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**Conference Call Transcript**

**NUVO Nuvelo and ARCA Biopharma Merger Conference Call and Webcast**

**Event Date/Time: Sep. 25. 2008 / 8:30AM ET**

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**PRESENTATION**

**Operator**

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Good morning and welcome to the Nuvelo and ARCA Biopharma merger conference call and web cast. Presenting on the call today we will have Dr. Ted W. Love, Chairman and CEO of Nuvelo, Mr. Richard B. Brewer, President and CEO of ARCA and Dr. Michael R. Bristow, Chairman and Chief Science and Medical Officer at ARCA.

At this time I would like to turn the call over to Miss Foderaro. You may begin.

### **Nicole Foderaro** *Nuvelo, Inc. IR*

Thank you. This presentation contains forward-looking statements which includes, without limitation, statements regarding the completion of the proposed merger transaction between Nuvelo and ARCA and Don Acquisition Sub, Inc. The transaction's anticipated benefit, timing, progress and anticipated completion of the combined company's clinical stage and research programs, including possible regulatory approval, 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 are 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 the 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 risks of the combined companies' financial resources will be insufficient to combined companies business objectives, uncertainties relating to the drug discovery and regulatory approval process, clinical development processes, enrollment rates for patients in our clinical trials, changes in

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relationships with strategic partners and dependence upon strategic partners for the performance of critical activities under collaborative agreement and the impact of competitive products and technological changes.

These and other factors identified and described in more detail in Nuvelo's filings in the SEC including without limitation Nuvelo's report on Form 10-Q for the quarter ended June 30, 2008, and subsequent filings. We disclaim any intent or obligations to update these forward-looking statements. Additional information and where to find it. Nuvelo intends to file a registration statement on Form F4 and a related proxy statement perspective in connection with the merger. Investors and security holders are urged to read the registration statement on Form S4 and the related proxy statement perspective when they come available because they will contain important information about the merger transaction. Investors and security holders may obtain free copies of these documents when they are available and other documents filed with the SEC on the SEC's website at [www.sec.gov](http://www.sec.gov).

In addition, investors and security holders may obtain copies by contacting Nuvelo investor relations at the e-mail address at [Nuvelo.com](mailto:investor@nuvelo.com) or by phone at 650-517-8000. In addition to the registration statement and related proxy statement perspective, 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, NE, Washington, D.C., 20459. 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. filings with the SEC are also available to the public for commercial document retrieval services on the SEC's website at [www.sec.gov](http://www.sec.gov) and from investor relations at Nuvelo as described above.

This communications shall not constitute the 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 law of any such jurisdiction. No offering of securities shall be made except by means of prospective meeting through the Securities Act of 1933 as amended.

Nuvelo, ARCA and the 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 and the merger transaction will be included in the proxy statement prospectus as described above. Additional information regarding the directors and executive officers at 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. I will now turn the call over to Dr. Ted W. Love.

**Ted Love *Nuvelo, Inc. Chairman, CEO***

Thanks, Nicole. Good morning and thank you all for joining us this morning to discuss the proposed merger of Arca biopharma and Nuvelo. Joining me on the call are Dick Brewer, President and COO of Arca, and Dr. Michael Bristow, Arca's Chairman and Chief Science Medical Officer. We also have Randy St. Laurent, Arca's Executive Vice President of Commercial Operation, Chris Ozeroff, Executive Vice President of Business Development and General Counsel; Pat Wheeler, Senior Vice President of Finance at ARCA; and Lee Bendekgey, Nuvelo Senior Vice President and CFO who will be available for Q&A.

Early this morning we announced that ARCA Biopharma, a privately held biopharmaceutical company headquartered in Broomfield, Colorado, and Nuvelo have signed a definitive merger agreement. This transaction is expected to create a late-stage cardiovascular company with near-term commercial product opportunity Gencaro as well as a mid-stage pipeline asset short-acting anticoagulant 172 which has the potential to lead long-term growth. I would like to start with a brief overview of Nuvelo's rationale for choosing to merge with ARCA and will then turn the call over to Dick and Mike to discuss the terms and timing of the deal, the combined company strategy, product candidate, and markets they will address.

After completing a very thorough evaluation of strategic alternatives for Nuvelo, we chose to partner with ARCA because we believe this complimenting transaction will bring the most value to our shareholders both immediately and longer term. This deal, if consummated, allows us to transform ourselves into a late-stage company with multiple significant milestones and a near-term commercialization opportunity backed by

promising cardiovascular pipelines.

The management team, which will be led by Dick Brewer, has the expertise to lead the development and commercialization of what we believe will be the first personalized cardiovascular drug, Gencaro. The company will also pursue the develop of anticoagulant NU172, a potential therapy for medical and surgical procedures where anticoagulation needs to be carefully titrated and where the current standard of care is heparin

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and protamine. In consideration of this merger, the Nuvelo team and I conducted extensive due diligence on Gencaro and we are impressed with both the data and the strategy to bring this product to market.

