquired an IPR&D asset through the Merger related to projects associated with Nuvelo s NU172 program. The Company, with the assistance of a valuation firm, determined the estimated fair value of this asset as of the acquisition date. The estimated fair value as of the acquisition date of $6.0 million was determined using an income approach, as well as discussions with Nuvelo s management and a review of certain program-related documents and forecasts of future cash flows. The initial determination and subsequent evaluation for impairment of the IPR&D asset required management to make significant judgments and estimates.

The IPR&D asset was considered an indefinite-lived intangible asset and was therefore not subject to amortization. However, the Company was required to review the asset for impairment at least annually. ARCA performed its annual test for impairment in 2009 as of November 30, 2009. The impairment test consisted of a comparison of the fair value of the IPR&D with its carrying amount. The income approach, a valuation method

Table of Contents

ARCA BIOPHARMA, INC.

(a development stage enterprise)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

that establishes the business value based on a stream of future economic benefits, such as net cash flows, discounted to their present value, included probability adjustments to projected expenses and revenue in order to reflect the expected probabilities of incurring development cost prior to commercialization and the probability of achieving commercial revenue due to risks associated with the drug discovery process and regulatory approval. A risk-adjusted discount rate was utilized to discount the probability adjusted net cash flows to their present value, to reflect the time value of money and risks of commercialization, sales, and competition, which are risk elements explicitly not addressed in the probability adjustments.

The evaluation considered multiple factors influencing the value of the asset, including:

- the impact of capital market conditions, particularly increases in the cost of capital for the biopharmaceutical industry;
- the impact of delays in the drug development timeline, including, but not limited to,
  - the impact of the limited development activity subsequent to the Merger,
  - the impact on the drugs projected revenue as a result of a delay in commercialization, considering the fixed patent expiry, and
  - the impact of increased risk of competition; and
- the increasing likelihood of new healthcare legislation that could negatively impact the reimbursement to be received and increase pricing pressure for the drug.

The evaluation of these factors, along with other uncertainties, lead the Company to believe that the in-process research and development asset no longer had value as the fair value indicated by the Company s analysis was zero. As the carrying amount of the IPR&D exceeded its estimated fair value, an impairment loss was recognized in an amount equal to that excess. Accordingly, the Company recorded a loss on impairment for the full balance of the asset totaling $6.0 million in the fourth quarter of 2009. The Company s related deferred tax liability of $2.3 million was also written-off, and was recorded on the consolidated statement of operations as benefit from income taxes.

(7) Restructuring

In the second quarter of 2009, the Company implemented a restructuring plan under which it terminated 44 employees from its research and development and selling, general and administrative functions. The Company implemented the restructuring plan in connection with its strategy to seek alternatives for commercializing Gencaro and to lower operating expenses to preserve the Company s capital resources. As a result of the restructuring plan, the Company recorded a restructuring charge of $1.1 million for personnel-related termination costs, of which $675,000 related to severance amounts to be paid in cash and $387,000 relates to the acceleration of vesting on outstanding stock options. The Company completed all payments associated with this restructuring plan by December 31, 2009.

During the third quarter of 2009, the Company negotiated early terminations of the lease obligations related to the facilities in Sunnyvale, CA and San Carlos, CA, which were assumed in the Merger, resulting in a net charge of approximately $1.2 million.

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

Table of Contents

ARCA BIOPHARMA, INC.

(a development stage enterprise)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(8) Related Party Arrangements

Transactions with the Company s President and Chief Executive Officer

Effective July 1, 2010, the Company entered into an unrestricted research grant with its President and Chief Executive Officer s research laboratory, or the Lab, for $269,000 for a one-year term for the advancement of research in chronic heart failure. For the period from July 1, 2009 through June 30, 2010, the Company provided funding to the Lab under another unrestricted research grant for $242,000. In the first half of 2009 the Company provided research funding for the lab of approximately $121,000, in accordance with a similar unrestricted research grant arrangement. Funding of the 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, 2010 and 2009 was $255,000 and $220,000, respectively, and $1.2 million from Inception through December 31, 2010.

The Company is a party to a materials transfer agreement with the University of Colorado, under which the Company has agreed to pay $35,000 per year to maintain the Heart Tissue Bank associated with the President and Chief Executive Officer s research lab at the University of Colorado. Total expense for the years ended December 31, 2010 and 2009 was $26,000 and $35,000, respectively, and was $201,000 from Inception through December 31, 2010.

(9) Commitments and Contingencies

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

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, 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. Per the lease agreement, base rent is subject to annual increases of approximately three percent per year. The rent expense for the lease is being recognized on a straight-line basis over the lease term. Tenant improvement reimbursements from the landlord totaled $593,000 which were recorded as deferred rent and are amortized as reductions to rent expense over the lease term. Rent expense under this lease for the years ended December 31, 2010 and 2009 was $123,000, and was $317,000 from Inception through December 31, 2010.

Table of Contents

ARCA BIOPHARMA, INC.

