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:

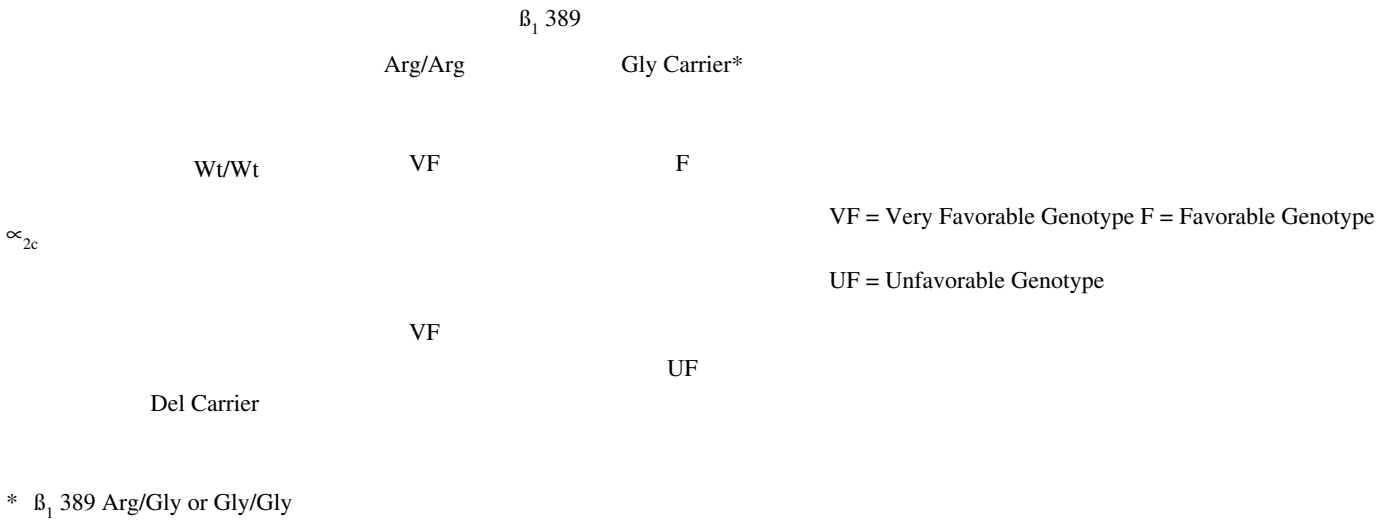
- The very favorable group, constituting an estimated 47-50% of the U.S. population and comprised of patients with the $ß_1$-Arg/Arg genotype. ARCA believes these individuals may have an enhanced therapeutic response to Gencaro because of its effect on this higher-functioning/constitutively active $ß_1$ 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;

Average	$ 663,000	$ 702,000	$ 670,000	$ 697,000	
Net new orders (units): [1]					
Northern California	39	36	102	81	
Southland / Los Angeles	25	84	159	268	
San Diego / Riverside	18	77	107	171	
Washington D.C. Area	33	48	220	193	
Corporate and Other	4	16	14	30	
Total	119	261	602	743	
Backlog (units at end of period): [2]					
Northern California	50	34			
Southland / Los Angeles	82	205			
San Diego / Riverside	24	91			
Washington D.C. Area	112	131			

Corporate and other	20	55
Total	288	516
Lots controlled (units at end of period):		
Lots owned:		
Northern California	1,326	1,290
Southland / Los Angeles	1,358	946
San Diego / Riverside	6,096	6,603
Washington D.C. Area	3,814	3,433
Corporate and Other	142	151
	12,736	12,423
Lots under option	13,762	16,825
Total	26,498	29,248

(1) Net new orders for any period represent the aggregate of all homes ordered by customers, net of cancellations, excluding joint ventures.

(2) Backlog represents the number of new homes subject to pending sales contracts, excluding joint ventures.