As some of you know, Dick and I work closely with each other at Genotech on the [Gusto] trial and commercialization of Activase to gain more than 80% market share. I'm excited to be working with Dick again and also with Mike and the ARCA team. I will now turn the call over to Dick to discuss the terms of the deal and strategy of the combined company.

**Dick Brewer ARCA President, CEO**

Thanks, Ted. Good morning, everybody. This is an exciting time for everyone at ARCA, I can tell you that. For those of you who may not be familiar with us, let me take a few minutes to describe our company. First, we're focused on developing genetically targeted therapies for cardiovascular diseases. As we announced this week, a new drug application for our lead product, Gencaro bucindolol hydrochloride, was accepted by the FDA and this keeps us on track for an expected regulatory decision in mid 2009. With this news in hand, we are excited about the merger with Nuvelo because we expect it to provide us with the financial resources, the people and the pipeline to build a leading cardiovascular company. We're all aware that a number of transactions of this type have had trouble sustaining or gaining value longer term; however, and I think this is important, in this case we believe a strategic synergy exists in this relationship and that is present in this transaction that hasn't necessarily permeated the other ones and that's what makes this different and promising.

The merged company will offer shareholders a short-term value creating milestone with the potential approval of Gencaro in mid 2009, and we also have a strengthened pipeline with NU172 to support continued growth. Before I describe what the combined company will look like, I'd like to take a moment to review the key terms of the definitive merger agreement between Nuvelo and ARCA. Under the agreement, ARCA will become a wholly owned subsidiary of Nuvelo. Nuvelo will issue new shares of its common stock to ARCA shareholders in a tax re-exchange. As a result, ARCA's current equity holders are expected to own or have the right to acquire approximately 67% of the common stock of the combined company. The current Nuvelo stockholders are expected to own approximately 33% of the common stock of the combined company.

Now, the Boards of both companies have approved the definitive merger and ARCA and Nuvelo shareholders' approval will also be required to complete this merger. The officers and directors and certain significant stockholders of ARCA have already executed voting agreements in favor of the transaction as have certain Nuvelo stockholders. Nuvelo plans to file an S4 and related proxy statement prospectus with the US Securities and Exchange Commission in the coming weeks. We expect a shareholder vote and closing of the deal by the end of this year or very early next year. The agreement contains closing conditions as well as termination rights exercisable by either party under certain conditions. If the merger is consummated, we plan to rename the combined company ARCA biopharma, Inc. and change its NASDAQ ticker symbol.

In order to comply with NASDAQ listing requirements, Nuvelo intends to seek stockholder approval to effect a reverse stock split of its common stock in conjunction with the closing of this transaction. As Ted pointed out, the merger company will combine known industry leaders with significant cardiovascular drug development and commercialization experience.

Joining me on the management team is our chairman and ARCA's founder and our Chief Science and Medical Officer, Mike Bristow, who currently serves in that position at ARCA. He is a leading heart failure expert and was previously the chief science and medical officer at Myogen before the company was sold to Gilead. Randy St. Laurent, current EVP of Commercial Operations at ARCA and former Vice President of Commercial Development at Scios will be a part of the new management team as will James Carr, ARCA's Vice President of Marketing who was instrumental in the successful commercialization of Coreg, the leading beta blocker treatment for heart failure. Lee Bendekgey, Nuvelo's Senior Vice President and CFO, will stay on as Nuvelo's CFO through the closing of the deal and will help with the transition. We're very grateful to Lee for that.

Ted Love, a cardiologist who formerly led drug development at Genentech in addition to leading Nuvelo through Phase 3 development of its lead cardiovascular product, alvimoprase, will join the Board of Directors of the combined company. The Board will also include Dr. Bill Freytag, John Zabriskie, Jean-Francois Formela, Dr. Burton E. Sobel, Mary Pendegrass, Mike Bristow, myself and other investor representatives.



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From a logistical standpoint, our corporate headquarters will be in Broomfield, Colorado, where we are right now. In order to maintain a seamless Gencaro regulatory process and NU172 development, we will operate out of both the Colorado and California facilities. The combined management team will work together to integrate the two companies with an anticipated initial combined work force of 60 to 70 employees.

Finally, I'd like to take a moment to discuss our financial resources. As Nuvelo previously reported, the company ended the second quarter of 2008 with \$76 million in cash, cash equivalents, marketable securities and restricted cash. In addition, their guidance for anticipated 2008 net

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cash used in operating activities remains the same, that is between 43 and 48 million for the full year, or between 16 and 21 million for the second half of 2008. We anticipate that Nuvelo's year end cash balance, along with the additional year end funds that we expect at ARCA, will provide adequate resources to last at least through 2009.

