ARCA biopharma, Inc.
Form 10-K
March 27, 2009
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, 2008

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 (Address of Principal Executive Offices)	80021 (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 Global 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 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, 2008, the last business day of the most recently completed second fiscal quarter, was $29,925,354 based on the last sale price of the common stock as reported on that day by the Nasdaq Global Market.

As of March 17, 2009, the Registrant had 7,567,399 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 2009 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***

We have included or incorporated by reference into this Annual Report on Form 10-K statements that may constitute forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. Forward-looking statements may be identified by words including anticipate, plan, believe, intend, estimate, expect, should, may, potential and similar expressions. Such statements are based on our management s current expecta involve risks and uncertainties. Our actual results and performance could differ materially from those projected in the forward-looking statements as a result of many factors discussed in this Annual Report, including those set forth in this Item 1, as well as under Item 1A. Risk Factors and Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operations. We do not intend to update any of the forward-looking statements after the date of this Annual Report to conform these statements to actual results unless required by law.

Merger Transaction

On January 27 2009, ARCA biopharma, Inc., formerly known as Nuvelo, Inc., or Nuvelo, completed the merger contemplated by that Agreement and Plan of Merger and Reorganization, dated September 24, 2008, as amended October 28, 2008, by and among Nuvelo, Dawn Acquisition Sub, Inc., a wholly-owned subsidiary of Nuvelo, or Merger Sub, and ARCA biopharma, Inc., or ARCA, a privately held developmental-stage biopharmaceutical company based in Broomfield, Colorado, which merger agreement, as amended, is referred to herein as the Merger Agreement.

In accordance with the Merger Agreement, immediately prior to the consummation of the merger, Nuvelo effected a reverse stock split of its common stock. Pursuant to this reverse stock split, each 20 shares of Nuvelo s common stock that were issued and outstanding immediately prior to the merger were converted into one share of Nuvelo s common stock. In addition, pursuant to the Merger Agreement, Merger Sub merged with and into ARCA, with ARCA continuing after the merger as the surviving corporation and a wholly owned subsidiary of Nuvelo. Immediately following the merger, Nuvelo changed its name to ARCA biopharma, Inc. On January 28, 2009, ARCA s common stock began trading on the Nasdaq Global Market under the new symbol ABIO.

The business combination is treated as a reverse merger for accounting purposes, and as such, historical financial information included in our future filings with the SEC will be the financial information of ARCA as the accounting acquirer in the merger. However, since the merger was consummated after the end of the period covered by this report, the historical financial information included in this report is that of Nuvelo prior to the merger and not that of ARCA.

Unless the context otherwise requires, all references herein to ARCA, the Company, we, us and our refer to ARCA both before and after the completion of the merger, and all references to Nuvelo refer to Nuvelo and its business prior to the completion of the merger and the name change. All share and per share amounts contained in this report give effect to the reverse stock split completed in connection with the merger.

Nuvelo s Business Prior to the Merger

Prior to the completion of the merger, Nuvelo was developing drugs for acute cardiovascular disease, gastro-intestinal, or GI, diseases and other debilitating medical conditions. Its development pipeline included NU172, a direct thrombin inhibitor that has completed Phase I development for use as a short-acting anticoagulant during medical or surgical procedures, and Phase I clinical candidate NU206, a recombinant, secreted protein for the potential treatment of GI, diseases, including inflammatory bowel disease, mucositis and bone disease.

Table of Contents

On March 17, 2008, Nuvelo announced its decision to discontinue clinical development of its clinical-stage product candidate, alfimeprase, and restructure its operations in order to make additional resources available for its other research and development programs. As part of the restructuring plan, Nuvelo reduced its workforce by approximately 19% and recorded a restructuring expense of $2.5 million, including $1.3 million of termination benefits and $1.2 million of non-cash stock-based compensation expense.

Overview

ARCA is a biopharmaceutical company whose principal focus is developing genetically-targeted therapies for heart failure and other cardiovascular diseases.

ARCA s lead product candidate is Gencaro™ (bucindolol hydrochloride), a pharmacologically unique beta-blocker and mild vasodilator, which is under review by the U.S. Food and Drug Administration, or FDA, for chronic heart failure, or HF. ARCA also plans to pursue several significant follow-on indications for Gencaro. Gencaro is an oral tablet formulation, dosed twice daily. ARCA has identified common genetic variations, or genetic markers, that predict patient response to Gencaro. Subject to approval by the FDA, ARCA, through its collaboration with Laboratory Corporation of America, or LabCorp, anticipates introducing a test for these genetic markers with the market launch of Gencaro, potentially making Gencaro the first genetically-personalized cardiovascular drug. When prescribed using the test for these markers, ARCA believes that Gencaro can become an important new therapy for many chronic heart failure patients, with the potential for positive clinical outcomes in a defined genetic subpopulation, and good tolerability. In September 2008, the FDA formally accepted for filing ARCA s New Drug Application, or NDA, for Gencaro as a potential treatment for HF. In accordance with the Prescription Drug User Free Act, or PDUFA, the FDA s goal is to complete its review of the Gencaro NDA by May 31, 2009, and ARCA anticipates an FDA decision on the approvability of Gencaro in the second or third quarter of 2009. Gencaro was the subject of a major North America based heart failure Phase III trial, known as BEST, which ARCA believes will provide the primary basis for approval of Gencaro in the U.S.

Chronic heart failure is one of the largest health care problems in the United States and the rest of the world. Beta-blockers are part of the current standard of care for HF, and are considered to be among the most effective drug classes for the disease. However, a significant percentage of eligible patients in the United States is not being treated, or does not tolerate or respond well to those beta-blockers currently approved for the treatment of HF. ARCA believes that new therapies for which patient response can be predicted before a drug is prescribed can help improve the current standard of practice in the treatment of HF.

ARCA has collaborated with LabCorp to develop the Gencaro Test, a companion test for the genetic markers that predict clinical response to Gencaro. The proposed use of the Gencaro Test, if approved by the FDA, will be to enable a physician to determine, prior to therapy, whether a patient is likely to have a good response to Gencaro. LabCorp has developed the Gencaro Test to be administered using a blood test or a cheek swab, and to provide prompt results to the treating physician. The Gencaro Test was submitted through the Premarket Approval, or PMA, process in January 2009, and an FDA decision on approval, based on FDA guidance, is expected in conjunction with the FDA decision on Gencaro. ARCA intends to closely coordinate the commercial launch of Gencaro and the Gencaro Test with LabCorp.

ARCA holds worldwide rights to Gencaro and plans to commercialize the drug in the U.S. through its own specialized sales force. ARCA s commercial effort in the United States will focus on cardiologists specializing in heart failure, and selected other physicians. ARCA intends to seek partners to assist it in commercializing Gencaro in international markets. ARCA believes that Gencaro will have market exclusivity under federal and international laws following commercial launch, and will also potentially have protection under patent applications, which ARCA believes would substantially extend market exclusivity. ARCA also plans to pursue several significant follow-on indications for Gencaro, including various forms of cardiac arrhythmias.

ARCA is also evaluating continued development of NU172, a novel, short-acting anticoagulant. ARCA believes that NU172 may have potential as a new therapy in indications where heparin paired with its antidote,

Table of Contents

protamine, is the current standard of care, such as coronary artery bypass graft (CABG) surgery, kidney dialysis and a variety of vascular surgical and coronary interventions. NU172 recently completed a successful Phase Ib study. ARCA is currently exploring collaborations for the other research and development programs that Nuvelo had conducted prior to the merger.

ARCA believes that its expertise in cardiovascular pathophysiology and genetics, and its clinical and commercial experience, will enable it to identify and develop other cardiovascular therapies, with an emphasis on those that may be personalized using genetic markers. ARCA is currently exploring such opportunities.

Market Opportunity

HF is one of the world s most significant health care challenges. Industry sources estimate that about 6 million Americans have HF and nearly 550,000 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 $34 billion in direct and indirect healthcare costs. 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.

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, ARCA believes 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.

Table of Contents

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. ARCA believes 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. ARCA believes 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.

ARCA Strategy

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

Obtain FDA approval for Gencaro for the treatment of chronic heart failure and initiate U.S. commercialization. ARCA believes that Gencaro has a clinical record that supports its approvability. Gencaro s NDA was accepted for filing by the FDA in September 2008. ARCA expects a decision by the FDA on the approvability of Gencaro in the second or third quarter of 2009. If Gencaro is approved, ARCA currently intends to market it in the United States as the first pharmacogenetic cardiovascular therapy through its own sales force. ARCA plans to differentiate Gencaro based on its pharmacogenetic profile, unique mode of action, the Gencaro Test s expected ability to predict response, favorable tolerability and improved clinical endpoints. ARCA plans to support its commercialization effort with a publication strategy, appropriate contacts with key opinion leaders, a heart failure patient registry and an effective reimbursement strategy, in compliance with applicable federal requirements.

Build a specialty sales and marketing capability. In anticipation of the potential commercial launch of Gencaro in the U.S., ARCA is building a specialty sales and marketing organization, focusing on cardiologists that specialize in heart failure, and other physicians who treat heart failure or are influential in this setting. ARCA s management and employees, including its chief executive officer and its executive vice president in charge of commercialization, have extensive experience in the commercialization of cardiovascular therapies, including specialty sales and marketing organizations. ARCA also intends to use this sales and marketing organization to commercialize future product candidates in the U.S.

Expand Gencaro indications. ARCA plans to pursue clinical development of several potential additional indications for Gencaro, including the prevention of several forms of arrhythmia. ARCA believes these indications have pharmacogenetic potential, reasonable clinical development paths, will help differentiate Gencaro, and could potentially be successfully marketed by the specialty sales and marketing organization ARCA is currently building.

Develop NU172. ARCA s second investigational compound under consideration is NU172, a novel, short-acting anticoagulant that ARCA is evaluating for development as a potential new therapy in indications where heparin paired with its antidote, protamine, are the current standard of care, such as CABG surgery, kidney dialysis and a variety of vascular surgical and coronary interventions. NU172 recently completed a successful Phase Ib study.

Build a cardiovascular pipeline. ARCA s management and employees, including its chief executive officer and chief science and medical officer, have extensive experience in cardiovascular research, molecular genetics, cardiovascular clinical development, and the commercialization of cardiovascular

Table of Contents

therapies. ARCA intends to leverage this expertise to seek to identify, acquire, develop and commercialize other cardiovascular products or candidates, with an emphasis on pharmacogenetic applications.

Gencaro

Gencaro (bucindolol hydrochloride) is a pharmacologically unique beta-blocker and mild vasodilator which is under review by the FDA for the treatment of chronic heart failure. ARCA also plans to pursue several significant follow-on indications for Gencaro. Gencaro is considered part of the beta-blocker class because of its property of blocking both beta-1, or $ß_1$ and beta-2, or $ß_2$ receptors in the cardiac nervous system from binding with other molecules that activate these receptors. Because of its mild vasodilator effects, 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 has been tested clinically in approximately 4,500 patients. Gencaro was the subject of a Phase III heart failure mortality trial of over 2,700, mostly U.S. patients, known as the BEST trial. The BEST trial included a DNA bank of over 1,000 patients, which was used to conduct studies of the effect of genetic variation on bucindolol response.

At the time of the BEST trial, ARCA s founding scientists, Dr. Michael Bristow and Dr. Stephen Liggett, hypothesized that the unique pharmacologic properties of Gencaro would interact with common genetic variations or polymorphisms of the $ß_1$, and alpha2C, or $\propto_{2C}$, 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, or polymorphisms, 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. ARCA believes that these polymorphisms, which are detectable using standard genetic testing technology, can serve as diagnostic markers for predicting enhanced therapeutic response to Gencaro, and avoiding adverse events, in individual patients.

Table of Contents

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 ARCA researchers indicate that in human myocardial preparations, Gencaro significantly inactivates high functioning 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 ARCA 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 $\propto_{2C}$ receptors, to produce the unique pharmacogenetic profile of Gencaro. ARCA believes that these two properties, and their pharmacogenetic implications, are unique to Gencaro. These receptors, their genetic variants, and the biological system in which they function, are illustrated below:

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 the constitutively active (active in the absence of NE stimulation) state of certain ß$_1$ receptors.

There are two common genetic variations of the ß$_1$ receptor, each of which ARCA estimates is present in approximately 50% of the U.S. population. One of these variations is known as the βArg/Arg variant. Laboratory studies indicate that this variation results in a higher functioning ß$_1$ 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. Heart failure patients with this genotype may have the potential for greater cardiomyopathic ß$_1$ signaling. The other variation, the βGly 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$_1$-Arg/Arg receptor.

Gencaro has a powerful interaction with the higher-functioning ß$_1$-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

Table of Contents

ability of being able to stop the signaling of constitutively active receptors. ARCA believes that individuals with the $ß_1$-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 $ß_1$-Gly carrier genotype.

The other receptor that appears to give Gencaro its pharmacogenetic properties is the $\propto_{2C}$ receptor. This receptor is 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. Approximately 10-13% of the general population in the U.S. has a modified $\propto_{2C}$ receptor resulting from at least one modified gene that functions poorly. Patients with this variant, also known as the deletion variant , or $\propto_{2C}$ 322 325 DEL, are believed to have a diminished ability to regulate the amount of NE released by the cardiac nerve. The remaining 85% of the population has a normal functioning version of this receptor, referred to as the $\propto_{2C}$-wild type.

Individuals with the deletion variant of the $\propto_{2C}$ receptor tend to have abnormally high levels of NE in their cardiac nervous system. Gencaro, unlike other ß-blocking agents, exhibits the pharmacologic property of sympatholysis , or the ability to lower systemic NE levels, through effects that are mediated at least in part by blockade of $ß_2$ receptors residing on sympathetic nerve terminals. Therefore, when chronic heart failure patients with the deletion variant of the $\propto_{2C}$ receptor are treated with Gencaro, some of them may be more likely to experience an exaggerated lowering of NE resulting from Gencaro interacting with this variant, leading to a loss of efficacy. This risk may be more pronounced with late stage chronic heart failure patients, who are more dependent on high NE levels to support cardiac function. In contrast to those with the $\propto_{2C}$ deletion variant, the majority of patients with the $\propto_{2C}$-wild type variant appear to experience only a mild reduction in NE levels from Gencaro. In these patients, mild NE lowering by Gencaro appears to have a favorable therapeutic effect. In addition, patients with the $ß_1$-Arg/Arg genotype can tolerate the greater amount of NE lowering associated with $\propto_{2C}$ DEL genotypes, and in these patients any amount of sympatholysis appears to be beneficial.

The DNA substudy of patients from the BEST trial conducted by Drs. Bristow and Liggett indicated that the combinations of these polymorphisms in individual patients appear to influence the response to Gencaro with respect to significant clinical endpoints. As a result, ARCA anticipates three broad treatment groups for Gencaro:

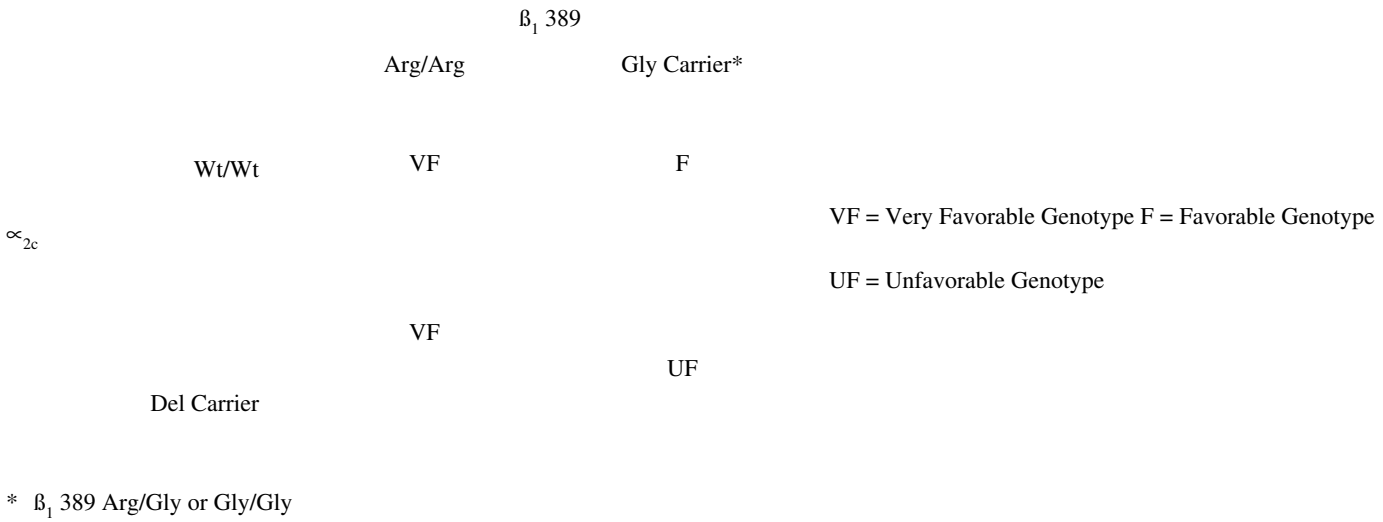
- The very favorable group, constituting an estimated 47-50% of the U.S. population and comprised of patients with the $ß_1$-Arg/Arg genotype. ARCA believes these individuals may have an enhanced therapeutic response to Gencaro because of its effect on this higher-functioning/constitutively active $ß_1$ receptor variant, and a favorable response to NE lowering, regardless of their $\propto_{2C}$ receptor genotype and the degree of bucindolol-associated sympatholysis.

- A second favorable group, constituting an estimated 40% of the U.S. population, and comprised of individuals with the $ß_1$-Gly carrier $ß_1$ receptor and wild-type $\propto_{2c}$ receptor. ARCA believes these individuals will benefit therapeutically from Gencaro (although not as much as the very favorable group), because of Gencaro s enhanced efficacy in the wild-type $\propto_{2C}$ receptor population, combined with some (although reduced) efficacy in $ß_1$-Gly carriers.

- A third and much smaller, unfavorable group, constituting about 10-13% of the U.S. population, comprised of individuals with both $ß_1$-Gly carrier $ß_1$ receptors and the deletion variant $\propto_{2C}$ receptors. In these patients, compensatory support to the failing heart may be compromised when Gencaro is administered, likely due to the inability of the lower functioning $ß_1$-Gly carrier $ß_1$ receptor to compensate for marked NE lowering from the deletion variant $\propto_{2C}$ receptor. Clinical data suggest Gencaro should not be administered to these patients.

Table of Contents

Diagram of subgroups based on ß$_1$ - and ∝$_{2c}$-AR genotype status:



* ß$_1$ 389 Arg/Gly or Gly/Gly

∝$_{2c}$ 322-325 Wt/Del or Del/Del

The BEST Trial

Bucindolol was originally developed by BMS for hypertension, and was licensed in the early 1990 s to Intercardia, a biopharmaceutical company. Around the time of completion of the Phase II clinical trials with bucindolol, a group of leading heart failure researchers proposed to the U.S. Department of Veteran Affairs Cooperative Clinical Studies Program that a large mortality study of beta-blockers be conducted in chronic heart failure. This grant application was approved, and shortly thereafter the U.S. National Heart, Lung and Blood Institute agreed to join in the sponsorship of the trial, known as the Beta-Blocker Evaluation of Survival Trial, or BEST. The Steering Committee of the BEST trial selected bucindolol as the agent to be tested against placebo, and Intercardia joined the trial as a sponsor.

The BEST trial was a double-blind, placebo-controlled, multi-center study of bucindolol on mortality and morbidity in an advanced chronic heart failure population. Most of the patients were from the United States. The basis for the selection of bucindolol as the tested ß-blocker included its Phase II clinical results and its high tolerability in more advanced HF patients. The trial was planned to run four and one-half years, and enroll 2,800 patients. 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.

The BEST trial began in 1995 and enrolled a total of 2,708 chronic heart failure patients. The patients were the most advanced clinical heart failure population ever studied in a large mortality trial, based on baseline systolic blood pressure and other criteria, and clinical stability was not an entry criterion for the trial. 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. Other pre-specified secondary endpoints included death from cardiovascular causes, a composite of death or heart transplantation, heart failure hospitalization, improvement in left ventricular ejection fraction, incidence of myocardial infarction, quality of life, and any change in the need for concomitant heart failure therapy, including administration of intravenous inotropic agents, intravenous diuretics, or increase in doses of orally-administered diuretics.

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

Table of Contents

BEST trial participants. As a result, some investigators began to prescribe these other beta-blockers to patients in the trial, which threatened to destroy the trial s integrity. At the time the BEST study was terminated, approximately 70% of the trial information was available, with 2,708 of a projected 2,800 patients enrolled and 797 out of 916 deaths reported. A companion trial to the BEST trial, known as the BEAT trial, studying European patients with left ventricular dysfunction and a history of heart attack, was terminated when BEST was terminated, with approximately 10% of trial information available (including 343 of 2,000 patients enrolled and 53 out of 630 deaths reported).

Following termination, the preliminary results of both studies 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.

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 35% 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%. Also, beginning in 2005, ARCA began to more fully analyze the overall BEST results in accordance with FDA-approved, pre-specified statistical plans, which had not been done by the sponsors when the BEST trial was terminated. For example, as re-analyzed by ARCA in accordance with the statistical plan, there appeared to be a 13% risk reduction on the primary endpoint in the BEST trial of mortality for the entire patient population taking bucindolol, with a p-value of 0.053. In addition, the pre-specified main secondary endpoint, reduction in the progression of heart failure, had not been analyzed when the BEST trial ended. As analyzed by ARCA, the results of the BEST trial indicated a 20% risk reduction on this secondary endpoint for the entire patient population taking bucindolol, that was highly statistically significant (p = 0.00003). The endpoint of heart failure progression, in similar forms, was the original basis of approval for the two beta-blockers currently approved in the U.S. for HF.

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	**Very Favorable patients**	Favorable patients	Unfavorable patients
(% of study population)	**(47%)**	(40%)	(13%)
All Cause Mortality (ACM), TTE	**i38%***	i25%	h4%
Cardiovascular Mortality (CVM), TTE	**i48%***	i40%*	h11%
ACM + transplantation	**i43%***	i24%	h4%
Heart failure (HF) Morbidity & Mortality, CRF, TTE	**i34%****	i20%	i1%
HF M&M, TTE (Adj.)	**i42%****	i27%	i16%
HF Hosp days/patient	**i48%****	i17%	h19%
AF prevention (from AE db)	**i62%***	i11%	i4%
VT/VF prevention (from AE db)	**i70%****	i44%	i9%

1 Covariate adjusted, transplant censored analysis

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

Table of Contents

While the results of the DNA substudy of the BEST trial indicate that Gencaro s efficacy varies by genotype with the most robust clinical effects found in patients with the very favorable genotype, they also indicate that patients with the favorable genotype may also benefit from the drug. The results of the DNA substudy indicate that patients in the unfavorable genotype group are not recommended for Gencaro. ARCA estimates that approximately 10-13% of the U.S. HF patient population falls into the unfavorable genotype group. In addition to these results, there was a 45-47% reduction in myocardial infarction in all patients in the BEST trial taking bucindolol. This result, which is unique to Gencaro, was supported by the limited results of the companion BEAT trial in Europe, in which Gencaro, with only approximately 10% of the trial information available, demonstrated a statistically significant improvement in combined myocardial infarction endpoints versus placebo, in patients with left ventricular dysfunction and a history of myocardial infarction.

Regulatory Strategy

In 2005, ARCA approached the FDA to discuss the results of the DNA substudy and ARCA s revised analysis of data from the BEST trial, as well as the prospect of an NDA for Gencaro for the treatment of HF. Through a number of meetings over the next several years, ARCA received guidance from the FDA on the potential NDA and the coordination of the NDA with a potential application for approval of the Gencaro Test.

The regulatory strategy for Gencaro and the Gencaro Test has been guided by this interaction with the FDA. In the NDA submitted for Gencaro, it is ARCA s position that Gencaro is approvable based on the full clinical program associated with its development, including data from the total patient cohort population in the BEST trial. The Gencaro clinical development program encompassed numerous clinical studies, including four randomized and placebo controlled studies in patients with HF or myocardial infarction, of which two, the BEST and BEAT trials, evaluated rigorous clinical endpoints, including mortality, hospitalization and myocardial infarction. The remaining clinical studies include the Phase II study conducted by BMS for the treatment of hypertension, several safety studies in other patient populations and a Phase I program in healthy subjects. The NDA presents the pharmacogenetic data from the DNA substudy conducted by Drs. Bristow and Liggett as important to the prescribing information in the proposed label for Gencaro, but not as the basis for its approval.

ARCA believes that the clinical trial results for Gencaro, including the results of the BEST trial and DNA substudy, demonstrate the efficacy and safety of Gencaro for treatment of patients with HF, both for decreasing the risk of mortality and cardiovascular or heart failure hospitalization, and also for reducing the risk of ischemic events and myocardial infarction. The primary endpoint of mortality (when analyzed in accordance with the pre-specified plan) was reduced in all BEST trial patients on bucindolol by 13%, with a p-value of 0.053. While the FDA typically views significance as a p-value of less than 0.05, the Gencaro p-value is within the range found sufficient for approval based on certain FDA precedent. This primary endpoint result is enhanced by the response of the BEST trial patient population with respect to eight secondary endpoints, all of which were positive and statistically significant. As pre-specified with FDA, heart failure progression was the most important secondary endpoint, and was positive and statistically significant; a heart failure progression endpoint was FDA s basis of approval for the two beta-blockers approved for HF. ARCA also believes that other statistical analyses and the attributes of the BEST trial itself add to its credibility.

ARCA believes Gencaro s status as a beta-blocker adds further support to its clinical record, as this class has a well-established record of safety and efficacy. The results of the BEST trial are supported by qualitatively consistent results from almost every trial in the beta-blocker class for the treatment of HF. ARCA believes the use of class effects to support marketing approval of Gencaro by the FDA is consistent with prior precedent, especially within the precedent of approvals in cardiovascular and heart-specific therapies.

ARCA believes that the pharmacogenetic data generated from the DNA substudy conducted by Drs. Bristow and Liggett create a separate public health rationale for approval of Gencaro. These DNA substudy results are not the primary basis for approval as set forth in the Gencaro NDA, but ARCA believes they will represent an important part of the prescribing information in the label being sought for Gencaro. ARCA believes the genetic

Table of Contents

results will provide physicians with a tool to help predict individual patient response prior to therapy. This unique attribute of Gencaro represents a new approach in treating HF, one that ARCA believes has the potential to improve the standard of care.

Licensing and Partnership Obligations

ARCA has licensed worldwide rights to Gencaro, including all preclinical and clinical data, from Cardiovascular Pharmacology and Engineering Consultants, LLC, or CPEC, who has licensed rights in Gencaro from BMS; ARCA has 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. Under this license agreement, ARCA is obligated under the CPEC license to make an $8.0 million milestone payment within 180 days after receiving approval from the FDA. ARCA also has the obligation under the CPEC license to make milestone payments of up to $13.0 million in the aggregate upon regulatory marketing approval in the U.S., Europe and Japan. Under the CPEC and BMS licenses, ARCA is obligated to pay royalties based on a percentage of annual sales of Gencaro in any jurisdiction worldwide, which in the aggregate are likely to average from the mid- to high-teens depending on actual annual sales. ARCA has an option to reduce these royalty rates by making a lump-sum payment.

