

NUVELO INC
Form 425
November 18, 2008

Filed by Nuvelo, Inc. Pursuant to Rule 425

Under the Securities Act of 1933

And Deemed Filed Pursuant to Rule 14a-12

Under the Securities Exchange Act of 1934

Subject Company: ARCA biopharma, Inc.

Commission File No. 333-154839

EXCERPTED FROM:

NOVEMBER 17, 2008

THE WALL STREET

TRANSCRIPT

Questioning Market Leaders For Long Term Investors

THE FOLLOWING REPORT IS EXCERPTED FROM

THE WALL STREET TRANSCRIPT

COMPANY INTERVIEW

RICHARD B. BREWER

ARCA biopharma, Inc.

NOTICE

The Wall Street Transcript does not in any way endorse or guarantee the accuracy or reliability of any of the information, statements or opinions expressed in the reports or comments of other firms or individuals. We take due care to report or transcribe accurately what has been written or said by others but because of the possibility of human or mechanical error, we cannot assume any liability for the correctness of the transcription. We point out further that, of course, all opinions expressed are subject to change without notice. Neither the information or any opinion which may be expressed constitutes a solicitation for the purchase or sale of any securities referred to herein. For further information, contact the individual or investment organization concerned.

CHIEF EXECUTIVE OFFICER FORUMS/INTERVIEWS

Important Note: Wall Street Transcript forums and interviews with Chief Executive Officers are published verbatim as editorial content and include forward-looking statements (as such term is defined in the United States Private Securities Litigation Reform Act of 1995). These forward-looking statements may be subject to and be made pursuant to the safe-harbor provisions of Section 27A of the United States Securities Act of 1933, as amended, and Section 21E of the United States Securities Exchange Act of 1934, as amended. Since these statements are based on factors that involve risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Such factors are often included in the company's filings of reports with the United States Securities and Exchange Commission, including Forms 10-K, 10-Q, 8-K and Proxy Statements; the company's annual and interim reports to shareholders and similar documents. In carrying out our responsibilities to our readers and to the Chief Executive Officers selected for forums or interviews, we are required to offer, and we offer, each Chief Executive Officer an opportunity to back-up the interview and provide our readers and potential investors with specific financial data, including earnings statements, balance sheet statements and other material business and financial data, through the sponsored publication of such reports or highlights therefrom, with meaningful information.

Edgar Filing: NUVELO INC - Form 425

Founded 1963

Published by Wall Street Transcript Corporation

48 West 37th Street, 8th Floor, New York, NY 10018

Copyright 2008 Wall Street Transcript Corporation

All Rights Reserved

COMPANY INTERVIEW

ARCA biopharma, Inc./Nuvelo (Nuvo)

RICHARD B. BREWER, President and Chief Executive Officer of ARCA biopharma, Inc., has more than 30 years of experience in the biotechnology industry, developing and commercializing drugs for major unmet medical needs, particularly in heart disease. Prior to joining ARCA, Mr. Brewer was managing partner of Crest Asset Management, providing guidance to and investing in biotechnology opportunities. Before that, Mr. Brewer was President and CEO of Scios, Inc., where he led the successful approval and launch of Natrecor® (nesiritide), the first new drug for acute heart failure in more than a decade, and guided Scios through a \$2.4 billion merger with Johnson and Johnson. Before Scios, Mr. Brewer served as Chief Operating Officer of Heartport, a cardiovascular device company developing minimally invasive approaches to major heart surgery. Prior to that, he spent over a decade at Genentech in various management positions, including Senior Vice President of Sales and Marketing and Senior Vice President of Genentech Europe and Canada. Mr. Brewer holds a BS from Virginia Polytechnic Institute and an MBA from Northwestern University.

SECTOR BIOTECHNOLOGY

(AKY613)TWST: May we start with a short overview and history of your company?

Mr. Brewer: Yes, I would be happy to. Arca Biopharma was founded in 2004 by Dr. Michael Bristow and Chris Ozeroff in Boulder, Colorado. This company was formed around the development of a pharmacologically unique beta-blocker by the name of Gencaro, or bucindolol hydrochloride. This drug is unique in that it interacts with certain selected receptors in the heart and in the nervous system of the heart to potentially effect a good outcome, in terms of mortality and hospitalization reduction, in patients with a specific genotype. We believe that Gencaro may represent an important advance in personalized medicine in heart failure. So our company is focused on the development of this drug as a personalized medicine, coupled with a companion diagnostic test that we expect physicians will be able use easily in their offices to determine which patients will benefit the most from this drug.

TWST: How does Gencaro work?