While we'll need to provide further guidance once the transaction is complete, we expect the combined cash position will fund operations through the anticipated FDA cardio renal advisory meeting, if there is one in the first half of 2009, and the regulatory decision for Gencaro, which is expected, as I said earlier, in mid-next year, mid 2009. So I'd like to end my comments by reiterating how pleased I am at the prospects of the merger between Nuvelo and ARCA. We have a very compelling product before the FDA and now we have the promise of another product in our pipeline. I believe the merger also provides the cash, the people, the facilities to build a leading cardiovascular company and enhanced value for both ARCA and Nuvelo shareholders. I'd like to turn over the call now to Dr. Mike Bristow who will provide you with a brief overview of Gencaro and NU172. Mike.

**Mike Bristow ARCA Chairman and Chief Science and Medical Officer**

Thanks, Dick. As already mentioned, the combined company has a pipeline of advanced and mid-stage cardiovascular compounds that could address large markets and significant unmet medical needs. I'd like to start with a review of our near-term commercial opportunity, Gencaro, and then move on to NU172. Gencaro, or bucindolol, is a genetically targeted beta blocker with unique vasodilating properties for the treatment of patients with chronic heart failure. As Dick mentioned, the NDA for Gencaro was recently accepted for review by the FDA and the PDUFA data has been set for May 31, 2009.

Gencaro has unique pharmacological properties and has been shown to interact with beta 2, alpha 2C, and beta 1 adrenergic receptors which help regulate cardiac function. The Phase 3 pivotal trial, known as the BEST trial, is the largest morbidity and mortality study of beta blockers and chronic heart failure in terms of the number of events experienced by the patient population. In this trial, we conducted a prospectively designed DNA sub study and found that patients with different genetic variance or polymorphisms in the myocardial beta 1 or sympathetic neuronal alpha 2C adrenergic receptor have different responses to Gencaro.

From this knowledge of the patient's receptor status, we can subdivide and predict patient responses to Gencaro in to three categories, very favorable, unfavorable and favorable. The best study showed that 50% of patients carry a genotype that produces very favorable results with Gencaro compared to standard beta blockers. In data presented at the Heart Fair Society of America annual meeting on Monday, Gencaro was shown to significantly and substantially reduce hospitalization and death among heart failure patients in this genetic subgroup.

As a result we know that 50% of the nearly 6 million heart failure patients could benefit from treatment with Gencaro compared to other beta blockers. From the study we also know that 10% of patients have a gene type associated with complete loss of clinical efficacy and, therefore, an unfavorable response and we can identify these patients who would not benefit from the drug up front through the use of genetic testing.

The personalization of heart failure treatment is important because the current treatment is largely trial and error. Beta blockers have become the standard of care for patients with heart failure and less ventricular dysfunction. However, clinicians have no way of telling which beta blockers work best for a specific patient. Being able to predict patient response to therapy would be considered a real benefit for clinicians and their patients. There are approximately 6 million Americans living with heart failure and 550,000 new cases diagnosed annually. The annual mortality rate for symptomatic heart failure patients is up to 10% to 20% and clearly needs to be further reduced.

As we've said, the NDA for Gencaro was recently accepted for review by the agency. If the FDA decides to convene a cardio renal advisory meeting, we anticipate that it would take place in the first half of 2009, leading to a potential regulatory decision in mid 2009 and potential commercialization in the first half of 2010. I'd also like to discuss our partnership with Laboratory Corporation of America. We are working with LabCorp to develop a test that terms a patient's genotype by identifying genetic variations by the alpha 2C and beta one adrenergic receptors. LabCorp is anticipating a submission of a pre market approval application for the test toward the end of this year or early in 2009.

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Let's turn now to NU172, the second product candidate of the combined company. We are excited about the prospects of this product and its ability to extend both our clinical and commercial reach within the cardiovascular community. NU172 is an [aptamer] designed to directly inhibit thrombin's ability to stimulate blood clot formation. It is being evaluated for its potential to address markets where short-acting anticoagulation is needed, such as coronary artery bypass surgery, kidney dialysis, and a variety of vascular, surgical and coronary interventions. In CABG surgery, for example, it is important to have the patient anticoagulated during the procedure, but after the surgery one wants to avoid excessive bleeding and allow for normal clotting. The current standard of care for such a procedure is heparin, but then you have to use its anecdote, protamine, to reverse anticoagulation once the procedure is complete.

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NU172 has successfully completed Phase 1 proof of concept clinical testing, demonstrating its ability to produce rapid and predictable onset and offset of anticoagulation without the need for an anecdote. This leads us to believe it has the potential to eliminate the need to use two drugs for anticoagulation in medical procedures, and we also believe NU172 has the potential to address some of the other limitations of heparin and protamine. The NU172 Phase 1b trial completed in August evaluated the safety, tolerability and pharmacokinetics of intravenous bolus plus four-hour infusion dosing of NU172.

The study demonstrated the drug's ability to produce dose dependent increases in anticoagulation measured by activated clotting time, or ACT, prothrombin time and activated partial thromboplastin time. The highest dose resulted in an average ACT of approximately three times baseline and all measurements were maintained throughout the four-hour infusion. Once the infusion ended, the ACT and other coagulation parameters showed a rapid return towards baseline, consistent with a short plasma half life of NU172 observed in the previous 1A trial. In addition, NU172 was well tolerated with no serious adverse events.