ARCA has also 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. ARCA has no material future financial obligations under this license. ARCA has also licensed the nonexclusive rights to develop and commercialize diagnostics for these receptor polymorphisms, for the purpose of prescribing Gencaro, from the licensee of these rights, CardioDx, Inc. ARCA has certain milestone and royalty obligations under this license agreement, which have been assumed by LabCorp under the parties collaboration agreement.

The Gencaro Test

If cleared or approved, ARCA believes 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, ARCA believes it is critical to the successful commercialization of Gencaro to develop a companion genetic test that is simple to administer and widely available.

ARCA has collaborated with LabCorp to develop and commercialize the Gencaro Test. Under the terms of the collaboration, which has a 10-year term, ARCA has licensed to LabCorp the rights to commercialize a receptor genotype diagnostic for the $ß_1$ and $\propto_{2c}$ 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 and in coordination with ARCA s commercial plan. LabCorp has assumed all financial obligations of ARCA s license for the diagnostic technology, and retains all the economic benefits.

LabCorp has developed the commercial method for the Gencaro Test, which will use either a blood draw or a cheek swab to obtain a sample. ARCA believes that the Gencaro Test involves a straightforward genetic test that relies on well-validated technology. Based on FDA guidance, LabCorp has submitted a PMA regulatory submission, which was formally accepted by the FDA in January 2009, with the expectation of a decision on approval in the second or third quarter of 2009. LabCorp and ARCA believe that no further clinical trials will be required for the Gencaro Test submission, though there is no guarantee that FDA will not require additional clinical data. The clinical basis for the Gencaro Test will be the clinical studies discussed in ARCA s NDA for Gencaro, which the LabCorp submission cross-references.

Table of Contents

ARCA and LabCorp are developing a joint commercialization and marketing plan, which addresses commercial performance metrics such as turnaround time and distribution, the coordination of the drug and diagnostic sales and marketing programs, and strategies for third-party reimbursement.

Marketing and Sales

ARCA s strategy is to market Gencaro as the first pharmacogenetically targeted cardiovascular therapy for HF patients. For the U.S. market, ARCA currently plans to build its own specialized sales force, which it expects to be experienced in heart failure and cardiovascular drug sales. Cardiologists specializing in heart failure and selected other physicians will be the focus of ARCA s specialty sales force. ARCA believes a relatively small number of cardiologists and other heart failure specialists treat a significant percentage of HF patients, and, ARCA believes, also have a disproportionate influence on the prescribing practices of other health care providers that treat HF. Accordingly, ARCA believes that the HF market may be successfully targeted by a specialized sales strategy. Commercialization of Gencaro in the U.S. will require substantial additional capital resources. If sufficient capital is not available on acceptable terms, we may consider alternative commercialization strategies.

Additional elements of ARCA s U.S. marketing and sales strategy include:

Publication plan. ARCA has developed a plan that it believes is consistent with applicable federal laws and regulations.

National and regional key opinion leader development. ARCA plans to develop appropriate contacts with key decision makers in the heart failure market.

Registry. ARCA intends to develop an observational database integrating genetic and HF data.

Reimbursement. ARCA plans to implement a comprehensive reimbursement plan for Gencaro and the Gencaro Test in connection with the commercial launch of both products and in compliance with applicable federal requirements.

ARCA holds world-wide rights to Gencaro and has filed its patent applications covering Gencaro in the major international pharmaceutical markets. ARCA plans to accelerate its international commercialization strategy for Gencaro in 2009, by obtaining guidance from foreign regulatory agencies and engaging in discussions with potential international partners.

Competition

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. During the 12-month period ended January 31, 2009, total sales of beta-blockers approved for use in HF were approximately $4.6 billion in the U.S., with generic formulations accounting for a substantial majority of the market. ARCA estimates up to 50% of these revenues could be attributable to patients with heart failure. While reports vary on the proportion of the beta-blocker market represented by heart failure, ARCA believes HF contributes to a significant portion of the U.S. market.

The companies that sell the existing therapies are much larger than ARCA and have much greater resources. In addition, ARCA s proposed prescribing information for Gencaro includes a recommendation for genetic

14

Table of Contents

testing, which will add additional cost and procedures to the process of prescribing Gencaro, and which could make it more difficult for ARCA to compete against existing therapies.

Additionally, Gencaro may also compete against existing therapies whose follow-on indications may include treatment for HF. For example, Forest Laboratories may apply for approval to use Bystolic, a drug currently used to treat high blood pressure, for treatment of heart failure. If approved for treatment of heart failure, Gencaro may not be successful in competing against Bystolic, an already well-known name brand.

Other Potential Indications for Gencaro

ARCA is exploring the potential of Gencaro for the prevention of atrial fibrillation, and/or ventricular tachycardia/ventricular fibrillation. ARCA believes these could be attractive follow-on indications. ARCA believes that data from the BEST trial suggests that Gencaro has potential for these indications, and that the clinical response is also pharmacogenetic, based on the same genetic markers that stratify response on HF endpoints.

Development Pipeline

ARCA intends to leverage its management s experience in cardiovascular research, genetics, clinical development, and commercialization to acquire and develop other cardiovascular products or candidates, with an emphasis on pharmacogenetic applications. ARCA is evaluating further clinical development of NU172, a novel, short-acting anticoagulant, as a potential new therapy in indications where heparin paired with its antidote, protamine, are the current standard of care, such as CABG surgery, kidney dialysis and a variety of vascular surgical and coronary interventions.

NU172 is an aptamer, a single-stranded nucleic acid that forms a well-defined, three-dimensional shape conceptually similar to an antibody. NU172 was designed to directly inhibit thrombin s ability to stimulate blood clot formation in the setting of medical or surgical procedures where human blood is exposed to foreign materials. ARCA believes that NU172 has potential as a therapy for use in CABG surgeries, kidney dialysis, and other vascular and coronary interventions. Approximately 450,000 CABG procedures and 50 million dialysis procedures are performed annually in the U.S. In these procedures, heparin is often paired with its antidote protamine as the anticoagulation effect of heparin needs to be reversed once the procedure has been completed. Data from the Phase I trial and preclinical studies suggest that NU172 has the potential to produce rapid and predictable onset and offset of anticoagulation, work in stagnant blood, avoid thrombocytopenia, and has the potential for non-renal clearance. These studies also suggest that NU172 may have a short half-life in patients, giving it the potential to be rapidly reversed without the need for an antidote.

The development of NU172 is subject to a collaboration agreement with Archemix Corporation, under which ARCA is responsible for development and worldwide commercialization of NU172 and other potential product candidates that may be developed under this collaboration. In February 2008, Nuvelo paid Archemix a $1.0 million milestone fee in connection with the dosing of the first patient in the Phase I trial for NU172. If ARCA enrolls the first patient in a Phase II trial of NU172, ARCA will be obligated to pay Archemix a $3.0 million milestone fee.

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. ARCA outsources all manufacturing and analytical testing of the API of Gencaro and the drug product. Third party contract manufacturing organizations have been selected by ARCA on the basis of their technical and regulatory expertise. ARCA s approach with its contract manufacturing partners has been to replicate the manufacturing processes that were used to support the pivotal clinical trials with Gencaro, and to minimize any changes from these baseline processes, thereby reducing technical and regulatory risk.

Table of Contents

ARCA has contracted with Groupe Novasep to manufacture commercial quantities of the API for Gencaro. Registration batches have been completed to support the NDA submission for Gencaro, with all batches meeting specifications.

For drug product production, ARCA has 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. This is consistent with dosages studied in pivotal clinical trials of Gencaro, and ARCA believes they support the appropriate titration and chronic dosages required for HF patients. Registration batches have been successfully completed to support the NDA submission for Gencaro.

ARCA s manufacturing focus for the remainder of 2009 will be to complete the process validation programs and to build product inventory in anticipation of potential commercial launch. ARCA believes both facilities have adequate production capacity to support the projected market demand for Gencaro.

Research and Development Expenses

For the years ended December 31, 2008 and 2007, Nuvelo incurred research and development expenses of $27.8 million and $42.7 million, respectively. For the years ended December 31, 2008 and 2007, ARCA incurred research and development expenses of $11.0 million and $10.2 million, respectively. During 2009, ARCA expects to focus its research and development efforts on obtaining Gencaro approval, investigating potential new indications, developing an international regulatory strategy and furthering its cardiovascular pipeline development. Due to the significant reduction in the scope of Nuvelo s research and development efforts, ARCA anticipates a significant reduction in combined research and development spending in 2009 as compared with 2008.

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. ARCA anticipates that all of its 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 ARCA s 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.

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.

Table of Contents

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 I, 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. In Phase II, 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 III, 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 the 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 ARCA s NDA for Gencaro as a potential treatment for chronic heart failure.

Under 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 acceptance of the application to the time the FDA decides to issue a complete response, or approve the NDA. The PDUFA date for Gencaro is May 31, 2009. The review process is often significantly extended by FDA requests for additional information or clarification. The FDA may ultimately decide that the NDA does not satisfy the criteria for approval.

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 III clinical trial. Data from clinical trials are not always conclusive and FDA may interpret data differently than ARCA interprets data. For instance, ARCA believes that results from a single Phase III study, the BEST study, are sufficient to support approval of Gencaro s NDA. 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 III 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 IV 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 agency may decide later to suspend or withdraw product approval if compliance with regulatory standards is not maintained or if safety problems are recognized after the product reaches the market. In addition, the FDA requires surveillance programs to monitor approved products that have been commercialized, and the agency has the power to require additional clinical studies, to require changes in labeling or to prevent further marketing of a product based on the results of these post-marketing programs. The FDA also has authority to request implementation of a risk evaluation and mitigation strategy, or REMS, that could restrict distribution of Gencaro or require ARCA to provide additional risk information to prescribers.

Table of Contents

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

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

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

Table of Contents

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 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, with the expectation of a decision on approval in the second or third quarter of 2009.

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. Based on discussions with FDA, ARCA believes that the clinical trials in the Gencaro NDA are sufficient to support the Gencaro Test submission and that no further clinical trials will be required. Following the FDA s guidance from these discussions, the Gencaro Test regulatory filing cross-referenced the Gencaro NDA.

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

Table of Contents

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

ARCA believes that both patent protection and data exclusivity statutes will give Gencaro market exclusivity in the U.S. and in major international markets. Upon approval 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 FDA. This period can be extended under certain circumstances, and ARCA believes 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, ARCA believes that its patent portfolio will extend Gencaro s market exclusivity. ARCA has filed patent applications in the United States and in major international markets that claim the use of Gencaro with the genetic polymorphisms of the $ß_1$ and $\propto_{2c}$ receptors that predict Gencaro response. ARCA believes that this patent strategy will effectively serve to exclude generic competition, if the prescribing information in the Gencaro label includes a recommendation to genotype patients, a use covered by the patent applications. Consequently, if the patents are granted and ARCA s patent strategy is successful, ARCA believes that the possibility of generic competition with Gencaro will be significantly reduced until the expiration of these patents, which would be in 2025. ARCA also believes that if these patents are granted, 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.

ARCA also owns or has rights in a number of patents and patent applications relating to a number of clinical candidate molecules, including NU172. ARCA estimates that the primary patents for NU172 would expire in the U.S. and in Europe in 2026.

Table of Contents

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. ARCA cannot predict whether any such extensions will be granted.

Employees

As of February 28, 2009, the Company had 85 employees, 81 of whom are full-time, including 21 of Nuvelo s employees who have been retained for a transition period of up to 12 weeks from the closing date of the merger. Most of these employees operate out of the Broomfield, Colorado, and San Carlos, California locations while others operate from home-based offices in other states. None of the Company s employees are represented by any collective bargaining unit. The Company believes that it maintains good relations with its 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 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 described above, Nuvelo changed its name to ARCA biopharma, Inc. The Company has two wholly-owned subsidiaries, Hyseq Diagnostics, Inc., which is inactive, and ARCA biopharma Colorado, Inc. Its principal offices are located in Broomfield, Colorado. It also has facilities in San Carlos, California.

The Company files its 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 the Company s annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports on the Company s 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 the Company s corporate office by calling (720) 940-2200. Information found on the Company s website is not incorporated by reference into this report.

Table of Contents

Item 1A. ***Risk Factors***

An investment in our securities involves certain risks, including those set forth below and elsewhere in this report. In addition to the risks set forth below and elsewhere in this report, other risks and uncertainties not known to us, that are beyond our control or that we deem to be immaterial may also materially adversely affect our business operations. All of the following risks could materially and adversely affect our business, financial condition or results of operations. In such a case, you could lose all of or a part of your original investment. You should carefully consider the risks described below as well as other information and data included in this report.

Risks Related to ARCA s Business

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

ARCA is a development stage biopharmaceutical company with a limited operating history. In addition, to date ARCA has not generated any product revenue and has historically funded its operations through investment capital. ARCA s future growth depends on its ability to emerge from the developmental stage and successfully commercialize Gencaro and its other product candidates, which in turn, will depend, among other things, on ARCA s ability to:

- develop and obtain regulatory approval for Gencaro or other product candidates;
- successfully partner a companion genetic test with the commercial launch of Gencaro;
- build an internal specialty sales and marketing capability or enter into agreements with third parties to provide sales and marketing functions;
- pursue additional indications for Gencaro and develop other product candidates, including other cardiovascular therapies;
- raise additional capital to support the commercialization of Gencaro and other product candidates;
- increase the size of its organization;
- obtain commercial quantities of Gencaro or other product candidates at acceptable cost levels; and
- successfully conduct and complete clinical trials for Gencaro and other product candidates.

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

If ARCA is not able to obtain FDA approval and successfully develop and commercialize Gencaro or another product candidate in a timely manner, it may not be able to continue its business operations.

ARCA currently has no products that have received regulatory approval for commercial sale. The process to develop, obtain regulatory approval for and commercialize potential product candidates is long, complex and costly. The Gencaro NDA is currently under FDA review. Gencaro is ARCA s only product candidate at a late stage of clinical development. As a result, ARCA s business is substantially dependent on its ability to obtain regulatory approval for and successfully commercialize Gencaro in a timely manner.

In addition to Gencaro, ARCA currently plans to develop other product candidates, and is evaluating further clinical development of NU172, which has completed one Phase I clinical trial. This product candidate must be rigorously tested in clinical trials, and be shown to be safe and effective, before the FDA or other regulatory authorities outside the U.S. will consider it for approval.

Table of Contents

Failure to demonstrate that one or more of ARCA s product candidates is safe and effective, or significant delays in demonstrating such safety and efficacy, could adversely affect ARCA s business. Failure to obtain marketing approval of one or more of ARCA s product candidates from appropriate regulatory authorities, or significant delays in obtaining such approval, could also adversely affect ARCA s business. If approved for sale, ARCA s product candidates must be successfully commercialized. Failure to successfully commercialize one or more of ARCA s product candidates could damage ARCA s business, and, in particular, if the NDA for Gencaro is not approved, or is substantially delayed, or if ARCA is unable to successfully commercialize Gencaro, it may not be able to earn sufficient revenues to continue its business.

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

ARCA is currently building its sales organization. If Gencaro is approved by the FDA for commercial sale, ARCA intends to market Gencaro in the U.S. to physicians, hospitals and other health care providers using its own sales force. While certain ARCA employees have experience in establishing and managing a sales force, these employees have no such experience since being with ARCA. Commercialization of Gencaro in the U.S., particularly the establishment of a sales organization, will require substantial additional capital resources. If sufficient capital is not available on acceptable terms, we would need to consider alternative commercialization strategies for Gencaro. ARCA will need to incur significant additional expenses and commit significant additional management resources to establish a sufficient sales force for Gencaro.

ARCA may not be able to successfully establish these capabilities even if it is able to secure sufficient capital resources for its commercialization efforts. If ARCA elects to rely on third parties to sell Gencaro and any other products, then it may receive less revenue than if it sold such products directly. In addition, ARCA may have little or no control over the sales efforts of those third parties. In the event ARCA is unable to sell Gencaro and other selected product candidates, either directly or through third parties, the commercialization of Gencaro may be delayed indefinitely and ARCA s business may be harmed

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

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

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

Under ARCA s agreement with LabCorp, LabCorp is responsible for determining the appropriate regulatory pathway for the Gencaro Test and obtaining market clearance or approval from the FDA. Based on FDA guidance, LabCorp has submitted a PMA regulatory submission, which the FDA formally accepted in January 2009. The FDA may decide that the Gencaro Test should be evaluated for clearance under the FDA s 510(k) notification process. LabCorp and ARCA do not believe that any further clinical trials will be required for the Gencaro Test PMA, though there is no guarantee that 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 ARCA s commercial efforts, or if the information concerning the differential response to

Table of Contents

Gencaro resulting from certain genetic variation is not included in the approval label for Gencaro, the commercial launch of Gencaro may be significantly and adversely affected. In such cases, ARCA could be forced to identify a new third-party test provider and obtain regulatory approval for that provider s genetic test, which could substantially delay and negatively affect the commercial prospects for Gencaro.

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

The Gencaro Test is an important component of the commercial strategy for Gencaro. ARCA believes that the Gencaro Test helps predict patient response to Gencaro, and that this aspect of the drug is important to its ability to compete effectively with current therapies. The Gencaro Test adds an additional step in the prescribing process, an additional cost for the patient and payors, the risk that the test results may not be rapidly available and the possibility that it may not be available at all to hospitals and medical centers. Although ARCA anticipates that Gencaro will be the first genetically-targeted cardiovascular drug, Gencaro will be one of a number of successful drugs in the beta-blocker class currently on the market. Prescribers may be more familiar with these other beta-blockers, and may be resistant to prescribing Gencaro as an HF therapy without efforts on ARCA s part to educate prescribers. Any one of these factors could affect prescriber behavior, which in turn may substantially impede market acceptance of the Gencaro Test, which could cause significant harm to Gencaro s ability to compete, and in turn harm ARCA s business.

ARCA will need to significantly increase the size of its organization and may experience difficulties in managing its growth.

ARCA expects that it will need to substantially increase and modify its operations in the future to commercialize Gencaro and to conduct clinical trials for and commercialize any additional indications or markets for Gencaro and any future product candidates that ARCA acquires or develops, as well as to support the administrative functions of a public company. Future growth will impose significant added responsibilities on members of management, including the need to identify, recruit, retain and integrate additional employees. ARCA s future financial performance and its ability to commercialize its product candidates and to compete effectively will depend, in part, on its ability to manage any future growth effectively. To that end, ARCA must be able to:

- manage its clinical trials effectively;
- integrate current and additional management, administrative, financial and sales and marketing personnel;
- hire new personnel necessary to effectively commercialize product candidates it licenses;
- develop its administrative, accounting and management information systems and controls; and
- hire and train additional qualified personnel.

Unless ARCA is able to generate sufficient product revenue, ARCA will continue to incur losses from operations and may not achieve or maintain profitability.

ARCA s historical losses, among other things, have had and will continue to have an adverse effect on ARCA s stockholders equity and working capital. Even if ARCA receives regulatory approval for any of its product candidates, including Gencaro, sales of such products may not generate sufficient revenue for it to achieve or maintain profitability. ARCA expects to incur increased general and administrative expenses and higher sales and marketing expenses. As a result, it expects to continue to incur significant and increasing operating losses for the foreseeable future. Because of the numerous risks and uncertainties associated with developing therapeutic drugs, ARCA may experience larger than expected future losses and may never reach profitability.

Table of Contents

ARCA is dependent on key personnel, and it must attract and retain qualified employees, collaborators and consultants.

The success of ARCA s business is highly dependent on the principal members of ARCA s scientific and management staff, including its Chairman of the Board, Michael R. Bristow, and its President and Chief Executive Officer, Richard, B. Brewer. The loss of the services of any such individual might seriously harm ARCA s product development efforts. Recruiting and training personnel with the requisite skills is challenging and extremely competitive.

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

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

To receive regulatory approval for the commercial sale of any product candidates, ARCA must demonstrate safety and efficacy in humans to the satisfaction of regulatory authorities through preclinical studies and adequate and well-controlled clinical trials of the product candidates. This process is expensive and can take many years, and failure can occur at any stage of the testing. ARCA s failure to adequately demonstrate the safety and efficacy of its product candidates will prevent regulatory approval and commercialization of such products. With respect to Gencaro, the FDA could determine that the preclinical studies and clinical trials conducted by or on Gencaro s behalf were inadequate, and such a determination would prevent regulatory approval and commercialization of Gencaro. For instance, ARCA filed an NDA for Gencaro in July 2008, based primarily on a single Phase III trial. The FDA guidelines generally suggest that sponsors conduct two adequate and well-controlled studies to demonstrate the safety and efficacy of a product candidate such as Gencaro in support of FDA approval. FDA interpretation of the statutory requirements also states that a single study may be sufficient to support approval if the FDA determines that, based on relevant science and other confirmatory evidence, there is strong evidence to establish the safety and efficacy of the drug candidate using a single adequate and well-controlled study. If the FDA determines that the clinical data for Gencaro is not sufficiently strong to demonstrate Gencaro s safety and efficacy for chronic heart failure, then Gencaro may not be approved by the FDA for ARCA s proposed indications, may be approved for a more limited indication, or the FDA may require ARCA to conduct additional studies before approving Gencaro for chronic heart failure. Even if ARCA conducted additional studies and submitted the attendant data, FDA may ultimately decide that the NDA does not satisfy the criteria for approval.

In the event that ARCA or its collaborators conduct preclinical studies that did not comply with Good Laboratory Practices or incorrectly design or carry out human clinical trials or those clinical trials fail to demonstrate clinical significance, ARCA will not likely be able to obtain FDA approval for product development candidates. ARCA s inability to successfully and effectively complete clinical trials for any product candidates on schedule or at all will severely harm ARCA s business. Significant delays in clinical development could materially increase product development costs or allow ARCA s competitors to bring products to market before it does, impairing ARCA s ability to effectively commercialize any future product candidates. ARCA does not know whether planned clinical trials will begin on time, will need to be redesigned or will be completed on schedule, if at all. Clinical trials can be delayed for a variety of reasons, including:

- delays or failures in obtaining regulatory authorization to commence a trial because of safety concerns of regulators relating to ARCA s product candidates or similar product candidates of ARCA s competitors or failure to follow regulatory guidelines;

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 ARCA s clinical trial protocol from an institutional review board, or IRB, to conduct a clinical trial at a prospective study site;
- delays in recruiting patients to participate in a clinical trial, which may be due to the size of the patient population, eligibility criteria, protocol design, perceived risks and benefits of the drug, availability of other approved and standard of care therapies, availability of clinical trial sites;
- other clinical trials seeking to enroll subjects with similar profile;
- failure of ARCA s clinical trials and clinical investigators to be in compliance with the FDA s Good Clinical Practices;
- unforeseen safety issues, including negative results from ongoing preclinical studies;
- inability to monitor patients adequately during or after treatment;
- difficulty monitoring multiple study sites; and
- failure of ARCA s third-party contract research organizations, clinical site organizations and other clinical trial managers, to satisfy their contractual duties, comply with regulations or meet expected deadlines.

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

In September 2008, the FDA formally accepted for filing ARCA s NDA, for Gencaro, with the goal of completing its review of the NDA by May 31, 2009. Filing of the NDA indicates that the application is sufficiently complete to allow for FDA to review ARCA s data supporting the safety profile and effectiveness of Gencaro, but does not guarantee approval. All of ARCA s product candidates are prone to the risks of failure inherent in drug development. The results from preclinical animal testing and early human clinical trials may not be predictive of results obtained in later human clinical trials. Further, although a new product may show promising results in preclinical or early human clinical trials, it may subsequently prove unfeasible or impossible to generate sufficient safety and efficacy data to obtain necessary regulatory approvals. The data obtained from preclinical and clinical studies are susceptible to varying interpretations that may delay, limit or prevent regulatory approval, and the FDA and other regulatory authorities in the United States and elsewhere exercise substantial discretion in the drug approval process. The numbers, size and design of preclinical studies and clinical trials that will be required for FDA or other regulatory approval will vary depending on the product candidate, the disease or condition for which the product candidate is intended to be used and the regulations and guidance documents applicable to any particular product candidate. The FDA or other regulators can delay, limit or deny approval of any product candidate for many reasons, including, but not limited to:

side effects;

safety and efficacy;

Table of Contents

- defects in the design of clinical trials;

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

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

In light of widely publicized events concerning the safety of certain drug products, regulatory authorities, members of Congress, the Government Accountability Office, medical professionals and the general public have raised concerns about potential drug safety issues. These events have resulted in the withdrawal of certain drug products, revisions to certain drug labeling that further limit use of the drug products and establishment of risk management programs that may, for instance, restrict distribution of drug products. The increased attention to drug safety issues may result in a more cautious approach by the FDA to clinical trials and approval. Data from clinical trials may receive greater scrutiny with respect to safety and the product s risk/benefit profile, which may make the FDA or other regulatory authorities more likely to terminate clinical trials before completion, or require longer or additional clinical trials that may result in substantial additional expense, and a delay or failure in obtaining approval or approval for a more limited indication than originally sought. Aside from issues concerning the quality and sufficiency of submitted preclinical and clinical data, the FDA may be constrained by limited resources from reviewing and determining the approvability of the Gencaro NDA by May 31, 2009. Indeed, in early 2008, the FDA announced that due to a lack of resources, NDAs may not be reviewed within the performance goals under PDUFA, and from time to time, the FDA has extended the review period for NDAs.

In addition, the manufacture and tableting of Gencaro is done by third party suppliers, who must pass a pre-approval inspection of their facilities before ARCA can obtain marketing approval. The FDA could also request additional information or data, including data from an additional Phase III study, which may extend the review period.

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

ARCA has no manufacturing capacity which puts it at risk of lengthy and costly delays of bringing its products to market.

ARCA does not currently operate manufacturing facilities for clinical or commercial production of its product candidates, including their active pharmaceutical ingredients, or API. ARCA has no experience in drug formulation or manufacturing, and it lacks the resources and the capabilities to manufacture any of its product candidates on a clinical or commercial scale. ARCA does not intend to develop facilities for the manufacture of product candidates for clinical trials or commercial purposes in the foreseeable future.

ARCA has contracted with Groupe Novasep to manufacture commercial quantities of the API for Gencaro. For drug production, ARCA has contracted with Patheon, Inc. to manufacture the Gencaro tablets. In addition, ARCA is dependent upon other third-party contract manufacturers to develop the necessary production processes and produce the volume of cGMP-grade material needed to complete the anticipated Phase II study of NU172. These contract manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required to successfully produce, store and distribute ARCA s products. In the event of

Table of Contents

errors in forecasting production quantities required to meet demand, natural disaster, equipment malfunctions or failures, technology malfunctions, strikes, lock-outs or work stoppages, regional power outages, product tampering, war or terrorist activities, actions of regulatory authorities, business failure, strike or other difficulty, ARCA may be unable to find an alternative third-party manufacturer in a timely manner and the production of its product candidates would be interrupted, resulting in delays and additional costs, which could impact ARCA s ability to commercialize and sell its product candidates.