(a development stage enterprise)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Below is a summary of the future minimum lease payments committed under Company s facility in Broomfield, Colorado as of December 31, 2010 (in thousands):

2011	$ 244
2012	251
2013	128
Total future minimum rental payments	$ 623

University of Cincinnati

On December 2, 2009, the Company entered into an agreement with the University of Cincinnati that gives the Company the exclusive option to license exclusive, worldwide rights to a portfolio of certain patent rights relating to genetic polymorphisms of adrenergic cardiac receptors, including, but not limited to, the option to exclusively license all of the rights previously sublicensed nonexclusively under the agreement with CardioDx, Inc, which terminated on April 10, 2010. These rights include those for developing and commercializing diagnostics for the receptor polymorphisms that may indicate which patients will respond most favorably to Gencaro. The agreement has been amended to extend the period of the option from December 2, 2010 through March 31, 2011. As consideration for the option, the Company has assumed the reasonable costs of prosecuting the associated patent rights.

Laboratory Corporation of America

In February 2007, the Company entered into a commercialization and licensing agreement with Laboratory Corporation of America, or LabCorp, to develop, make, market and sell diagnostic tests in connection with the medical prescription of the Company s lead compound, Gencaro. Under the agreement the Company has licensed to LabCorp certain rights to commercialize a diagnostic test. The license agreement has a term of 10 years. LabCorp has the right to cancel the agreement and give the rights to the diagnostic back to the Company. In addition, the Company granted to LabCorp 16,698 shares of common stock. The shares are subject to a restricted stock agreement in which shares vest upon the attainment of certain regulatory approval and drug product sales milestones.

Cardiovascular Pharmacology and Engineering Consultants, LLC, or CPEC

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

Table of Contents

ARCA BIOPHARMA, INC.

(a development stage enterprise)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Dendreon

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

(10) Collaborative Agreements

Archemix

In July 2006, Nuvelo entered into a collaboration agreement with Archemix Corporation, or Archemix. Under the agreement, Archemix was responsible for the discovery of short-acting aptamers targeting the coagulation cascade for use in acute cardiovascular procedures, and the Company was responsible for development and worldwide commercialization of these product candidates. In August 2006, Nuvelo made an upfront license fee payment to Archemix of $4.0 million, and pursuant to the terms of the agreement committed to funding at least $5.25 million of Archemix s research over the first three years of the agreement. As of July 2009, this funding commitment had been satisfied. Archemix had the right to receive payments totaling up to $35.0 million per development compound contingent upon the achievement of specified development and regulatory milestones, along with potential royalty payments based on sales of licensed compounds. In February 2008, Nuvelo paid Archemix a $1.0 million milestone fee that was accrued upon dosing of the first patient in the Phase 1 trial for NU172.

On April 20, 2010, the Company amended its collaboration agreement with Archemix for the discovery and development of novel aptamers with anti-coagulation activities, or the Amended Agreement. In the Amended Agreement, the parties modified certain financial provisions and certain other provisions to reflect the termination of the research and collaboration and limitation of the agreement to NU172. In summary, the agreement was amended, as follows:

Pursuant to the previous agreement, ARCA funded a research collaboration under which Archemix generated candidate aptamers for ARCA s selection for further development and commercialization. In the Amended Agreement, ARCA is given sole control over the development, manufacture and commercialization of NU172, and no further research or development collaboration is provided for.

Under the previous agreement, for each product resulting from the collaboration, ARCA had the obligation to fund the development and commercialization of such product and pay milestones and royalties to Archemix on the net sales for such product. However, Archemix had the option to share in 25% of the expenses incurred and profits obtained from the development and commercialization of such product, which election Archemix could make after the inception of the Phase 3 clinical trial for the product. In the Amended Agreement, Archemix no longer has such participation right, but will have the right to receive milestones and royalties on the net sales of NU172, if any, on the same terms and conditions as those under the previous agreement.

The Amended Agreement revises the exclusivity provision to provide that Archemix will not, by itself or in collaboration with a third party, develop, manufacture or commercialize short-acting aptamers

74

Table of Contents

ARCA BIOPHARMA, INC.

(a development stage enterprise)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

that directly inhibit thrombin or are used as a treatment for viral or bacterial infections, and in either case cause a therapeutically-useful level of anticoagulation.

Pursuant to the previous agreement, ARCA had the obligation to purchase Archemix common stock in an Archemix initial public offering under certain conditions and subject to certain terms. In the Amended Agreement, this obligation is eliminated.