As previously mentioned, the compound will be ready to interface to development in CABG in the fourth quarter of this year or the first quarter of 2009. As you can see, we have a number of near-term milestones with our two lead product candidates and we are also actively engaged in evaluating additional pharmacogenetically targeted cardiovascular therapies and their targets. I'll now hand the call back over to Dick for concluding remarks.

**Dick Brewer** *ARCA President, CEO*

Okay. Thanks, Mike. We strongly believe that the future of heart failure medicine will reside in the personalization of treatment and we believe that Gencaro has the potential to achieve just exactly this. We're enthusiastic about this opportunity and the potential of these two companies to develop and commercialize Gencaro and other cardiovascular products that address large markets and significant medical needs. In fact, we've already begun to build a foundation of our commercial team with the addition of Randy St. Laurent as head of our commercial operations, and have also hired, as I mentioned earlier, VP of Marketing and a VP of Reimbursement which, as you all know, is critically important to get right.

In addition, Ted, Randy and I have spent a significant part of our careers analyzing the commercial plans for cardiovascular products, including TPA and (inaudible) for example, and based upon our own marketing research, we believe we can adequately penetrate the target market of heart failure patients with a commercial effort of approximately 100 to 125 individual sales representatives. With the seasoned management team, expanded pipeline of cardiovascular opportunities and a strengthened financial resource, we believe we're well positioned to achieve our milestones and provide for enhanced shareholder value in the near term. Before we open the call up to questions, I'd like to reiterate our upcoming milestones or things that you can expect from us.

First, we anticipate a potential FDA advisory meeting in the first half of 2009. Our PDUFA date is May 31, 2009, as Mike mentioned, and pending a positive regulatory decision, we expect to commercialize Gencaro in the first half of 2010. In addition, the Phase 2 NU172 development is expected to begin in the fourth quarter of this year or the first quarter of 2009 and, as you can see, there are multiple significant milestones ahead for the company that have the potential to drive company valuation and we look forward to updating you on all of these as we achieve them. I think now is the time to open up the lines for questions. Operator, please pull for questions and thank you for listening.

**QUESTION AND ANSWER**

**Operator**

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(OPERATOR INSTRUCTIONS) Your first question comes from Liana Moussatos of Pacific Growth Equities.

**Dick Brewer** *ARCA President, CEO*

Hello.

**Liana Moussatos** *Pacific Growth Equities Analyst*

Can you hear me?

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**Dick Brewer** *ARCA President, CEO*

We can now.

**Liana Moussatos** *Pacific Growth Equities Analyst*

Great. Sorry. Can you talk a little bit about the commercialization strategy for the lead product? You mentioned that the active ingredient is bucindolol and you have a test, a genetic test that LabCorp is developing and you mentioned some time frame in there. How do you propose to commercialize it? Is it going to be a test or a combined drug test?

**Dick Brewer** *ARCA President, CEO*

Think of it as a combined drug and test. LabCorp, as Mike pointed out, is developing the specific genetic tests. That genetic test should be approved at about the same time Gencaro is and we're working with LabCorp very carefully to coordinate these activities. In practice, the way that this would work is that once the physician has decided a patient needs to be on beta blockade, and let me reiterate beta blockade is the standard of care in the treatment of chronic heart failure, once the physician makes that decision, then the question is which drug to use and if you had a way of identifying in advance who might benefit differentially or who shouldn't take the drug, you would certainly like to have that information, and that's what the LabCorp test provides. So the physician would order the test. It's a very simple test, probably a buccal swab, for example, that would be sent to that specimen would be sent off to LabCorp. Shortly thereafter a report would be sent back to the physician which would describe the patient's genotype as very favorable or perhaps the patient shouldn't be on the drug, and then a prescription is made. This is an oral compound, as you know, and it fits exactly into the treatment procedures and regimens that exist today. Mike, you want to elaborate on that?

**Mike Bristow** *ARCA Chairman and Chief Science and Medical Officer*

Yes, I would only say that this is actually the first companion genetic test and drug developed prospectively and we've worked very closely with the FDA to develop the template for this, which really involves the cedar branch of the FDA evaluating the drug and then CDRH, the diagnostic device branch evaluating the test, and all of this is organized through the office of combination products. So the individual components here are being evaluated by the branches of the FDA that ordinarily evaluate these components and then there's a great deal of integration in terms of the review. Because this hasn't been done before, this required actually some thought and so we've had extensive interactions with the FDA. All I can say is so far this is going quite smoothly.

