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NUVELO INC  
Form 425  
October 06, 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. 000-22873

October 2008

Safe Harbor Statement

This presentation contains forward-looking statements which include, without limitation, statements

regarding the completion of the proposed merger, the merger'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 to complete the merger 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

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Merger Creates Valuable Company

Late-stage cardiovascular company

Near-term commercial opportunity with filed NDA

Attractive portfolio to fuel long-term growth

Addressing major market opportunities

Experienced cardiovascular leadership

Funding expected to be adequate for value-creating milestones

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Value-Driving Near-Term Milestones

Milestone

NDA acceptance by FDA

Completion of merger

Initiate Phase 2 NU172 trial

LabCorp PMA submission to FDA  
for Gencaro genetic test

Anticipated FDA CRAC meeting

FDA decision on Gencaro

Potential launch of Gencaro

Expected Timing

H2:08

Q408/Q109

Q408/Q109

Q408/Q109

H1:09

PDUFA Date: 5/31/09

H1:10

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Gencaro \* (bucindolol  
hydrochloride) : Personalizing  
Heart Failure Treatment

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\* Trade name pending FDA approval

Gencaro<sup>®</sup>

First Personalized Treatment for Heart Failure

Next-generation beta-blocker with unique pharmacology

First genetically-targeted cardiovascular drug candidate

Companion genetic test being developed by LabCorp

Potential to target ~50% of heart failure (HF) patients

Very Favorable  
genotype is target patient population for  
treatment

Several significant potential follow-on indications

Potential prevention of several forms of cardiac arrhythmias

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Established, Large Market Opportunity

~6 million US patients living with heart failure

~550K newly diagnosed patients annually

Beta-blockers current standard of care

Beta-blockers should be prescribed to all patients with stable HF due to reduced LVEF ..  
(ACC/AHA Guidelines 2005)

Difficult to determine if therapy is working with current standard of care

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Personalized  
to Improve Outcomes

Personalized medicine designed to:

Maximize response

Minimize side effects

Reduce costs to the health care system

Gencaro: Personalized treatment for improved outcomes

Common genetic variations predict individual patient response

Easy-to-administer accompanying genetic test

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Partnered with LabCorp

Easy-to-administer genetic test

Turnaround time for results expected  
within 48 hours



Test results will identify most favorable  
responders

510K/PMA track within FDA

Coordinated with Gencaro NDA

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Gencaro Unique Pharmacology  
No Class Effect  
Compound,  
(Device)  
Molecular Pharmacologic Properties  
1  
AR  
Blockade  
2  
AR  
Blockade  
1  
AR  
Blockade  
3  
AR  
Effects,  
NO  
2c

AR  
Modulated  
NE  
Lowering  
1  
Arg/Arg  
Inverse  
Agonism  
Bucindolol  
++++  
++++  
+  
Full  
agonist  
+++  
++  
Carvedilol  
++++  
+++  
++++  
Antagonist  
+  
?  
Metoprolol  
++++  
++  
0  
0  
0  
0  
Mild  
Vasodilatation  
Ideal NE  
Lowering  
Optimum  $\beta$   
Blockade  
10

Genetic Basis Of Gencaro Response  
Mediated through individual genetic variation  
Arg/Arg  
1  
389  
AR  
Better bucindolol antagonism

-  
increased survival  
-  
reduced hospitalization  
Favorable receptor  
type  
Gly Variant  
1  
389 AR  
Standard bucindolol  
antagonism  
Low function receptor  
Adverse when combined with  
2c  
Del genotypes  
1.  
1  
-AR blockade/  
R\* inactivation  
WT  
2c  
AR  
Tonically inhibits NE release  
Mild, ideal NE lowering with  
bucindolol  
Favorable receptor type when  
combined with  
1  
389 Gly  
genotypes  
Deletion Variant  
2c  
AR  
Less inhibition of NE release  
Marked NE lowering with  
bucindolol  
Adverse receptor type when  
combined with  
1  
389 Gly  
genotypes  
2. Sympatholysis, via  
2  
-AR blockade  
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Comparison of Beta-blocker Studies\*: US & ROW