(11) Equity Distribution Agreement

On December 8, 2009, the Company entered into an equity distribution agreement, or the Agreement, with Wedbush Securities Inc., or the Agent, under which the Company may, from time to time, offer and sell its common stock through the Agent. On April 30, 2010, the Company amended the Agreement to permit it to sell up to an aggregate of $20 million in shares, which have been registered on a registration statement on Form S-3 (File No. 333-148288). Subject to the filing and effectiveness of a Registration Statement on Form S-3, additional sales of the Company s common stock through the Agent, if any, will be made by means of ordinary brokers transactions on the Nasdaq market or otherwise at market prices prevailing at the time of sale, in block transactions, or as otherwise agreed upon by the Company and the Agent. The Agent will use commercially reasonable efforts to sell the Company s common stock from time to time, based upon instructions from the Company, including any price, time or size limits or other customary parameters or conditions the Company may impose. The Company will pay the Agent a commission, or allow a discount, as the case may be, in each case equal to 4.5% of the gross sales proceeds of any common stock sold through the Agent, acting as an agent, under the Agreement. The Company may also sell shares of common stock to the Agent, as principal for its own account, at a price to be agreed upon at the time of sale. In the year ended December 31, 2010, the Company sold 1,164,600 shares of common stock under this Agreement and realized $7.2 million of proceeds, net of $338,000 of offering costs.

(12) Legal Matters

On February 9, 2007, Nuvelo and certain of Nuvelo s former and then current officers and directors were named as defendants in a purported securities class action lawsuit filed in the United States District Court for the Southern District of New York. The suit alleges violations of the Securities Exchange Act of 1934 related to the clinical trial results of alfimeprase, which Nuvelo announced on December 11, 2006, and seeks damages on behalf of purchasers of Nuvelo s common stock during the period between January 5, 2006 and December 8, 2006. Specifically, the suit alleges that Nuvelo misled investors regarding the efficacy of alfimeprase and the drug s likelihood of success. The plaintiff seeks unspecified damages and injunctive relief. Three additional lawsuits were filed in the Southern District of New York on February 16, 2007, March 1, 2007 and March 6, 2007, respectively. In July 2007, the Court granted Nuvelo s motion to transfer the cases to the Northern District of California. The cases were consolidated with the original lawsuit, and plaintiffs filed a consolidated complaint in the Northern District of California on November 9, 2007. Nuvelo filed a motion to dismiss plaintiffs consolidated complaint on December 21, 2007. On June 12, 2008, the Court held a hearing on the motion to dismiss. On December 4, 2008, the Court issued an order dismissing plaintiffs complaint, and granting leave to amend. On January 23, 2009, plaintiffs filed an amended complaint, alleging similar claims. On March 24, 2009, defendants filed a motion to dismiss the amended complaint. On July 15, 2009, the Court held a hearing on the motion to dismiss. On August 17, 2009, the Court granted in part and denied in part defendants motion. ARCA filed its answer to plaintiff s complaint on October 1, 2009.

On December 29, 2010, ARCA and the other defendants reached a settlement of the litigation with the plaintiffs, after participating in mediation before a retired federal judge. On February 25, 2011, the parties

ARCA BIOPHARMA, INC.

(a development stage enterprise)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

entered into a settlement agreement, which has been submitted to the Court for approval. ARCA s insurance carriers have agreed to fund the settlement, subject to a reservation of rights by one carrier. If the Court approves the settlement, the litigation will be dismissed against all the defendants. Members of the class who participate in the settlement will provide a release to the defendants, which prevents them from ever asserting any related claims against the defendants. Members of the class, if any, who opt out of the settlement, would not be bound by this release. Although ARCA s insurance carriers have agreed to pay most of the legal fees that have been incurred in defending this litigation, ARCA has separately agreed with its legal counsel to pay $167,000 in legal defense costs incurred on or before December 29, 2010, but only if ARCA obtains additional funding of at least $10 million in 2011. If ARCA does not obtain such additional funding in 2011, ARCA will have no such payment obligation.

In addition, on or about December 6, 2001, Variagenics, Inc. was sued in a complaint filed in the United States District Court for the Southern District of New York naming it and certain of its officers and underwriters as defendants. The complaint purportedly is filed on behalf of persons purchasing Variagenics stock between July 21, 2000 and December 6, 2000, and alleges violations of Sections 11, 12(a)(2) and 15 of the Securities Act of 1933, as amended and Section 10(b) of the Securities Exchange Act of 1934, as amended, and Rule 10b-5 promulgated thereunder. The complaint alleges that, in connection with Variagenics July 21, 2000 initial public offering, or IPO, the defendants failed to disclose additional and excessive commissions purportedly solicited by and paid to the underwriter defendants in exchange for allocating shares of Variagenics stock to preferred customers and alleged agreements among the underwriter defendants and preferred customers tying the allocation of IPO shares to agreements to make additional aftermarket purchases at predetermined prices. Plaintiffs claim that the failure to disclose these alleged arrangements made Variagenics registration statement on Form S-1 filed with the SEC in July 2000 and the prospectus, a part of the registration statement, materially false and misleading. Plaintiffs seek unspecified damages. On or about April 19, 2002, an amended complaint was filed which makes essentially the same allegations. ARCA is involved in this litigation as a result of Nuvelo s merger with Variagenics in January 2003. On April 1, 2009 the parties entered into a settlement agreement. On October 5, 2009, the Court approved the settlement agreement. ARCA s share of the settlement is approximately $385,000. Although the settlement has been approved, it has been appealed by members of the class. ARCA believes that any attorneys fees, loss or settlement payment with respect to this suit will be paid by its insurance provider. However, it is possible that ARCA could be forced to incur material expenses in the litigation if the parties cannot complete a settlement, and, in the event of an adverse outcome, ARCA s business could be harmed.