**Dick Brewer** *ARCA President, CEO*

Now, you're just to follow up and complete the answer, you asked about the strategy, the basic commercialization strategy for the drug and the test. In addition to what we've just said, we're very fortunate to have some experience in this particular arena, that is heart failure. Not only Mike, as an expert cardiologist, clinician, and scientist, but Randy and I and Ted and Burt Sobel, for that matter, all are very familiar with this market and have been successful in commercializing drugs in this particular arena with these particular cardiologist physicians. So we feel like we have a pretty good practical handle on how this is going to work, given that we've done it before.

I mentioned earlier that we've conducted a relatively large amount of marketing research and we continue to do that to refine the offering, obviously, but what we find here is that physicians are very interested and enthusiastic about the ability to predict in advance who can benefit from the drug and who might not take the drug. They don't have that ability right now. And everybody knows that there are patients who do really well on compounds and those who don't, but nobody knows how to figure out who's who. So we offer something that's not only interesting to the cardiologist, but also quite practical in terms of their practice. We'll initiate our commercialization efforts with about 125 of our own representatives. We intend to do this ourselves in the United States; might have a partner outside of the United States, and we'll begin that process by first addressing the key thought leaders in the heart failure community and then diffusing the technology down from there.

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**Liana Moussatos** *Pacific Growth Equities Analyst*

That's definitely a step forward for personalized medicine. Another question, are you going to get royalties off the test?

**Dick Brewer** *ARCA President, CEO*

No, we don't.

**Liana Moussatos** *Pacific Growth Equities Analyst*

Okay. And so just from selling bucindolol, when the doctor makes a prescription, that will be do you owe any royalties to anybody else from that?

**Dick Brewer** *ARCA President, CEO*

We do, but the royalties I would say are of the standard rate and type. That's how it's going to go, yes.

**Liana Moussatos** *Pacific Growth Equities Analyst*

Okay. Single digit, double digit royalties just for modeling?

**Dick Brewer** *ARCA President, CEO*

Well, it's tiered, so it's single digit to begin with.



**Liana Moussatos** *Pacific Growth Equities Analyst*

Okay.

**Dick Brewer** *ARCA President, CEO*

We hope to take double digit.

**Liana Moussatos** *Pacific Growth Equities Analyst*

Okay. And the other question is bucindolol right now is a generic drug?

**Dick Brewer** *ARCA President, CEO*

No, it's not, actually.

**Liana Moussatos** *Pacific Growth Equities Analyst*

So it's not on the market at all?

**Dick Brewer** *ARCA President, CEO*

It's not on the market anywhere.

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**Mike Bristow** *ARCA Chairman and Chief Science and Medical Officer*

It's never been introduced in any market, any formulation.

**Liana Moussatos** *Pacific Growth Equities Analyst*

Okay, great. Okay, great.

**Dick Brewer** *ARCA President, CEO*

Thank you.

**Liana Moussatos** *Pacific Growth Equities Analyst*

All right. Thank you, appreciate it.

**Dick Brewer** *ARCA President, CEO*

You bet.

**Operator**

Your next question comes from the line of Mark Monane of Needham.

**Mark Monane** *Needham Analyst*

Good morning and thanks for reviewing the announcement with us. The announcement of genetic testing and its use in cancer and cancer therapeutics is well known. Maybe you could spend a little time thinking about what the activity is in thinking about genetics and cardio vascular at this point and what is the incentive for the doctors, as you have seen, for them to order the testing and then prescribe the medication?

**Mike Bristow** *ARCA Chairman and Chief Science and Medical Officer*

Sure, Mike Bristow here, Mark. We just got back from the Heart Fair Society of America annual meeting where a lot of this was presented and heart failure cardiologists are a very academic and intellectual lot, I would say, and are anxiously awaiting the arrival of pharmacogenetic approaches to therapeutics and I would say the uptake on this probably exceeds our expectations. They're very interested in just the concept of being able to order a genetic test which is a biomarker that is sure and certain that will be able to help them decide who is going to respond to their therapy and, more importantly perhaps, who has little or no chance of responding. Basically, this takes the guesswork out of medicine and it also gets us into the modern era in terms of therapeutics.

**Mark Monane** *Needham Analyst*

I bet that's helpful to think about that. In terms of the commercialization strategy then, what's the patent position on this drug and who gets it? I think you reviewed what royalties are available or what royalties will be a part of this ongoing sales effort?

**Dick Brewer** *ARCA President, CEO*

As we mentioned earlier, Mark—by the way, good morning. The situation with regard to the patent is pretty good for us, we think. We have a strong use patent circumstance here, we also have statutory coverage to [Hatch-Waxman] which will go out five or seven years in this country depending and that same type of statutory protection, if you will, is also available in the EU. It's different, but it's basically ten years there. So you can think about this from the point of view of when we commercialize, we'll have the advantage of Hatch-Waxman in the very least of cases, if

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you will, and then we also have the advantage of our IP strategy which will potentially take our coverage out to 2024. So we kind of no matter how you look at it, we're we think we're in pretty darn good shape with regard to our protection, if you will, in this market.