-20%

US

COPERNICUS

Carvedilol

n = 482

Bucindolol

n=2708  
Metoprolol  
n =1071  
Bucindolol  
(VF  
Genotype)  
n= 493  
Metoprolol  
n = 3991  
Carvedilol  
n = 2289  
Trial Name  
BEST  
MERIT  
BEST  
MERIT  
COPERNICUS  
Trial Location  
US  
US  
US  
WW  
WW  
All-cause Mortality  
-13%  
+5%  
-38%  
-34%  
-35%  
CV Mortality  
-16%  
-4%  
-48%  
-38%  
No Data  
Mortality + Cardiac  
Transplant  
-14%  
-43%  
-32%  
No Data  
Mortality & HF  
Hospitalizations  
-21%  
-16%  
-35%  
-31%  
-33%  
HF Hospitalizations, TTE  
-23%



No Data

-36%

NA

-28%

HF hospitalization days

-24%

No Data

-48%

-36%

-41%

Total MI in HF Patients

-45-47%

No Data

-48%

No Data

No Data

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\* Not head-to-head studies

BEST: Clinical Responses by Genotypes

\*p<0.05; \*\*p<0.007

Endpoint

Very Favorable

Genotype (47%)

Favorable

Genotype (40%)

Unfavorable

Genotype (13%)

AC Mortality (ACM),

Time-to-Event (TTE)

38% \*

25%

4%

CV Mortality, (CVM),

TTE

48% \*

40%\*

11%

HF Progression, TTE

34% \*\*

20%

1%

HF Hosp/pt

43% \*

16%

26%

HF Hosp days/pt

48% \*\*

17%

19%

Composite endpoint consisting of: HF mortality, cardiac transplant, HF hospitalizations,  
and HF emergency room visits

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NDA submission to  
the FDA: 7/31/08  
Potential FDA  
Cardio-Renal  
Advisory  
Committee  
(CRAC)

meeting  
Potential  
commercial  
launch  
PDUFA Date:  
5/31/09  
FDA  
acceptance of  
NDA filing:  
9/19/08  
2008  
2009  
2010  
Gencaro Pathway to Market  
LabCorp PMA  
submission to the  
FDA for  
complementary  
genetic test  
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Targeted Sales/Marketing

Cardiologists initiate and influence beta-blocker prescriptions

Penetrate U.S. market with specialized sales force

Unique and desirable offering in large market

Expected to be only drug with companion test  
to predict response

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Pricing and Reimbursement

Current beta-blocker pricing:

Generic products are nominally priced

Branded products ranging from \$2.44 -



\$4.74 /day  
(AWP)

While majority of patients are Part D eligible, most opt for supplemental commercial prescription coverage

Expected to be on formulary with reasonable pricing

Test anticipated to be covered via medical benefit, Part B

Potential favorable pharmacoeconomics for Gencaro  
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Attractive portfolio to fuel  
long-term growth  
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NU172: Targeting

Major Unmet Need

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~ 400,000 coronary artery bypass  
graft (CABG) procedures annually in  
U.S.\*

Potential for expansion into other  
medical or surgical procedures

Heparin anticoagulation

Protamine antidote for reversal  
once procedure is complete

\*American Heart Association

Anticoagulation for Medical/Surgical  
Procedures

Large Population

Standard of Care

Ideal Profile for Short-Term  
Anticoagulation  
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Reduced bleeding risk  
during and post  
procedure

No drug induced  
thrombocytopenia

Synthetic (no animal  
based products)

Potent anticoagulation

Active against clot  
bound thrombin

Effective in static blood

Predictable dosing

Rapid onset

Rapid offset without  
need for antidote

Administration

Safety

Efficacy

NU172 Proof-of-Concept Achieved  
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Favorable safety profile  
with no adverse events

Dose-dependant

increases in  
anticoagulation

Anticoagulation  
maintained stably  
throughout 4-hour  
infusion

Rapid return toward  
baseline upon drug  
discontinuation

Short plasma half-life

2.0mg/kg IV bolus  
followed by escalating  
infusion doses for up to  
4 hours

Highest infusion dose:  
6.0mg/kg/hr

Phase 1b Results: Rapid and predictable onset and offset of  
anticoagulation

Administration

Safety

Efficacy



NU172: Rapid and Predictable  
Onset/Offset of Anticoagulation  
Phase 1b Results  
21  
Avg  
ACT of Subjects Receiving  
2.0 mg/kg bolus + 6 mg/kg/hr 4-hr infusion

0  
100  
200  
300  
400  
500  
0  
50  
100  
150  
200  
250  
300  
Time (mins  
post bolus)  
ACT= 395 at 5 mins  
post-bolus  
Infusion  
Stopped

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October 2008

#### 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  
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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.

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 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.