

Edgar Filing: NUVELO INC - Form 425

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

2

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

3

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

4

Gencaro * (bucindolol
hydrochloride) : Personalizing
Heart Failure Treatment

5

* Trade name pending FDA approval

Gencaro[®]

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

6

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

7

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

8

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

9

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 β
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
11

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

12

* 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

13

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
14

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

15

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
16

Attractive portfolio to fuel
long-term growth
17

NU172: Targeting

Major Unmet Need

18

~ 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
19

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
20

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

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

22

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.

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, 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 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.