Three Months and Nine Months Ended September 30, 2007 Compared with Three Months and Nine Months Ended September 30, 2006

Net Income

Net income was $2 million and $40 million for the three months and nine months ended September 30, 2007, a decrease of $26 million and $50 million, respectively, when compared to the same periods in 2006. The decrease in net income for the three months ended September 30, 2007 was primarily due to impairments charges and write-downs on our housing and land assets after minority interest and taxes of $23 million compared to nil for the same period in 2006 and lower home and lot sales and reduced margins as a result of continued housing market challenges. These decreases were partially offset by a reversal of an uncertain tax position provision in the amount of $25 million.

Results of Operations

Company-wide: Housing revenue was $117 million and $376 million for the three months and nine months ended September 30, 2007, a decrease of $43 million and $99 million, respectively, when compared to the same periods in 2006. The decrease in housing revenue was a result of 51 and 121 fewer homes closed during the three months and nine months ended September 30, 2007 when compared to the same periods in 2006. Excluding impairments of $31 million for the three months ended September 30, 2007, the gross margin on housing revenue was $21 million or 18% compared with $42 million or 26% for the same period in 2006. Excluding impairments of $31 million for the nine months ended September 30, 2007, the gross margin on housing revenue for the nine months ended September 30, 2007 was $70 million or 19% compared with $132 million or 28% for the same period in 2006. The decrease in the gross margin percentage was a result of either reduced prices or an increase in homebuyer incentives and product mix.

Table of Contents

Land revenue totaled $4 million and $10 million for the three months and nine months ended September 30, 2007, compared with $15 million and $67 million for the three months and nine months ended September 30, 2006. The decrease was primarily the result of fewer lots sold during the three months ended September 30, 2007 when compared to the same period in 2006. Excluding impairments of $3 million for the three months and nine months ended September 30, 2007, the gross margin on land revenue totaled nil, compared with $8 million and $35 million, respectively for the same periods in 2006. Our land revenues and margins may vary significantly from period to period due to the timing and nature of land sales as they generally occur on an opportunistic basis and additionally such revenues are also affected by local market conditions.

During the three months and nine months ended September 30, 2007 we recognized impairment charges and write-downs on our housing and land inventory of $34 million compared to nil for the same period in 2006. The impairment charges and write-downs recognized on our housing and land inventory related to 555 finished lots located in the Inland Empire of California and 875 optioned lots in the Central Valley of California. The Inland Empire and Central Valley of California are two markets that have experienced difficult market conditions in 2007, in particular, as a result of recent tightening of lending standards in the mortgage market.

Northern California: Housing revenue was $24 million and $64 million for the three months and nine months ended September 30, 2007, respectively, a decrease of $5 million and nil when compared to the same periods in 2006. The decrease in revenue when comparing the three months ended September 30, 2007 and 2006 was primarily attributable to a decrease in homes closed. The gross margin on housing revenue for the three months ended September 30, 2007 was $4 million or 17% compared with $4 million or 13% for the same period in 2006. The gross margin on housing revenue for the nine months ended September 30, 2007 was $11 million or 18% compared with $12 million or 20% for the same period in 2006. The decrease in the gross margin percentage was a result of either reduced selling prices or increases in homebuyer incentives and product mix. During the three months and nine months ended September 30, 2007, there were $3 million of option write-offs compared to nil in the same periods in 2006.

Southland / Los Angeles: Housing revenue was $27 million and $132 million for the three months and nine months ended September 30, 2007, respectively, a decrease of $27 million and nil when compared to the three months and nine months ended September 30, 2006. The decrease when comparing the three months ended September 30, 2007 and 2006 was primarily due to a decrease in homes closed. The gross margin on housing revenue for the three months ended September 30, 2007 was $5 million or 18% compared with $11 million or 21% for the same period in 2006. The gross margin on housing revenue for the nine months ended September 30, 2007 was $25 million or 19% compared with $28 million or 21% for the same period in 2006.