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

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

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

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

If a product candidate of ARCA is approved by the FDA or by another regulatory authority, ARCA would be held to extensive regulatory requirements over product manufacturing, testing, distribution, labeling, packaging, adverse event reporting and other reporting to regulatory authorities, storage, advertising, marketing, promotion, distribution, and record keeping. Regulatory approvals may also be subject to significant limitations on the indicated uses or marketing of the product candidates. Potentially costly follow-up or post-marketing clinical studies may be required as a condition of approval to further substantiate safety or efficacy, or to investigate specific issues of interest to the regulatory authority. Previously unknown problems with the product candidate, including adverse events of unanticipated severity or frequency, may result in additional regulatory controls or restrictions on the marketing or use of the product or the need for postmarketing studies, and could include suspension or withdrawal of the products from the market.

Furthermore, ARCA s third-party manufacturers and the manufacturing facilities that they use to make ARCA s product candidates are regulated by the FDA. Quality control and manufacturing procedures must continue to conform to cGMP after approval. Drug manufacturers and their subcontractors are required to register their facilities and products manufactured annually with the FDA and certain state agencies and are

Table of Contents

subject to periodic unannounced inspections by the FDA, state and/or other foreign authorities. Any subsequent discovery of problems with a product, or a manufacturing or laboratory facility used by ARCA or its collaborators, may result in restrictions on the product, or on the manufacturing or laboratory facility, including a withdrawal of the drug from the market or suspension of manufacturing. Any changes to an approved product, including the way it is manufactured or promoted, often require FDA approval before the product, as modified, can be marketed. ARCA and its third-party manufacturers will also be subject to ongoing FDA requirements for submission of safety and other post-market information.

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

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

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

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

Table of Contents

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

- issue untitled or warning letters;
- suspend or withdraw ARCA s regulatory approval for approved products;
- seize or detain products or recommend a product recall of a drug or medical device, or issue a mandatory recall of a medical device;
- refuse to approve pending applications or supplements to approved applications filed by ARCA;
- suspend any of ARCA s ongoing clinical trials;
- impose restrictions on ARCA s operations, including costly new manufacturing requirements, and restrictions on ARCA s sales, marketing and/or distribution of ARCA s products;
- seek an injunction;
- pursue criminal prosecutions;
- close the facilities of ARCA s contract manufacturers; or
- impose civil or criminal penalties.

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

Any medical device for which LabCorp obtains clearance or approval, and the manufacturing processes, reporting requirements, post-approval clinical data and promotional activities for such product, will be subject to continued regulatory review, oversight and periodic inspections by the FDA and other domestic and foreign regulatory bodies. With respect to the Gencaro Test, to the extent applicable, LabCorp and certain of its suppliers will be required to comply with the FDA s Quality System Regulation, or QSR, and International Standards Organization, or ISO, requirements which cover the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage and shipping of any product for which clearance or approval is obtained. Regulatory bodies, such as the FDA, enforce the QSR and other regulations through periodic inspections. The failure by LabCorp, or certain of its third-party manufacturers or suppliers, as the case may be, to comply with applicable statutes and regulations administered by the FDA and other regulatory bodies, or the failure to timely and adequately respond to any adverse inspectional observations or product safety issues, could result in, among other things, enforcement actions. If any of these actions were to occur, it could harm ARCA s reputation and cause product sales and profitability of Gencaro to suffer and may prevent ARCA from generating revenue.

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

If LabCorp or certain of its third party suppliers fail to supply the Gencaro Test, the product sales and profitability of Gencaro will suffer.

LabCorp is ARCA s single-source supplier of the Gencaro Test. If LabCorp or its third party suppliers were to cease or interrupt production of or otherwise fail to supply the Gencaro Test, or the materials required to produce it, in a timely manner or at all, ARCA could be unable to obtain a contract manufacturer of companion genetic test for Gencaro for an indeterminate period of time. This could adversely affect ARCA s ability to satisfy demand for Gencaro, which could cause product sales and profitability of Gencaro to suffer and may have an adverse effect on the ARCA s financial condition and results of operations.

Table of Contents

Medical devices related to Gencaro, such as the Gencaro Test, may in the future be subject to product recalls that could harm ARCA s reputation, business and financial results.

The FDA and similar foreign governmental authorities have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture. In the case of the FDA, the authority to require a mandatory recall must be based on an FDA finding that there is a reasonable probability that the device would cause serious adverse health consequences or death. In addition, foreign governmental bodies have the authority to require the recall of ARCA s products in the event of material deficiencies or defects in design or manufacture. Manufacturers may, under their own initiative, initiate a field correction or removal, known as a recall, for a product if any material deficiency in a device is found. A government-mandated or voluntary recall by ARCA s third-party suppliers, including LabCorp, could occur as a result of component failures, manufacturing errors, design or labeling defects or other deficiencies and issues. Any such recalls would divert managerial and financial resources and may have an adverse effect on the ARCA s financial condition and results of operations.

If medical devices related to Gencaro, such as the Gencaro Test, cause or contribute to a death or a serious injury, or malfunction in certain ways, ARCA s third-party suppliers will be subject to medical device reporting regulations, which can result in voluntary corrective actions or agency enforcement actions.

Under the FDA s medical device reporting regulations, medical device manufacturers are required to report to the FDA information that a device has or may have caused or contributed to a death or serious injury or has malfunctioned in a way that would likely cause or contribute to death or serious injury if the malfunction of the device or one of ARCA s similar devices were to recur. If ARCA s third-party suppliers, including LabCorp, fail to report these events to the FDA within the required timeframes, or at all, the FDA could take enforcement action against ARCA s third-party suppliers, including LabCorp. Any such adverse event involving the Gencaro Test also could result in future voluntary corrective actions, such as recalls or customer notifications, or agency action, such as inspection or enforcement action. Any corrective action, whether voluntary or involuntary, taken by ARCA s third-party suppliers, including LabCorp, may significantly affect ARCA s ability to market Gencaro. In such cases, ARCA could be forced to identify a new third-party test provider for the Gencaro Test.

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

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

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

Table of Contents

risks or discomforts. In addition, patients participating in clinical trials may die before completion of the trial or suffer adverse medical events unrelated to investigational products.

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

Federal regulatory reforms may adversely affect ARCA s or its suppliers ability to sell products profitably.

From time to time, legislation is drafted and introduced in the U.S. Congress that could significantly change the statutory provisions governing the clearance or approval, manufacture and marketing of a medical device. In addition, FDA regulations and guidance are often revised or reinterpreted by the agency in ways that may significantly affect the way that medical devices are marketed and promoted. It is impossible to predict whether legislative changes will be enacted or FDA regulations, guidance or interpretations changed, and what the impact of such changes, if any, may be.

Without limiting the generality of the foregoing, in September 2007, the Food and Drug Administration Amendments Act of 2007, or the Amendments, were enacted. The Amendments require, among other things, that the FDA propose, and ultimately implement, regulations that will require manufacturers to label medical devices with unique identifiers unless a waiver is received from the FDA. Once implemented, compliance with those regulations may require manufacturers to take additional steps in the manufacture and labeling of medical devices. These steps may require additional resources and could be costly. In addition, the Amendments require medical device manufacturers to, among other things, comply with clinical trial registration requirements once clinical trials are initiated.

ARCA s failure to establish and manage a distribution network for its products could delay or compromise the commercialization of Gencaro and other future products.

ARCA has not yet established systems and processes necessary for distributing products to customers. ARCA plans to contract with one or more wholesale distributors to warehouse its products and distribute them to retail, hospital and other pharmacy suppliers that would then distribute its products directly to patients. This distribution network will require significant coordination with its sales and marketing and finance organizations. Failure to secure contracts with distribution services could negatively impact the distribution of ARCA s products, if any, and failure to coordinate financial systems could negatively impact its ability to accurately report product revenue, if any. If ARCA is unable to effectively establish and manage the distribution process, then the commercialization of Gencaro and other product candidates may be delayed or severely compromised and ARCA s results of operations may be harmed.

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

Gencaro is a new type of beta-blocker and vasodilator being developed for heart failure and other indications. While ARCA anticipates that this drug will be the first genetically-targeted cardiovascular drug, Gencaro will be one of a number of successful drugs in the beta-blocker class currently on the market. Currently,

Table of Contents

there are three branded beta-blockers indicated for chronic heart failure in New York Health Association, or NYHA class II-IV patients: TOPROL-XL (once-a-day formulation), Coreg and Coreg CR (once-a-day). TOPROL-XL and Coreg have generic equivalents commercially available in the U.S. (Metoprolol Succinate and Carvedilol, respectively). The price of the generic forms of these drugs will be less than the anticipated price of Gencaro, if approved. As a result, Gencaro may not be successful in competing against these existing drugs.

Additionally, Forest Laboratories may apply for approval to use Bystolic, a drug currently used to treat high blood pressure, for treatment of heart failure. If approved for treatment of heart failure, Gencaro may not be successful in competing against Bystolic, an already well-known name brand. Accordingly, ARCA may not achieve its revenue goals, and its business may be harmed.

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

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

Gencaro or ARCA s other product candidates may not gain market acceptance among physicians, patients and the medical community. The degree of market acceptance of Gencaro or ARCA s other product candidates will depend on a number of factors, such as its effectiveness and tolerability, as compared with competitive drugs. Also, prevalence and severity of side-effects could negatively affect market acceptance of Gencaro or ARCA s other product candidates. For example, side-effects of Gencaro observed during clinical trials included fatigue, dizziness and slowed heart beat. Failure to achieve market acceptance of Gencaro would significantly harm ARCA s business.

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

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

- governmental payors, such as Medicare and Medicaid;
- private health insurers, including managed-care organizations; and
- other third-party payors.

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

Cost-control initiatives could decrease the price ARCA might establish for products, which could result in product revenues lower than anticipated. If the prices for ARCA s product candidates decrease or if

Table of Contents

governmental and other third-party payors do not provide adequate coverage and reimbursement levels, then ARCA s revenue and prospects for profitability will suffer.

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

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

- successfully and rapidly complete clinical trials for any future product candidates and obtain all requisite regulatory approvals in a cost-effective manner;
- build an adequate sales and marketing infrastructure;
- develop competitive formulations of its product candidates;
- attract and retain key personnel; and
- identify and obtain other product candidates on commercially reasonable terms.

If ARCA fails to identify and license or acquire other products or product candidates, then it may be unable to expand its business, and the acquisition or licensing of other products or product candidates may put a strain on ARCA s operations and will likely require ARCA to seek additional financing.

One of ARCA s key strategies is to license or acquire clinical-stage products or product candidates and further develop them for commercialization. The market for licensing and acquiring products and product candidates is intensely competitive and many of ARCA s competitors may have greater resources than ARCA. If ARCA undertakes any additional acquisitions, whether of product candidates or other biopharmaceutical companies, the process of integrating an acquired product, candidate or complementary company into ARCA s business may put a strain on its operations, divert personnel, financial resources and management s attention. If ARCA is not successful in identifying and licensing or acquiring other products or product candidates or completing future acquisitions, then it may be unable expand its pipeline of product candidates. In addition, any future acquisition would give rise to additional operating costs and will likely require ARCA to seek additional financing. Future acquisitions could result in additional issuances of equity securities that would dilute the ownership of existing stockholders. Future acquisitions could also result in the incurrence of debt, contingent liabilities or the amortization of expenses related to other intangible assets, any of which could adversely affect ARCA s operating results.

Any future product revenues could be reduced by imports from countries where ARCA s product candidates are available at lower prices.

Even if ARCA obtains FDA approval to market Gencaro or other products in the U.S., ARCA s sales in the U.S. may be reduced if ARCA s products are imported into the U.S. from lower priced markets, whether legally or illegally. In the U.S., prices for pharmaceuticals are generally higher than in the bordering nations of Canada and Mexico. There have been proposals to legalize the import of pharmaceuticals from outside the U.S. If such legislation were enacted, then ARCA s future revenues could be reduced.

Table of Contents

If ARCA encounters difficulties enrolling patients in its clinical trials, its trials could be delayed or otherwise adversely affected.

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

Patient enrollment is affected by factors including:

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

If ARCA has difficulty enrolling a sufficient number of patients to conduct its clinical trials as planned, ARCA may need to delay or terminate ongoing or planned clinical trials, either of which would have a negative effect on its business. Delays in enrolling patients in ARCA s clinical trials would also adversely affect its ability to generate product, milestone and royalty revenues and could impose significant additional costs on ARCA or on its collaborators.

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

ARCA, and its collaborators, will only receive regulatory approval for its product candidates if ARCA can demonstrate in carefully designed and conducted clinical trials that the product candidate is safe and effective. ARCA does not know whether its current or any future clinical trials will demonstrate sufficient safety and efficacy to obtain the requisite regulatory approvals or will result in marketable products. Clinical trials are lengthy, complex and expensive processes with uncertain results. ARCA has spent, and expects to continue to spend, significant amounts of time and money in the clinical development of its product candidates.

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

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

Table of Contents

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

ARCA may not achieve its projected development goals in the time frames it announces and expects.

ARCA sets goals for, and makes public statements regarding, the timing of certain accomplishments, such as the commencement and completion of clinical trials, the disclosure of trial results, the obtaining of regulatory approval and drug product sales, which ARCA sometimes refers to as milestones. These milestones may not be achieved, and the actual timing of these events can vary dramatically due to a number of factors such as delays or failures in ARCA s clinical trials, disagreements with current or future collaborative partners, the uncertainties inherent in the regulatory approval process and manufacturing scale-up and delays in achieving manufacturing or marketing arrangements sufficient to commercialize ARCA s products. There can be no assurance that ARCA s clinical trials will be completed, or that it will make regulatory submissions or receive regulatory approvals as planned. If ARCA fails to achieve one or more of these milestones as planned, its business will be materially adversely affected, and the price of ARCA s shares will decline.

ARCA would be subject to applicable regulatory approval requirements of the foreign countries in which ARCA markets its products, which are costly and may prevent or delay ARCA from marketing its products in those countries.

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

If ARCA cannot successfully integrate the Nuvelo organization, ARCA may not be able to operate efficiently after the merger or to realize any benefits from the merger.

Achieving the benefits of the merger will depend in part on the successful integration of ARCA s and Nuvelo s technical and business operations and remaining personnel in a timely and efficient manner. The integration process requires coordination of the personnel of both companies, involves the integration of systems, applications, policies, procedures, business processes and operations and is a complex, costly and time-consuming process. The difficulties of combining the operations of the companies include, among others:

- consolidating research and development operations;
- retaining key employees;
- consolidating corporate and administrative infrastructures;
- preserving the research and development and other important relationships of the companies;
- integrating and managing the technology of two companies;
- using the combined company s liquid capital and other assets efficiently to develop the business of the combined company;
- appropriately managing the liabilities of the combined company;

diverting management s attention from ongoing business concerns; and

coordinating geographically separate organizations.

Table of Contents

ARCA cannot assure you that it will receive any benefits of this or any other merger or acquisitions, or that any of the difficulties described above will not adversely affect the Company. The integration process may be difficult and unpredictable because of possible conflicts and differing opinions on business, scientific and regulatory matters. If the companies cannot successfully integrate their technical and business operations and personnel, ARCA may not realize the expected benefits of the merger.

ARCA expects to incur significant costs integrating the companies into a single business.

ARCA expects to incur significant costs integrating the technical and business operations and personnel of Nuvelo and ARCA, which may include costs for employee redeployment, relocation or severance, conversion of information systems, reorganization of facilities, disposition of excess facilities and relocation or disposition of excess equipment. The benefits of the merger may not be sufficient to justify these integration costs.

Integrating the companies may divert the attention of ARCA s management away from its operations.

ARCA s successful integration of Nuvelo s technical and business operations and personnel into its own organization may place a significant burden on ARCA s management and internal resources. The diversion of management s attention and any difficulties encountered in the transition and integration process could result in delays in ARCA s clinical trial and product development programs and could otherwise harm ARCA s business, financial condition and operating results.

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

As a public company, ARCA has incurred and will continue to incur significant levels of legal, accounting and other expenses. The Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, and related rules of the SEC and Nasdaq regulate corporate governance practices of public companies and impose significant requirements relating to disclosure controls and procedures and internal control over financial reporting. Compliance with these public company requirements has increased ARCA s costs, required additional resources and made some activities more time consuming. ARCA is required to expend considerable time and resources complying with public company regulations.

Failure to establish and maintain effective internal control over financial reporting could have a material adverse effect on ARCA s business, operating results and stock price.

Maintaining effective internal control over financial reporting is necessary for ARCA to produce reliable financial reports and is important in helping to prevent financial fraud. Prior to the recently completed merger involving Nuvelo, ARCA was not subject to the Sarbanes-Oxley Act. Therefore, ARCA s management only performed an evaluation of Nuvelo s internal control over financial reporting as of December 31, 2008 in accordance with the provisions of the Sarbanes-Oxley Act. Material weaknesses may exist when ARCA reports on the effectiveness of its internal control over financial reporting for purposes of its reporting requirements under the Exchange Act or Section 404 of the Sarbanes-Oxley Act for ARCA s fiscal year ending December 31, 2009. The existence of one or more material weaknesses would preclude a conclusion that ARCA maintains effective internal control over financial reporting. Such a conclusion would be required to be disclosed in ARCA s future Annual Reports on Form 10-K and could impact the accuracy and timing of its financial reporting and the reliability of its internal control over financial reporting, which could harm ARCA s reputation and cause the market price of its common stock to drop.

ARCA s investments in marketable debt securities are subject to credit risk that may adversely affect their fair value.

ARCA maintains a significant portfolio of investments in marketable debt securities, which are recorded at fair value. To minimize ARCA s exposure to credit risk, ARCA invests in securities with strong credit ratings

Table of Contents

and has established guidelines relative to diversification and maturity with the objective of maintaining safety of principal and liquidity. ARCA does not invest in derivative financial instruments, mortgage-backed securities or auction rate securities, and ARCA has not recorded any losses on ARCA s securities due to credit or liquidity issues. Since 2007, rising delinquency and default rates on subprime mortgages and declining home prices have caused a significant decline in the value of residential mortgage-backed securities, which has negatively impacted the entire credit market in the U.S. In recent months, certain other financial instruments have also sustained downgrades in credit ratings and declines in value. Further deterioration in the credit market may have an adverse effect on the fair value of ARCA s investment portfolio.

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

The U.S. economy was in a recession through much or all of 2008, which has continued and deepened in 2009. As the global financial crisis has broadened and intensified, a severe recession appears likely. Business activity across a wide range of industries and regions is substantially reduced, and many companies are in serious difficulty due to the lack of consumer spending, reduced access to credit, cash flow shortages, deterioration of their businesses and lack of liquidity in the capital markets. Challenging economic and market conditions may also result in:

- reductions to our workforce;
- increased price competition, which may adversely affect the revenue and gross margins we anticipate from any of our product candidates, once commercialized;
- financial strain on the health care system, which may lead to lower than anticipated sales of our product candidates, once commercialized;
- the bankruptcy or insolvency of our collaborators and third party manufacturers; and
- difficulties in forecasting, budgeting and planning due to limited visibility into economic conditions.

A prolonged national or regional economic recession, or other events that have produced or could produce major changes economic patterns, such as the housing market crisis, the credit crisis or a terrorist attack, could have a material adverse effect on our business, results of operations and financial condition.

Risks Related to ARCA s Capital Structure and Stock Price Volatility

ARCA is evaluating whether and when to raise additional funds through the public or private debt and equity markets.

ARCA believes that its current cash, cash equivalents and marketable securities balances are sufficient to fund operations through at least December 31, 2009. However, because of ARCA s substantial capital requirements necessary to fund commercialization of Gencaro, if approved, ARCA will seek to access the public or private debt and equity markets. Additional funding may not be available to ARCA, and, if available, may not be on acceptable terms.

ARCA s future capital requirements depend on a number of factors, including, but not limited to, the following:

- timing and outcomes of regulatory approvals, in particular the approval of ARCA s NDA for Gencaro by the FDA;
- the costs of commercializing ARCA s product candidates once regulatory approvals are obtained, including the costs of establishing or contracting for marketing, sales and manufacturing capabilities, and other costs related to increasing the size of ARCA s organization;

the extent to which ARCA is able to acquire or in-license new products, technologies or businesses;

Table of Contents

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

the terms and timing of any additional collaborative, strategic partnership or licensing agreements that ARCA may establish.

If ARCA s available cash and cash equivalents and funding received or made available are insufficient to satisfy its liquidity requirements, or if ARCA develops additional products or pursues additional applications for its products or conducts additional clinical trials beyond those currently contemplated, ARCA may seek to sell additional equity or incur additional indebtedness. The sale of additional equity or convertible debt securities may result in additional dilution to ARCA s stockholders. If ARCA raises additional funds through the incurrence of additional indebtedness, the obligations related to such indebtedness would be senior to rights of holders of ARCA capital stock and could contain covenants that would restrict ARCA s operations. Any required additional funds may not be available on reasonable terms, if at all. If ARCA is unable to obtain additional financing, it may be required to modify or limit its planned research, development and commercialization strategies, which could adversely affect its business.

Continued disruption in financial markets may affect ARCA s ability to access sufficient funding.

The global financial crisis and the broad domestic economic downturn have disrupted credit and equity markets globally, which has reduced the availability of investment capital and credit. A continuation or worsening of these conditions may make it difficult or impossible for us to refinance our indebtedness and access adequate funding to raise additional capital if needed, and may otherwise have a material adverse effect on our liquidity and capital resources.

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

Nasdaq rules impose restrictions on ARCA s ability to raise funds through a private offering of ARCA s common stock, convertible debt or similar instruments without obtaining stockholder approval. Under Nasdaq rules, an offering of more than 20% of ARCA s total shares outstanding for less than the greater of book or market value requires stockholder approval unless the offering qualifies as a public offering for purposes of the Nasdaq rules. As of March 17, 2009, ARCA had 7,567,399 shares of common stock outstanding, 20% of which is approximately 1,513,479 shares. If ARCA were to seek to raise funds through a private offering of stock, convertible debt or similar instruments, it would be limited in how much funding it could raise privately without requiring a stockholder vote and may instead be required to raise funding through a more costly public offering of its securities.

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

ARCA s executive officers, directors and their affiliates beneficially own approximately 49% of the outstanding common stock of ARCA as of January 27, 2009. Accordingly, these executive officers, directors and their affiliates, acting individually or as a group, have substantial influence over the outcome of a corporate action of ARCA requiring stockholder approval, including the election of directors, any merger, consolidation or sale of all or substantially all of ARCA s assets or any other significant corporate transaction. These stockholders may also delay or prevent a change in control of ARCA, even if such change in control would benefit the other stockholders of ARCA. The significant concentration of stock ownership may adversely affect the value of ARCA s common stock due to investors perception that conflicts of interest may exist or arise.

Table of Contents

ARCA s stock price is expected to be volatile.

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

- the regulatory status of Gencaro and the Gencaro Test, and whether and when they are approved for sale, if at all, and the labeling or other conditions of use imposed by the FDA;
- the results of ARCA s future clinical trials and any future NDAs of its current and future product candidates;
- the entry into, or termination of, key agreements, including key strategic alliance agreements;
- the results and timing of regulatory reviews relating to the approval of ARCA s product candidates;
- failure of any of ARCA s product candidates, if approved, to achieve commercial success;
- general and industry-specific economic conditions that may affect ARCA s research and development expenditures;
- the results of clinical trials conducted by others on drugs that would compete with ARCA s product candidates;
- issues in manufacturing ARCA s product candidates or any approved products;
- the initiation of material developments in or the conclusion of litigation to enforce or defend any of the ARCA s intellectual property rights;
- the loss of key employees;
- the introduction of technological innovations or new commercial products by competitors of ARCA;
- changes in estimates or recommendations by securities analysts, if any, who cover ARCA s common stock;
- future sales of ARCA s common stock;
- changes in the structure of health care payment systems; and

period-to-period fluctuations in ARCA s financial results.

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

In the past, following periods of volatility in the market price of a company s securities, stockholders have often instituted class action securities litigation against those companies. Such litigation, if instituted, could result in substantial costs and diversion of management attention and resources, which could significantly harm ARCA s profitability and reputation.

Our existing indebtedness could adversely affect our financial condition, prevent us from fulfilling our financial obligations and limit our ability to obtain additional investment capital and credit.

ARCA s subsidiary, ARCA biopharma Colorado, Inc., or ARCA Colorado, is a party to a Loan and Security Agreement dated July 17, 2007, as amended January 21, 2009, with Silicon Valley Bank, or SVB, under which SVB provided a growth capital facility of up to $4.0 million dollars, to be used solely for working capital and to fund ARCA s general business requirements. As of March 2, 2009, approximately $3.5 million aggregate principal amount was outstanding under the SVB credit facility. No additional drawings are permitted under the credit facility. The credit facility is not subject to any prepayment penalties. All borrowings under this agreement bear interest at a floating per annum rate equal to SVB s prime rate, which was 4.0% as of March 2, 2009.

Table of Contents

The agreement contains customary affirmative and negative covenants including, without limitation, (i) covenants requiring ARCA Colorado to comply with applicable laws, provide to SVB copies of ARCA s financial statements, maintain appropriate levels of insurance, protect, defend and maintain the validity and enforceability of ARCA Colorado s material intellectual property, and (ii) covenants restricting ARCA Colorado s ability to dispose of all or substantially all of its assets, engage in other lines of business, change its senior management, enter into transactions constituting a change of control, assume additional indebtedness, incur liens on its assets, among other covenants. ARCA Colorado s obligations under the credit facilities are secured by all of ARCA Colorado s assets.

This indebtedness could have important consequences to you. For example, it could:

- make it more difficult to satisfy our financial obligations to third parties other than SVB;
- increase our vulnerability to adverse economic and industry conditions;
- require us to dedicate a substantial portion of our cash to debt service, thereby reducing the availability of our cash to fund acquisitions, working capital, capital expenditures, research and development efforts and other general corporate purposes;
- limit our flexibility in planning for, or reacting to, changes in our business and the industry in which we operate;
- place us at a competitive disadvantage compared to our competitors that have less or no debt;
- limit our ability to borrow additional funds; and
- limit our ability to make future acquisitions.

The SVB credit facility was to mature on March 23, 2009, but ARCA and SVB are in discussions to refinance the existing credit facility and extend the credit facility s maturity date until December 1, 2010. Pending the execution and delivery of definitive documentation reflecting the refinancing of the credit facility, SVB has agreed to extend the maturity date of the credit facility until April 6, 2009. We may not be able to refinance the existing SVB credit facility on commercially reasonable terms or at all.

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

Sales in the public market of substantial amounts of ARCA s common stock could depress prevailing market prices of its common stock. As of March 17, 2009, ARCA had 7,567,399 shares of common stock outstanding. All of these shares are freely transferable without restriction or further registration under the Securities Act, except for shares held by ARCA s directors, officers and other affiliates and unregistered shares held by non-affiliates. Although ARCA does not believe that its directors, officers and other affiliates have any present intentions to dispose of large amounts of any shares of common stock owned by them, there can be no assurance that such intentions will not change in the future. The sale of these additional shares could depress the market price of ARCA s common stock.

As of March 17, 2009, ARCA had approximately 1.1 million shares of ARCA s common stock which may be issued upon exercise of outstanding stock options. If and when these options are exercised, such shares are available for sale in the open market without further registration under the Securities Act. The existence of these outstanding options may negatively affect ARCA s ability to complete future equity financings at acceptable prices and on acceptable terms. The exercise of those options, and the prompt resale of shares of ARCA s common stock received, may also result in downward pressure on the price of ARCA s common stock.