**Mark Monane *Needham Analyst***

To the best that was helpful. To the best of your knowledge, is there a drug that's out there in the real world that you're modeling that could be a predictor, prognosticator of what could happen when you think about using a drug in a special population? Is this akin to EGFR drugs where the mutation is present or 5Q minus with revlimid or or NitroMed for African-Americans? How should we think about its use? Is it a special population or how should we think about that?

**Mike Bristow *ARCA Chairman and Chief Science and Medical Officer***

Mike Bristow here. Let me take a shot at that. I don't think it's equivalent to the EGFR story where you have very small percentages of sub populations identified. Here we have a 50% sub population identified so and the reason for that is this is the major (inaudible) homozygote that is responsive, a major (inaudible) homozygote of a beta 1 adrenergic receptor polymorphism at the code on [39] position. So I think this is absolutely not comparable to the NitroMed situation where that approach, of course, was non-genetic, 180 degrees in what we're trying to do. What we're basically saying is it doesn't matter in terms of what some other phenotypic characteristics are, including skin color, what really matters is your genetics which transfers into biology which interfaces and interacts directly with our drug in terms of its leading pharmacologic properties.

**Ted Love *Nuvelo, Inc. Chairman, CEO***

Actually, Mike I have to add to that. I think one of the beauties of this is that it actually is about genetics. One of the challenges at NitroMed is that it probably is genetic, but it ended up being skin color, which is a real limitation. I think the challenge here in heart failure is that you know you want to treat these patients with the beta blocker, you know currently that some patients get a good outcome and some patients don't get a good outcome and the beauty of this is that you can pre specify which patients will respond to this drug. So it takes the guesswork, as Mike said, out of the whole process. So I think it's very different than the situation with NitroMed. I think the other point to emphasize is that we know that you want to use a beta blocker in these patients and beta blockers are already the standard of care in the treatment of heart failure, so we're going in to, if you will, a pre existing situation where people know you want to put the patient on bucindolol or another beta blocker.

**Mark Monane *Needham Analyst***

And so is the strategy, Ted, to follow up on that, is it if a patient's already on beta blocker, there may be a better beta blocker for these patients if they're in the right group and for new patients that I know that unfortunately heart attacks happen and there's new heart failure patients every

year, will there be a new patient strategy as well, so a switch on a new patient strategy?

**Mike Bristow** *ARCA Chairman and Chief Science and Medical Officer*

Right. Mike Bristow here. I'll take a shot at that. So we've actually done marketing survey work on this issue, who would you actually order the genetic testing and consider bucindolol in and the answer coming back is new patients, [denovo] patients patients, something like 40%, 50% of those perhaps, and then patients not doing well on another beta blocker who actually might have the very favorable genotype and respond better to bucindolol, as you might imagine, a fairly high percentage of those. So, we think there's going to be interest in certain clinical scenarios for this drug and the reason is actually that in the very favorable genotype, the clinical responses to this drug are quite substantial. I mean if you line up the results, which is always a dangerous thing to do between different clinical trials with placebo controls, the results with bucindolol in the very favorable group actually numerically exceeds the best results that have been achieved with other drugs in non-targeted populations, so this creates a certain amount of interest and desire, I think, to consider genetic testing.

**Randy St. Laurent** *ARCA EVP Commercial Operations*

I agree, Mike. I'd like to add one thing. I also believe that we will be able to get patients who are on extremely low doses of carvedilol, metoprolol and also receive also target patients that are on non-evidence based beta blockers as well.

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**Mike Bristow** *ARCA Chairman and Chief Science and Medical Officer*

Right. So what Randy's referring to is the tolerability of this drug is actually quite good and probably exceeds the other beta blocker approved for heart failure. The evidence of that is that the NHLBI, who is a VA cooperative studies program who jointly sponsored the bucindolol Phase 3 trial chose bucindolol because of its excellent tolerability in advanced heart failure populations and you actually routinely get to higher doses relative to target doses with this drug than with carvedilol or metoprolol CR.

**Dick Brewer** *ARCA President, CEO*

Mark, this is Dick. Just to round this out. You mentioned switching as a strategy. I want to reiterate, switching is not our strategy. From our perspective, that's not a good strategy no matter what. Patients who are on a drug and doing okay, physicians are loathed to make any changes, especially in complex situations. We need to worry about a switching strategy. Six million heart failure patients that exist that are diagnosed today and unfortunately a fraction are not on beta blockade for reasons that relate to lots of interesting historical issues. So there's a large fraction, maybe 40% of the patients who technically, theoretically should be on beta blockade and they aren't and there are another half million new patients diagnosed every year. Mike called those denovo patients and for sure they are certainly eligible for beta blockade, ought to be on beta blockade according to the AHA and ACC guidelines, and we have the opportunity to help physicians make the decision as to which patients can benefit. So it's better to think of it not in terms of a switching strategy.

**Mark Monane** *Needham Analyst*

Thanks very much for the added numbers of information and congratulations

**Dick Brewer** *ARCA President, CEO*

I'm sorry, we can't hear that.