San Diego / Riverside: Housing revenue was $20 million and $70 million for the three months and nine months ended September 30, 2007, respectively, a decrease of $4 million and $30 million when compared to the three months and nine months ended September 30, 2006. The decrease was primarily due to a decrease in homes closed. Excluding impairments of $31 million for the three months ended September 30, 2007, the gross margin on housing revenue was $6 million or 29% compared with $11 million or 45% for the same period in 2006. Excluding impairments of $31 million for the nine months ended September 30, 2007, the gross margin on housing revenue for the nine months ended September 30, 2007 was $17 million or 25% compared with $37 million or 36% for the same period in 2006. The decrease in the gross margin percentage was a result of either reduced selling prices or increases in homebuyer incentives and product mix.

Washington D.C. Area: Housing revenue was $45 million and $98 million for the three months and nine months ended September 30, 2007, respectively, an increase of $1 million and a decrease of $56 million when compared to the three months and nine months ended September 30, 2006. The increase when comparing the three months ended September 30, 2007 and 2006 was primarily attributable to an increase in homes closed. The gross margin on housing revenue for the three months ended September 30, 2007 was $6 million or 14 % compared with $12 million or 27% for the same period in 2006. The gross margin on housing revenue for the nine months ended September 30, 2007 was $13 million or 14% compared with $47 million or 30% for the same period in 2006. The decrease in the gross margin percentage was a result of either reduced selling prices or increases in homebuyer incentives and product mix.

Other Income and Expenses:

Equity in earnings / (loss) from housing and land joint ventures was a loss of $6 million for the three months and nine months ended September 30, 2007, a decrease of $17 million and $19 million when compared to the same periods in 2006. The decrease in the contribution from our joint ventures during the three months and nine months ended September 30, 2007 was primarily a result of an impairment charge of $7 million in one of our joint ventures. The impairment charge was related to 271 improved lots in the Inland Empire of California, a market which has experienced difficult market conditions in 2007.

Table of Contents

Selling, general and administrative expenses were $16 million and $50 million for the three months and nine months ended September 30, 2007, respectively, compared with $14 million and $35 million for the same periods in 2006. Included in selling, general and administrative expense was net stock compensation expense of $1 million and income of $4 million for the three months ended September 30, 2007 and 2006, respectively.

Sales Activity:

Net new home orders for the three months ended September 30, 2007 totaled 130 units compared to 264 units for the same period in 2006. As at September 30, 2007, we have closed or in backlog 890 homes. We had lower than anticipated net new orders in the third quarter, and now anticipate approximately 1,000 home closings in 2007. The decline in the third quarter net new orders arose primarily in the Southland and San Diego / Riverside markets where we have fewer active selling communities and the demand was impacted by tighter lending standards.

Liquidity and Capital Resources

Financial Position:

Our total assets as of September 30, 2007 were $1,382 million, a decrease of $19 million compared to December 31, 2006. The decrease is due primarily to a decrease in cash and cash equivalents partially offset by increases in housing and land inventory and deferred taxes.

Our total debt as of September 30, 2007 was $691 million, an increase of $73 million compared to December 31, 2006. Total debt as of September 30, 2007 consisted mainly of project specific financings, which represent construction and development loans that are repaid from home and lot sales proceeds. As new homes are constructed, further loan facilities are arranged on a rolling basis. Our major project specific lenders are Bank of America, Housing Capital Corporation, Wells Fargo and Union Bank of California. Other debt includes a promissory note due to a subsidiary of our largest stockholder, Brookfield Asset Management Inc., project specific financings related to our other operations and loans outstanding relating to mortgages we originated that are repaid when the underlying mortgages are sold to permanent lenders. As of September 30, 2007, the average interest rate on our debt was 7.5% per year, with maturities as follows:

	Maturities				
($ millions)	**2007**	**2008**	**2009**	**Post 2009**	**Total**
Northern California	$	$ 100	$ 62	$	$ 162
Southland / Los Angeles	5	35	9	26	75
San Diego / Riverside	19	82	120		221
Washington D.C. Area	74	38	40		152
Other	3		70	8	81
Total	$ 101	$ 255	$ 301	$ 34	$ 691

Cash Flow:

Our principal uses of working capital include purchases of land, land development and home construction. Cash flows for each of our communities depend upon the applicable stage of the development cycle and can differ substantially from reported earnings. Early stages of development require significant cash outlays for land acquisitions, site approvals and entitlements, construction of model homes, roads, certain utilities and other amenities and general landscaping. Because these costs are capitalized, income reported for financial statement purposes during such early stages may significantly exceed cash flow. Later, cash flow can significantly exceed earnings reported for financial statement purposes, as cost of sales include charges for substantial amounts of previously expended costs. A summary of lots owned and their stage of development at September 30, 2007 compared with the same period in 2006 follows:

	2007	**2006**
Housing units and model homes	916	1,079
Lots ready for house construction	1,923	978

Graded lots and lots commenced grading	1,548	2,823
Undeveloped land	8,349	7,543
	12,736	12,423

Cash used in our operating activities during the nine months ended September 30, 2007 was $131 million, compared with $67 million for the same period in 2006. The increase in cash used is primarily a result of an investment in housing and land inventory of $73 million and the paydown of accounts payable and liabilities of $81 million after excluding the

Table of Contents

reversal of $52 million in income tax liabilities. The investment in housing and land inventory includes the acquisition of 405 lots for $15 million and expenditures in strategic market areas of $33 million.

Cash used in our investing activities in joint ventures for the nine months ended September 30, 2007 was $25 million compared with $40 million for the same period in 2006. The cash invested in joint ventures was primarily related to housing and land development activities in the Company s joint ventures.

Cash provided by our financing activities for the nine months ended September 30, 2007 was $70 million, compared with cash used of $79 million for the same period in 2006.

Deferred Taxes:

Our Company was formed in the course of a reorganization in 2002 by Brookfield Properties of its United States homebuilding operations and was withdrawn from the Brookfield Properties consolidated tax group. The tax provisions that apply in connection with the reorganization, including the departure of a member from a consolidated group, are detailed and complex and are therefore subject to uncertainty. Our accounts payable and other liabilities primarily included $51 million related to the uncertainties in tax attributes which were recorded when we left the Brookfield Properties consolidated tax group with $115 million of net operating losses and other uncertain tax positions. During the first quarter of 2007, the Company reversed accrued liabilities of $26 million related to the tax cost of properties in excess of fair value deducted against taxable income in previous years as a result of receiving a final assessment from income tax authorities in respect of an examination of a prior tax year. During the third quarter of 2007, the Company reversed the remaining accrued liability of $25 million which related to net operating losses deducted against taxable income in previous years as a result of this uncertain tax position becoming statute-barred in September 2007.

Contractual Obligations and Other Commitments

Our contractual obligations and other commitments have not changed materially from those reported in Management s Discussion and Analysis of Financial Conditions and Results of Operations in our Annual Report on Form 10-K for the fiscal year ended December 31, 2006.

We generally fund the development of our communities through the use of project specific financings. As of September 30, 2007, we had available project specific debt lines of $190 million that were available to complete land development and construction activities.

A total of $356 million of our project specific and other financings mature prior to the end of 2008. The high level of maturities in 2007 and 2008 is due to our expected project completions over this period. Although the level of our maturing debt is high, we expect to generate sufficient cash flow from our assets in 2007 and 2008 to repay these obligations. Our net debt to total capitalization ratio as of September 30, 2007, which is defined as total interest-bearing debt less cash divided by total interest-bearing debt less cash plus stockholders equity and minority interest, was 57% compared to 53% at December 31, 2006. For a description of the specific risks facing us if, for any reason, we are unable to meet these obligations, refer to the section of our Annual Report on Form 10-K for the year ended December 31, 2006 entitled Risk Factors Our Debt and Leverage Could Adversely Affect our Financial Condition.

Our project specific financings require Brookfield Homes Holdings Inc., a wholly-owned subsidiary of our company, to maintain a tangible net worth of at least $250 million, a net debt to capitalization ratio of no greater than 65% and a net debt to tangible net worth ratio of no greater than 2.50 to 1. Our revolving credit facility with Brookfield Asset Management Inc. requires us to maintain minimum stockholders equity of $300 million and a consolidated net debt to book capitalization ratio of no greater than 70%. As of September 30, 2007, we have the capacity to fully draw our available project specific debt lines of $190 million.