Table of Contents

As of March 17, 2009, approximately 210,000 shares of ARCA s common stock were issuable upon the exercise of outstanding warrants, which were all exercisable as of this date. Once a warrant is exercised, if the shares of ARCA common stock issued upon the exercise of any such warrant are not available for sale in the open market without further registration under the Securities Act, then the holder can arrange for the resale of shares either by invoking any applicable registration rights, causing the shares to be registered under the Securities Act and thus freely transferable, or by relying on an exemption to the Securities Act. If these registration rights, or similar registration rights that may apply to securities ARCA may issue in the future, are exercised, it could result in additional sales of ARCA s common stock in the market, which may have an adverse effect on ARCA s stock price.

ARCA may need to raise significant additional capital to finance its capital requirements, including the research, development and commercialization of its drug products. If future securities offerings are successful, they could dilute ARCA s current stockholders equity interests and reduce the market price of its common stock.

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

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

ARCA has implemented anti-takeover provisions that could discourage, prevent or delay a takeover, even if the acquisition would be beneficial to ARCA s stockholders.

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

- establish a classified board of directors so that not all members of ARCA s board may be elected at one time;
- authorize the issuance of up to 5 million additional shares of preferred stock that could be issued by ARCA s board of directors to increase the number of outstanding shares and hinder a takeover attempt;
- limit who may call a special meeting of stockholders;
- prohibit stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of ARCA s stockholders; and
- establish advance notice requirements for nominations for election to ARCA s board of directors or for proposing matters that can be acted upon at a stockholder meeting.

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

Table of Contents

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

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

- the board of directors approved the transaction where the stockholder acquired 15% or more of the corporation s stock;
- after the transaction in which the stockholder acquired 15% or more of the corporation s stock, the stockholder owned at least 85% of the corporation s outstanding voting stock, excluding shares owned by directors, officers and employee stock plans in which employee participants do not have the right to determine confidentially whether shares held under the plan will be tendered in a tender or exchange offer; or
- on or after this date, the merger or sale is approved by the board of directors and the holders of at least two-thirds of the outstanding voting stock that is not owned by the stockholder.

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

- lengthen the time required for a person or entity to acquire control of ARCA through a proxy contest for the election of a majority of ARCA s board of directors;
- discourage bids for ARCA s common stock at a premium over market price; and
- generally deter efforts to obtain control of ARCA.

Risks Related to Intellectual Property and Other Legal Matters

ARCA is party to securities litigation, and defending these lawsuits could hurt ARCA s business. The volatility of the market price could engender additional class action securities litigation.

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

For example, in December 2006, after Nuvelo announced that alfimeprase did not meet its primary endpoint in the first of two planned Phase III trials for the treatment of acute peripheral arterial occlusion and in the first of two planned Phase III trials for the treatment of catheter occlusion, the closing price of one share of Nuvelo s common stock was $81 (as adjusted for the 20-to-1 reverse stock split) on the day of the announcement, as compared with a closing price of $391 (as adjusted for the 20-to-1 reverse stock split) on the trading day prior to the announcement. On February 9, 2007, Nuvelo and certain of Nuvelo s former and current officers and directors were named as defendants in a purported securities class action lawsuit filed in the U.S. District Court for the Southern District of New York. The suit alleged violations of the Securities Exchange Act of 1934 related to the clinical trial results of alfimeprase, which Nuvelo announced on December 11, 2006, and sought damages on behalf of purchasers of Nuvelo s common stock during the period between January 5, 2006 and December 8,

43

Table of Contents

2006. Specifically, the suit alleged that Nuvelo misled investors regarding the efficacy of alfimeprase and the drug s likelihood of success. The plaintiff sought unspecified damages and injunctive relief. Three additional lawsuits were filed in the Southern District of New York on February 16, 2007, March 1, 2007 and March 6, 2007, respectively. On April 10, 2007, three separate motions to consolidate the cases, appoint lead plaintiff, and appoint lead plaintiff s counsel were filed. On April 18, 2007, Nuvelo filed a motion to transfer the four cases to the Northern District of California. The Court granted Nuvelo s motion to transfer the cases to the Northern District of California in July 2007. Plaintiffs have filed motions for consolidation, lead plaintiff and lead plaintiff s counsel in the Northern District of California. Plaintiffs filed their consolidated complaint in the Northern District of California on November 9, 2007. Nuvelo filed a motion to dismiss plaintiffs consolidated complaint on December 21, 2007. Plaintiffs filed an opposition to Nuvelo s motion to dismiss on February 4, 2008. On June 12, 2008, the Court held a hearing on the motion to dismiss.

On December 4, 2008, the Court issued an order dismissing plaintiff s complaint, and granting leave to amend. On January 23, 2009, the plaintiffs filed an amended complaint, alleging similar claims. Based on the Court s December 4, 2008 order, and plaintiff s amended complaint, ARCA believes that any attorneys fees, loss or settlement payment with respect to this suit will be paid by its insurance providers. However, it is possible that ARCA could be forced to incur material expenses in the litigation if the case is not finally dismissed, or if the parties cannot achieve a settlement, and, in the event of an adverse outcome, ARCA s business could be harmed.

In addition, Variagenics, with which Nuvelo merged in 2003, has been named as a defendant in a securities class action lawsuit alleging the failure to disclose additional and excessive commissions purportedly solicited by and paid to underwriters who are also named defendants in the lawsuit. Plaintiffs in the suit allege that underwriters took these commissions and in exchange allocated shares of Variagenics stock to their preferred customers through alleged agreements with these preferred customers that tied the allocation of initial public offering shares to agreements by the customers to make additional aftermarket purchases at pre-determined prices. As a result of Nuvelo s merger with Variagenics, ARCA is obligated to continue to defend against this litigation. ARCA believes that any attorneys fees, loss or settlement payment with respect to this suit will not be material to ARCA s financial position or results of operations, and that any loss, settlement payment or attorneys fees accrued with respect to the suit will be paid by Nuvelo s insurance provider. Because of a recent court ruling, the settlement class, as defined in the settlement papers, is no longer feasible. While a new complaint has not been filed against Nuvelo, there are several focus cases against other issuers in which new complaints have been filed. Defendant issuers in the focus cases filed motions to dismiss the new complaints. On March 26, 2008, the District Court issued an order granting in part and denying in part the focus issuers motions to dismiss. The focus issuers had been advised that plaintiffs intended to file new complaints against Nuvelo, but none have been filed yet. ARCA believes that any attorneys fees, loss or settlement payment with respect to this suit will be paid by Nuvelo s insurance provider. However, it is possible that ARCA could be forced to incur material expenses in the litigation if the parties cannot achieve a settlement, and, in the event of an adverse outcome, ARCA s business could be harmed.

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

ARCA faces product liability exposure related to the testing of its product candidates in human clinical trials, and may face exposure to claims by an even greater number of persons once it begins marketing and distributing its products commercially. If ARCA cannot successfully defend itself against product liability claims, then it will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for its products and product candidates;
- injury to its reputation;
- withdrawal of clinical trial participants;

Table of Contents

costs of related litigation;

substantial monetary awards to patients and others;

loss of revenues; and

the inability to commercialize its products and product candidates.

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

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

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

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

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

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

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

ARCA s ability to commercialize Gencaro and other product candidates depends upon its ability to develop, manufacture, market and sell these drugs without infringing the proprietary rights of third parties. A number of pharmaceutical and biotechnology companies, universities and research institutions have or may be granted patents that cover technologies similar to the technologies owned by or licensed to ARCA. ARCA may choose to seek, or be required to seek, licenses under third party patents, which would likely require the payment of license fees or royalties or both. ARCA may also be unaware of existing patents that may be infringed by Gencaro, the genetic testing ARCA intends to use in connection with Gencaro or its other product candidates. Because patent applications can take many years to issue, there may be other currently pending applications that may later result in issued patents that are infringed by Gencaro or ARCA s other product candidates. Moreover, a license may not be available to ARCA on commercially reasonable terms, or at all.

Table of Contents

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

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

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

ARCA s intellectual property rights may not preclude competitors from developing competing products and ARCA s business may suffer.

ARCA s competitive success will depend, in part, on ARCA s ability to obtain and maintain patent protection for its inventions, technologies and discoveries, including intellectual property that ARCA licenses. The patent positions of biotechnology companies involve complex legal and factual questions, and ARCA cannot be certain that ARCA s patents and licenses will successfully preclude others from using ARCA s technology. Although Gencaro has an established patent strategy, the timing of the grant of a patent cannot be predicted. Patent applications describing and seeking patent protection of methods, compositions or processes relating to proprietary inventions involving human therapeutics could require ARCA to generate data, which may involve substantial costs. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued. Consequently, ARCA cannot be certain that any of its patent applications will result in the issuance of patents or, if any patents are issued, that they will provide significant market protection or will not be circumvented or challenged and found to be unenforceable or invalid. In some cases, patent applications in the U.S. and certain other jurisdictions are maintained in secrecy until patents issue, and since publication of discoveries in the scientific or patent literature often lags behind actual discoveries, ARCA cannot be certain of the priority of inventions covered by pending patent applications. Moreover, ARCA may have to participate in interference proceedings declared by the U.S. Patent and Trademark Office to determine priority of invention or in opposition proceedings in a foreign patent office, any of which could result in substantial cost to ARCA, even if the eventual outcome is favorable. There can be no assurance that a court of competent jurisdiction would hold any patents issued valid. An adverse outcome could subject ARCA to significant liabilities to third parties, require disputed rights to be licensed from third parties or require ARCA to cease using such technology. ARCA could also incur substantial costs in seeking to enforce its proprietary rights against infringement.

While the composition of matter patents on the compound have expired, ARCA holds the intellectual property arising from the discovery of the interaction of Gencaro with the polymorphisms of the $ß_1$ and $\propto_{2c}$ receptors. ARCA has filed patent applications that claim the use of Gencaro with the diagnosis of a patient s receptor genotype. ARCA s NDA requested a label that will include a claim that efficacy varies based on receptor genotype and a recommendation in the prescribing information that prospective patients be tested for their receptor genotype. Under applicable law, a generic bucindolol label would likely be required to include this recommendation as it pertains directly to the safe or efficacious use of the drug. Such a label could be considered as inducing infringement, carrying the same liability as direct infringement. Even if the patents are granted, the approved label may not contain language covered by the patents, or ARCA may be unsuccessful in enforcing them.

Table of Contents

ARCA may not be able to effectively protect its intellectual property rights in some foreign countries, as many countries do not offer the same level of legal protection for intellectual property as the U.S. Furthermore, the patent applications describing ARCA s proprietary methods are filed only in the U.S.

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

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

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

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

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

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

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

Not applicable.

Table of Contents

Item 2. ***Properties***

The Company s headquarters facility consists of approximately 15,000 square feet of newly constructed office space in Broomfield, Colorado, which is leased until June 2013. It also leases approximately 1,500 square feet of laboratory facilities located in Aurora, Colorado.

In January 2005, the Company entered into a seven-year facility lease agreement for 61,826 square feet of industrial space in San Carlos, California. A subtenant leases approximately 6,754 square feet of this space, and the Company currently plans to sublet additional portions of this facility.

The Company also leases approximately 139,000 square feet of space in Sunnyvale, California, which it has leased to a subtenant through May 31, 2011.

The Company believes that these facilities are adequate to meet its current needs.

Item 3. ***Legal Proceedings***

On February 9, 2007, Nuvelo and certain of Nuvelo s former and current officers and directors were named as defendants in a purported securities class action lawsuit filed in the United States District Court for the Southern District of New York. The suit alleges violations of the Securities Exchange Act of 1934 related to the clinical trial results of alfimeprase, which Nuvelo announced on December 11, 2006, and seeks damages on behalf of purchasers of Nuvelo s common stock during the period between January 5, 2006 and December 8, 2006. Specifically, the suit alleges that Nuvelo misled investors regarding the efficacy of alfimeprase and the drug s likelihood of success. The plaintiff seeks unspecified damages and injunctive relief. Three additional lawsuits were filed in the Southern District of New York on February 16, 2007, March 1, 2007 and March 6, 2007, respectively. On April 10, 2007, three separate motions to consolidate the cases, appoint lead plaintiff, and appoint lead plaintiff s counsel were filed. On April 18, 2007, Nuvelo filed a motion to transfer the four cases to the Northern District of California. The Court granted Nuvelo s motion to transfer the cases to the Northern District of California in July 2007. Plaintiffs have filed motions for consolidation, lead plaintiff and lead plaintiff s counsel in the Northern District of California. Plaintiffs filed their consolidated complaint in the Northern District of California on November 9, 2007. Nuvelo filed a motion to dismiss plaintiffs consolidated complaint on December 21, 2007. Plaintiffs filed an opposition to Nuvelo s motion to dismiss on February 4, 2008. On June 12, 2008, the Court held a hearing on the motion to dismiss.

On December 4, 2008, the Court issued an order dismissing plaintiff s complaint, and granting leave to amend. On January 23, 2009, plaintiffs filed an amended complaint, alleging similar claims. Based on the Court s December 4, 2008 order, and plaintiff s amended complaint, ARCA believes that any attorneys fees, loss or settlement payment with respect to this suit will be paid by its insurance providers. However, it is possible that ARCA could be forced to incur material expenses in the litigation if the case is not finally dismissed, or if the parties cannot achieve a settlement, and, in the event of an adverse outcome, ARCA s business could be harmed.

In addition, on or about December 6, 2001, Variagenics, Inc. was sued in a complaint filed in the United States District Court for the Southern District of New York naming it and certain of its officers and underwriters as defendants. The complaint purportedly is filed on behalf of persons purchasing Variagenics stock between July 21, 2000 and December 6, 2000, and alleges violations of Sections 11, 12(a)(2) and 15 of the Securities Act of 1933, as amended, and Section 10(b) of the Securities Exchange Act of 1934, as amended, and Rule 10b-5 promulgated thereunder. The complaint alleges that, in connection with Variagenics July 21, 2000 initial public offering, or IPO, the defendants failed to disclose additional and excessive commissions purportedly solicited by and paid to the underwriter defendants in exchange for allocating shares of Variagenics stock to preferred customers and alleged agreements among the underwriter defendants and preferred customers tying the allocation of IPO shares to agreements to make additional aftermarket purchases at predetermined prices. Plaintiffs claim that the failure to disclose these alleged arrangements made Variagenics registration statement

Table of Contents

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. On or about July 15, 2002, Variagenics and the individuals filed a motion to dismiss. The Company is involved in this litigation as a result of Nuvelo s merger with Variagenics in January 2003. On July 16, 2003, Nuvelo s board of directors approved a settlement proposal initiated by the plaintiffs. However, because of a recent court ruling, the settlement class, as defined in the settlement papers, is no longer feasible. While a new complaint has not been filed against Nuvelo, there are several focus cases against other issuers in which new complaints have been filed. Defendant issuers in the focus cases filed motions to dismiss the new complaints. On March 26, 2008, the District Court issued an order granting in part and denying in part the focus issuers motions to dismiss. The focus issuers had been advised that plaintiffs intended to file new complaints against Nuvelo, but none have been filed yet. ARCA believes that any attorneys fees, loss or settlement payment with respect to this suit will be paid by Nuvelo s insurance provider. However, it is possible that ARCA could be forced to incur material expenses in the litigation if the parties cannot achieve a settlement, and, in the event of an adverse outcome, ARCA s business could be harmed.

Item 4. ***Submission of Matters to a Vote of Security Holders***

A special meeting of the stockholders of Nuvelo was held on Wednesday, January 7, 2009 to consider matters related to the then still-proposed merger contemplated by the Merger Agreement. At the special meeting, the following proposals were approved by Nuvelo s stockholders:

1. To approve the issuance of shares of Nuvelo s common stock pursuant to the Merger Agreement; and

2. To adjourn the special meeting to solicit additional proxies in favor of a proposal to amend Nuvelo s amended and restated certificate of incorporation to effect a reverse stock split of the issued and outstanding shares of Nuvelo s common stock.

The following is a tabulation of the votes cast with respect to these proposals:

		Votes	
Proposal	**For**	**Against**	**Abstain**
1	26,184,584	3,495,798	179,936
2	25,401,442	4,118,506	340,370

At the special meeting, notice of the time and date of the adjourned meeting, 9:00 a.m. Pacific time on January 23, 2009, was provided and the special meeting was adjourned. On January 23, 2009, at the adjourned meeting, Nuvelo s stockholders approved the proposal to amend Nuvelo s amended and restated certificate of incorporation to effect a reverse stock split of the issued and outstanding shares of Nuvelo s common stock. The following is a tabulation of the votes cast with respect to this proposal:

	Votes	
For	**Against**	**Abstain**
27,518,491	4,391,237	212,480

Table of Contents

PART II

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

Nuvelo s common stock began trading on the Nasdaq Global Market on August 8, 1997 as Hyseq, Inc. (HYSQ) and has traded under the symbol NUVO from January 31, 2003 to January 27, 2009 (except for the period between June 19, 2003 and March 19, 2004, where we temporarily traded under the symbol NUVOD). After the close of market on January 27, 2009, Nuvelo completed a 20-to-1 reverse stock split of its common stock and changed its name to ARCA biopharma, Inc. On January 28, 2009, ARCA s common stock began trading on the Nasdaq Global Market on a post-reverse-split basis under the new symbol ABIO. Unless otherwise indicated, all per share amounts, except for the par value per share, in this Form 10-K have been adjusted retroactively to reflect the reverse stock split.

The following table sets forth, for the periods indicated, the high and low sales prices for Nuvelo s common stock, as reported by the Nasdaq Global Market under these symbols and as adjusted for the reverse stock split:

	High	Low
Year ended December 31, 2007		
First quarter	$ 82.40	$ 60.80
Second quarter	132.60	51.00
Third quarter	60.60	30.40
Fourth quarter	54.00	25.20
Year ended December 31, 2008		
First quarter	$ 37.60	$ 11.00
Second quarter	19.40	11.00
Third quarter	15.00	6.80
Fourth quarter	9.40	4.21

Stockholders

As of March 17, 2009, ARCA had approximately 177 stockholders of record of its common stock, and the last sale price reported on the Nasdaq Global Market for Nuvelo s common stock was $4.00 per share.

Dividend Policy

The holders of ARCA s common stock are entitled to dividends in such amounts and at such times, if any, as may be declared by ARCA s Board of Directors out of legally available funds. Nuvelo has not paid any dividends on its common stock, and ARCA does not anticipate paying any cash dividends on its common stock in the foreseeable future.

Securities Authorized for Issuance Under Equity Compensation Plans

Information relating to Nuvelo s equity compensation plans as of December 31, 2008, under which Nuvelo s 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.

50

Table of Contents

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

Not applicable.

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

We have included or incorporated by reference into this Management s Discussion and Analysis of Financial Condition and Results of Operations and elsewhere in this Annual Report on Form 10-K, and from time to time our management may make, statements that constitute forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act. Forward-looking statements may be identified by words including anticipate, plan, believe, intend, estimate, expect, should, may, potential and sim expressions. Such statements are based on our management s current expectations and involve risks and uncertainties. Our actual results and performance could differ materially from those projected in the forward-looking statements as a result of many factors discussed in this Annual Report, including those set forth in this Item 7 as well as under Item 1. Business and Item 1A. Risk Factors. We do not intend to update any of the forward-looking statements after the date of this Annual Report to conform these statements to actual results unless required by law.

Merger of ARCA and Nuvelo

On January 27, 2009, ARCA, which then was named Nuvelo, Inc., or Nuvelo, completed the merger contemplated by that Agreement and Plan of Merger and Reorganization, dated September 24, 2008, as amended October 28, 2008, by and among Nuvelo, Dawn Acquisition Sub, Inc., a wholly-owned subsidiary of Nuvelo, or Merger Sub, and ARCA biopharma, Inc., or ARCA, a privately held developmental-stage biopharmaceutical company based in Broomfield, Colorado, which merger agreement, as amended, is referred to herein as the Merger Agreement.

In accordance with the Merger Agreement, immediately prior to the consummation of the merger, Nuvelo effected a reverse stock split of its common stock. Pursuant to this reverse stock split, each 20 shares of Nuvelo s common stock that were issued and outstanding immediately prior to the merger were converted into one share of Nuvelo s common stock. In addition, pursuant to the Merger Agreement, Merger Sub merged with and into ARCA, with ARCA continuing after the merger as the surviving corporation and a wholly-owned subsidiary of Nuvelo. Immediately following the merger, Nuvelo changed its name to ARCA biopharma, Inc.

Unless otherwise indicated, all references herein to ARCA refer to ARCA both before and after the completion of the merger, and all references to Nuvelo refer to Nuvelo prior to the completion of the merger and the name change. The financial information included in this Management s Discussion and Analysis of Financial Condition and Results of Operations is that of Nuvelo, not that of ARCA.

Under the terms of the Merger Agreement, holders of ARCA capital stock prior to the merger were entitled to receive shares of post-merger ARCA common stock, such that Nuvelo stockholders were expected to own approximately 33% of the common stock of the combined company immediately after the merger and ARCA stockholders, together with holders of ARCA options and warrants, were expected to own or had the right to acquire approximately 67% of the common stock of the combined company immediately after the merger, after giving effect to the issuance of shares pursuant to outstanding options and warrants primarily on the treasury stock method. The merger is intended to qualify for federal income tax purposes as a tax-free reorganization under the provisions of Section 368(a) of the U.S. Internal Revenue Code of 1986, as amended.

The merger will be treated by ARCA as a reverse merger and accounted for as a business combination using the purchase method of accounting in accordance with Statement of Financial Accounting Standards No. 141 (Revised 2007), *Business Combinations* (SFAS 141R). For accounting purposes, ARCA is considered to have acquired Nuvelo in the merger, as the stockholders of ARCA prior to the merger now have a controlling interest

Table of Contents

in the combined company and ARCA s management is the management of the combined company. As a result, the results of operations and financial position of Nuvelo as reported herein are not indicative of the future results of operations and financial position of the combined company

In connection with the merger, approximately 26 of Nuvelo s employees were terminated in January 2009, and a substantial majority of the remaining Nuvelo employees are retained for a transition period of up to 12 weeks. Total termination benefits related to employees terminated in January 2009 and those on a transition plan were estimated to be $5.0 million.

Overview

ARCA biopharma, Inc., or ARCA, is a biopharmaceutical company developing genetically-targeted therapies for heart failure and other cardiovascular diseases. ARCA s lead product candidate is Gencaro (bucindolol hydrochloride), a twice-a-day oral formulation that has been developed for the treatment of chronic heart failure. ARCA believes it has identified common genetic variations that help predict patient response to Gencaro. The FDA accepted ARCA s NDA for Gencaro in September 2008. ARCA believes that Gencaro, if approved, will be the first genetically-targeted cardiovascular drug.

ARCA holds worldwide rights to Gencaro and, if it is approved, currently plans to commercialize the drug in the U.S., through its own specialized sales force. ARCA intends to seek commercial partners outside the United States. ARCA has collaborated with Laboratory Corporation of America, or LabCorp, to develop and launch a companion genetic test for Gencaro, in conjunction with any commercialization of Gencaro.

ARCA is in the development stage and, since inception, ARCA s activities have been focused primarily on conducting research and development, hiring personnel and raising capital to support these activities. ARCA has incurred net losses since inception and expects to incur net losses in the future as research and development activities continue and it prepares to commercialize Gencaro.

ARCA s costs associated with Gencaro have represented substantially all of ARCA s research and development expenses to date. ARCA expects significant costs for the foreseeable future while it awaits the FDA s decision on the NDA for Gencaro and builds its sales and marketing organization in anticipation of the potential commercial launch of Gencaro. ARCA has not generated any revenues from sales of commercial products since inception and does not expect to generate any revenues unless and until the NDA for Gencaro is approved. During 2009, ARCA expects to focus its research and development efforts on obtaining Gencaro approval, investigating potential new indications, developing an international regulatory strategy and furthering its cardiovascular pipeline development. Due to the significant reduction in the scope of Nuvelo s research and development efforts, ARCA anticipates a significant reduction in combined spending in 2009 as compared with 2008.

NU172

NU172 is a novel, short-acting anticoagulant that ARCA plans to develop as a potential new therapy in indications where heparin paired with its antidote, protamine, are the current standard of care, such as coronary artery bypass graft (CABG) surgery, kidney dialysis and a variety of vascular surgical and coronary interventions.

ARCA is developing NU172 through a collaboration with Archemix Corporation, under which ARCA is responsible for development and worldwide commercialization of NU172 and other potential product candidates that may be developed under this collaboration. In February 2008, Nuvelo paid Archemix a $1.0 million milestone fee in connection with the dosing of the first patient in the Phase I trial for NU172. If ARCA enrolls the first patient in a Phase II trial of NU172, ARCA will be obligated to pay Archemix a $3.0 million milestone fee. ARCA is currently conducting preclinical studies and evaluating a potential Phase II study in CABG patients in 2009.

Table of Contents

Unless otherwise indicated, the following discussions of historical results of operations, cash flows information, and sources and uses of capital are that of Nuvelo prior to the merger with ARCA.

Results of Operations

Contract Revenues

Contract revenues were $15.3 million in 2008, as compared with $46.9 million in 2007.

In 2008, Nuvelo recorded as revenue $15.0 million that was received from Bayer HealthCare AG, or Bayer, in connection with the termination of its collaboration agreement in June 2007. Following Nuvelo s decision to discontinue further clinical development of alfimeprase that was announced in March 2008, the $15.0 million, which had been recorded as deferred revenue, was recognized as revenue in May 2008 upon the expiration of the notice period, as defined in the termination agreement with Bayer.

In 2007, Nuvelo recorded as revenue $44.9 million of the $50.0 million up-front license fee received from Bayer in January 2006 as a result of the termination of its collaboration agreement in June 2007. The up-front license fee had been recorded as deferred revenue upon receipt and was being recognized on a straight-line basis over the performance period under the agreement, originally estimated to be through September 2020.

Research and Development Expenses

	Years Ended December 31, 2008	2007	% Change
	(In thousands)		
Research and development	$ 27,764	$ 42,654	(35%)

Research and development, or R&D, expenses primarily consist of clinical trial and drug manufacturing costs, personnel costs, including related stock-based compensation expense, license, collaboration and allocated facilities expenses.

R&D expenses for Nuvelo s significant programs were as follows for the periods indicated (including upfront fees and collaboration cost-sharing credits, and excluding occupancy costs and stock-based compensation expense):

Program	Since Inception	Years Ended December 31, 2008	2007
		(In millions)	
Alfimeprase	$ 124.2	$ 4.8	$ 8.3
NU172	$ 18.4	$ 5.3	$ 8.0
NU206	$ 14.1	$ 4.5	$ 3.6

The decrease in R&D expenses of $14.9 million in 2008, as compared with 2007, was primarily attributable to the following: a $4.1 million decrease in rNAPc2-related expenses due to Nuvelo s suspension of development of rNAPc2 in 2007, a $3.5 million decrease in alfimeprase-related expenses due to the discontinuance of development of alfimeprase announced in March 2008, a $2.7 million decrease in NU172-related expenses, and a $3.4 million decrease in employees stock-based compensation expense as a result of a reduction in headcount. The decrease in NU172-related expenses in 2008 was primarily due to a decrease in manufacturing costs, partially offset by increases in clinical trial and collaboration expenses as a result of the initiation of the Phase I trials in 2008.