**Mark Monane** *Needham Analyst*

Oh. I said congratulations on the new adventure. I know there's some new and old friends there and thanks for reviewing the numbers and commercialization strategy with us.

**Dick Brewer** *ARCA President, CEO*

Thank you, Mark.

**Mike Bristow** *ARCA Chairman and Chief Science and Medical Officer*

Thanks, Mark.

**Operator**

(OPERATOR INSTRUCTIONS) You have a follow-up question from the line of Liana Moussatos of Pacific Growth.

**Liana Moussatos** *Pacific Growth Equities Analyst*

The Phase 3 data, what percent of the patients that you screened with the test had adverse events that bucindolol would be contraindicated versus nonresponders versus responders?

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**Dick Brewer** *ARCA President, CEO*

Right. So we use a combination of genetic tests, as I mentioned. One is of the beta one [code on 389 RH glypolymorphism], the other is the alpha 2C insertion deletion polymorphism and so there's a gene variant at each of those that creates a scenario where bucindolol basically loses all efficacy and that's 10% of the general population. It was 13% of the BEST trial population and when you have a situation where there's no chance or little chance of efficacy, this is a scenario where a drug shouldn't be used. And so, in fact, in the NDA, in the proposed labeling, we call that out and say these patients should not be treated with the drug.

**Liana Moussatos** *Pacific Growth Equities Analyst*

And is that because of nonresponse or adverse events or both?

**Dick Brewer** *ARCA President, CEO*

Well, nonresponse, if you have nonresponse, all you can see is adverse events.

**Liana Moussatos** *Pacific Growth Equities Analyst*

Okay. So it's both. Okay.

**Dick Brewer** *ARCA President, CEO*

Yes.

**Liana Moussatos** *Pacific Growth Equities Analyst*



And then approximate cost of the test and was the test unique to bucindolol or does it also screen for other beta blockers?

**Dick Brewer** *ARCA President, CEO*

Right. So the approximate cost will be inexpensive by molecular diagnostic standards. We're not—we haven't settled on that yet, but it's not something that's going to be prohibitive.

**Liana Moussatos** *Pacific Growth Equities Analyst*

Does that mean less than \$500?

**Dick Brewer** *ARCA President, CEO*

It does. Okay. And your other question, I'm sorry, was?

**Liana Moussatos** *Pacific Growth Equities Analyst*

Has this test been tried with other beta blockers, too?

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**Dick Brewer** *ARCA President, CEO*

Yes. The answer is absolutely yes and if you want to see the data in regard to that, at least the best data available, there's a paper published in August in the Journal of American College and Cardiology demonstrating that carvedilol and metoprolol do not have the same reaction as bucindolol. The first author is Sehnert. The reason for that, we believe, is neither one of those drugs have the unique molecular properties of bucindolol that interact with these genetic variances. This is a very special pharmacologic line up between drug and gene variant or receptor variant.

**Ted Love** *Nuvelo, Inc. Chairman, CEO*

I want to stress, that was a key thing that we focused on. Obviously we did not want to enter into a merger if bucindolol was simply taking us back to where we currently are. So we very much focused on that and clearly we saw good evidence, as Mike pointed out, that this is really a unique characteristic of bucindolol and a unique opportunity presented by Gencaro.

**Liana Moussatos** *Pacific Growth Equities Analyst*

Thank you very much. Thank you very much. Appreciate it.

**Dick Brewer** *ARCA President, CEO*

Thank you.

**Operator**

Your next question comes from the line of [Doug Floren] of DCF Capital.

**Rich Vandenberg Analyst**

[Rich Vandenberg]. Question for you, Mike. For those of us not as familiar with the story. Can you take us through the time line a bit? I know you mentioned this is a prospectively defined of the BEST trial. The BEST trial I guess was published back in 2001. I guess you would probably say (inaudible) negative trial obviously did not show an overall survival benefit. Where does the prospective portion of that genetic analysis come in? Obviously you were one of the investigators on the original trial. Take us through how that whole process went on.

**Mike Bristow ARCA Chairman and Chief Science and Medical Officer**

Sure. I was actually the head of the sub studies in BEST and because this trial was a basically a private/public partnership with three sponsors, we ended up with a very large sub study budget and we set up this very ambitious set of sub studies. The highest priority, the highest ranked sub study reviewed competitively was the DNA bank which we very much wanted in this trial. So we set up the first DNA bank ever to be set up at a heart fair clinical trial. This was set up in 1995. I can tell you that setting a DNA bank up in 1995 was a bit of a challenge. And in order to get DNA out, I think, we had a procedure.