Off-Balance Sheet Arrangements

In the ordinary course of business, we use lot option contracts and joint ventures to acquire control of land to mitigate the risk of declining land values. Option contracts for the purchase of land permit us to control the land for an extended period of time, until options expire and/or we are ready to develop the land to construct homes or sell the land. This reduces our financial risk associated with land holdings. As of September 30, 2007, we had $111 million of primarily non-refundable option deposits and advanced costs. The total exercise price of these options is $655 million. Pursuant to FIN 46R, as described in Note 2 to our consolidated financial statements included elsewhere in this Form

10-Q, we have consolidated $71 million of these option contracts.
Please see Note 2 to our consolidated financial statements included elsewhere in this Form 10-Q for additional information about our lot options.

Table of Contents

We also control 4,256 lots through joint ventures. As of September 30, 2007, our investment in housing and land joint ventures was $108 million. We have provided varying levels of guarantees of debt in our joint ventures. As of September 30, 2007, we had recourse guarantees of $19 million and limited maintenance guarantees of $114 million with respect to debt in our joint ventures. During the nine months ended September 30, 2007, we have not had any loan re-margin requirements on our debt in our joint ventures.

We obtain letters of credit, performance bonds and other bonds to support our obligations with respect to the development of our projects. The amount of these obligations outstanding at any time varies in accordance with our development activities. If these letters of credit or bonds are drawn upon, we will be obligated to reimburse the issuer of the letter of credit or bonds. As of September 30, 2007, we had for these purposes $22 million in letters of credit outstanding and $233 million in performance bonds. The costs to complete related to our letters of credit and performance bonds are $14 million and $115 million, respectively. We do not believe that any of these letters of credit or bonds are likely to be drawn upon.

Forward-Looking Statements

This quarterly report on Form 10-Q contains forward-looking statements within the meaning of the United States federal securities laws. The words may, believe, will, anticipate, expect, estimate, project, future, and o expressions that are predictions of or indicate future events and trends and that do not relate to historical matters identify forward-looking statements. The forward-looking statements in this quarterly report on Form 10-Q include, among others, statements with respect to:

anticipated home closings and the timing thereof;

future housing market conditions;

strategies for shareholder value creation;

cash flow generation and our ability to repay our debt obligations;

the visibility on our future cash flow;

the effect of interest rate changes on our cash flows;

the effect on our business of existing lawsuits; and

whether or not our letters of credit or performance bonds will be drawn upon.

Undue reliance should not be placed on forward-looking statements because they involve known and unknown risks, uncertainties and other factors, which may cause the actual results to differ materially from the anticipated future results expressed or implied by such forward-looking statements. Factors that could cause actual results to differ materially from those set forward in the forward-looking statements include, but are not limited to:

changes in general economic, real estate and other conditions;

mortgage rate and availability changes;

availability of suitable undeveloped land at acceptable prices;

adverse legislation or regulation;

ability to obtain necessary permits and approvals for the development of our land;

availability of labor or materials or increases in their costs;

ability to develop and market our master-planned communities successfully;

confidence levels of consumers;

ability to raise capital on favorable terms;

adverse weather conditions and natural disasters;

relations with the residents of our communities;

risks associated with increased insurance costs or unavailability of adequate coverage;

ability to obtain surety bonds;

competitive conditions in the homebuilding industry, including product and pricing pressures; and

additional risks and uncertainties, many of which are beyond our control, referred to in our Form 10-K for the year ended December 31, 2006 and our other SEC filings.

We undertake no obligation to publicly update any forward-looking statements unless required by law, whether as a result of new information, future events or otherwise. However, any further disclosures made on related subjects in subsequent reports on Forms 10-K, 10-Q and 8-K should be consulted.

Table of Contents

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Exchange Rates

We conduct business in U.S. dollars only, so we are not exposed to currency risks.