The timing, cost of completing the clinical development of any product candidate, and any potential future product revenues will depend on a number of factors, including the maintenance of existing collaboration agreements with cost-sharing arrangements, disease or medical condition to be treated, clinical trial design and endpoints, availability of patients to participate in trials and the relative efficacy of the product versus treatments already approved.

53

Table of Contents

General and Administrative Expenses

	Years Ended December 31, 2008	2007	% Change
	(In thousands)		
General and administrative	$ 14,939	$ 20,762	(28%)

General and administrative, or G&A, expenses primarily consist of personnel costs, including related stock-based compensation expense, consulting and professional fees, insurance, facilities and depreciation expenses, and various other administrative costs.

The decrease in G&A expenses of $5.8 million in 2008, as compared with 2007, was primarily due to a $4.6 million decrease in personnel related costs, of which $2.0 million was related to employee stock-based compensation expense, as a result of a reduction in headcount and a $1.1 million charge related to the impairment of software implementation costs in 2007. In connection with the recently completed merger, Nuvelo incurred $1.8 million of expenses in 2008, which were primarily related to financial advisory, accounting and legal fees, as well as costs of preparing, printing and distributing the proxy statement for the special meeting of Nuvelo s stockholders. These merger-related expenses were largely offset by reductions in temporary services, consulting and other professional fees in 2008 as compared with 2007.

Restructuring Expense

On March 17, 2008, Nuvelo announced its decision to discontinue alfimeprase clinical development and restructure to make additional resources available for its other research and development programs. In connection with the restructuring, Nuvelo reduced its workforce by approximately 19% and recorded a restructuring expense of $2.5 million, including $1.3 million of termination benefits and $1.2 million of non-cash stock-based compensation expense.

On August 1, 2007, Nuvelo announced a reduction in its workforce by approximately 30% to realign its organization to focus on core development programs that it believed would produce nearest-term proof-of-concept data. In addition, Nuvelo announced the decision to suspend development of rNAPc2 in all indications including cancer and acute coronary syndromes. As a result, Nuvelo recorded a restructuring expense of $2.3 million, including $1.4 million of termination benefits and $0.9 million of non-cash stock-based compensation expense.

Facility Exit Costs

In December 2006, Nuvelo ceased use of its facility in Sunnyvale, California, referred to herein as the Sunnyvale facility, as it was no longer required for its business, and recorded a liability to reflect the estimated fair value of future lease-related payments for the remainder of the lease term, less estimated sublease income. In March 2008, Nuvelo determined that the likelihood of subleasing the Sunnyvale facility during the remainder of the lease term had become remote and, therefore, recorded a $1.5 million charge to reflect such change in the sublease assumption. Nuvelo continued to actively market the facility for sublease. In December 2008, Nuvelo entered into a sublease agreement and recorded a $2.1 million credit, to reflect the change in estimated fair value of the remaining lease obligations after taking into consideration of future cash flows from the sublease. For the year ended December 31, 2008, Nuvelo recorded a net $0.6 million credit as a result of the changes in the sublease assumption. Additionally, in connection with the execution of the sublease agreement, the landlord of the Sunnyvale facility agreed to release Nuvelo from the facility restoration obligation. As a result, Nuvelo reversed this accrual and recorded a $0.8 million credit in December 2008.

Table of Contents

Impairment of Goodwill

In 2008, Nuvelo performed a goodwill impairment test due to the significant decline of its stock price subsequent to the announcement of the discontinuation of alfimeprase discussed above. As a result of the impairment test, Nuvelo determined that goodwill was impaired. Accordingly, Nuvelo recorded an impairment charge of the full balance of goodwill totaling $4.7 million in 2008.

Interest Income, Net

Net interest income was $2.4 million in 2008, as compared with $6.6 million in 2007. The decrease in net interest income in 2008 was primarily due to declining balances in cash equivalents and marketable securities and a substantial reduction in the yield on cash equivalents and marketable securities.

Other Income

In connection with the sale of Nuvelo s subsidiary in December 2004, Nuvelo received a convertible promissory note with a principal amount of $0.9 million, for which Nuvelo had initially assessed the value to be zero due to its assessment of the probability of collection. In December 2008, Nuvelo received a full payment of the promissory note. As a result, Nuvelo recorded the $0.9 million as other income in its statement of operations.

Net Loss

Since Nuvelo s inception, Nuvelo has incurred significant net losses, and as of December 31, 2008, its accumulated deficit was $500.4 million. Nuvelo incurred a net loss of $29.9 million in 2008, as compared with a net loss of $12.3 million in 2007. The increase in net loss was primarily due to a decrease in contract revenues and an impairment of goodwill, partially offset by an overall reduction in R&D and G&A expenses, as noted above.

Liquidity and Capital Resources

Cash and Cash Equivalents, Marketable Securities and Restricted Cash

	December 31, 2008	December 31, 2007
	(In thousands)	
Cash and cash equivalents	$ 35,891	$ 32,061
Marketable securities	15,081	65,506
Restricted cash(1)	6,000	6,000
	$ 56,972	$ 103,567

(1) ARCA has a $6.0 million letter of credit issued to the landlord of its Sunnyvale facility as required by the lease agreement of this facility, and the letter of credit is being collateralized by a certificate of deposit of the same amount, which is recorded as restricted cash.

As of December 31, 2008, Nuvelo had total cash and cash equivalents, marketable securities and restricted cash of $57.0 million, as compared to $103.6 million as of December 31, 2007. The decrease of $46.6 million resulted primarily from operating expenditures during the period.

As of December 31, 2008, all of Nuvelo s investments in marketable securities were classified as available-for-sale securities, as defined by Statement of Financial Accounting Standards No. 115, *Accounting for Certain Investments in Debt and Equity Securities.* They were recorded at their fair value and primarily consisted of corporate debt securities. Nuvelo has made its investments in accordance with its investment policy. The primary objectives of Nuvelo s investment policy are liquidity and safety of principal.

55

Table of Contents

Cash Flows from Operating, Investing and Financing Activities

	Years Ended December 31,	
	2008	2007
	(In thousands)	
Net cash provided by (used in):		
Operating activities	$ (46,508)	$ (45,958)
Investing activities	50,183	21,085
Financing activities	155	(3,401)
Net increase (decrease) in cash and cash equivalents	$ 3,830	$ (28,274)

The net cash used in operating activities in 2008 was comparable with 2007. Reductions in R&D and G&A expenses in 2008 were largely offset by the receipt of $15.0 million from Bayer related to the termination of the collaboration agreement in 2007.

The increase in net cash provided by investing activities in 2008 as compared with 2007 was primarily due to an increase in maturities, net of purchases, of marketable securities.

The change in net cash provided by or used in financing between 2008 and 2007 was primarily because Nuvelo paid in full in 2007 the remaining principal balances related to its related party line of credit and the loans from Silicon Valley Bank totaling $3.8 million.

Sources and Uses of Capital

Nuvelo s primary sources of liquidity to date have been financing activities and collaboration receipts. Nuvelo s primary uses of capital resources to date have been to fund operating activities, including research, clinical development and drug manufacturing expenses, license payments, and spending on capital items.

Under the collaboration agreement with Archemix, Archemix is responsible for the discovery of short-acting aptamers targeting the coagulation cascade for use in acute cardiovascular procedures, and ARCA is responsible for development and worldwide commercialization of these product candidates. If the first patient is enrolled in a Phase II trial of NU172, which may occur in 2009, a $3.0 million milestone fee is payable to Archemix. In addition, ARCA is obligated to purchase Archemix common stock having a value equal to the lesser of $10.0 million or 15% of the total gross proceeds raised by Archemix in a qualified public offering of Archemix stock occurring within five years of the effective date of the collaboration agreement.

ARCA believes that its current cash, cash equivalents and marketable securities balances are sufficient to fund operations through at least December 31, 2009. However, because of ARCA s substantial capital requirements necessary to fund commercialization of Gencaro, if approved, ARCA will seek to access public or private debt or equity markets. ARCA s future capital requirements depend on a number of factors, including, but not limited to, the following:

- timing and outcomes of regulatory approvals, in particular the approval of ARCA s NDA for Gencaro by the FDA;
- the costs of commercializing ARCA s product candidates once regulatory approvals are obtained, including the costs of establishing or contracting for marketing, sales and manufacturing capabilities, and other costs related to the size of ARCA s organization;
- the extent to which ARCA is able to acquire or in-license new products, technologies or businesses;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights; and

the terms and timing of any additional collaborative, strategic partnership or licensing agreements that ARCA may establish.

Table of Contents

If ARCA s available cash and cash equivalents and funding received or made available are insufficient to satisfy its liquidity requirements, or if ARCA develops additional products or pursues additional applications for its products or conducts additional clinical trials beyond those currently contemplated, ARCA may seek to sell additional equity or incur additional indebtedness. The sale of additional equity or convertible debt securities may result in additional dilution to ARCA s stockholders. If ARCA raises additional funds through the incurrence of additional indebtedness, the obligations related to such indebtedness would be senior to rights of holders of ARCA capital stock and could contain covenants that would restrict ARCA s operations. Should additional capital not be available to ARCA in the near term, ARCA may be required to delay or suspend research, development and/or commercialization activities to conserve its cash resources. Should ARCA be unable to raise additional capital or if the terms of available capital are not acceptable to ARCA, ARCA s management believes that the level of activities and expenditures can be adjusted, if necessary, such that current funds available to ARCA would allow ARCA to continue operations through at least December 31, 2009.

Critical Accounting Policies and Estimates

Nuvelo s discussion and analysis of its operating results and financial condition is based upon Nuvelo s consolidated financial statements, which were prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of the financial statements required Nuvelo to make estimates, judgments, and assumptions that affected the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent amounts. While Nuvelo believed its estimates, judgments and assumptions were reasonable, the inherent nature of estimates is that actual results will likely differ from the estimates made. Nuvelo s significant accounting policies are described in Note 1 to the Consolidated Financial Statements included in this Report. Nuvelo believed the following critical accounting policies affected its most significant judgments, assumptions, and estimates used in the preparation of its consolidated financial statements and, therefore, are important in understanding its financial condition and results of operations.

Clinical Trial and Drug Manufacturing Expenses

Costs related to clinical trial and drug manufacturing activities were based upon estimates of the services received and related expenses incurred by the contract research organizations, or CROs, clinical study sites, drug manufacturers, collaboration partners, laboratories, consultants, or otherwise. Related contracts varied 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. Nuvelo monitored the activity levels through close communication with the CROs and other vendors, including detailed invoice and task completion review, analysis of expenses against budgeted amounts, and pre-approval of any changes in scope of the services to be performed. Nuvelo also requested certain significant vendors to provide an estimate of costs incurred but not invoiced on a periodic basis. For accrual of expenses related to CROs and clinical study sites, Nuvelo s estimate was primarily based on patient enrollment or progress made against specified milestones or targets in each period, which was reported by the CROs or other third parties. All estimates may differ from the actual amounts subsequently invoiced. No adjustments for material changes in estimates were recognized in any period presented.

In accordance with Statement of Financial Accounting Standards No. 2, *Accounting for Research and Development Costs,* Nuvelo capitalized clinical trial drug manufacturing costs as clinical trial supplies, a current asset on Nuvelo s balance sheet, as long as there were alternative future uses for the related clinical trial drug material in other indications not currently being studied. During 2007 and 2008, Nuvelo determined that there were no alternative future uses of clinical trial supplies for all current drug programs and that all expenditures related to clinical trial supplies were charged to expense as incurred.

On January 1, 2008, Nuvelo adopted EITF Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities* (EITF 07-3). EITF 07-3 requires that an entity defer and capitalize nonrefundable advance payments made for research and

Table of Contents

development activities until the related goods are delivered or the related services are performed. The adoption of EITF 07-3 did not have a material effect on Nuvelo s consolidated financial position and results of operations.

Revenue Recognition

Nuvelo recognized revenue in accordance with Staff Accounting Bulletin No. 104, *Revenue Recognition* (SAB 104), when (i) persuasive evidence of an arrangement existed, (ii) delivery has occurred or services have been rendered, (iii) the price was fixed and determinable, and (iv) collectibility was reasonably assured. In situations where there were no continuing performance obligations, or continuing obligations were perfunctory or inconsequential, Nuvelo recognized up-front non-refundable fees as revenues on the effective date of the related agreement. Up-front non-refundable licensing fees that required continuing involvement in the form of development, manufacturing or other commercialization efforts by Nuvelo were recognized as revenue ratably over the performance period. Judgment was required in determining this performance period, and the effects of any changes to the estimated period are recognized prospectively.

Nuvelo evaluated revenue from agreements that had multiple elements to determine whether the components of the arrangement represented separate units of accounting as defined in EITF Issue No. 00- 21, *Revenue Arrangements with Multiple Deliverables* (EITF 00-21). To recognize revenue for a delivered item in a multiple element arrangement, EITF 00-21 requires that the delivered items have value to the customer on a stand-alone basis, there is objective and reliable evidence of fair value of the undelivered items, and delivery of any undelivered items is probable and within Nuvelo s control if delivered items have a general right of return. The determination that multiple elements in an arrangement met the criteria for separate units of accounting required Nuvelo to exercise its judgment.

Stock-based Compensation

Nuvelo accounted for stock-based compensation expense in accordance with the provisions of Statement of Financial Accounting Standards No. 123 (revised 2004), *Share-Based Payment* (SFAS 123R). Under SFAS 123R, employee stock-based compensation cost is generally measured at the grant date, based on the fair value of the award, and is recognized as an expense over the employee s requisite service period, net of estimated forfeitures.

Nuvelo used the Black-Scholes option pricing model as management believed that it was the most appropriate fair-value method for Nuvelo s stock-based awards. The Black-Scholes option pricing model requires assumptions to be made for the expected term of the awards, expected volatility of Nuvelo s stock price, risk-free interest rates and expected dividend yields. These assumptions were highly subjective and involve inherent uncertainties and were based on management s best estimates and judgment. If alternative assumptions were used instead of those presented in the notes to the financial statements, stock-based compensation expense could be materially different from amounts recorded in the financial statements under SFAS 123R. In addition, under SFAS 123R Nuvelo was required to estimate the expected forfeiture rate of awards and only recognized expense for those awards expected to vest. If the actual forfeiture rate was materially different from the estimate, the stock-based compensation expense could be materially different from amounts recorded in the financial statements. For options granted prior to January 1, 2006, Nuvelo continued to use the graded-vested (multiple-option) method for expense attribution. For options granted since January 1, 2006, Nuvelo used the straight-line (single-option) method for expense attribution, estimates forfeitures based on historical data and only recognized expense for those shares expected to vest. Adjustments to the forfeiture rate were made if actual forfeitures differed from previous estimates.

To determine the expected term of the options granted, Nuvelo used historical data, including post-vesting termination behavior and the contractual term to estimate future exercises and cancellations. The expected volatility was based on a combination of historic and implied volatility of Nuvelo s common stock. The risk-free

Table of Contents

interest rate assumptions were based on the yield of U.S. Treasury instruments with similar durations as the expected term of the related awards. The expected dividend yield assumption was based on Nuvelo s historic and expected dividend payouts.

Nuvelo accounted for stock-based compensation expense for non-employee awards based on the fair values estimated using the Black-Scholes model on the date of grant and re-measured at each reporting date until vested, in compliance with Emerging Issues Task Force No. 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*. Nuvelo used the straight-line method to expense the value associated with non-employee awards.

Goodwill and Other Long-Lived Assets Impairment Assessments

Nuvelo tested goodwill for impairment using a fair value approach at the reporting unit level on an annual basis or when events indicated that the carrying value of the asset might be impaired in accordance with Statement of Financial Accounting Standards No. 142, *Goodwill and other Intangible Assets*, (SFAS 142). Consistent with the determination that Nuvelo had only one reporting segment, it had determined that there was only one reporting unit and, therefore, goodwill was tested at the entity level. Nuvelo elected October 31st as its measurement date. Nuvelo completed its last annual goodwill test as of October 31, 2007, and no impairments were recognized.

SFAS 142 requires a two-step test for goodwill impairment. In the first step, Nuvelo compared the fair value of Nuvelo to its carrying value. Nuvelo generally based its fair value on its market capitalization, which was based on quoted market prices of its common stock, taking into account other factors that might affect the fair value of Nuvelo as a whole. Significant judgment is required to evaluate the fair value of a company, as quoted market prices of a company s common stock and consequently market capitalization may experience significant fluctuations in reaction to disclosures of new information about the company. If the fair value of Nuvelo exceeded the carrying value of its net assets, goodwill was not impaired and Nuvelo was not required to proceed to the second step of the impairment test.

After Nuvelo announced its decision to discontinue alfimeprase clinical development in 2008, it experienced a significant decline of its stock price. Nuvelo management determined that Nuvelo s fair value was lower than the carrying value of its net assets and that its goodwill was impaired. As a result, Nuvelo proceeded to perform the second step of the goodwill impairment test in order to determine the implied fair value of the goodwill and compare it to the carrying value of goodwill. The activities in the second step included valuing the tangible and intangible assets and liabilities of Nuvelo based on their fair value and determining the implied goodwill based upon the difference between the fair value of the reporting unit and the net fair values of identified tangible and intangible assets and liabilities. Based on the results of the second step of calculating the implied goodwill, Nuvelo recorded an impairment charge of the full balance of goodwill totaling $4.7 million.

In accordance with Statement of Financial Accounting Standards No. 144, *Accounting for Impairment or Disposal of Long-Lived Assets* (SFAS 144), Nuvelo evaluated long-lived assets, other than goodwill, for impairment whenever events or changes in circumstances indicated that the carrying value of an asset might not be recoverable based on expected undiscounted cash flows attributable to that asset. The amount of any impairment was measured as the difference between the carrying value and the fair value of the impaired asset.

Assumptions and estimates about future values and remaining useful lives are complex and often subjective. They can be affected by a variety of factors, including external factors such as industry and economic trends, competition to Nuvelo s products and internal factors such as changes in Nuvelo s business strategy and Nuvelo s internal forecasts. Although Nuvelo believed the assumptions and estimates Nuvelo made in the past were reasonable and appropriate, different assumptions and estimates and certain events could materially impact Nuvelo s reported financial results.

Table of Contents

Exit and Disposal Activities

Nuvelo recorded costs and liabilities associated with exit and disposal activities, as defined in SFAS 146, at fair value in the period the liability was incurred. SFAS 146 requires that the estimated future cash flows to be used in the fair value calculation be discounted using a credit-adjusted risk-free interest rate and that such interest rate shall have a maturity date that approximates the expected timing of future cash flows. Future cash flows related to lease obligations shall include the effect of sublease rental income and other lease operating expenses. Nuvelo re-evaluated its sublease assumptions on a quarterly basis considering current market data, including vacancy rates and lease activities for similar facilities within the area. In periods subsequent to initial measurement, changes to the liability resulting from changes in sublease assumptions were measured using the same credit-adjusted risk-free rate that was applied in the initial period. In addition, accretion of the liability due to the passage of time was recorded as an expense.

In December 2006, Nuvelo exited the facility located in Sunnyvale, California, and recorded a liability of $26.6 million related to the remaining lease obligations, less estimated sublease income, for the remainder of the lease term. As of March 31, 2008, Nuvelo determined that the likelihood of subleasing this facility during the remainder of the lease term had become remote and, therefore, recorded an additional $1.5 million charge to reflect such change in the sublease assumption. Nuvelo continued to actively market the facility for sublease. In December 2008, Nuvelo entered into a sublease agreement and recorded a credit of $2.1 million in its statement of operations, to reflect the change in estimated fair value of the remaining lease obligations after taking into consideration future cash flows from the sublease. For the year ended December 31, 2008, Nuvelo recorded a net credit of $0.6 million due to the above changes in sublease assumption.

Income Taxes

Income taxes were accounted for under the liability method pursuant to Statement of Financial Accounting Standards No. 109, *Accounting for Income Taxes* (SFAS 109). Under SFAS 109, deferred tax assets and liabilities are recognized for the 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. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date.

Nuvelo recorded a valuation allowance to reduce deferred tax assets to an amount that was more likely than not to be realized. Assessment of the realization of deferred income tax assets requires that estimates and assumptions be made as to the taxable income of future periods. Nuvelo s deferred tax assets had been reduced to zero, as Nuvelo s management believed that it was more likely than not that the deferred tax assets would not be realized. Projection of future period earnings was inherently difficult as it involved consideration of numerous factors such as Nuvelo s overall strategies and estimates of new product development and acceptance, product lifecycles, selling prices and volumes, responses by competitors, manufacturing costs and assumptions as to operating expenses and other industry specific and macro and micro economic factors. In addition, consideration was also given to ongoing and constantly evolving global tax laws and Nuvelo s own tax minimization strategies.

Utilization of Nuvelo s net operating loss and research and development credit carryforwards were subject to an annual limitation under the change in ownership provisions of the Internal Revenue Code of 1986 and similar state law provisions as a result of certain transactions that Nuvelo entered into prior to 2006. On January 27, 2009, Nuvelo completed its business combination with ARCA. A change of ownership of Nuvelo per IRC Section 382 occurred, and accordingly, ARCA s ability to utilize these carryforwards has been substantially reduced.

On January 1, 2007, Nuvelo adopted the provisions of FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes*, *an interpretation of FASB Statement No. 109* (FIN 48). FIN 48 requires that a

Table of Contents

position taken or expected to be taken in a tax return be recognized in the financial statements when it is more likely than not (i.e. a likelihood of more than 50%) that the position would be sustained upon examination by tax authorities. A recognized tax position is then measured at the largest amount of benefit that is greater than 50% likely of being realized upon ultimate settlement.

Recent Accounting Pronouncements

In September 2006, the FASB issued Statement 157, *Fair Value Measurements* (SFAS 157). SFAS 157 establishes a framework for measuring fair value by providing a standard definition of fair value as it applies to assets and liabilities. SFAS 157, which does not require any new fair value measurements, clarifies the application of other accounting pronouncements that require or permit fair value measurements. The effective date for the Company was January 1, 2008. However, in February 2008, the FASB issued FASB Staff Position No. FAS 157-2, *Effective Date of FASB Statement No. 157* (FSP 157-2), which delays the effective date of SFAS 157 for all nonfinancial assets and nonfinancial liabilities, except items that are recognized or disclosed at fair value on a recurring basis (at least annually), until fiscal years beginning after November 15, 2008. ARCA is evaluating the impact of adopting SFAS 157 and FSP 157-2 on its consolidated financial statements.

In December 2007, the FASB issued SFAS 141R, which replaces SFAS 141. SFAS 141R requires the acquirer of a business to recognize and measure the identifiable assets acquired, the liabilities assumed, and any non-controlling interest in the acquiree at fair value on the acquisition date. SFAS 141R also requires that transactions costs related to the business combination be expensed as incurred and that changes in accounting for business combination related deferred tax asset valuation allowances and income tax uncertainties after the measurement period be recognized as current period income tax expense. SFAS 141R applies prospectively to business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2008. The effective date for Nuvelo was January 1, 2009. ARCA will account for the reverse merger with Nuvelo in accordance with the provisions of SFAS 141R.

In December 2007, the FASB ratified the consensus reached by the EITF on EITF Issue 07-1, *Accounting for Collaborative Arrangements* (EITF 07-1). EITF 07-1 requires collaborators to present the results of activities for which they act as the principal on a gross basis and report any payments received from (made to) other collaborators based on other applicable GAAP or, in the absence of other applicable GAAP, based on analogy to authoritative accounting literature or a reasonable, rational, and consistently applied accounting policy election. The effective date for Nuvelo was January 1, 2009. ARCA has not yet determined the impact of EITF 07-1 on its consolidated financial statements.

Off-Balance Sheet Arrangements

Nuvelo had 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, Nuvelo entered into contractual arrangements under which Nuvelo agreed to indemnify certain parties from any losses incurred relating to the services they performed on Nuvelo s 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. Historically, payments made related to these indemnifications had been insignificant. In addition, Nuvelo had entered into indemnity agreements with each of its directors and officers. Such indemnity agreements contain provisions, which are in some respects broader than the specific indemnification provisions contained in Delaware law. Nuvelo also maintained an insurance policy for its 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 of ARCA biopharma, Inc., formerly known as Nuvelo, Inc.:

We have audited the accompanying consolidated balance sheets of ARCA biopharma, Inc., formerly known as Nuvelo, Inc., as of December 31, 2008 and 2007, and the related consolidated statements of operations, stockholders equity, and cash flows for the years then ended. These financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these 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. We were not engaged to perform an audit of the Company s internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company s internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, 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 financial statements referred to above present fairly, in all material respects, the consolidated financial position of ARCA biopharma, Inc., formerly known as Nuvelo, Inc., at December 31, 2008 and 2007, and the consolidated results of its operations and its cash flows for the years then ended, in conformity with U.S. generally accepted accounting principles.

/s/ Ernst & Young LLP

Palo Alto, California

March 25, 2009

Table of Contents

ARCA BIOPHARMA, INC.

(FORMERLY KNOWN AS NUVELO, INC.)

CONSOLIDATED BALANCE SHEETS

	As of December 31, 2008	2007
	(In thousands, except share and per share information)	
ASSETS		
Cash and cash equivalents	$ 35,891	$ 32,061
Marketable securities	15,081	65,506
Collaboration receivable	441	588
Other current assets	715	1,831
Total current assets	52,128	99,986
Restricted cash	6,000	6,000
Property and equipment, net	6,833	8,906
Goodwill		4,671
Other assets	1,084	1,120
Total assets	$ 66,045	$ 120,683
LIABILITIES AND STOCKHOLDERS EQUITY		
Accounts payable	$ 1,262	$ 2,307
Accrued compensation and employee benefits	876	2,350
Accrued clinical trial and drug manufacturing costs	1,124	3,232
Current portion of deferred revenue	250	250
Current portion of deferred rent	1,459	1,400
Current portion of accrued facility exit costs	6,007	7,389
Other current liabilities	368	1,259
Total current liabilities	11,346	18,187
Non-current portion of deferred revenue	813	16,063
Non-current portion of deferred rent	4,138	5,597
Non-current portion of accrued facility exit costs	7,164	13,098
Other liabilities	76	79
Total liabilities	23,537	53,024
Commitments and contingencies (Notes 8 and 14)		
Stockholders equity:		
Preferred stock, par value $0.001; 5,000,000 shares authorized; none issued and outstanding as of December 31, 2008 and 2007		
Common stock, par value $0.001; 100,000,000 shares authorized; 2,686,957 and 2,671,076 issued and outstanding as of December 31, 2008 and 2007, respectively	3	3
Additional paid-in capital	542,930	538,120
Accumulated other comprehensive income	11	49
Accumulated deficit	(500,436)	(470,513)
Total stockholders equity	42,508	67,659

Total liabilities and stockholders equity	$ 66,045	$ 120,683

Note: The above consolidated financial statements are those of Nuvelo, Inc. prior to the merger with ARCA biopharma, Inc.
See accompanying Notes to Consolidated Financial Statements.

Table of Contents

ARCA BIOPHARMA, INC.

(FORMERLY KNOWN AS NUVELO, INC.)