(13) Stock-based Compensation

Warrants

As of December 31, 2010, warrants to purchase 341,201 shares of common stock were outstanding and exercisable at exercise prices ranging from $3.82 to $241.44, with a weighted average exercise price per share of $19.64. These warrants, which were granted as part of various financing and business agreements, expire at various times between February 2011 and August 2018. 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.

Stock Plans

The Company s equity incentive plan was amended, as approved by shareholders 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

Table of Contents

ARCA BIOPHARMA, INC.

(a development stage enterprise)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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 326,323 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, 2010, options to purchase 428,690 shares were outstanding under the Equity Plan, and 458,625 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, 2010 are the 1995 Employee Stock Option Plan, the Non-Employee Director Stock Option Plan and the 2002 Equity Incentive Plan. As of December 31, 2010, options to purchase 13,852 shares were outstanding under these stock plans. Additionally, as of December 31, 2010, options to purchase 5,303 shares granted outside of any of Nuvelo s stock plans were outstanding. In conjunction with the Merger, the Company discontinued grants under its 2004 Stock Option Plan effective January 27, 2009. As of December 31, 2010, options to purchase 505,393 shares with a weighted average exercise price of $2.39 per share were outstanding under this plan. Options and awards outstanding under this plan will continue to vest according to the original terms of each grant. No new awards will be granted under this plan. Subsequent to the Merger, the Company has granted stock-based compensation awards under the Equity Plan.

The Company granted options to purchase 128,170 and 491,974 shares of common stock in the years ended December 31, 2010 and 2009, respectively. The fair values of employee stock options granted in the years ended December 31, 2010 and 2009 were estimated at the date of grant using the Black-Scholes model with the following assumptions and had the following estimated weighted average grant date fair value per share:

	Years Ended December 31,	
	2010	2009
Expected term	5.7 years	6.4 years
Expected volatility	86%	79%
Risk-free interest rate	2.70%	1.32%
Expected dividend yield	0%	0%
Weighted average grant date fair value per share	$ 2.04	$ 3.21

Table of Contents

ARCA BIOPHARMA, INC.

(a development stage enterprise)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

A summary of ARCA s stock option activities for the years ended December 31, 2010 and 2009, and related information as of December 31, 2010, is as follows:

	For the years ended December 31,			
	2010		2009	
	Number of Options	Weighted Average Exercise Price	Number of Options	Weighted Average Exercise Price
Options outstanding, beginning of period	921,104	$ 69.60	584,668	$ 1.74
Assumed in Merger		0.00	278,025	284.59
Fractional option adjustment		0.00	(41)	1.74
Granted	128,170	2.95	491,974	4.56
Exercised	(49,487)	2.80	(63,123)	1.80
Forfeited and cancelled	(46,549)	729.70	(370,399)	49.03
Options outstanding, end of period	953,238	$ 31.87	921,104	$ 69.60
Options exercisable, end of period	676,972	$ 43.49	543,279	$ 115.67
Options vested and expected to vest	938,391	$ 32.33		

The total intrinsic value of options exercised for the years ended December 31, 2010 and 2009 was $208,000 and $105,000, respectively. As of December 31, 2010, the unrecognized compensation expense related to unvested options, excluding estimated forfeitures, was $552,000, which compensation expense is expected to be recognized over a weighted average period of 2.1 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.

The following table summarizes information about stock options outstanding and exercisable as of December 31, 2010:

	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
$ 0.06 - $ 0.60	7,488	4.42	$ 0.52	7,488	$ 0.52
0.90 - 0.90	203,691	5.83	0.90	203,691	0.90
1.68 - 2.69	175,644	7.07	2.07	115,545	1.96
2.73 - 2.90	151,905	8.59	2.87	72,733	2.85
2.97 - 5.29	172,998	8.75	3.95	91,956	4.61
5.57 - 73.40	136,210	7.74	15.65	80,257	22.63
81.90 - 753.75	105,302	3.80	252.43	105,302	252.43

953,238	7.06	$ 31.87	676,972	$ 43.49

Table of Contents

ARCA BIOPHARMA, INC.

(a development stage enterprise)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

For the years ended December 31, 2010 and 2009 and for the period from Inception through December 31, 2010, 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, 2010
	2010	2009	
Research and development	$ 128	$ 114	$ 379
Selling, general and administrative	330	344	1,208
Restructuring Expense		387	387
Total	$ 458	$ 845	$ 1,974

Stock-based compensation expense related to non-employees was negligible in 2010 and 2009. 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.

Stock Option and Restricted Stock Award Modifications

As discussed above in Note 7, the restructuring plan implemented by the Company in the second quarter of 2009 modified certain outstanding unvested stock options held by the affected employees. Outstanding stock options held by affected employees not formerly employed by Nuvelo were modified such that vesting was accelerated on outstanding options representing the number of options that would have vested in one year had such employees continued to provide service to the Company, and the post-termination exercise period of the outstanding stock options was extended to approximately one year. The Company accelerated the vesting on 55,441 stock options.