Interest Rates

We are exposed to financial risks that arise from the fluctuations in interest rates. Our interest bearing assets and liabilities are mainly at floating rates, so we would be negatively affected, on balance, if interest rates increase. In addition, we have interest rate swap contracts which effectively fix $235 million of our variable rate debt at an average rate of 6.63% per annum. Based on our net debt levels as of September 30, 2007, a 1% change up or down in interest rates would have either a negative or positive effect of approximately $5 million on our cash flows.

Our interest rate swaps are not designed as hedges under SFAS 133, Accounting for Derivative Instruments and Hedging Activities . We are exposed to market share risk associated with changes in the fair values of the swaps, and such changes must be reflected in our income statements. As of September 30, 2007, the fair value of the interest rate swaps totaled $0.3 million.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures. As of the end of our fiscal quarter ended September 30, 2007, an evaluation of the effectiveness of our disclosure controls and procedures (as defined in Rules 13a 15(e) and 15d 15(e) of the United States Securities Exchange Act of 1934 (the Exchange Act)) was carried out under the supervision and with the participation of our Chief Executive Officer (CEO) and Chief Financial Officer (CFO). Based upon that evaluation, the CEO and CFO have concluded that as of the end of such fiscal quarter, our disclosure controls and procedures are effective: (i) to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission rules and forms; and (ii) to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our CEO and CFO, to allow timely decisions regarding required disclosure.

It should be noted that while our management, including the CEO and CFO, believe our disclosure controls and procedures provide a reasonable level of assurance that such controls and procedures are effective, they do not expect that our disclosure controls and procedures or internal controls will prevent all error and all fraud. A control system, no matter how well conceived or operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

There was no change in our internal control over financial reporting during the quarter ended September 30, 2007, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

We are party to various legal actions arising in the ordinary course of our business. We believe that none of these actions, either individually or in the aggregate, will have a material adverse effect on our financial condition or results of operations.

Item 1A. Risk Factors

There have been no material changes in our risk factors from those disclosed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2006.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

Our Board of Directors approved a share repurchase program that allows us to repurchase in aggregate up to $144 million of our outstanding common shares, of which the remaining amount approved for repurchase at September 30, 2007 was approximately $49 million. Since the initial approval of the program in February 2003, the following annual share repurchases have been made under the program: 2003 1,192,749 shares at an average price of $18.19; 2004 76,400 shares at an average price of $25.39; 2005 707,500 shares at an average price of $47.81; and 2006

Table of Contents

964,200 shares at an average price of $39.30. Separately, during the fourth quarter of 2005 we repurchased 3,000,000 of our shares through a fixed price tender offer at a purchase price of $55.00 per share.

During the three months ended September 30, 2007, we did not repurchase any shares of our common stock:

Period	Total Number of Shares Purchased	Average Price Paid Per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Maximum Approximate Dollar Value of Shares that May Yet be Purchased Under the Plans or Programs
July 1, 2007 July 31, 2007				$ 48,750,330
August 1, 2007 August 31, 2007				$ 48,750,330
September 1, 2007 September 30, 2007				$ 48,750,330
Total				$ 48,750,330

Item 3. Defaults Upon Senior Securities

None.

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

None.

Item 5. Other Information

None.

Item 6. Exhibits

(a) Exhibits.

31.1 Rule 13a 14(a) certification by Ian G. Cockwell, President and Chief Executive Officer.

31.2 Rule 13a 14(a) certification by Paul G. Kerrigan, Executive Vice President and Chief Financial Officer.

32.1 Certification of the Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350.

Table of Contents

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of 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, on this 9th day of November, 2007.

BROOKFIELD HOMES CORPORATION

By: /s/ PAUL G. KERRIGAN
Paul G. Kerrigan
Executive Vice President and Chief Financial Officer

Table of Contents

EXHIBIT INDEX

Exhibit	Description
31.1	Rule 13a 14(a) certification by Ian G. Cockwell, President and Chief Executive Officer
31.2	Rule 13a 14(a) certification by Paul G. Kerrigan, Executive Vice President and Chief Financial Officer
32.1	Certification of the Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350