

Edgar Filing: NUVELO INC - Form 425

NUVELO INC  
Form 425  
January 13, 2009

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

The following is a presentation made by ARCA biopharma, Inc. and Nuvelo, Inc. beginning on January 12, 2009.

J.P. Morgan  
27  
th  
Annual Healthcare  
Conference  
January 12  
15, 2009

Safe Harbor Statement

2

This presentation contains forward-looking statements which include, without limitation, statements regarding the completion of the proposed merger transaction between Nuvelo, Inc., ARCA biopharma, Inc. and Dawn Acquisition Sub, Inc. the proposed merger's anticipated benefits, timing, progress and anticipated completion of the companies' clinical stage and research programs, the timing of regulatory approval, the potential benefits that patients may

experience from the use of the companies' clinical stage compounds, and the cash position of the companies following the merger, 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 the companies' managements' 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 proposed merger in a timely fashion, the risk that Nuvelo's and ARCA's business operations will not be integrated successfully; the companies' inability to further identify, develop and achieve commercial success for products and technologies; the risk that the companies' financial resources will be insufficient to meet their business objectives; uncertainties relating to drug discovery and the regulatory approval process; clinical development processes; enrollment rates for patients in the companies' 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 September 30, 2008 and subsequent filings. Nuvelo and ARCA disclaim any intent or obligation to update these forward-looking statements.

Introducing: ARCA *biopharma*\*

3

Pioneering Genetically-Targeted  
Cardiovascular Therapies

\*ARCA, Nuvelo merger is expected to be  
completed in 1/2009

Multiple Near & Long Term Value  
Creating Aspects

4

Value-Driving Near-Term Milestones

Milestone

Expected Timing

NDA acceptance by FDA

H2:08

Completion of merger

1/2009

LabCorp PMA submission to FDA for Gencaro genetic test  
Q1:09

Anticipated FDA CRAC meeting  
H1:09

FDA decision on Gencaro  
PDUFA Date: 5/31/09

Anticipated launch of genetic registry post approval  
Q3:09

Potential launch of Gencaro  
Q1:10 or Q4:09

5



Introducing Gencaro \*  
(bucindolol hydrochloride)  
Investigational drug currently under FDA  
review  
Next-generation beta-blocker with  
unique pharmacology  
Potentially first genetically-targeted

heart failure drug

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  
Potential follow-on indications

Potential prevention of atrial fibrillation  
and/or ventricular tachycardia/ventricular  
fibrillation being explored  
\* Trade name pending FDA approval

6

Genetic Basis of Gencaro  
Response  
Mediated Through Individual Genetic Variation  
7  
Cardiac myocyte  
Arg/Arg  
1

389

AR

Better

bucindolol

antagonism

increased survival

reduced hospitalization

Very

favorable

receptor

type

Gly

Variant

1

389

AR

Standard

bucindolol

antagonism

Adverse when combined with

2c

Del genotypes

WT

2c

AR

Mild, ideal NE lowering with

bucindolol

Favorable receptor type when  
combined with

1

389 Gly

genotypes

Deletion Variant

2c

AR

Marked

NE

lowering

with

bucindolol

Adverse

receptor

type

when

combined with

1

389 Gly

genotypes

BEST: Clinical Responses by Genotypes

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

Endpoint

Very Favorable

Genotype (47%)

{ β

1

389 Arg/Arg

+ any a

2C

}

Favorable

Genotype (40%)

{β

1

389 Gly

carrier

+ a

2C

Wt/Wt}

Unfavorable

Genotype (13%)

{β

1

389 Gly

carrier

+ a

2C

Del carrier }

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

8

Bucindolol  
n = 2708  
Metoprolol  
n = 1071  
Carvedilol  
n = 482  
Bucindolol



(VF  
Genotype)  
n = 493  
Metoprolol  
n = 3991  
Carvedilol  
n = 2289  
Trial Name  
BEST  
MERIT  
COPERNICUS  
BEST  
MERIT  
COPERNICUS  
Trial Location  
US  
US  
US  
US  
WW  
WW  
All-cause Mortality  
-13%  
+5%  
-20%  
-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

No Data

HF hospitalization days

-24%

No Data

-48%

-36%

-41%

Total MI in HF Patients

-45-47%

No Data

-48%

No Data

No Data

Comparison of Beta blocker Studies\*:

US & ROW

9

\* Not head-to-head studies

Marketing Research:

Gencaro

Demand

> 600 cardiologists with established HF practices interviewed  
or surveyed to date

Demand for Gencaro  
is anticipated to be strong

Peak genetic test ordering opportunity for targeted patient  
population segments

>60% of beta-blocker naïve HF patients

>60% of HF patients that are difficult to titrate or have been deemed  
non-responsive to existing beta-blocking agents

Cardiologists expected to value Gencaro s:

Improvement in clinical outcomes

Ability to predict response

10

ARCA Primary Market Research; 11/2008

LabCorp Relationship

Easy-to-administer genetic  
test

Quick turnaround time for  
results expected

Test results will identify  
genetic markers that  
predict clinical response

510K/PMA track within FDA

Coordinated with Gencaro  
NDA  
11

Established, Large Market Opportunity  
Beta-blockers = current standard of  
care in chronic heart failure

Beta-blockers should be prescribed  
to all patients with stable HF due to  
reduced LVEF

(ACC/AHA Guidelines  
2005)

~6 million US HF patients

~550K newly diagnosed  
patients annually

12



Commercial Strategy

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

Defend market exclusivity

Hatch-Waxman protection until 2017

Potential patent protection until 2025

13

Competitive Environment  
Limited Competitive Threats

Current beta blockers have  
generic equivalents on the  
market

Promotion is very limited

Known future competitors  
do not have a companion  
genetic test or any known  
PGt interactions

14

### Pricing and Reimbursement

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

Current branded beta-blocker products range from \$2.54 - \$4.74 /day (AWP)

Gencaro expected to be on formulary with reasonable pricing

Test anticipated to be covered via medical benefit; Part B for Medicare patients

15

Gencaro US Approval Process

FDA filed New Drug Application  
9/28/08

Clinical site inspections proceeding

FDA Pre-Approval Inspection of manufacturer  
scheduled

Regulatory department actively communicating  
with the agency

FDA's 2009 performance goal: Review and act on  
90% of NDAs by PDUFA date

16



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 NDA filing:

9/28/08

2008

2009

2010

Gencaro Pathway to Market

17

LabCorp PMA

submission to the

FDA for

complementary

genetic test

Value-Driving Near-Term Milestones

Milestone

Expected Timing

NDA acceptance by FDA

H2:08

Completion of merger

1/2009

LabCorp PMA submission to FDA for Gencaro genetic test  
Q1:09

Anticipated FDA CRAC meeting  
H1:09

FDA decision on Gencaro  
PDUFA Date: 5/31/09

Anticipated launch of genetic registry post approval  
Q3:09

Potential launch of Gencaro  
Q1:10 or Q4:09  
18

Personalized Medicine:  
Recently in the News  
19

THANK YOU

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 merger. Investors and security holders are urged to read the registration statement on Form S-4 and the related proxy statement/prospectus/consent solicitation which contain important

information  
about  
the  
merger  
transaction.  
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](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  
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.  
21