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

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

79

Table of Contents

ARCA BIOPHARMA, INC.

(a development stage enterprise)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(14) 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 $109,000 and $157,000 for the years ended December 31, 2010 and 2009, respectively, and has contributed $503,000 from Inception through December 31, 2010.

(15) Income Taxes

The Company recorded a $2.3 million benefit from income taxes in 2009 on the consolidated statement of operations due to the write-off of the deferred tax liability related to the IPR&D asset. See Note 5 for discussion of loss on impairment of IPR&D recorded as a result of the annual test for impairment performed in the fourth quarter of 2009.

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, 2010, for federal income tax purposes, the Company has net operating loss carryforwards of approximately $88.9 million, and approximately $616,000 of research and development credits that may be used to offset future taxable income. The net operating loss carryforwards will expire beginning 2025 through 2030. 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.

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 $38.9 million at December 31, 2010, reflecting an increase of approximately $10.4 million from December 31, 2009. The deferred tax assets are primarily comprised of net operating loss carryforwards and research and experimentation credit carryforwards. As of December 31, 2010 the Company has not performed a 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.

Table of Contents

ARCA BIOPHARMA, INC.

(a development stage enterprise)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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, 2010	2009
U.S. federal income tax benefit at statutory rates	$ (2,947)	$ (3,997)
State income tax benefit, net of federal effect	(253)	(630)
Research and experimentation credits	(53)	(136)
Gain on bargain purchase		(10,232)
Settlement of liabilities assumed in the Merger	(5,273)	
Adjustments in tax basis of tangible and intangible assets acquired in the Merger	(1,816)	
Non-deductible merger costs		2,219
Deferred tax liability on impaired IPR&D asset		(2,281)
Other	(54)	(173)
Change in valuation allowance	10,396	12,949
	$	$ (2,281)

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.

Table of Contents

ARCA BIOPHARMA, INC.

(a development stage enterprise)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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 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):

	December 31,	
	2010	2009
Deferred tax assets:		
Current deferred tax assets:		
Accrued vacation	$ 30	$ 44
Total current deferred tax assets	30	44
Valuation allowance	(30)	(44)
Net current deferred tax assets		
Noncurrent deferred tax assets:		
Net operating loss carryforwards	33,807	26,536
Charitable contribution carryforwards	414	317
Research and experimentation credits	616	563
Capitalized intangibles	3,480	473
Stock based compensation	374	336
Depreciation and amortization		56
Other	199	117
Total noncurrent deferred tax assets	38,890	28,398
Valuation allowance	(38,808)	(28,398)
Net noncurrent deferred tax assets	82	
Deferred tax liabilities:		
Noncurrent deferred tax liabilities:		
Depreciation and amortization	$ (82)	
Total noncurrent deferred tax liabilities	(82)	
Net 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 2005. 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, 2010 and 2009, 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, 2010 and 2009.

(16) Subsequent Events

To preserve the Company s capital resources, in February 2011, the Company reduced its research and development and general and administrative workforce by 36%. The reduction is expected to reduce the Company s projected cash use by approximately $200,000 per quarter.

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, 2010. 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, 2010 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 2010, 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.

Table of Contents

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

On March 3, 2011, Dr. J. William Freytag tendered his resignation as a member of the Board of Directors of ARCA biopharma, Inc. (ARCA), effective immediately. Dr. Freytag s resignation is not a result of any disagreements with ARCA relating to its operations, policies or practices prior to his resignation. ARCA does not currently have plans to appoint a replacement director to fill the vacancy left by Dr. Freytag s resignation.

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 2011 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 2011 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 Security Ownership of Certain Beneficial Owners and Management and Executive Compensation in our Definitive Proxy Statement to be filed pursuant to Regulation 14A under the Exchange Act, relating to our 2011 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 2011 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 2011 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 55 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.(8)
3.2	Second Amended and Restated Bylaws of the Registrant, as amended.(10)
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)

Table of Contents

Exhibit Number	Description
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.(17)
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.(18)
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(15)
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(15)
10.9§	License and Sublicense Agreement, dated October 28, 2003, by and between ARCA Discovery, Inc. and CPEC, L.L.C.(13)
10.10§	Amendment to License and Sublicense Agreement, dated February 22, 2006, by and between ARCA Discovery, Inc. and CPEC L.L.C.(14)
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.(13)
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.(13)