CONSOLIDATED STATEMENTS OF OPERATIONS

	Year Ended December 31,	
	2008	2007
	(In thousands, except per share data)	
Contract revenues	$ 15,251	$ 46,861
Operating expenses:		
Research and development	27,764	42,654
General and administrative	14,939	20,762
Restructuring	2,470	2,336
Facility exit costs	(1,342)	
Impairment of goodwill	4,671	
Total operating expenses	48,502	65,752
Operating loss	(33,251)	(18,891)
Interest income, net	2,428	6,590
Other income	900	
Net loss	$ (29,923)	$ (12,301)
Basic and diluted net loss per share	$ (11.17)	$ (4.61)
Weighted average shares used in computing basic and diluted net loss per share	2,679	2,667

Note: The above consolidated financial statements are those of Nuvelo, Inc. prior to the merger with ARCA biopharma, Inc.
See accompanying Notes to Consolidated Financial Statements.

Table of Contents

ARCA BIOPHARMA, INC.

(FORMERLY KNOWN AS NUVELO, INC.)

CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY

For the Years Ended December 31, 2008 and 2007

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders Equity
	Share	Amount		(in thousands)		
Balance at December 31, 2006	2,657	$ 3	$ 528,042	$ 10	$ (458,212)	$ 69,843
Components of comprehensive loss:						
Net loss					(12,301)	(12,301)
Change in unrealized gains or losses on available-for-sale securities				45		45
Change in unrealized gains or losses on hedging instruments				(6)		(6)
Comprehensive loss						(12,262)
Issuance of common stock upon exercise of stock options and under employee stock purchase plan	9		426			426
Issuance of common stock upon cashless exercise of warrants	5					
Stock-based compensation expense			9,652			9,652
Balance at December 31, 2007	2,671	3	538,120	49	(470,513)	67,659
Components of comprehensive loss:						
Net loss					(29,923)	(29,923)
Change in unrealized gains or losses on available-for-sale securities				(38)		(38)
Comprehensive loss						(29,961)
Issuance of common stock under employee stock purchase plan and upon vesting of restricted stock units	16		201			201
Stock-based compensation expense			4,609			4,609
Balance at December 31, 2008	2,687	$ 3	$ 542,930	$ 11	$ (500,436)	$ 42,508

Note: The above consolidated financial statements are those of Nuvelo, Inc. prior to the merger with ARCA biopharma, Inc.
See accompanying Notes to Consolidated Financial Statements.

Table of Contents

ARCA BIOPHARMA, INC.

(FORMERLY KNOWN AS NUVELO, INC.)

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended December 31,	
	2008	2007
	(In thousands)	
Cash flows from operating activities:		
Net loss	$ (29,923)	$ (12,301)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	2,285	2,343
Stock-based compensation expense	4,609	9,652
Non-cash accretion expense and facility exit costs	131	1,915
Impairment of assets	4,671	1,117
Gain on sale of assets	(8)	(130)
Changes in operating assets and liabilities:		
Collaboration receivable	147	7,971
Other current assets	1,116	2,800
Other assets	36	301
Accounts payable	(1,045)	(4,140)
Accrued compensation and employee benefits	(1,474)	(748)
Accrued clinical trial and drug manufacturing costs	(2,108)	(11,183)
Deferred revenue	(15,250)	(31,860)
Deferred rent	(1,400)	(1,343)
Accrued facility exit costs	(8,204)	(8,044)
Accrued interest		(2,172)
Other current and non-current liabilities	(91)	(136)
Net cash used in operating activities	(46,508)	(45,958)
Cash flows from investing activities:		
Maturities of marketable securities	94,996	143,936
Purchases of marketable securities	(44,609)	(116,606)
Increase in restricted cash		(6,000)
Purchases of property and equipment	(222)	(381)
Proceeds from sale of assets	18	136
Net cash provided by investing activities	50,183	21,085
Cash flows from financing activities:		
Proceeds from issuance of common stock upon exercise of stock options and under employee stock purchase plan	201	426
Payments on related party line of credit		(2,292)
Payments on bank loans		(1,492)
Payments on capital lease obligations	(46)	(43)
Net cash provided by (used in) financing activities	155	(3,401)
Net increase (decrease) in cash and cash equivalents	3,830	(28,274)
Cash and cash equivalents at beginning of year	32,061	60,335
Cash and cash equivalents at end of year	$ 35,891	$ 32,061

Supplemental disclosures of cash flow information:		
Interest paid	$ 5	$ 2,312

Note: The above consolidated financial statements are those of Nuvelo, Inc. prior to the merger with ARCA biopharma, Inc.
See accompanying Notes to Consolidated Financial Statements.

Table of Contents

ARCA BIOPHARMA, INC.

(FORMERLY KNOWN AS NUVELO, INC.)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Organization and Summary of Significant Accounting Policies

Organization

Nuvelo, Inc. (Nuvelo) was incorporated as Hyseq, Inc. in Illinois in 1992 and reincorporated in Nevada in 1993. On January 31, 2003, it merged with Variagenics, Inc., a publicly traded Delaware corporation based in Massachusetts, and, in connection with the merger, changed its name to Nuvelo, Inc. On March 25, 2004, Nuvelo was reincorporated from Nevada to Delaware.

On January 27, 2009, Nuvelo completed its business combination with ARCA biopharma, Inc. (ARCA) in accordance with the terms of the Agreement and Plan of Merger and Reorganization, dated September 24, 2008, by and among Nuvelo, Dawn Acquisition Sub, Inc., a wholly-owned subsidiary of Nuvelo (Merger Sub), and ARCA, which was amended on October 28, 2008 (as amended, the Merger Agreement). Pursuant to the Merger Agreement, Merger Sub merged with and into ARCA, with ARCA continuing after the merger as the surviving corporation and a wholly-owned subsidiary of Nuvelo. Immediately following the merger, Nuvelo changed its name to ARCA biopharma, Inc. All references herein to Nuvelo refer to Nuvelo prior to the completion of the merger and the name change. See Note 2 for further discussion of the merger.

Prior to the merger, Nuvelo was a biopharmaceutical company engaged in the discovery, development and commercialization of novel drugs for acute cardiovascular disease, cancer and other debilitating medical conditions.

Reverse Stock Split

On January 23, 2009, Nuvelo s stockholders approved an amendment to Nuvelo s amended and restated certificate of incorporation to effect a reverse stock split of the issued and outstanding shares of Nuvelo s common stock. Pursuant to the approval by the stockholders, Nuvelo s board of directors approved the reverse stock split at a ratio of 20-to-1. The reverse stock split became effective after the close of the markets on January 27, 2009.

All share and per share amounts for all periods presented in the consolidated financial statements and notes have been adjusted retroactively to reflect the effect of the reverse stock split, except for the par value per share and the number of shares of common stock and preferred stock authorized for issuance, which are not affected by the reverse stock split.

Basis of Presentation and Principles of Consolidation

The consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles (GAAP) and include the accounts of Nuvelo and its subsidiaries. All inter-company transactions and accounts have been eliminated in consolidation. Since the merger with ARCA was consummated after December 31, 2008, the accompanying consolidated financial statements and notes reflect the results of operations and financial position of Nuvelo prior to the merger, and do not include the results of operations and financial position of ARCA. Because the merger with ARCA will be treated as a reverse merger, with ARCA considered to be acquiring Nuvelo (see Note 2), the results of operations and financial position of Nuvelo as reported herein are not indicative of the future results of operations and financial position of the combined company.

Table of Contents

Use of Estimates

Conformity with GAAP requires the use of estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent amounts. Nuvelo based its estimates on historical experience and on assumptions that were believed to be reasonable under the circumstances, the results of which formed the basis for the judgments made about the carrying values of assets and liabilities that were not readily apparent from other sources. Future results may differ from these estimates. Nuvelo believed significant judgment was involved in evaluating whether alternative future use existed for materials and equipment acquired for use in research and development, in estimating goodwill and long-lived asset impairment, facility exit costs, clinical trial accruals, stock-based compensation, income taxes and in determining revenue recognition.

Liquidity

Nuvelo s primary sources of liquidity were from financing activities and collaboration receipts. Nuvelo s primary uses of capital resources were to fund operating activities, including research, clinical development and drug manufacturing expenses, license payments, and spending on capital items.

In order to fund the commercialization of Gencaro, if approved, and to continue development of the current product pipeline, ARCA will need to seek access to the public or private debt and equity markets. Should additional capital not be available to ARCA in the near term, or not be available on acceptable terms, ARCA will not be able to meet its cash requirements under its current operating plan, and therefore will need to reduce its planned expenditures, perhaps significantly, to preserve cash. If necessary, ARCA will implement, beginning as early as the third quarter of 2009, appropriate plans and measures to reduce operating expenses and preserve its cash such that it can continue operations through at least December 31, 2009.

Concentration Risk

Nuvelo was relying on a number of sole-source service providers and suppliers to manufacture bulk drug substance, fill and finish its drug product candidates, and label and package them, and Nuvelo did not have long-term supply agreements with these third-party manufacturers. If these service providers and suppliers are unable to produce the drug product candidates in the quantities and with the quality required, if and when they are needed, ARCA could incur significant additional expenses and efforts to complete its ongoing and anticipated clinical trials.

Cash Equivalents and Marketable Securities

Cash equivalents consisted of money market funds and debt securities with maturities of 90 days or less at the time of purchase. Nuvelo considered its investments in marketable debt securities, which have consisted of U.S. Treasury, U.S. government agency, corporate debt and asset-backed securities, as available for use in current operations. Accordingly, Nuvelo classified these investments as short-term, even though the stated maturity date may be more than one year from the current balance sheet date. Nuvelo invested 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.

Nuvelo classified all cash equivalents and marketable securities as available-for-sale securities, as defined by Statement of Financial Accounting Standards No. 115, *Accounting for Certain Investments in Debt and Equity Securities,* and recorded investments at fair value. Unrealized holding gains and losses on available-for-sale securities, net of any tax effect, were excluded from earnings and were reported in accumulated other comprehensive income (loss), a separate component of stockholders equity, until realized. The specific identification method was utilized to calculate the cost to determine realized gains and losses from the sale of available-for-sale securities. Realized gains and losses and declines in value judged to be other than temporary were included in interest income in the statements of operations.

Table of Contents

Restricted Cash

Restricted cash represented a certificate of deposit used to collateralize a letter of credit as required by the lease agreement for the unoccupied facility in Sunnyvale, California. See Note 6, Facility Exit Costs, for discussion of the related lease commitment, and Note 8, Commitments, for discussion of the letter of credit arrangement.

Property and Equipment

Property and equipment were recorded at cost less accumulated depreciation. Depreciation expense was calculated using the straight-line method over the estimated useful lives of the assets. Leasehold improvements were related to Nuvelo s office space in San Carlos, California. The lease term on this office space is seven years. Leasehold improvements were amortized over the shorter of the estimated useful lives of the assets or the lease term. Maintenance and repairs were charged to expenses as incurred. Estimated useful lives were as follows:

Category	Estimated Useful Lives
Leasehold improvements	Shorter of lease term or economic life
Furniture and equipment	Five years
Computer software and equipment	Two to three years

Goodwill and Other Long-Lived Assets Impairment Assessments

Nuvelo assessed goodwill for impairment in accordance with Statement of Financial Accounting Standards No. 142, *Goodwill and other Intangible Assets* (SFAS 142), which requires that goodwill be tested for impairment at the reporting unit level (reporting unit) at least annually and more frequently upon the occurrence of certain events, as defined by SFAS 142. Consistent with Nuvelo s determination that it had only one reporting segment, it had determined that there was only one reporting unit. Nuvelo had tested goodwill for impairment in the annual impairment test on October 31st and also reviewed for signs of impairment on a quarterly basis, using the two-step process required by SFAS 142. See Note 5 for further discussion of the goodwill impairment tests performed in 2007 and 2008.

In accordance with Statement of Financial Accounting Standards No. 144, *Accounting for Impairment or Disposal of Long-Lived Assets,* Nuvelo evaluated long-lived assets, other than goodwill, for impairment whenever events or changes in circumstances indicated that the carrying value of an asset might not be recoverable based on expected undiscounted cash flows attributable to that asset. The amount of any impairment was measured as the difference between the carrying value and the fair value of the impaired asset. In June 2007, Nuvelo recorded a $1.1 million charge related to an impairment of software implementation costs that were previously capitalized and deemed not recoverable, as it determined that the likelihood of completing the software implementation is remote. The $1.1 million charge was included in general and administrative expenses for the year ended December 31, 2007.

Exit and Disposal Activities

Nuvelo recorded costs and liabilities associated with exit and disposal activities, as defined in Statement of Financial Accounting Standards No. 146, *Accounting for Costs Associated with Exit or Disposal Activities* (SFAS 146), at fair value in the period the liability was incurred. SFAS 146 requires that the estimated future cash flows to be used in the fair value calculation be discounted using a credit-adjusted risk-free interest rate and that such interest rate shall have a maturity date that approximates the expected timing of future cash flows. Future cash flows related to lease obligations include the effect of sublease rental income and other lease operating expenses. Nuvelo re-evaluated its sublease assumptions on a quarterly basis considering current market data, including vacancy rates and lease activities for similar facilities within the area. In periods subsequent to

Table of Contents

initial measurement, changes to a liability resulting from changes to the sublease assumptions were measured using the same credit-adjusted risk-free rate that was applied in the initial period. In addition, accretion of the liability due to the passage of time was recorded as a general and administrative expense.

Fair Value Disclosures

On January 1, 2008, Nuvelo adopted Statement of Financial Accounting Standards No. 157, *Fair Value Measurements* (SFAS 157). SFAS 157 establishes a common definition for fair value to be applied to U.S. GAAP requiring use of fair value, establishes a framework for measuring fair value, and expands disclosure about such fair value measurements. In February 2008, the FASB issued FASB Staff Position No. FAS 157-2, *Effective Date of FASB Statement No. 157* (FSP 157-2), which defers the effective date of SFAS 157 for all nonfinancial assets and nonfinancial liabilities, except items that are recognized or disclosed at fair value on a recurring basis (at least annually), until fiscal years beginning after November 15, 2008. The implementation of SFAS 157 for financial assets and financial liabilities did not have a material impact on Nuvelo s consolidated financial position and results of operations. ARCA is currently assessing the impact of adopting SFAS 157 for nonfinancial assets and nonfinancial liabilities on its financial position and results of operations.

SFAS 157 defines fair value 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). SFAS 157 classifies the inputs used to measure fair value 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 following table represents Nuvelo s fair value hierarchy for its financial assets (cash equivalents and marketable securities) measured at fair value on a recurring basis as of December 31, 2008 (in thousands):

	Level 1	Level 2	Level 3	Total
Money market fund	$ 34,935	$	$	$ 34,935
Corporate debt securities		15,081		15,081
Total	$ 34,935	$ 15,081	$	$ 50,016

The money market fund, which is expected to maintain a net asset value of $1 per share, was categorized in Level 1 of the fair value hierarchy. Corporate debt securities were categorized in Level 2 of the fair value hierarchy. The fair value of these securities was generally based on pricing models which took into consideration market prices of identical or similar securities from multiple sources and the securities accreted balance on the reporting day.

Statement of Financial Accounting Standards No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities,* allows entities to voluntarily choose, at specified election dates, to measure many financial instruments and certain other items at fair value that are not currently required to be measured at fair value. To date, Nuvelo has not elected this fair value option for any assets or liabilities.

Revenue Recognition

Nuvelo recognized revenue in accordance with Staff Accounting Bulletin No. 104, *Revenue Recognition,* when (i) persuasive evidence of an arrangement existed, (ii) delivery has occurred or services have been rendered, (iii) the price was fixed and determinable, and (iv) collectibility was reasonably assured. In situations

Table of Contents

where there were no continuing performance obligations, or continuing obligations were perfunctory or inconsequential, up-front non-refundable fees were recognized as revenues on the effective date of the related agreement. Up-front non-refundable licensing fees that required continuing involvement in the form of development, manufacturing or other commercialization efforts by Nuvelo were recognized as revenue ratably over the performance period.

Nuvelo evaluated revenue from agreements that had multiple elements to determine whether the components of the arrangement represented separate units of accounting as defined in Emerging Issues Task Force (EITF) Issue No. 00-21, *Revenue Arrangements with Multiple Deliverables* (EITF 00-21). To recognize revenue for a delivered item in a multiple element arrangement, EITF 00-21 requires that the delivered items have value to the customer on a stand-alone basis, there is objective and reliable evidence of fair value of the undelivered items, and delivery of any undelivered items is probable and within Nuvelo s control if delivered items have a general right of return.

Clinical Trial and Drug Manufacturing Expenses

Costs related to clinical trial and drug manufacturing activities were based upon estimates of the services received and related expenses incurred by contract research organizations (CROs), clinical study sites, drug manufacturers, collaboration partners, laboratories, consultants, or otherwise. Related contracts varied 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 were monitored through communications with the CROs and other vendors, including detailed invoices and task completion review, analysis of expenses against budgeted amounts, and pre-approval of any changes in scope of the services to be performed. Certain significant vendors would also provide an estimate of costs incurred but not invoiced on a periodic basis. Expenses related to the CROs and clinical study sites were primarily based on patient enrollment or progress made against specified milestones or targets in each period.

In accordance with Statement of Financial Accounting Standards No. 2, *Accounting for Research and Development Costs,* Nuvelo capitalized clinical trial drug manufacturing costs as clinical trial supplies, a current asset on the balance sheet, as long as there were alternative future uses for the related clinical trial drug material in other indications not currently being studied. During 2008 and 2007, Nuvelo determined that there were no alternative future uses for all current drug supplies and that all expenditures related to clinical trial supplies were charged to expense as incurred.

On January 1, 2008, Nuvelo adopted EITF Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities* (EITF 07-3). EITF 07-3 requires that an entity defer and capitalize nonrefundable advance payments made for research and development activities until the related goods are delivered or the related services are performed. The adoption of EITF 07-3 did not have a material effect on Nuvelo s consolidated financial position and results of operations.

Stock-based Compensation

Nuvelo accounted for stock-based compensation expense in accordance with the provisions of Statement of Financial Accounting Standards No. 123 (revised 2004), *Share-Based Payment* (SFAS 123R). Under SFAS 123R, employee stock-based compensation cost is generally measured at the grant date, based on the fair value of the award, and is recognized as an expense over the employee s requisite service period, net of estimated forfeitures.

Nuvelo used the Black-Scholes option-pricing model as it believed that it was the most appropriate fair-value method for its stock-based awards. The Black-Scholes option-pricing model requires assumptions to be made for the expected term of the awards, expected volatility of Nuvelo s stock price, risk-free interest rates and expected dividend yields. Nuvelo then amortized compensation cost for awards expected to vest over the related

Table of Contents

vesting periods. For options granted prior to January 1, 2006, Nuvelo continued to use the graded-vested (multiple-option) method for expense attribution. For options granted after January 1, 2006, Nuvelo was using the straight-line (single-option) method for expense attribution, estimates forfeitures based on historical data and only recognized expense for those shares expected to vest. Adjustments to the forfeiture rate were made if actual forfeitures differed from previous estimates.

For all option grants, Nuvelo considered historical data, including post-vesting termination behavior, and the contractual term to estimate future exercises and cancellations, and therefore the expected term of each option. The expected volatility was based on a combination of historic and implied volatility of Nuvelo s common stock. The risk-free interest rate assumptions were based on the yield of U.S. Treasury instruments with similar durations as the expected term of the related awards. The expected dividend yield assumption was based on Nuvelo s historic and expected dividend payouts.

Nuvelo accounted for stock-based compensation expense for non-employee awards based on the fair values estimated using the Black-Scholes model on the date of grant and re-measured at each reporting date until vested, in compliance with EITF Issue No. 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services.* Nuvelo was using the straight-line method to expense the value associated with non-employee awards over the expected service period.

The fair values of employee stock options granted under Nuvelo s stock option plans during the periods presented 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 values per share:

	Year Ended December 31,	
	2008	2007
Assumptions:		
Expected term	4.63 years	4.94 years
Expected volatility	0.95	0.88
Risk-free interest rate	2.78%	4.65%
Expected dividend yield		
Weighted-average grant date fair value per share	$ 21.62	$ 49.40

The fair values of purchase rights granted under Nuvelo s employee stock purchase plan during the periods presented 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 values per share:

	Year Ended December 31,	
	2008	2007
Assumptions:		
Expected term	0.25 years	0.25 years
Expected volatility	0.98	0.84
Risk-free interest rate	1.77%	4.51%
Expected dividend yield		
Weighted-average grant date fair value per share	$ 6.06	$ 18.80

Income Taxes

Income taxes were accounted for under the liability method pursuant to Statement of Financial Accounting Standards No. 109, *Accounting for Income Taxes* (SFAS 109). Under SFAS 109, deferred tax assets and liabilities are recognized for the 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. Deferred tax assets and liabilities are measured using enacted tax rates expected to

Table of Contents

apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. A valuation allowance is recorded to reduce deferred income tax assets to an amount that is more likely than not to be realized.

On January 1, 2007, Nuvelo adopted the provisions of FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes An Interpretation of FASB Statement No. 109* (FIN 48). FIN 48 provides detailed guidance for the financial statement recognition, measurement and disclosure of uncertain tax positions recognized in the financial statements in accordance with SFAS 109. Tax positions must meet a more-likely- than-not recognition threshold at the effective date to be recognized upon the adoption of FIN 48 and in subsequent periods. The adoption of FIN 48 did not have a material impact on Nuvelo s results of operations or financial position.

Net Loss Per Share

Basic and diluted net loss per share are presented in conformity with Statement of Financial Accounting Standards No. 128, *Earnings Per Share* (SFAS 128), for all periods presented. In accordance with SFAS 128, basic and diluted net loss per share was computed using the weighted average number of shares of common stock outstanding during the period. In 2008 and 2007, Nuvelo excluded the following outstanding shares of common stock equivalents, as they were anti-dilutive (in thousands):

	December 31,	
	2008	2007
Stock options and restricted stock units	279	337
Warrants	43	43
	322	380

Accumulated Other Comprehensive Income

As of December 31, 2008 and 2007, accumulated other comprehensive income consisted of unrealized gain on available-for-sale securities, net of any related tax effects, of $11,000 and $49,000, respectively.

Reclassification

Certain prior period amounts have been reclassified to conform to the current period s presentation, including accounts payable and other current liabilities in the balance sheets and the statements of cash flows, as well as common stock and additional paid-in capital in the balance sheets and the statements of stockholders equity as a result of the reverse stock split discussed above. These reclassifications did not have any effect on the working capital, total liabilities or total stockholders equity.

Recent Accounting Pronouncements

In September 2006, the FASB issued Statement 157, *Fair Value Measurements* (SFAS 157). SFAS 157 establishes a framework for measuring fair value by providing a standard definition of fair value as it applies to assets and liabilities. SFAS 157, which does not require any new fair value measurements, clarifies the application of other accounting pronouncements that require or permit fair value measurements. The effective date for Nuvelo was January 1, 2008. However, in February 2008, the FASB issued FASB Staff Position No. FAS 157-2, *Effective Date of FASB Statement No. 157* (FSP 157-2), which defers the effective date of SFAS 157 for all nonfinancial assets and nonfinancial liabilities, except items that are recognized or disclosed at fair value on a recurring basis (at least annually), until fiscal years beginning after November 15, 2008. ARCA is evaluating the impact of adopting SFAS 157 and FSP 157-2 on its financial statements.

Table of Contents

In December 2007, the FASB issued Statement 141 (Revised 2007), *Business Combinations* (SFAS 141R), which replaces SFAS 141. SFAS 141R requires the acquirer of a business to recognize and measure the identifiable assets acquired, the liabilities assumed, and any non-controlling interest in the acquiree at fair value on the acquisition date. SFAS 141R also requires that transactions costs related to the business combination be expensed as incurred and that changes in accounting for business combination related deferred tax asset valuation allowances and income tax uncertainties after the measurement period be recognized as current period income tax expense. SFAS 141R applies prospectively to business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2008. The effective date for Nuvelo was January 1, 2009. ARCA will account for the reverse merger with Nuvelo in accordance with the provisions of SFAS 141R (see Note 2).

In December 2007, the FASB ratified the consensus reached by the EITF on EITF Issue 07-1, *Accounting for Collaborative Arrangements* (EITF 07-1). EITF 07-1 requires collaborators to present the results of activities for which they act as the principal on a gross basis and report any payments received from (made to) other collaborators based on other applicable GAAP or, in the absence of other applicable GAAP, based on analogy to authoritative accounting literature or a reasonable, rational, and consistently applied accounting policy election. The effective date for Nuvelo was January 1, 2009. ARCA has not yet determined the impact of EITF 07-1 on its financial statements.

2. Merger with ARCA biopharma, Inc.

As discussed in Note 1, on January 27, 2009, Nuvelo completed its business combination with ARCA in accordance with the terms of the Merger Agreement, which was entered into by and among Nuvelo, Merger Sub and ARCA on September 24, 2008 and was amended on October 28, 2008. Pursuant to the Merger Agreement, Merger Sub merged with and into ARCA, with ARCA continuing after the merger as the surviving corporation and a wholly-owned subsidiary of Nuvelo. Immediately following the merger, Nuvelo changed its name to ARCA biopharma, Inc., and ARCA s common stock began trading on the Nasdaq Global Market under a new symbol ABIO starting January 28, 2009.

Under the terms of the Merger Agreement, holders of ARCA capital stock prior to the merger were entitled to receive shares of post-merger ARCA common stock, such that Nuvelo stockholders were expected to own approximately 33% of the common stock of the combined company immediately after the merger and ARCA stockholders, together with holders of ARCA s options and warrants, were expected to own or had the right to acquire approximately 67% of the common stock of the combined company immediately after the merger, after giving effect to the issuance of shares pursuant to outstanding options and warrants primarily on the treasury stock method. The merger is intended to qualify for federal income tax purposes as a tax-free reorganization under the provisions of Section 368(a) of the U.S. Internal Revenue Code of 1986, as amended.

The merger will be treated by ARCA as a reverse merger and accounted for as a business combination using the purchase method of accounting in accordance with SFAS 141R. For accounting purposes, ARCA is considered to have acquired Nuvelo in the merger, as the stockholders of ARCA prior to the merger now have a controlling interest in the combined company and ARCA s management is the management of the combined company.

In connection with the merger, approximately 26 of Nuvelo s employees were terminated in January 2009, and a substantial majority of the remaining employees are retained for a transition period of up to 12 weeks. Total termination benefits related to employees terminated in January 2009 and those on a transition plan were estimated to be $5.0 million.