Mr. Brewer: Gencaro is a pharmacologically unique beta-blocker and mild vasodilator. Gencaro is considered part of the beta-blocker class because of its ability to block both beta-1 and beta-2 receptors in the cardiac nervous system from binding with other molecules that activate these receptors. Clinical studies also indicate that Gencaro lowers systemic levels of the neurotransmitter norepinephrine, which is released by cardiac and other sympathetic nerves. These two properties interact with common genetic variations in the beta-1 and alpha-2c cardiac receptors to produce the unique pharmacological profile of Gencaro.

COMPANY INTERVIEW ARCA BIOPHARMA, INC.

I m very excited about the potential to commercialize the first genetically personalized cardiovascular drug. We ve heard a lot about personalized medicine over the last 10 years, starting with the sequencing of the genome, but there really haven t been that many drugs that have been developed where genetic biomarkers were important to the usage of the compound. We believe there is a better, more personalized way to practice cardiovascular medicine than the current standard of treatment, and we are excited to be potentially commercializing a drug that improves care.

TWST: How is this personalized medicine ?

Mr. Brewer: If you are a patient with heart failure, chances are your doctor will want to establish beta-blocker therapy for you very quickly. The guidelines from the American Heart Association and the American College of Cardiology recommend that beta-blockers be used for patients unless they are contraindicated. Beta-blockers are very well established in heart failure as a therapy that can reduce mortality and generally improve outcomes for these patients over time. Carvedilol and metoprolol are the only two beta-blockers indicated for heart failure, which has been the case for more than 10 years, with millions of patients having been treated successfully. But while these are good drugs, this approach to treatment is based upon a one-size-fits-all mentality. In other words, treatment is not based upon the potential for a particular patient to respond optimally or not respond at all.

Our approach is different. If Gencaro and the companion test are approved, a patient who is diagnosed with heart failure will be administered a simple genetic test, which will be analyzed to determine that particular patient s genotype as it relates to the cardiac muscle and nerve fiber in the heart.

The test is expected to identify which patients can expect enhanced efficacy, as well as those with a likelihood of a standard beta-blocker response, and a small unfavorable subgroup of patients with a low probability of benefitting from treatment. If that patient has the right genetic makeup for our drug, the patient would then be prescribed Gencaro.

This is important because, under the current standard treatment, it s difficult to predict how an individual patient will respond to a beta-blocker, and it can take weeks or months to know whether or not the patient is receiving therapeutic benefit.

TWST: How long does it take for the diagnostic test results to be reported?

Mr. Brewer: These results are expected to take somewhere between 36 and 48 hours.

TWST: And there is no imminent danger for the patient in that time period?

Mr. Brewer: No, typically not.

TWST: How far have you gotten in development?

Mr. Brewer: We submitted our New Drug Application with the FDA in July of this year and the FDA accepted our filing in September. The FDA s PDUFA date, which is the target date for their decision on our application, is May 31, 2009.

TWST: How do you differentiate Gencaro from the competition?

Mr. Brewer: The profile here is really a bit more complex than with the other drugs because the efficacy and safety profile of Gencaro is, to a degree, dependent upon the genotype of the patient in whom the drug is being used. The beta-blockers currently on the market don t interact with the alpha-2c receptors on the sympathetic nerve or the

COMPANY INTERVIEW ARCA BIOPHARMA, INC.

beta-1 receptor sites in exactly the same way that Gencaro does. Because Gencaro is pharmacologically unique in that regard, we can determine in advance, by the use of a simple genetic test, who is likely to benefit the most and who may not benefit at all with our drug. And that's the major differentiator between our product and everybody else, because with our product the physician can potentially have a much better sense, in advance of using the drug, that the patient is going to do well or the patient shouldn't be on it at all. You can't do that with the existing drugs.

TWST: Any sense what your market size is?

Mr. Brewer: Congestive heart failure is one of the world's most significant healthcare challenges. Industry sources estimate there are 6 million patients in the United States with diagnosed heart failure. Total sales of beta-blockers, the current standard of care to treat heart failure, were nearly \$4 billion in the U.S. in 2007.

Our target market will be the approximately 50% of heart failure patients that we believe have a very favorable genotype as these are the patients who we expect will respond best to Gencaro.

TWST: Could you comment on your upcoming merger with Nuvelo?

Mr. Brewer: We are very pleased to be merging with Nuvelo. Nuvelo brings to the merger several things, first of course is cash. At the end of the third quarter, they had approximately \$65 million. The second is a product called NU172 that we're very interested in developing for use as a short-acting anticoagulant in coronary artery bypass graft surgery, kidney dialysis and a variety of vascular surgical and coronary interventions. Finally, Nuvelo brings some outstanding talent that we will need to help round out our own infrastructure as we move toward commercialization plans.