Table of Contents

Exhibit Number	Description
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.(13)
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.(13)
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.(13)
10.16§	Diagnostic, Collaboration and Option Agreement, dated June 23, 2006, by and between ARCA Discovery, Inc. and CardioDX, Inc.(13)
10.17§	Amendment to Diagnostic, Collaboration and Option Agreement, dated October 1, 2007, by and between ARCA Discovery, Inc. and CardioDX, Inc.(13)
10.18§	Manufacturing Agreement, dated September 11, 2006, by and between ARCA Discovery, Inc. and Patheon, Inc.(13)
10.19§	Development, Commercialization and Licensing Agreement, dated February 1, 2007, by and between ARCA Discovery, Inc. and Laboratory Corporation of America Holdings, Inc.(14)
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.(13)
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.(13)
10.22	Materials Transfer Agreement, dated October 14, 2005, by and between ARCA Discovery, Inc. and the University of Colorado.(13)
10.23	Equity Distribution Agreement, dated December 8, 2009, between ARCA biopharma, Inc. and Wedbush Securities, Inc.(9)
10.24	Amendment no. 1, dated April 30, 2010 to the Equity Distribution Agreement dated December 8, 2009 between ARCA biopharma, Inc. and Wedbush Securities, Inc.(19)
10.25	Lease Surrender and Termination Agreement, dated August 5, 2009, by and between ARCA biopharma, Inc. and The Irvine Company LLC.(10)
10.26	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.(11)
10.27§	Exclusive Option Agreement, dated December 2, 2009, by and between ARCA biopharma, Inc. and the University of Cincinnati.(17)
10.28	Agreement Term Extension Letter dated December 8, 2010, of the Exclusive Option Agreement by and between ARCA biopharma, Inc. and the University of Cincinnati.(21)
10.29	Agreement Term Extension Letter dated December 21, 2010, of the Exclusive Option Agreement by and between ARCA biopharma, Inc. and the University of Cincinnati.(22)
10.30	Agreement Term Extension Letter dated January 21, 2011, of the Exclusive Option Agreement by and between ARCA biopharma, Inc. and the University of Cincinnati.(23)
10.31	ARCA Discovery, Inc. 2004 Stock Incentive Plan.(7)
10.32	Amendment No. 1 to the ARCA Discovery, Inc. 2004 Stock Incentive Plan.(7)
10.33	Amendment No. 2 to the ARCA Discovery, Inc. 2004 Stock Incentive Plan.(7)
10.34	Amendment No. 3 to the ARCA Discovery, Inc. 2004 Stock Incentive Plan.(7)

Table of Contents

Exhibit Number	Description
10.35	Amendment No. 4 to the ARCA Discovery, Inc. 2004 Stock Incentive Plan.(7)
10.36	Amendment No. 5 to the ARCA Discovery, Inc. 2004 Stock Incentive Plan.(7)
10.37	Amendment No. 6 to the ARCA Discovery, Inc. 2004 Stock Incentive Plan.(7)
10.38	ARCA biopharma, Inc. 2004 Stock Incentive Plan, Form of Executive Incentive Stock Option Agreement.(7)
10.39	ARCA biopharma, Inc. 2004 Stock Incentive Plan, Form of Non-Executive Incentive Stock Option Agreement.(7)
10.40	ARCA biopharma, Inc. 2004 Stock Incentive Plan, Form of Nonqualified Stock Option Agreement.(7)
10.41	ARCA biopharma, Inc. 2004 Equity Incentive Plan (f/k/a Nuvelo, Inc. 2004 Equity Incentive Plan), Form of Partial Acceleration Stock Option Agreement.(8)
10.42	ARCA biopharma, Inc. 2004 Equity Incentive Plan (f/k/a Nuvelo, Inc. 2004 Equity Incentive Plan), Form of No Acceleration Stock Option Agreement.(8)
10.43	ARCA biopharma, Inc. 2004 Equity Incentive Plan (f/k/a Nuvelo, Inc. 2004 Equity Incentive Plan), Form of Director Stock Option Agreement.(8)
10.44	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)
10.45	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)
10.46	Form of Indemnification Agreement between Nuvelo, Inc. and its directors and officers.(1)
10.47	Nuvelo, Inc. Amended Executive Change in Control and Severance Benefit Plan.(4)
10.48	Amended and Restated Employment and Retention Agreement, dated June 4, 2008, by and between ARCA biopharma, Inc. and Michael R. Bristow.(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 Employment Agreement, dated June 12, 2008, by and between ARCA biopharma, Inc. and Christopher D. Ozeroff.(8)
10.51	Assignment and Assumption Agreement, dated January 26, 2009, by and between ARCA biopharma, Inc. and ARCA biopharma Colorado, Inc.(8)
10.52	Amended and Restated ARCA biopharma, Inc. 2004 Equity Incentive Plan(12)
10.53	ARCA biopharma, Inc. Employee Severance Benefit Plan(20)
10.54	ARCA biopharma, Inc. 2009 Reduction in Force Severance Benefit Plan(20)
10.55	Form of Option Amendment pursuant to ARCA biopharma, Inc. 2004 Equity Incentive Plan and ARCA biopharma, Inc. 2004 Stock Option Plan (change of control)(20)
10.56	Form of Option Agreement and Grant Notice pursuant to ARCA biopharma, Inc. 2004 Equity Incentive Plan (NDA/change of control acceleration)(20)
10.57	Employment Agreement, dated February 11, 2009, by and between ARCA biopharma, Inc. and Patrick Wheeler. (17)
10.58	Form of Indemnification Agreement between ARCA biopharma, Inc. and its directors and officers.(8)
14.1	Code of Business Conduct and Ethics(10)

Table of Contents

Exhibit Number	Description
16.1	Letter from Ernst & Young LLP to the Securities and Exchange Commission, dated March 30, 2009.(16)
23.1*	Consent of KPMG LLP, Independent Registered Public Accounting Firm.
24.1*	Power of Attorney (included in the signature page hereto).
31.1*	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. sec. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

* Filed herewith.