We had an oversight committee I was also on and a procedure consisting of submitting a grant application, having it competitively reviewed and in that grant application in order for that to be funded, had to be a hypothesis of a sample size calculation. So in 1998, Steve [Liggit], who is a coscientific founder with me of ARCA, had just discovered the huge almost astounding pharmacologic difference in these beta-1 389 polymorphisms and we were sent word to Steve that he should apply for DNA, he should submit a grant application and he did in 1998. This was while the trial was still going on. And the obvious hypothesis that anyone would come up with as they looked at the data was the beta one arch version of the beta one receptor, patients who had that would respond much better to the beta blockade, in this case bucindolol, so that was the hypothesis and the hypothesis was confirmed.

We ended up with over a thousand patients and a huge number of clinical end points in those patients invest and so the pharmacogenic sub study is as large as your standard Phase 3 clinical trial, in terms of the number of end points, so it's prospective and it's large. The P values in the very favorable subgroup on approvable end points exceed what is required by the FDA for approval based on a single trial. So for all of these reasons, we think the pharmacogenetic sub study will be looked at seriously by the FDA.

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In addition, it turns out that the entire cohort data from BEST are actually much better than were originally interpreted and there are several reasons for that. One is that in the original analysis, an unadjusted analysis was used and it turns out that the previous sponsor of bucindolol actually had negotiated in their statistical analysis plan with the agency to use an adjusted analysis with censoring for transplant which wasn't done on the analysis that was published in the New England Journal. So the data actually from the entire cohort are somewhat different and better than what was originally published. So, for example, for all cause mortality, the primary end point, the reduction of that actually has a P value of 0.053. Remember, this trial was stopped early for loss of investigator [equipoise]. It wasn't stopped for futility.

About 92% of the projected number of end points based on the sample size calculations were available, but it wasn't 100% and, finally, there were eight secondary end points in BEST, seven in the protocol and one that was in the stat plan agreed to by the agency to represent an approvable end point, something called heart failure progression and morbidity and mortality index. All eight of those secondary end points were positive and that approvable end point of heart failure progression has a P value of 4 zeros and a 3 on it. So the the entire cohort data (inaudible) are actually quite strong from a regulatory standpoint and scientific standpoint. We actually are going for approval based on results in the entire cohort and then within the label, we're going to be describing which patients should be treated pharmacogenetically with this drug.

**Rich Vandenberg Analyst**

That's helpful. Make sure I understand it correctly, the subgroup sort of analysis, on a calendar basis, you sort of got the back half of the enrollment of the test of the enrollment of the

**Mike Bristow ARCA Chairman and Chief Science and Medical Officer**

Yes. Again, 1995, you can imagine the reaction to from IRBs in terms of genetic testing, multiple levels of epicable review required dealing with federal agencies and local IRBs, so there was a bit of a lag on start up. But looking at the pharmacogenetic subgroup, it doesn't differ really from the cohort in any of the graphics or baseline characteristics.

**Rich Vandenberg Analyst**

Got it. Correct me if my understanding is wrong, but my thought was the BEST trial overall had a 10% reduction in mortality that was not significant, just going off your numbers that you're basically this subgroup is half the patients, is it fair to assume that you had a 20% advantage in your subgroup?

**Mike Bristow ARCA Chairman and Chief Science and Medical Officer**

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In the pharmacogenetic subgroup, in the very favorable, it is a 38% reduction in mortality, all cause and it is a 48% reduction in cardiovascular mortality.

**Rich Vandenberg Analyst**

Got it. Does that imply that there is actually a risk taking these drugs for the nonresponders, that there is actually no benefit gained and

**Mike Bristow ARCA Chairman and Chief Science and Medical Officer**

I would argue as a clinician and pharmacology that no benefit equals risk for any drug.

**Rich Vandenberg Analyst**

Fair enough. Thanks a lot for that explanation.

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**Dick Brewer** *ARCA President, CEO*

Thanks, Doug.

**Operator**

Your next question comes from the line of [Duane Nash] of Pacific Growth.

**Duane Nash** *Pacific Growth Analyst*

Thanks very much, but my question has already been answered.

**Operator**

(OPERATOR INSTRUCTIONS) This will conclude the Q&A portion of today's call. I will now turn the call over to Mr. Brewer.

**Dick Brewer** *ARCA President, CEO*

Okay. Thanks everybody for participating on the call today. We look forward to updating you on our progress as we make it and, of course, in closing this deal by the end of the year. Thanks again, have a good day.

**Operator**

Thank you for participating in today's conference. You may now disconnect.

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### **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](http://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 intends to file a registration statement on Form S-4, and a related proxy statement/prospectus, in connection with the merger. Investors and security holders are urged to read the registration statement on Form S-4 and the related proxy statement/prospectus when they become available because they will contain important information about the merger transaction. Investors and security holders may obtain free copies of these documents (when they are available) and other documents filed with the SEC at the SEC's website at [www.sec.gov](http://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](mailto:ir@nuvelo.com) or by phone at 650-517-8000.

In addition to the registration statement and related proxy statement/prospectus, 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](http://www.sec.gov), and from Investor Relations at Nuvelo as described above.

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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 will be included in the proxy statement/prospectus of 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.