TWST: Are there going to be any other drugs in the pipeline after the merger?

Mr. Brewer: Yes, there will be NU172, as I just mentioned, which completed a Phase 1b proof-of-concept trial this past August. This trial demonstrated that NU172 rapidly produced and maintained anticoagulation with a rapid return toward baseline after the infusion ended, with no antidote required. With Phase 1 development complete, NU172 is now poised to enter Phase 2.

TWST: Could you give us a sense of the cardiovascular drug development and commercialization expertise of your management team?

Mr. Brewer: We have a team that possesses deep expertise in the development and commercialization of cardiovascular drugs. Dr. Michael Bristow, co-founder of ARCA biopharma, is a very well known cardiovascular scientist and clinician, as well as one of the fathers of beta-blockade as used in heart failure in this country. Mike is one of the scientists who pioneered that when it was very controversial to even be thinking about beta-blockade and heart failure. Mike has significant development expertise working at Myogen as one of its founders, which was sold to Gilead in 2006, and when I was CEO at Scios, Mike played a key role as a senior regulatory consultant in helping us move Natrecor, a treatment for heart failure, through the Cardio-Renal Advisory Committee.

I myself have many years' experience in the actual commercialization of pharmaceutical products, most of which have been cardiovascular over the years. I have been in the pharmaceutical and biotechnology business for 35 years. I was heavily involved in the development of Genentech's TPA product. As CEO of Scios, I oversaw the development and commercialization of Natrecor. At the time it was approved, Natrecor was the first IV compound introduced to treat

COMPANY INTERVIEW ARCA BIOPHARMA, INC.

acutely decompensated heart failure in more than 25 years. We sold Scios to Johnson & Johnson, and some of the key folks from Scios who were responsible for the actual on the ground commercialization of Natrecor and other cardiovascular compounds are now at ARCA.

In addition, Nuvelo brings Ted Love, who has significant experience as a clinician and cardiologist, and will be a member of the Board of Directors of the new company. Ted's been the CEO of Nuvelo since 2001, so he knows how to run a public company. Ted and I actually worked together at Genentech some years ago on TPA, so we know each other and appreciate each other's styles and what each of us brings to the table from a development and commercialization point of view. So I believe that we have probably one of the best teams in the industry to get this done.

TWST: Will you remain as the CEO of the combined company?

Mr. Brewer: I will, yes.

TWST: As far as your balance sheet is concerned, if the merger is completed, you will have enough cash to last through the end of 2009, is that correct?

Mr. Brewer: That's correct. The cash position of the combined company at the close of the merger is expected to fund operations at least through 2009, including the potential FDA advisory meeting in the first half of 2009 and our PDUFA date at the end of May 2009.

TWST: Any thoughts of partnerships and collaborations with a major pharmaceutical company?

Mr. Brewer: No, we are not interested in that actually. We believe, based on our experience, that it's better to hold onto our assets and to not partner them in the United States. Outside of the United States is a different story, but even that is up for debate. We can believe we can launch Gencaro in the United States with a relatively small, highly focused, and experienced sales force. We don't believe we need thousands of representatives to make this a success. And that means we can hold onto our asset, commercialize it ourselves, and the option value of our company increases dramatically, versus partnering it out.

TWST: What else would you like to touch upon that I might have left out?

Mr. Brewer: I'm very excited about the potential to commercialize the first genetically-personalized cardiovascular drug. We've heard a lot about personalized medicine over the last 10 years, starting with the sequencing of the genome, but there really haven't been that many drugs that have been developed where genetic biomarkers were important to the usage of the compound. Now there have been some of course, but mostly in the cancer arena. But with regard to personalized medicine in cardiovascular medicine, there really isn't anything to my knowledge other than what we're doing with Gencaro.

We believe there is a better, more personalized way to practice cardiovascular medicine than the current standard of treatment, and we are excited to be potentially commercializing a drug that improves care.

TWST: Thank you. (WT)

RICHARD B. BREWER

President, CEO

ARCA Biopharma

8001 Arista Place

Suite 200

Broomfield, CO 80021

(720) 940-2200

www.arcabiopharma.com

About Nuvelo

Nuvelo, Inc. is dedicated to improving the lives of patients through the discovery, development and commercialization of novel drugs for acute cardiovascular disease, cancer and other debilitating medical conditions. Nuvelo's development pipeline includes NU172, a direct thrombin inhibitor which has completed Phase 1 development for use as a potential short-acting anticoagulant during medical or surgical procedures; and NU206, a Wnt pathway modulator in Phase 1 development for the potential treatment of chemotherapy/radiation therapy-induced mucositis and inflammatory bowel disease. In addition, Nuvelo is pursuing research programs in leukemia and lymphoma therapeutic antibodies and Wnt signaling pathway therapeutics to further expand its pipeline and create additional partnering and licensing opportunities.