Compensatory plan or agreement.

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

(1) Previously filed with the SEC as an Exhibit to and incorporated herein by reference from Hyseq, Inc. s Form S-1, filed on June 12, 1997, as amended, File No. 333-29091.

(2) Previously filed with the SEC as an Exhibit to and incorporated herein by reference from Nuvelo, Inc. s Form 10-Q, filed on November 8, 2006, File No. 000-22873.

(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.

(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.

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

(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.

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

(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 8-K, filed on December 8, 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 10-Q, filed on November 16, 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 8-K, filed on September 24, 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/A, filed on August 21, 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, filed on May 15, 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 10-Q/A, filed on November 6, 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 April 10, 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 8-K, filed on March 30, 2009, 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-K, filed on March 4, 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, 2010, 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 April 30, 2010, File No. 000-22873.
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(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 December 14, 2010, 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 December 22, 2010, 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 January 26, 2011, 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 8, 2011

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 8, 2011
/s/ PATRICK M. WHEELER **Patrick M. Wheeler**	Chief Financial Officer (Principal Financial Officer)	March 8, 2011
/s/ RICHARD B. BREWER **Richard B. Brewer**	Director	March 8, 2011
/s/ JEAN-FRANCOIS FORMELA **Jean-Francois Formela**	Director	March 8, 2011
/s/ LINDA GRAIS **Linda Grais**	Director	March 8, 2011
/s/ TED W. LOVE **Ted W. Love**	Director	March 8, 2011

/s/ MARY K. PENDERGAST	Director	March 8, 2011

Mary K. Pendergast

Table of Contents

Signature	Title	Date
/s/ Burton E. Sobel **Burton E. Sobel**	Director	March 8, 2011
/s/ John L. Zabriskie **John L. Zabriskie**	Director	March 8, 2011

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.(8)
3.2	Second Amended and Restated Bylaws of the Registrant, as amended.(10)
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)

Table of Contents

Exhibit Number	Description
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.(17)
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.(18)
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(15)
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(15)
10.9§	License and Sublicense Agreement, dated October 28, 2003, by and between ARCA Discovery, Inc. and CPEC, L.L.C.(13)
10.10§	Amendment to License and Sublicense Agreement, dated February 22, 2006, by and between ARCA Discovery, Inc. and CPEC L.L.C.(14)
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.(13)
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.(13)
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.(13)
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.(13)
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.(13)
10.16§	Diagnostic, Collaboration and Option Agreement, dated June 23, 2006, by and between ARCA Discovery, Inc. and CardioDX, Inc.(13)
10.17§	Amendment to Diagnostic, Collaboration and Option Agreement, dated October 1, 2007, by and between ARCA Discovery, Inc. and CardioDX, Inc.(13)
10.18§	Manufacturing Agreement, dated September 11, 2006, by and between ARCA Discovery, Inc. and Patheon, Inc.(13)
10.19§	Development, Commercialization and Licensing Agreement, dated February 1, 2007, by and between ARCA Discovery, Inc. and Laboratory Corporation of America Holdings, Inc.(14)