Table of Contents

3. Financial Instruments

Available-for-sale Investments

The cost and fair value of Nuvelo s available-for-sale investments as of December 31, 2008 and 2007 were as follows (in thousands):

	December 31, 2008			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Money market fund	$ 34,935	$	$	$ 34,935
Corporate debt securities	15,070	43	(32)	15,081
	$ 50,005	$ 43	$ (32)	$ 50,016
Reported as:				
Cash equivalents				$ 34,935
Marketable securities				15,081
				$ 50,016

	December 31, 2007			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Corporate debt securities	$ 78,521	$ 47	$ (16)	$ 78,552
Asset-backed securities	9,936	18		9,954
Money market funds	8,243			8,243
	$ 96,700	$ 65	$ (16)	$ 96,749
Reported as:				
Cash equivalents				$ 31,243
Marketable securities				65,506
				$ 96,749

The following is a summary of amortized cost and estimated fair value of available-for-sale investments by contract maturity (in thousands):

	December 31, 2008		December 31, 2007	
	Amortized Cost	Estimated Fair Value	Amortized Cost	Estimated Fair Value
Due in less than one year	$ 50,005	$ 50,016	$ 94,724	$ 94,754
Due in more than one year			1,976	1,995
Total	$ 50,005	$ 50,016	$ 96,700	$ 96,749

The following is a summary of available-for-sale investments with unrealized losses and their related fair value by the period of time each investment has been in an unrealized loss position (in thousands):

	December 31, 2008		December 31, 2007	
	Unrealized Losses	Estimated Fair Value	Unrealized Losses	Estimated Fair Value
Unrealized loss position for less than one year	$ (32)	$ 5,338	$ (16)	$ 35,236

Table of Contents

Due to the short maturities of investments, the type and quality of security held, the relatively small size of unrealized losses compared to fair value, the short duration of such unrealized losses, and Nuvelo s intent and ability to hold these investments for a period of time sufficient to allow for any anticipated recovery in market value, Nuvelo believed these unrealized losses to be temporary in nature.

Fair Value of Other Financial Instruments

The carrying amount of other financial instruments, including cash and accrued liabilities, approximated fair value due to their short maturities. As of December 31, 2008 and 2007, Nuvelo did not have any debt or foreign exchange forward contracts outstanding.

4. Property and Equipment, Net

Property and equipment, net, consisted of the following (in thousands):

	December 31,	
	2008	**2007**
Leasehold improvements	$ 10,472	$ 10,458
Machinery, equipment and furniture	5,848	6,132
Computers and software	2,312	2,264
	18,632	18,854
Accumulated depreciation and amortization	(11,799)	(9,948)
	$ 6,833	$ 8,906

5. Goodwill

Nuvelo tested goodwill for impairment using a fair value approach at the reporting unit level on an annual basis or when events indicated that the carrying value of the asset might be impaired in accordance with SFAS 142. Consistent with the determination that Nuvelo had only one reporting segment, it had determined that there was only one reporting unit and, therefore, goodwill was tested at the entity level. Nuvelo had elected October 31st as its measurement date. Nuvelo completed its last annual goodwill test as of October 31, 2007, and no impairments were recognized.

SFAS 142 requires a two-step test for goodwill impairment. In the first step, Nuvelo compared the fair value of Nuvelo to its carrying value. Nuvelo generally based its fair value on its market capitalization, which was based on quoted market prices of its common stock, taking into account other factors that might affect the fair value of Nuvelo as a whole. Significant judgment is required to evaluate the fair value of a company, as quoted market prices of a company s common stock and consequently market capitalization may experience significant fluctuations in reaction to disclosures of new information about the company. If the fair value of Nuvelo exceeded the carrying value of its net assets, goodwill was not impaired and Nuvelo was not required to proceed to the second step of the impairment test.

After Nuvelo announced its decision to discontinue alfimeprase clinical development in 2008 (see Note 7, Restructuring), it experienced a significant decline of its stock price. Nuvelo management determined that Nuvelo s fair value was lower than the carrying value of its net assets and that its goodwill was impaired. As a result, Nuvelo proceeded to perform the second step of the goodwill impairment test in order to determine the implied fair value of its goodwill and compare it to the carrying value of goodwill. The activities in the second step included valuing the tangible and intangible assets and liabilities of Nuvelo based on their fair value and determining the implied goodwill based upon the difference between the fair value of the reporting unit and the net fair values of identified tangible and intangible assets and liabilities. Based on the results of the second step

Table of Contents

of calculating the implied goodwill, Nuvelo recorded an impairment charge of the full balance of goodwill totaling $4.7 million.

6. Facility Exit Costs

In December 2006, Nuvelo approved a plan to exit a 139,000-square-foot leased facility in Sunnyvale, California (the Sunnyvale facility) and restore it for potential sublease. The term of the lease for the facility expires on May 31, 2011. On December 31, 2006, Nuvelo exited the Sunnyvale facility and recorded a liability of $26.6 million to reflect the estimated fair value of future lease-related payments less estimated net income from sublease rental. Future lease-related payments are scheduled to be made periodically until the lease expires.

The balance of accrued facility exit costs represented the value of the lease liability based on assumptions regarding the vacancy period, sublease terms, and the probability of subleasing this space. The estimates and assumptions were re-evaluated each quarter and were based upon current market data, including vacancy rates and lease activities for similar facilities within the area.

As of March 31, 2008, Nuvelo determined that the likelihood of subleasing the Sunnyvale facility during the remainder of the lease term had become remote and, therefore, recorded a $1.5 million charge to reflect such change in the sublease assumption. Nuvelo continued to actively market the facility for sublease. In December 2008, Nuvelo entered into a sublease agreement, pursuant to which the sublease term commenced on March 1, 2009 and ends on May 31, 2011. Accordingly, Nuvelo recorded a credit of $2.1 million in its statement of operations in December 2008, to reflect the change in estimated fair value of the remaining lease obligations after taking into consideration future cash flows from the sublease agreement. As a result of the changes in the sublease assumption in 2008, Nuvelo recorded a net credit of $0.6 million, or $0.22 per share, in its statement of operations, under the caption Facility exit costs, for the year ended December 31, 2008.

The following table summarizes the activities related to accrued facility exit costs for the years ended December 31, 2008 and 2007 (in thousands):

Balance as of December 31, 2006	$ 26,616
Amounts paid during the period	(8,044)
Non-cash accretion	1,915
Balance as of December 31, 2007	$ 20,487
Amounts paid during the period	(8,204)
Non-cash accretion	1,473
Net change in fair value due to changes in sublease assumption	(585)
Balance as of December 31, 2008	$ 13,171

The non-cash accretion expense of $1.5 million and $1.9 million was included in general and administrative expenses for the years ended December 31, 2008 and 2007, respectively.

Nuvelo had recorded an accrual of $0.8 million for facility restoration obligation related to the Sunnyvale facility. In connection with the execution of the sublease agreement in December 2008, the landlord of the Sunnyvale facility agreed to release Nuvelo from this facility restoration obligation. As a result, Nuvelo reversed this accrual and recorded a credit of $0.8 million in its statement of operations under the caption Facility exit costs in December 2008.

7. Restructuring

On March 17, 2008, Nuvelo announced its decision to discontinue alfimeprase clinical development and restructure to make additional resources available for its other research and development programs. In connection

Table of Contents

with the restructuring, Nuvelo reduced its workforce by approximately 19% and recorded a restructuring expense of $2.5 million, including $1.3 million of termination benefits and $1.2 million of non-cash stock-based compensation expense, for the year ended December 31, 2008. As of December 31, 2008, $0.2 million of termination benefits remained unpaid and were classified under accrued compensation and employee benefits in the balance sheet.

On August 1, 2007, Nuvelo announced a reduction in its workforce by approximately 30% to realign its organization to focus on core development programs that it believed would produce nearest-term proof-of-concept data. In addition, Nuvelo suspended development of rNAPc2 in all indications including cancer and acute coronary syndromes. Nuvelo had completed the restructuring plan and recorded a restructuring expense of $2.3 million, including $1.4 million of termination benefits and $0.9 million of non-cash stock-based compensation expense, for the year ended December 31, 2007. Of the $1.4 million termination benefits, $1.0 million was paid in 2007 and the remaining balance was paid in 2008.

8. Commitments

In January 2005, Nuvelo entered into a seven-year facility lease agreement for 61,826 square feet of space in San Carlos, California, at $2.35 per square foot per month, subject to annual increases of $0.07 per square foot per month. Nuvelo used this facility for its headquarters prior to the merger. The lease term commenced on September 1, 2005, and contains an option to cancel after five years upon payment of certain amounts specified in the lease, two options to extend the lease for five additional years, each at 95% of the then-current fair market rental rate (but not less than the existing rental rate), rights of first refusal over all vacant space in the building during the first two years of the lease, and an expansion option for a specified amount of space. The lease contains a tenant improvement allowance of $8.9 million, which was fully utilized in 2005 and recorded to leasehold improvements and deferred rent, with the respective balances being charged to depreciation and credited to rent expense over the lease term. The rent expense for the lease on the San Carlos facility was being recognized as expense on a straight-line basis. In March 2006, the lease on this property was amended to provide for the exercise of the expansion option over 7,624 square feet of rentable space. The amendment allows for a tenant improvement allowance of $1.0 million, which was fully utilized in 2006, and the related lease rental payments commenced in August 2006. Currently, approximately 6,754 square feet of space in the San Carlos facility are subleased by a subtenant. The term of the sublease, which started in February 2008 and expires in January 2011, can be extended by the subtenant for three additional periods of one year each, subject to certain conditions contained in the sublease agreement.

The lease for the Sunnyvale facility, which expires on May 31, 2011, requires a letter of credit issued to the facility s landlord in the amount of $6.0 million. The letter of credit is being collateralized by a certificate of deposit of the same amount, which was recorded as restricted cash in the balance sheet. As of December 31, 2006, Nuvelo ceased use of the Sunnyvale facility, as it was no longer required for its business (see Note 6, Facility Exit Costs).

In December 2008, Nuvelo entered into a sublease agreement for its Sunnyvale facility. The term of the sublease commenced on March 1, 2009 and ends on May 31, 2011. The sublease agreement requires the subtenant to pay a monthly base rent of $57,000, except during the first four months of the term, and a substantial majority of the facility operating expenses charged by the facility s landlord.

Table of Contents

As of December 31, 2008, future minimum rental payments and sublease rentals under non-cancelable operating leases were as follows (in thousands):

Years Ending December 31,	
2009	$ 8,329
2010	8,628
2011	4,979
2012	1,539
Total future minimum rental payments	23,475
Less aggregate future minimum rentals to be received from subleases	(1,854)
	$ 21,621

Rent expense before sublease rentals was $0.7 million for each of the years ended December 31, 2008 and 2007. Total sublease rentals were $0.2 million in 2008, and there were no sublease rentals in 2007.

9. Stockholders Equity and Stock-based Compensation

Warrants

As of December 31, 2008, warrants to purchase 42,511 shares of common stock were outstanding and exercisable at exercise prices ranging from $241.44 to $497.40, with a weighted average exercise price per share of $391.38. These warrants, which were granted as part of various financing and business agreements, expire at various times between January 2009 and February 2011. 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

On March 14, 2007, Nuvelo s 2004 Equity Incentive Plan and Employee Stock Purchase Plan were amended to increase the number of shares available for issuance under the plans by 100,000 and 25,000 shares, respectively. On May 31, 2007, the increases for the plans were approved by Nuvelo s stockholders.

Nuvelo s stock plans have outstanding grants of stock awards to employees, directors or consultants. In general, the plans authorize 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 Nuvelo prior to the merger under the employee stock plans become exercisable at a rate of 25% per year for a period of four years from date of grant and have a maximum term of ten years. The exercise prices of stock options under employee stock plans 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.

In May 2004, Nuvelo adopted the 2004 Equity Incentive Plan (2004 Plan) to authorize the grant 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 2004 Plan, awards may be granted to employees, directors and consultants of Nuvelo, except for incentive stock options, which may be granted only to employees. The 2004 Plan supersedes all prior stock plans (detailed below), and no new awards will be granted under these prior stock plans. As a result of the adoption of the 2004 Plan, all shares previously reserved for issuance under the prior stock plans and remaining for grant are now reserved for issuance under the 2004 Plan. Additionally, shares outstanding under the prior stock plans that are subject to options that expire or otherwise are forfeited become reserved for issuance under the 2004 Plan. As of December 31, 2008, options to purchase 235,807 shares and 1,365 restricted stock units were outstanding under the 2004 Plan, and 328,217 shares were reserved for future awards.

Table of Contents

Nuvelo s other stock plans under which options remained outstanding as of December 31, 2008 are the 1995 Employee Stock Option Plan, the Non-Employee Director Stock Option Plan and the 2002 Equity Incentive Plan. As of December 31, 2008, options to purchase 20,249 shares were outstanding under these stock plans. Additionally, as of December 31, 2008, options to purchase 21,969 shares granted outside of any of Nuvelo s stock plans were outstanding.

In December 2004, Nuvelo s Board of Directors approved an Executive Change in Control and Severance Benefit Plan for executive officers and other eligible employees, which was amended and restated in May 2005 and again in August 2007 (Severance Plan). The purpose of the Severance Plan is to provide for the payment of severance benefits and/or change in control benefits to certain eligible employees, and the Severance Plan supersedes and replaces any change in control and/or severance plans adopted previously. The Severance Plan provides that, upon a change in control of Nuvelo as defined under the Severance Plan, all Nuvelo stock options and stock awards held by a plan participant will become fully vested. Such shares held by a plan participant will also become fully vested if the participant is terminated without cause or constructively terminated within one month preceding a change in control. In addition, if a participant is terminated without cause or constructively terminated outside the context of change in control, he or she shall be immediately credited with an additional year of vesting with respect to Nuvelo stock options and stock awards held. The merger with ARCA in January 2009 qualified as a change in control as defined under the Severance Plan. As a result, unvested options and restricted stock units that were held by Nuvelo s executive officers and one other eligible employee to purchase a total of approximately 39,300 shares became fully vested upon the consummation of the merger.

Under Nuvelo s employee stock purchase plan (ESPP), eligible employees may elect to purchase shares of Nuvelo s common stock through payroll deductions at a price equal to the lower of 85% of the fair market value of the stock as of the first or last business day of each three-month period. As of December 31, 2008, there were 11,351 shares available for issuance under the ESPP. During 2008 and 2007, Nuvelo issued 14,986 shares and 8,875 shares of its common stock under the ESPP at a weighted average price per share of $13.39 and $47.40, respectively.

Stock-based Compensation Expense Stock Options, Restricted Stock Units and ESPP

Stock-based compensation expense related to employees stock options, restricted stock units and ESPP purchase rights was as follows (in thousands):

	Year Ended December 31,	
	2008	2007
Research and development	$ 337	$ 3,712
General and administrative	3,035	5,008
Restructuring	1,237	926
Total	$ 4,609	$ 9,646

Nuvelo terminated two executives in connection with each of its reductions in force announced in March 2008 and August 2007 (see Note 7, Restructuring). These former executives were entitled to a 12-month acceleration in vesting of their stock options in accordance with the Severance Plan. For the years ended December 31, 2008 and 2007, Nuvelo recorded stock-based compensation expense of $1.2 million and $0.9 million, respectively, as a result of the acceleration in vesting of executives stock options and classified the expense as part of restructuring costs.

Stock-based compensation expense related to non-employees was negligible in 2008 and 2007.

Nuvelo 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.

Table of Contents

A summary of Nuvelo s stock option activities for the years ended December 31, 2008 and 2007, and related information as of December 31, 2008, was as follows:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (In years)	Aggregate Intrinsic Value (In thousands)
Options outstanding at December 31, 2006	398,083	$ 327.00		
Granted	79,887	69.60		
Exercised	(60)	82.20		
Forfeited or expired	(144,807)	215.20		
Options outstanding at December 31, 2007	333,103	314.00		
Granted	65,398	30.09		
Exercised				
Forfeited or expired	(120,476)	227.43		
Balances at December 31, 2008:				
Options outstanding	278,025	$ 284.59	5.32	$
Options vested and expected to vest	255,255	$ 298.22	5.17	$
Options exercisable	213,353	$ 334.06	4.79	$

Employees options are generally vested over a four-year period. In 2007, 65,387 options that were granted to employees as part of the employee retention program vest over a three-year period.

For the years ended December 31, 2008 and 2007, the weighed average grant date fair value of options granted was $21.62 and $49.40 per share, respectively. The total intrinsic value of options exercised in 2007 was negligible, and no options were exercised in 2008. As of December 31, 2008, the unamortized compensation expense related to unvested options, excluding estimated forfeitures, was $7.4 million, and the weighted-average period over which compensation expense related to these options was expected to be recognized was 1.84 years.

The following table summarizes information about stock options outstanding and exercisable as of December 31, 2008:

	Options Outstanding			Options Exercisable	
Range of Exercise Prices	Number of Shares	Weighted Average Remaining Contractual Term (In years)	Weighted Average Exercise Price	Number of Shares	Weighted Average Exercise Price
$ 13.50 $ 31.30	42,186	7.44	$ 29.26	13,415	$ 25.60
33.20 81.90	41,243	6.36	70.24	29,720	72.06
89.50 179.20	27,304	4.88	147.90	26,013	148.80
183.30 183.30	46,036	4.96	183.30	39,792	183.30
184.20 203.50	59,324	4.60	198.76	53,893	198.80
222.19 1,901.28	61,932	4.34	819.01	50,520	928.52
	278,025	5.32	284.59	213,353	334.06

As of December 31, 2007, 225,604 options were exercisable at a weighted average exercise price of $370.40.

Table of Contents

A summary of Nuvelo s restricted stock unit activity for the years ended December 31, 2008 and 2007, was as follows:

	Number of Units	Aggregate Intrinsic Value (In thousands)
Units unvested at December 31, 2006		
Granted	9,150	
Vested		
Forfeited	(4,850)	
Units unvested at December 31, 2007	4,300	
Granted		
Vested	(1,437)	
Forfeited	(1,498)	
Balances at December 31, 2008:		
Units unvested	1,365	$ 8
Units vested and expected to vest	897	$ 5
Units exercisable		$

All restricted stock units granted in 2007 have a grant date fair value of $70.80 per unit and a three-year vesting period during which one-third of the units vest at the anniversary date of the grant. No restricted stock units were granted in 2008 or prior to 2007. Restricted stock units granted under the 2004 Plan have no exercise price and have a fair value equal to the average of the high and low prices of Nuvelo s common stock on the date of grant, in accordance with Nuvelo s stock award pricing practice. For the year ended December 31, 2008, the fair value of restricted stock units vested was $45,000. No restricted stock unit was vested in 2007. As of December 31, 2008, the unamortized compensation expense related to unvested restricted stock units, excluding estimated forfeitures, was $0.2 million, and the weighted average period over which compensation expense related to these restricted stock units was expected to be recognized was 1.09 years.

10. Collaborative Agreements

Archemix

In July 2006, Nuvelo entered into a collaboration agreement with Archemix Corporation. Under the agreement, Archemix is responsible for the discovery of short-acting aptamers targeting the coagulation cascade for use in acute cardiovascular procedures, and Nuvelo 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 it is also funding at least $5.25 million of Archemix s research over the first three years of the agreement. Archemix may receive payments totaling up to $35.0 million per development compound on the achievement of specified development and regulatory milestones, along with potential royalty payments based on sales of licensed compounds. In February 2008, Nuvelo paid Archemix a $1.0 million milestone fee that was accrued upon dosing of the first patient in the Phase I trial for NU172. If ARCA enrolls the first patient in a Phase II trial of NU172, which may occur in 2009, ARCA is obligated to pay Archemix a $3.0 million milestone fee. At the initiation of the first Phase III study for any licensed compound, Archemix has the option to elect to participate in profits from sales of the compound by funding its pro rata share of prior and future product development and commercialization expenses, in lieu of receiving milestone payments and royalties with respect to that compound. In addition, ARCA is obligated to purchase Archemix common stock having a value equal to the lesser of $10.0 million or 15% of the shares issued by Archemix in a qualified public offering of Archemix stock occurring within five years of the effective date of the 2006 collaboration agreement.

Table of Contents

Kirin

In March 2005, Nuvelo entered into a collaboration agreement with Kyowa Hakko Kirin Company, Limited for the development and commercialization of NU206. In accordance with the terms of this agreement, Nuvelo received a $2.0 million upfront cash payment from Kirin in April 2005, which was deferred and is being recognized on a straight-line basis over the related performance period through 2013. Nuvelo agreed to lead worldwide development, manufacturing and commercialization of the compound. All operating expenses and any profits related to the development and commercialization of NU206 are being shared 60% by Nuvelo and 40% by Kirin. If this agreement is terminated, or Kirin or ARCA elects under certain circumstances to no longer actively participate in the collaboration, the relationship with respect to NU206 will convert from an expense and profit-sharing structure to a royalty-based structure.

Dendreon

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 in February 2004. 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, which was recorded as research and development expense. Future milestone payments to Dendreon could reach as much as $23.5 million if all development and commercialization milestones are achieved. ARCA currently cannot predict if or when any of these milestones will be achieved. If rNAPc2 is commercialized, ARCA will also be responsible for paying royalties to Dendreon depending on sales of rNAPc2. In 2007, Nuvelo suspended its clinical development of rNAPc2, which could impact the license with Dendreon.

Amgen

In October 2004, Nuvelo obtained worldwide rights to develop and commercialize alfimeprase from Amgen Inc., in exchange for the future payment to Amgen of future development milestones and royalties. Future milestone payments under the license agreement could total as much as $35.0 million. In 2008, Nuvelo discontinued development of alfimeprase. ARCA cannot predict if or when any of these additional milestones will be achieved.

Bayer

In June 2007, Nuvelo and Bayer Healthcare AG terminated their January 2006 license and collaboration agreement for the development and commercialization of alfimeprase. As part of the termination agreement with Bayer, Nuvelo agreed to waive Bayer s obligation to provide Nuvelo 12 months notice of termination in consideration of Bayer s agreement to pay Nuvelo a lump sum of $15.0 million. Nuvelo also granted Bayer the option to reacquire rights to alfimeprase upon the initiation of a pivotal stroke trial or upon Nuvelo s public announcement that it is discontinuing further development of alfimeprase in the stroke indications. The notice period during which Bayer could exercise the option would begin upon Nuvelo making certain information available to Bayer and last for 30 days after delivery of the information.

As a result of the termination of the collaboration agreement with Bayer, Nuvelo recognized in June 2007 the remaining unamortized balance of the $50.0 million up-front license fee received from Bayer in January 2006, which totaled approximately $44.9 million. The up-front license fee had been recorded as deferred revenue upon receipt and was being recognized on a straight-line basis over the performance period under the agreement, originally estimated to be through September 2020.

On March 17, 2008, Nuvelo announced its decision to discontinue further clinical development of alfimeprase, including the programs in catheter occlusion and acute ischemic stroke. In April 2008, Nuvelo provided the information to Bayer as required by the termination agreement. The $15.0 million termination

Table of Contents

payment, which had been recorded as deferred revenue, was recognized as revenue in May 2008 upon the expiration of the notice period.

Under the original terminated agreement, Nuvelo was responsible for 60% of any costs for alfimeprase global development programs, and Bayer was responsible for the remaining 40%. Pursuant to this cost-sharing arrangement, a total of $3.0 million was billed to Bayer for Nuvelo s alfimeprase-related global development spending for the year ended December 31, 2007, and was recorded as an offset to research and development expenses in the statements of operations. The cost-sharing arrangement ended when the collaboration agreement was terminated in June 2007.

11. Note Receivable

In connection with the sale of its subsidiary, Callida Genomics, Inc. (Callida), to SBH Genomics, Inc. (SBH) on December 3, 2004, Nuvelo received a convertible promissory note from SBH with a principal amount of $0.9 million. The promissory note was convertible into SBH s preferred shares if SBH raised at least $2.0 million in venture capital financing within four years after the date of the sale. If SBH failed to raise at least $2.0 million in venture capital financing within this period, the promissory note became due and payable. No interest or principal was payable on the promissory note for the two years through December 3, 2006. Simple interest of prime rate plus 1% per annum was payable in the third and fourth years on a quarterly basis. Prime rate was set as of the second anniversary of the sale and adjusted on the third anniversary. Interest income was credited to income in the period received. Nuvelo had initially assessed the value of the promissory note to be zero due to its assessment of the probability of collection. In December 2008, Nuvelo received a full payment of the $0.9 million promissory note and recorded $0.9 million as other income in the statement of operations.

12. Income Taxes

The reconciliations between the amounts computed by applying the U.S. federal statutory tax rate of 34% to loss from continuing operations and the actual provision for income taxes were as follows (in thousands):

	Year Ended December 31,	
	2008	2007
Loss from continuing operations	$ (29,923)	$ (12,301)
Federal tax benefit at statutory rate	$ (10,174)	$ (4,182)
Current year net operating losses and temporary differences, for which a full valuation allowance is recorded	6,923	2,225
State taxes, net of federal benefit	1	1
Impairment of goodwill	1,588	
Stock-based compensation	1,061	1,956
Merger-related expenses	601	
Provision for income taxes	$	$

Table of Contents

Deferred Income Taxes

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets for financial reporting and the amounts used for income tax purposes. Significant components of Nuvelo s deferred tax assets for federal and state income taxes were as follows (in thousands):

	December 31,	
	2008	2007
Deferred tax assets:		
Property and equipment	$ 3,324	$ 3,598
Accruals and reserves	5,914	15,154
Net operating loss carryforwards	151,046	126,503
Research and other tax credit carryforwards	7,354	6,893
Capital loss carryforward discontinued operations	3,153	3,152
Capitalized research and development costs	10,653	10,846
Stock-based compensation	2,371	1,784
Other		7,200
Total deferred tax assets	183,815	175,130
Valuation allowance	(183,815)	(175,130)
Deferred tax assets, net of valuation allowance	$	$

Deferred tax assets were reduced by a valuation allowance, as management believed that it was more likely than not that the deferred tax assets would not be realized. The valuation allowance increased $8.7 million for the year ended December 31, 2008 and decreased by $3.8 million for the year ended December 31, 2007.

Net Operating Loss Carryforwards

The utilization of Nuvelo s net operating loss carryforwards and tax credit carryforwards are subject to annual limitation due to the ownership changes per the Internal Revenue Code and similar state provisions. Such an annual limitation may result in the expiration of the net operating loss before utilization. In 2007, Nuvelo completed a review of its ownership changes and concluded certain common stock offerings prior to 2006 resulted in ownership changes that triggered a net operating loss carryforward annual limitation. This annual limitation per Section 382 of the Internal Revenue Code results in approximately $119.0 million in net operating loss carryforwards for years up to and including 2005 expiring not utilized. Similarly, approximately $12.0 million of research tax credits will expire unused. Adjusting for the annual limitation, at December 31, 2008, Nuvelo had net operating loss carryforwards for federal income tax purposes of approximately $412.5 million which begin to expire in year 2009, and federal tax credits of approximately $3.0 million which begin to expire in 2026. At December 31, 2008, Nuvelo also had state net operating loss carryforwards of approximately $207.2 million which begin to expire in 2012 and state tax credits of approximately $6.6 million which have no expiration date.

Approximately $13.3 million of the federal net operating losses and $7.2 million of the state net operating losses relate to deductions from stock-based compensation. The benefit from the realization of these losses will be an adjustment to Additional Paid-in Capital.

On December 3, 2004, Nuvelo sold its subsidiaries, Callida and N-Mer. As of December 31, 2008, the related capital loss carryforward was $7.9 million, which will expire in 2009.

As discussed in Note 2, on January 27, 2009, Nuvelo completed its business combination with ARCA. A change in ownership of Nuvelo per Section 382 occurred, and accordingly, ARCA s ability to utilize the net operating loss carryforwards and tax credits has been substantially reduced.