Information about Nuvelo is available at our website at <http://www.nuvelo.com> or by phoning 650-517-8000.

About ARCA biopharma

ARCA biopharma, Inc. is a privately held company focused on developing and commercializing genetically targeted therapies for heart failure and other cardiovascular diseases. The Company's lead product candidate, Gencaro (bucindolol hydrochloride), is an investigational pharmacologically unique beta-blocker and mild vasodilator being developed for heart failure and other indications. ARCA has identified common genetic variations that predict individual patient response to Gencaro. The companion genetic test for Gencaro is in development by ARCA's partner, Laboratory Corporation of America. For more information please visit www.arcabiopharma.com.

Forward-looking statements

This press release contains forward-looking statements which include, without limitation, statements regarding the completion of the proposed merger transaction between Nuvelo, ARCA and Dawn Acquisition Sub, Inc., the transaction's anticipated benefits, timing, progress and anticipated completion of the combined company's clinical stage and research programs, including possible regulatory approval, the potential benefits that patients may experience from the use of the combined company's clinical stage compounds, and the cash position of the combined company, which statements are hereby identified as forward-looking statements for purposes of the safe harbor provided by the Private Securities Litigation Reform Act of 1995. Such statements are based on our management's current expectations and involve risks and uncertainties. Actual results and performance could differ materially from those projected in the forward-looking statements as a result of many factors, including, without limitation, failure of Nuvelo or ARCA's stockholders to approve the merger, the ability to complete the transaction contemplated by this communication in a timely fashion, the risk that Nuvelo's and ARCA's business operations will not be integrated successfully; the combined company's inability to further identify, develop and achieve commercial success for products and technologies; the risk that the combined company's financial resources will be insufficient to meet the combined company's business objectives; uncertainties relating to drug discovery and the regulatory approval process; clinical development processes; enrollment rates for patients in our clinical trials; changes in relationships with strategic partners and dependence upon strategic partners for the performance of critical activities under collaborative agreements; and the impact of competitive products and technological changes. These and other factors are identified

and described in more detail in Nuvelo's filings with the SEC, including without limitation Nuvelo's quarterly report on Form 10-Q for the quarter ended June 30, 2008 and subsequent filings. We disclaim any intent or obligation to update these forward-looking statements.

Additional Information and Where to Find It

Nuvelo has filed a registration statement on Form S-4, and a related proxy statement/prospectus/consent solicitation, in connection with the proposed merger. Investors and security holders are urged to read the registration statement on Form S-4 and the related proxy statement/prospectus/consent solicitation. Investors and security holders may obtain free copies of these documents and other documents filed with the SEC at the SEC's website at www.sec.gov. In addition, investors and security holders may obtain free copies of the documents filed with the SEC by contacting Nuvelo Investor Relations at the email address: ir@nuvelo.com or by phone at 650-517-8000.

In addition to the registration statement and related proxy statement/prospectus/consent solicitation, Nuvelo files annual, quarterly and special reports, proxy statements and other information with the SEC. You may read and copy any reports, statements or other information filed by Nuvelo, Inc. at the SEC public reference room at 100 F Street, N.E., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for more information. Please call the SEC at 1-800-SEC-0330 for further information on the public reference room. Nuvelo, Inc.'s filings with the SEC are also available to the public from commercial document-retrieval services and at SEC's website at www.sec.gov, and from Investor Relations at Nuvelo as described above.

This communication shall not constitute an offer to sell or the solicitation of an offer to sell or the solicitation of an offer to buy any securities, nor shall there be any sale of securities in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such jurisdiction. No offering of securities shall be made except by means of a prospectus meeting the requirements of Section 10 of the Securities Act of 1933, as amended.

Nuvelo, ARCA and their respective directors and executive officers may be deemed to be participants in the solicitation of proxies from the stockholders of Nuvelo in connection with the merger transaction. Information regarding the special interests of these directors and executive officers in the merger transaction is included in the proxy statement/prospectus/consent solicitation described above. Additional information regarding the directors and executive officers of Nuvelo is also included in Nuvelo's proxy statement for its 2008 Annual Meeting of Stockholders which was filed with the SEC on April 23, 2008 and its Annual Report on Form 10-K for the year ended December 31, 2007, which was filed with the SEC on March 12, 2008. These documents are available as described above.