Table of Contents

Exhibit Number	Description
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.(13)
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.(13)
10.22	Materials Transfer Agreement, dated October 14, 2005, by and between ARCA Discovery, Inc. and the University of Colorado.(13)
10.23	Equity Distribution Agreement, dated December 8, 2009, between ARCA biopharma, Inc. and Wedbush Securities, Inc.(9)
10.24	Amendment no. 1, dated April 30, 2010 to the Equity Distribution Agreement dated December 8, 2009 between ARCA biopharma, Inc. and Wedbush Securities, Inc.(19)
10.25	Lease Surrender and Termination Agreement, dated August 5, 2009, by and between ARCA biopharma, Inc. and The Irvine Company LLC.(10)
10.26	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.(11)
10.27§	Exclusive Option Agreement, dated December 2, 2009, by and between ARCA biopharma, Inc. and the University of Cincinnati. (17)
10.28	Agreement Term Extension Letter dated December 8, 2010, of the Exclusive Option Agreement by and between ARCA biopharma, Inc. and the University of Cincinnati.(21)
10.29	Agreement Term Extension Letter dated December 21, 2010, of the Exclusive Option Agreement by and between ARCA biopharma, Inc. and the University of Cincinnati.(22)
10.30	Agreement Term Extension Letter dated January 21, 2011, of the Exclusive Option Agreement by and between ARCA biopharma, Inc. and the University of Cincinnati.(23)
10.31	ARCA Discovery, Inc. 2004 Stock Incentive Plan.(7)
10.32	Amendment No. 1 to the ARCA Discovery, Inc. 2004 Stock Incentive Plan.(7)
10.33	Amendment No. 2 to the ARCA Discovery, Inc. 2004 Stock Incentive Plan.(7)
10.34	Amendment No. 3 to the ARCA Discovery, Inc. 2004 Stock Incentive Plan.(7)
10.35	Amendment No. 4 to the ARCA Discovery, Inc. 2004 Stock Incentive Plan.(7)
10.36	Amendment No. 5 to the ARCA Discovery, Inc. 2004 Stock Incentive Plan.(7)
10.37	Amendment No. 6 to the ARCA Discovery, Inc. 2004 Stock Incentive Plan.(7)
10.38	ARCA biopharma, Inc. 2004 Stock Incentive Plan, Form of Executive Incentive Stock Option Agreement.(7)
10.39	ARCA biopharma, Inc. 2004 Stock Incentive Plan, Form of Non-Executive Incentive Stock Option Agreement.(7)
10.40	ARCA biopharma, Inc. 2004 Stock Incentive Plan, Form of Nonqualified Stock Option Agreement.(7)
10.41	ARCA biopharma, Inc. 2004 Equity Incentive Plan (f/k/a Nuvelo, Inc. 2004 Equity Incentive Plan), Form of Partial Acceleration Stock Option Agreement.(8)

Table of Contents

Exhibit Number	Description
10.42	ARCA biopharma, Inc. 2004 Equity Incentive Plan (f/k/a Nuvelo, Inc. 2004 Equity Incentive Plan), Form of No Acceleration Stock Option Agreement.(8)
10.43	ARCA biopharma, Inc. 2004 Equity Incentive Plan (f/k/a Nuvelo, Inc. 2004 Equity Incentive Plan), Form of Director Stock Option Agreement.(8)
10.44	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)
10.45	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)
10.46	Form of Indemnification Agreement between Nuvelo, Inc. and its directors and officers.(1)
10.47	Nuvelo, Inc. Amended Executive Change in Control and Severance Benefit Plan.(4)
10.48	Amended and Restated Employment and Retention Agreement, dated June 4, 2008, by and between ARCA biopharma, Inc. and Michael R. Bristow.(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 Employment Agreement, dated June 12, 2008, by and between ARCA biopharma, Inc. and Christopher D. Ozeroff.(8)
10.51	Assignment and Assumption Agreement, dated January 26, 2009, by and between ARCA biopharma, Inc. and ARCA biopharma Colorado, Inc.(8)
10.52	Amended and Restated ARCA biopharma, Inc. 2004 Equity Incentive Plan(12)
10.53	ARCA biopharma, Inc. Employee Severance Benefit Plan(20)
10.54	ARCA biopharma, Inc. 2009 Reduction in Force Severance Benefit Plan(20)
10.55	Form of Option Amendment pursuant to ARCA biopharma, Inc. 2004 Equity Incentive Plan and ARCA biopharma, Inc. 2004 Stock Option Plan (change of control)(20)
10.56	Form of Option Agreement and Grant Notice pursuant to ARCA biopharma, Inc. 2004 Equity Incentive Plan (NDA/change of control acceleration)(20)
10.57	Employment Agreement, dated February 11, 2009, by and between ARCA biopharma, Inc. and Patrick Wheeler.(17)
10.58	Form of Indemnification Agreement between ARCA biopharma, Inc. and its directors and officers.(8)
14.1	Code of Business Conduct and Ethics(10)
16.1	Letter from Ernst & Young LLP to the Securities and Exchange Commission, dated March 30, 2009.(16)
23.1*	Consent of KPMG LLP, Independent Registered Public Accounting Firm.
24.1*	Power of Attorney (included in the signature page hereto).
31.1*	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. sec. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

Table of Contents

* 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.

(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.
(2) Previously filed with the SEC as an Exhibit to and incorporated herein by reference from Nuvelo, Inc. s Form 10-Q, filed on November 8, 2006, File No. 000-22873.
(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.
(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.
(5) Previously filed with the SEC as an Exhibit to and incorporated herein by reference from Nuvelo, Inc. s Form 8-K, filed on September 25, 2008, File No. 000-22873.
(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.
(7) Previously filed with the SEC as an Exhibit to and incorporated herein by reference from ARCA biopharma, Inc. s Form 8-K, filed on January 28, 2009, File No. 000-22873.
(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 8-K, filed on December 8, 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 10-Q, filed on November 16, 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 8-K, filed on September 24, 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/A, filed on August 21, 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, filed on May 15, 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 10-Q/A, filed on November 6, 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 April 10, 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 8-K, filed on March 30, 2009, 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-K, filed on March 4, 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, 2010, 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 April 30, 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 10-Q, filed on August 10, 2009, 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 December 14, 2010, 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 December 22, 2010, 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 January 26, 2011, File No. 000-22873.