Table of Contents

FIN 48

Nuvelo adopted FIN 48 which requires that it recognize the financial statement effects of a tax position when it is more likely than not, based on the technical merits, that the position will be sustained upon examination. No adjustment to Nuvelo s accumulated deficit was required upon its adoption of FIN 48 on January 1, 2007.

Nuvelo had cumulative unrecognized tax benefit of approximately $6.2 million as of January 1, 2007. The following table summarizes the activity related to the unrecognized tax benefit for the years ended December 31, 2008 and 2007 (in thousands):

Balance at January 1, 2007	$ 6,159
Increase related to current year tax position	1,075
Balance at December 31, 2007	7,234
Increase related to current year tax position	576
Decrease related to prior year tax position	(488)
Balance at December 31, 2008	$ 7,322

As of December 31, 2008 and 2007, the cumulative unrecognized tax benefit was netted against deferred tax assets with a full valuation allowance or other fully reserved amounts, and if recognized there would be no effect on Nuvelo s effective tax rate. The amount of existing unrecognized tax benefit was not expected to significantly increase or decrease within the next 12 months.

Nuvelo recognized interest accrued and penalties related to unrecognized tax benefits in general and administrative expense. During the years ended December 31, 2008 and 2007, Nuvelo recognized an insignificant amount in interest and penalties.

Nuvelo is currently open to audit under the statute of limitations by the Internal Revenue Service and the appropriate state income taxing authorities for all years due to the net loss carryovers from those years.

13. Segment and Revenue Concentration Data

Segment Data

Nuvelo was engaged in the discovery, development and commercialization of novel acute cardiovascular and cancer therapies. Nuvelo had only one reportable segment. The reportable segment reflected Nuvelo s structure, reporting responsibilities to the chief executive officer and the nature of the products under development.

Revenue Concentration Data

Revenues from collaborative agreements or other sources representing 10% or more of total revenues in each period were as follows:

	Year Ended December 31,	
	2008	**2007**
Source:		
Bayer	98%	99%
Kirin	*	*

* less than 10% of total revenues

87

Table of Contents

14. Legal Matters

On February 9, 2007, Nuvelo and certain of Nuvelo s former and current officers and directors were named as defendants in a purported securities class action lawsuit filed in the United States District Court for the Southern District of New York. The suit alleges violations of the Securities Exchange Act of 1934 related to the clinical trial results of alfimeprase, which Nuvelo announced on December 11, 2006, and seeks damages on behalf of purchasers of Nuvelo s common stock during the period between January 5, 2006 and December 8, 2006. Specifically, the suit alleges that Nuvelo misled investors regarding the efficacy of alfimeprase and the drug s likelihood of success. The plaintiff seeks unspecified damages and injunctive relief. Three additional lawsuits were filed in the Southern District of New York on February 16, 2007, March 1, 2007 and March 6, 2007, respectively. On April 10, 2007, three separate motions to consolidate the cases, appoint lead plaintiff, and appoint lead plaintiff s counsel were filed. On April 18, 2007, Nuvelo filed a motion to transfer the four cases to the Northern District of California. The Court granted Nuvelo s motion to transfer the cases to the Northern District of California in July 2007. Plaintiffs have filed motions for consolidation, lead plaintiff and lead plaintiff s counsel in the Northern District of California. Plaintiffs filed their consolidated complaint in the Northern District of California on November 9, 2007. Nuvelo filed a motion to dismiss plaintiffs consolidated complaint on December 21, 2007. Plaintiffs filed an opposition to Nuvelo s motion to dismiss on February 4, 2008. On June 12, 2008, the Court held a hearing on the motion to dismiss.

On December 4, 2008, the Court issued an order dismissing plaintiff s complaint, and granting leave to amend. On January 23, 2009, plaintiffs filed an amended complaint, alleging similar claims. Based on the Court s December 4, 2008 order, and plaintiff s amended complaint, ARCA believes that any attorneys fees, loss or settlement payment with respect to this suit will be paid by its insurance provider. However, it is possible that ARCA could be forced to incur material expenses in the litigation if the case is not finally dismissed, or if the parties cannot achieve a settlement, and, in the event of an adverse outcome, ARCA s business could be harmed.

In addition, on or about December 6, 2001, Variagenics, Inc. was sued in a complaint filed in the United States District Court for the Southern District of New York naming it and certain of its officers and underwriters as defendants. The complaint purportedly is filed on behalf of persons purchasing Variagenics stock between July 21, 2000 and December 6, 2000, and alleges violations of Sections 11, 12(a)(2) and 15 of the Securities Act of 1933, as amended and Section 10(b) of the Securities Exchange Act of 1934, as amended, and Rule 10b-5 promulgated thereunder. The complaint alleges that, in connection with Variagenics July 21, 2000 initial public offering, or IPO, the defendants failed to disclose additional and excessive commissions purportedly solicited by and paid to the underwriter defendants in exchange for allocating shares of Variagenics stock to preferred customers and alleged agreements among the underwriter defendants and preferred customers tying the allocation of IPO shares to agreements to make additional aftermarket purchases at predetermined prices. Plaintiffs claim that the failure to disclose these alleged arrangements made Variagenics registration statement on Form S-1 filed with the SEC in July 2000 and the prospectus, a part of the registration statement, materially false and misleading. Plaintiffs seek unspecified damages. On or about April 19, 2002, an amended complaint was filed which makes essentially the same allegations. On or about July 15, 2002, Variagenics and the individuals filed a motion to dismiss. Nuvelo is involved in this litigation as a result of Nuvelo s merger with Variagenics in January 2003. On July 16, 2003, Nuvelo s board of directors approved a settlement proposal initiated by the plaintiffs. However, because of a recent court ruling, the settlement class, as defined in the settlement papers, is no longer feasible. While a new complaint has not been filed against Nuvelo, there are several focus cases against other issuers in which new complaints have been filed. Defendant issuers in the focus cases filed motions to dismiss the new complaints. On March 26, 2008, the District Court issued an order granting in part and denying in part the focus issuers motions to dismiss. The focus issuers had been advised that plaintiffs intended to file new complaints against Nuvelo, but none have been filed yet. ARCA believes that any attorneys fees, loss or settlement payment with respect to this suit will be paid by Nuvelo s insurance provider. However, it is possible that ARCA could be forced to incur material expenses in the litigation if the parties cannot achieve a settlement, and, in the event of an adverse outcome, ARCA s business could be harmed.

Table of Contents

Item 9. ***Changes in and Disagreements with Accountants on Accounting and Financial Disclosure***
Not applicable.

Item 9A(T). ***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 Nuvelo s 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 Nuvelo s 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 Nuvelo s internal control over financial reporting as of December 31, 2008. 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 Nuvelo s internal control over financial reporting was effective as of December 31, 2008 based on these criteria.

This annual report does not include an attestation report of the Company s independent registered public accounting firm regarding internal control over financial reporting. Management s report was not subject to attestation by the Company s independent registered public accounting firm pursuant to temporary rules of the SEC that permit the Company to provide only management s report in this annual report.

Changes in Internal Control over Financial Reporting

During the fourth quarter of 2008, 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. Upon completion of the merger transaction on January 27, 2009, Nuvelo s and ARCA s operations were combined. As a result of the completion of the merger, we are evaluating our internal control policies and procedures and may make modifications to the design and effectiveness of our internal control policies and procedures.

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

Table of Contents

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 the Company have been detected.

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

None.

Table of Contents

PART III

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

The information required by this item is incorporated by reference to Election of Board of Directors, Section 16(a) Beneficial Ownership Reporting Compliance and Executive Officers in our Definitive Proxy Statement to be filed pursuant to Regulation 14A under the Securities Exchange Act of 1934, relating to our 2009 Annual Meeting of Stockholders.

We have adopted a Code of Business Conduct and Ethics (the Code of Conduct) that applies to all of our directors, officers and employees including our principal executive officer, principal financial officer, principal accounting officer and controller. The Code of Conduct is located on our website at www.arcabiopharma.com in the section titled, Investors, under the subsection titled, Corporate Governance. If we make any substantive amendments to the Code of Conduct or grant any waiver from a provision of the Code of Conduct to any executive officer or director, we intend to disclose the nature of the amendment or waiver on our website. Information found on our website is not incorporated by reference into this report.

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 2009 Annual Meeting of Stockholders.

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

The response to this item, except for Equity Compensation Plan Information disclosed below, 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 2009 Annual Meeting of Stockholders.

Equity Compensation Plan Information

The following table sets forth information as of December 31, 2008 for all of Nuvelo s equity compensation plans in existence prior to the merger:

Plan Category	No. of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights (a)	Weighted Average Exercise Price of Outstanding Options, Warrants and Rights (b)	No. of Securities Remaining Available for Future Issuance Under Equity Compensation Plans Excluding Securities Reflected in Column(a) (c)
Equity compensation plans approved by security holders	274,087	$ 274.17	339,568
Equity compensation plans not approved by security holders(1)	5,303	$ 750.00	
Total	279,390	$ 283.20	339,568

(1) Consists of option granted to an executive officer of Nuvelo described below which is not required to be and has not been approved by its stockholders.

Non-Stockholder Approved Equity Arrangements

In 2001, Nuvelo granted Dr. Ted W. Love options to purchase shares of common stock in connection with and as an inducement to his commencement of employment with Nuvelo. Specifically, on January 11, 2001,

Table of Contents

Nuvelo granted Dr. Love an option to purchase 7,802 shares of common stock at an exercise price of $750.00 per share, the closing price on the date of grant, of which 5,303 remained outstanding as of December 31, 2008. Dr. Love s employment as the president and chief executive officer of Nuvelo was terminated on January 27, 2009. Dr. Love continues to serve as a member of the board of directors of ARCA after the merger, and his stock options remain exercisable until his service as a board member terminates.

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 2009 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 2009 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 62 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. The Company will furnish a copy of any exhibit listed to requesting stockholders upon payment of the Company s reasonable expenses in furnishing those materials.

Exhibit Number	Description
2.1	Agreement and Plan of Merger, dated November 9, 2002, by and among Hyseq, Inc., Vertical Merger Corp. and Variagenics, Inc.(7)
2.2	Agreement and Plan of Merger, dated March 19, 2004, by and between Nuvelo, Inc. and Nuvelo, Inc., a Nevada corporation and Nuvelo, Inc. s predecessor in interest.(10)
2.3	Stock Purchase Agreement, dated December 3, 2004, between SBH Genomics, Inc., Radoje Drmanac, Snezana Drmanac, Nuvelo, Inc., and Affymetrix, Inc.(13)
2.4	Agreement and Plan of Merger and Reorganization, dated September 24, 2008, among Nuvelo, Inc., Dawn Acquisition Sub, Inc. and ARCA biopharma, Inc.(22)
2.5	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.(23)
3.1*	Amended and Restated Certificate of Incorporation of the Registrant, as amended.
3.2*	Amended and Restated Bylaws of the Registrant, as amended.
4.1	Form of Common Stock Certificate.(24)
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.
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.
4.5*	Warrant to Purchase Stock Agreement, dated August 19, 2008, by and between ARCA biopharma, Inc. and Silicon Valley Bank.
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.
4.7*	Warrant to Purchase Stock Agreement, dated October 10, 2008, by and between ARCA biopharma, Inc. and Boulder Ventures IV, L.P.
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.

Table of Contents

Exhibit Number	Description
4.9*	Warrant to Purchase Stock Agreement, dated October 10, 2008, by and between ARCA biopharma, Inc. and Boulder Ventures IV (Annex), L.P.
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.
4.11*	Warrant to Purchase Stock Agreement, dated October 10, 2008, by and between ARCA biopharma, Inc. and InterWest Partners IX, LP.
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.
4.13*	Warrant to Purchase Stock Agreement, dated October 10, 2008, by and between ARCA biopharma, Inc. and Atlas Venture Fund VII, L.P.
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.
4.15*	Warrant to Purchase Stock Agreement, dated October 10, 2008, by and between ARCA biopharma, Inc. and The Peierls Foundation, Inc.
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.
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.
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.
10.1§	Collaboration Agreement, dated March 31, 2005, by and between Kirin Brewery Company Ltd. and Nuvelo, Inc.(15)
10.2§	Amended and Restated Collaboration and License Agreement, dated July 31, 2006, by and between Nuvelo, Inc. and Archemix Corp.(18)
10.3	Lease, dated April 30, 2001, by and between The Irvine Company and Hyseq, Inc.(4)
10.4	First Amendment to Lease, dated August 1, 2002, by and between The Irvine Company and Hyseq, Inc.(6)
10.5	Second Amendment to Lease, dated October 21, 2003, by and between The Irvine Company and Nuvelo, Inc.(9)
10.6	Third Amendment to Lease, dated September 15, 2005, by and between The Irvine Company and Nuvelo, Inc.(17)
10.7	Lease Agreement, dated January 11, 2005, by and between Nuvelo, Inc. and BMR-201 Industrial Road LLC.(14)
10.8	First Amendment to Lease, dated May 10, 2005, by and between BMR-201 Industrial Road LLC and Nuvelo, Inc.(16)
10.9*	Lease, dated February 8, 2008, by and between ARCA Discovery, Inc. and Arista Place, LLC.
10.10*	Loan and Security Agreement, dated July 17, 2007, by and between ARCA biopharma, Inc. and Silicon Valley Bank.
10.11*	First Amendment to Loan and Security Agreement, dated January 21, 2009, by and between ARCA biopharma, Inc. and Silicon Valley Bank.

Table of Contents

Exhibit Number	Description
10.12*	Second Amendment to Loan and Security Agreement, dated March 23, 2009, by and between ARCA biopharma Colorado, Inc. and Silicon Valley Bank.
10.13*	Note and Warrant Purchase Agreement, dated September 24, 2008.
10.14*	Amendment to Note and Warrant Purchase Agreement, dated October 10, 2008.
10.15	Stock Option Plan, as amended.(2)
10.16	Non-Employee Director Stock Option Plan, as amended.(3)
10.17	Form of Non-Stockholder Approved Stock Option Agreement for Officers.(5)
10.18	Nuvelo, Inc. 2002 Equity Incentive Plan.(8)
10.19	Amended and Restated Nuvelo, Inc. 2004 Equity Incentive Plan.(19)
10.20	Form of Notice of Grant of Stock Option under Nuvelo, Inc. 2004 Equity Incentive Plan.(11)
10.21	Form of Nuvelo, Inc. Stock Option Agreement (Single Trigger Acceleration) under Nuvelo, Inc. 2004 Equity Incentive Plan.(11)
10.22	Form of Nuvelo, Inc. Stock Option Agreement (Double Trigger Acceleration) under Nuvelo, Inc. 2004 Equity Incentive Plan.(12)
10.23	Employee Stock Purchase Plan, as amended and restated on May 31, 2007.(19)
10.24	ARCA Discovery, Inc. 2004 Stock Incentive Plan.(24)
10.25	Amendment No. 1 to the ARCA Discovery, Inc. 2004 Stock Incentive Plan.(24)
10.26	Amendment No. 2 to the ARCA Discovery, Inc. 2004 Stock Incentive Plan.(24)
10.27	Amendment No. 3 to the ARCA Discovery, Inc. 2004 Stock Incentive Plan.(24)
10.28	Amendment No. 4 to the ARCA Discovery, Inc. 2004 Stock Incentive Plan.(24)
10.29	Amendment No. 5 to the ARCA Discovery, Inc. 2004 Stock Incentive Plan.(24)
10.30	Amendment No. 6 to the ARCA Discovery, Inc. 2004 Stock Incentive Plan.(24)
10.31	ARCA biopharma, Inc. 2004 Stock Incentive Plan, Form of Executive Incentive Stock Option Agreement.(24)
10.32	ARCA biopharma, Inc. 2004 Stock Incentive Plan, Form of Non-Executive Incentive Stock Option Agreement.(24)
10.33	ARCA biopharma, Inc. 2004 Stock Incentive Plan, Form of Nonqualified Stock Option Agreement.(24)
10.34 *	ARCA biopharma, Inc. 2004 Equity Incentive Plan (f/k/a Nuvelo, Inc. 2004 Equity Incentive Plan), Form of Partial Acceleration Stock Option Agreement.
10.35 *	ARCA biopharma, Inc. 2004 Equity Incentive Plan (f/k/a Nuvelo, Inc. 2004 Equity Incentive Plan), Form of No Acceleration Stock Option Agreement.
10.36 *	ARCA biopharma, Inc. 2004 Equity Incentive Plan (f/k/a Nuvelo, Inc. 2004 Equity Incentive Plan), Form of Director Stock Option Agreement.
10.37 *	ARCA biopharma, Inc. 2004 Equity Incentive Plan (f/k/a Nuvelo, Inc. 2004 Equity Incentive Plan), Form of Notice of Grant of Stock Option.
10.38 *	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.

Table of Contents

Exhibit Number		Description
10.39		Form of Indemnification Agreement between Nuvelo, Inc. and its directors and officers.(1)
10.40		Nuvelo, Inc. Amended Executive Change in Control and Severance Benefit Plan.(20)
10.41		Separation Agreement, dated April 14, 2008, by and between Nuvelo, Inc. and Michael D. Levy.(21)
10.42		Bonuses for Named Executive Officers Approved on January 25, 2008.(21)
10.43	*	Amended and Restated Employment and Retention Agreement, dated June 4, 2008, by and between ARCA biopharma, Inc. and Michael R. Bristow.
10.44	*	Amended and Restated Employment and Retention Agreement, dated July 7, 2008, by and between ARCA biopharma, Inc. and Richard B. Brewer.
10.45	*	Amended and Restated Employment Agreement, dated June 12, 2008, by and between ARCA biopharma, Inc. and Christopher D. Ozeroff.
10.46	*	Assignment and Assumption Agreement, dated January 26, 2009, by and between ARCA biopharma, Inc. and ARCA biopharma Colorado, Inc.
10.47	*	Assignment and Assumption Agreement, dated January 26, 2009, by and between ARCA biopharma, Inc. and ARCA biopharma Colorado, Inc.
10.48	*	Assignment and Assumption Agreement, dated January 26, 2009, by and between ARCA biopharma, Inc. and ARCA biopharma Colorado, Inc.
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23.1	*	Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm.
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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/ LEE BENDEKGEY
Lee Bendekgey

Principal Accounting Officer

Date: March 27, 2009

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Richard B. Brewer and Kathryn E. Falberg, 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/ RICHARD B. BREWER **Richard B. Brewer**	President and Chief Executive Officer and Director (Principal Executive Officer)	March 27, 2009
/s/ KATHRYN E. FALBERG **Kathryn E. Falberg**	Chief Financial Officer and Chief Operating Officer (Principal Financial Officer)	March 27, 2009
/s/ LEE BENDEKGEY **Lee Bendekgey**	Principal Accounting Officer	March 27, 2009
/s/ MICHAEL R. BRISTOW **Michael R. Bristow**	Director	March 27, 2009
/s/ JEAN-FRANCOIS FORMELA **Jean-Francois Formela**	Director	March 27, 2009
/s/ J. WILLIAM FREYTAG **J. William Freytag**	Director	March 27, 2009

/s/ LINDA GRAIS **Linda Grais**	Director	March 27, 2009
/s/ TED W. LOVE **Ted W. Love**	Director	March 27, 2009

Table of Contents

Signature	Title	Date
/s/ David G. Lowe **David G. Lowe**	Director	March 27, 2009
/s/ Mary K. Pendergast **Mary K. Pendergast**	Director	March 27, 2009
/s/ Burton E. Sobel **Burton E. Sobel**	Director	March 27, 2009
/s/ John L. Zabriskie **John L. Zabriskie**	Director	March 27, 2009

Table of Contents

EXHIBIT INDEX

Exhibit Number	Description
2.1	Agreement and Plan of Merger, dated November 9, 2002, by and among Hyseq, Inc., Vertical Merger Corp. and Variagenics, Inc.(7)
2.2	Agreement and Plan of Merger, dated March 19, 2004, by and between Nuvelo, Inc. and Nuvelo, Inc., a Nevada corporation and Nuvelo, Inc. s predecessor in interest.(10)
2.3	Stock Purchase Agreement, dated December 3, 2004, between SBH Genomics, Inc., Radoje Drmanac, Snezana Drmanac, Nuvelo, Inc., and Affymetrix, Inc.(13)
2.4	Agreement and Plan of Merger and Reorganization, dated September 24, 2008, among Nuvelo, Inc., Dawn Acquisition Sub, Inc. and ARCA biopharma, Inc.(22)
2.5	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.(23)
3.1*	Amended and Restated Certificate of Incorporation of the Registrant, as amended.
3.2*	Amended and Restated Bylaws of the Registrant, as amended.
4.1	Form of Common Stock Certificate.(24)
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.
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.
4.5*	Warrant to Purchase Stock Agreement, dated August 19, 2008, by and between ARCA biopharma, Inc. and Silicon Valley Bank.
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.
4.7*	Warrant to Purchase Stock Agreement, dated October 10, 2008, by and between ARCA biopharma, Inc. and Boulder Ventures IV, L.P.
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.
4.9*	Warrant to Purchase Stock Agreement, dated October 10, 2008, by and between ARCA biopharma, Inc. and Boulder Ventures IV (Annex), L.P.
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.
4.11*	Warrant to Purchase Stock Agreement, dated October 10, 2008, by and between ARCA biopharma, Inc. and InterWest Partners IX, LP.
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.
4.13*	Warrant to Purchase Stock Agreement, dated October 10, 2008, by and between ARCA biopharma, Inc. and Atlas Venture Fund VII, L.P.
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.
4.15*	Warrant to Purchase Stock Agreement, dated October 10, 2008, by and between ARCA biopharma, Inc. and The Peierls Foundation, Inc.

Table of Contents

Exhibit Number	Description
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.
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.
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.
10.1§	Collaboration Agreement, dated March 31, 2005, by and between Kirin Brewery Company Ltd. and Nuvelo, Inc.(15)
10.2§	Amended and Restated Collaboration and License Agreement, dated July 31, 2006, by and between Nuvelo, Inc. and Archemix Corp.(18)
10.3	Lease, dated April 30, 2001, by and between The Irvine Company and Hyseq, Inc.(4)
10.4	First Amendment to Lease, dated August 1, 2002, by and between The Irvine Company and Hyseq, Inc.(6)
10.5	Second Amendment to Lease, dated October 21, 2003, by and between The Irvine Company and Nuvelo, Inc.(9)
10.6	Third Amendment to Lease, dated September 15, 2005, by and between The Irvine Company and Nuvelo, Inc.(17)
10.7	Lease Agreement, dated January 11, 2005, by and between Nuvelo, Inc. and BMR-201 Industrial Road LLC.(14)
10.8	First Amendment to Lease, dated May 10, 2005, by and between BMR-201 Industrial Road LLC and Nuvelo, Inc.(16)
10.9*	Lease, dated February 8, 2008, by and between ARCA Discovery, Inc. and Arista Place, LLC.
10.10*	Loan and Security Agreement, dated July 17, 2007, by and between ARCA biopharma, Inc. and Silicon Valley Bank.
10.11*	First Amendment to Loan and Security Agreement, dated January 21, 2009, by and between ARCA biopharma, Inc. and Silicon Valley Bank.
10.12*	Second Amendment to Loan and Security Agreement, dated March 23, 2009, by and between ARCA biopharma Colorado, Inc. and Silicon Valley Bank.
10.13*	Note and Warrant Purchase Agreement, dated September 24, 2008.
10.14*	Amendment to Note and Warrant Purchase Agreement, dated October 10, 2008.
10.15	Stock Option Plan, as amended.(2)
10.16	Non-Employee Director Stock Option Plan, as amended.(3)
10.17	Form of Non-Stockholder Approved Stock Option Agreement for Officers.(5)
10.18	Nuvelo, Inc. 2002 Equity Incentive Plan.(8)
10.19	Amended and Restated Nuvelo, Inc. 2004 Equity Incentive Plan.(19)
10.20	Form of Notice of Grant of Stock Option under Nuvelo, Inc. 2004 Equity Incentive Plan.(11)
10.21	Form of Nuvelo, Inc. Stock Option Agreement (Single Trigger Acceleration) under Nuvelo, Inc. 2004 Equity Incentive Plan.(11)
10.22	Form of Nuvelo, Inc. Stock Option Agreement (Double Trigger Acceleration) under Nuvelo, Inc. 2004 Equity Incentive Plan.(12)

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Exhibit Number		Description
10.23		Employee Stock Purchase Plan, as amended and restated on May 31, 2007.(19)
10.24		ARCA Discovery, Inc. 2004 Stock Incentive Plan.(24)
10.25		Amendment No. 1 to the ARCA Discovery, Inc. 2004 Stock Incentive Plan.(24)
10.26		Amendment No. 2 to the ARCA Discovery, Inc. 2004 Stock Incentive Plan.(24)
10.27		Amendment No. 3 to the ARCA Discovery, Inc. 2004 Stock Incentive Plan.(24)
10.28		Amendment No. 4 to the ARCA Discovery, Inc. 2004 Stock Incentive Plan.(24)
10.29		Amendment No. 5 to the ARCA Discovery, Inc. 2004 Stock Incentive Plan.(24)
10.30		Amendment No. 6 to the ARCA Discovery, Inc. 2004 Stock Incentive Plan.(24)
10.31		ARCA biopharma, Inc. 2004 Stock Incentive Plan, Form of Executive Incentive Stock Option Agreement.(24)
10.32		ARCA biopharma, Inc. 2004 Stock Incentive Plan, Form of Non-Executive Incentive Stock Option Agreement.(24)
10.33		ARCA biopharma, Inc. 2004 Stock Incentive Plan, Form of Nonqualified Stock Option Agreement.(24)
10.34	*	ARCA biopharma, Inc. 2004 Equity Incentive Plan (f/k/a Nuvelo, Inc. 2004 Equity Incentive Plan), Form of Partial Acceleration Stock Option Agreement.
10.35	*	ARCA biopharma, Inc. 2004 Equity Incentive Plan (f/k/a Nuvelo, Inc. 2004 Equity Incentive Plan), Form of No Acceleration Stock Option Agreement.
10.36	*	ARCA biopharma, Inc. 2004 Equity Incentive Plan (f/k/a Nuvelo, Inc. 2004 Equity Incentive Plan), Form of Director Stock Option Agreement.
10.37	*	ARCA biopharma, Inc. 2004 Equity Incentive Plan (f/k/a Nuvelo, Inc. 2004 Equity Incentive Plan), Form of Notice of Grant of Stock Option.
10.38	*	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.
10.39		Form of Indemnification Agreement between Nuvelo, Inc. and its directors and officers.(1)
10.40		Nuvelo, Inc. Amended Executive Change in Control and Severance Benefit Plan.(20)
10.41		Separation Agreement, dated April 14, 2008, by and between Nuvelo, Inc. and Michael D. Levy.(21)
10.42		Bonuses for Named Executive Officers Approved on January 25, 2008.(21)
10.43	*	Amended and Restated Employment and Retention Agreement, dated June 4, 2008, by and between ARCA biopharma, Inc. and Michael R. Bristow.
10.44	*	Amended and Restated Employment and Retention Agreement, dated July 7, 2008, by and between ARCA biopharma, Inc. and Richard B. Brewer.
10.45	*	Amended and Restated Employment Agreement, dated June 12, 2008, by and between ARCA biopharma, Inc. and Christopher D. Ozeroff.
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